



Clinical Trial Results Website

**Sponsor**

Novartis Pharmaceuticals

**Generic Drug Name**

HDM201

**Trial Indication(s)**

Advanced solid and hematologic tumors

**Protocol Number**

CHDM201X2101

**Protocol Title**

A phase I, open label, multicenter, dose-escalation study of HDM201 in adult patients with advanced solid and hematological tumors characterized by wild-type TP53

**Clinical Trial Phase**

Phase 1

**Phase of Drug Development**

Phase 1



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### **Study Start/End Dates**

Study Start Date: July 2014 (Actual)  
Primary Completion Date: June 2020 (Actual)  
Study Completion Date: June 2020 (Actual)

### **Study Design/Methodology**

This was a multi-center, open-label, dose finding, phase I study of oral single agent HDM201, administered in subjects with wild-type TP53 advanced tumors (solid and hematological) who had progressed despite standard therapy or for whom no standard therapy existed.

The study consisted of a dose escalation part, to determine the maximum tolerated dose (MTD) and/or recommended dose for expansion (RDE) of HDM201, and a dose expansion part to further characterize anti-tumor activity of HDM201 in a specific regimen. In addition, the study also included a dose escalation part, in solid tumor subjects only, with HDM201 administered in combination with eltrombopag.

Four dosing regimens (1A, 1B, 2A, 2C) at different dose-levels were explored.

### **Centers**

15 centers in 8 countries: Spain(2), Taiwan(1), United States(2), Singapore(1), Germany(3), Netherlands(2), Japan(2), France(2)

### **Objectives:**

The primary objective of the trial was to determine the MTD and/or to identify the RDE of HDM201 with or without eltrombopag in one or more of the pre-defined regimens and indication group. The following related endpoint was assessed:

- Incidence of Dose Limiting Toxicities (DLTs) during the first cycle of treatment

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The secondary objectives were:

- To characterize the safety and tolerability of HDM201 with or without eltrombopag in terms of:
  - Incidence of adverse events (AEs) and serious adverse events (SAEs)
  - Number of participants with dose reductions or dose delays
  - Dose intensity
- To characterize the pharmacokinetics (PK) properties of HDM201
- To assess the pharmacodynamic effect of HDM201 by measuring the changes from baseline of pharmacodynamic biomarkers (GDF-15 in serum and p21 in tumor tissue)
- To assess the preliminary anti-tumor activity of HDM201 in solid tumors according to Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1) in terms of:
  - Number of participants with Best Overall Response (BOR)
  - Duration of response (DOR)
  - Progression-free survival (PFS)
- To assess the preliminary anti-tumor activity of HDM201 in hematological malignancies according to hematological malignancy response criteria in terms of:
  - Number of participants with Best Overall Response (BOR)
  - Duration of Response (DOR)

**Test Product (s), Dose(s), and Mode(s) of Administration**

HDM201 was used as an investigational product in this study. HDM201 was supplied as hard gelatin capsules of dosage strengths of 1 mg, 2.5 mg, 10 mg and 100 mg. Eltrombopag was administered orally in combination with HDM201 in participants with solid tumors in a few arms of the study.

Four dosing regimens (1A, 1B, 2A, 2C) of HDM201 administered orally at different dose-levels were explored in the 29 cohorts of the study.

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- Regimen 1A: HDM201 once every three weeks of a 3 week-cycle (on Day 1 of a 21 day-cycle).  
In regimen 1A the following doses of HDM201 were assessed:
  - 12.5 mg, 25 mg, 50 mg, 100 mg, 200 mg, 250 mg, 250 mg + eltrombopag and 350 mg in participants with solid tumors.
  - 250 mg, 350 mg and 400 mg in participants with hematological malignancies.
- Regimen 1B: HDM201 once a week for the first 2 weeks of a 4 week-cycle (on Day 1 and on Day 8 of a 28 day-cycle).  
In regimen 1B the following doses of HDM201 were assessed:
  - 120 mg, 150 mg, 150 mg + eltrombopag and 200 mg in participants with solid tumors.
  - 120 mg and 150 mg in participants with hematological malignancies.
- Regimen 2A: HDM201 once daily dosing for the first 2 weeks of a 4 week-cycle (2 weeks on treatment, 2 weeks off treatment).  
In regimen 2A the following doses of HDM201 were assessed:
  - 1mg, 2 mg, 4 mg, 7.5 mg, 15 mg and 20 mg in participants with solid tumors.
  - 20 mg and 30 mg in participants with hematological malignancies.
- Regimen 2C: HDM201 once daily dosing for the first week of a 3 week-cycle (1 week on treatment, 2 weeks off treatment).  
In regimen 2C the following doses of HDM201 were assessed:
  - 15 mg, 20 mg and 25 mg in participants with solid tumors.
  - 45 mg in participants with hematological malignancies.

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Participants could continue treatment with the study treatment until participant experienced unacceptable toxicity, disease progression and/or treatment was discontinued at the discretion of the investigator or the participant.

**Statistical Methods**

The primary variable was the incidence of DLTs in the first cycle of treatment. Estimation of the MTD was based upon the estimation of the probability of a DLT in the first cycle of treatment for subjects in the dose-determining set. An adaptive Bayesian logistic regression model (BLRM) guided by the escalation with overdose control principle guided the dose escalation of treatment with HDM201 to its MTD and/or RDE for each regimen separately. A two-parameter BLRM was fitted on the first cycle of treatment dose-limiting toxicity data (i.e. absence or presence of DLT) accumulated throughout the dose escalation to model the dose-toxicity relationship of HDM201.

Local read of Computed tomography/Magnetic resonance imaging (CT/MRI) assessments was used for all efficacy assessments of solid tumor activity on study.

Best overall response (BOR), progression-free survival (PFS), and duration of response (DOR) was defined as per RECIST 1.1 for subjects with solid tumors.

Evidence of anti-leukemic activity of HDM201 on subjects with hematological malignancy were evaluated using BOR and DOR, as per the hematological malignancy response criteria.

For all safety analyses, the safety set including all subjects who received at least one partial or full dose of HDM201 and had at least one valid post-baseline safety assessment was used.

**Study Population: Key Inclusion/Exclusion Criteria**

Key Inclusion Criteria:

- Patient with a TP53wt locally advanced or metastatic solid malignancy and with measurable or non-measurable (but evaluable) disease as determined by RECIST 1.1 criteria.
- Patients with the TP53wt hematological tumors (AML, ALL, HR-MDS) who have failed prior therapies or who are

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considered inappropriate candidates for standard induction therapy.

**Key Exclusion Criteria:**

- Prior treatment with compounds with the same mode of action
- Subjects with significant or uncontrolled cardiovascular disease
- History of thromboembolic or cerebrovascular events within the last 6 months, including transient ischemic attack, cerebrovascular accident, deep vein thrombosis, or pulmonary embolism
- Previous and concomitant therapy that precludes enrollment, as defined in the protocol
- Known Human Immunodeficiency Virus (HIV) infection and/or active Hepatitis B or Hepatitis C infection
- Patients who have undergone major surgery within the 2 weeks prior to starting study treatment or who have not fully recovered from previous surgery
- Women of child-bearing potential, unless they are using highly effective methods of contraception during dosing and for 2 weeks after study drug discontinuation
- Pregnant or nursing women

**Participant Flow Table**

In the tables below Not Completed refers to treatment discontinuation.

	<b>Solid tumors: HDM20 1 1A 12.5 mg</b>	<b>Solid tumors: HDM20 1 1A 25 mg</b>	<b>Solid tumors: HDM20 1 1A 50 mg</b>	<b>Solid tumors: HDM20 1 1A 100 mg</b>	<b>Solid tumors: HDM20 1 1A 200 mg</b>	<b>Solid tumors: HDM20 1 1A 250 mg</b>	<b>Solid tumors: HDM20 1 1A 350 mg</b>	<b>Solid tumors: HDM201 1A 250 mg + Eltrombopag</b>	<b>Solid tumors: HDM201 1B 120 mg</b>	<b>Solid tumors: HDM201 1B 150 mg</b>	<b>Solid tumors: HDM201 1B 200 mg</b>	<b>Solid tumors: HDM201 1B 150 mg + Eltrombopag</b>
<b>Arm/Group Description</b>	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 + Eltrombopag in solid tumors.
<b>Started</b>	1	1	4	4	5	6	5	3	29	8	3	7
<b>Completed</b>	0	0	0	0	0	0	0	0	0	0	0	0
<b>Not Completed</b>	1	1	4	4	5	6	5	3	29	8	3	7
Adverse Event	0	0	0	0	3	1	1	1	1	0	0	0
Disease progression	1	1	4	3	2	5	3	2	23	8	3	4
Protocol deviation	0	0	0	0	0	0	1	0	0	0	0	0
Subject/guardian decision	0	0	0	1	0	0	0	0	3	0	0	1
Physician Decision	0	0	0	0	0	0	0	0	2	0	0	1
Death	0	0	0	0	0	0	0	0	0	0	0	1

	<b>Solid tumors: HDM201 2A 1 mg</b>	<b>Solid tumors: HDM201 2A 2 mg</b>	<b>Solid tumors: HDM201 2A 4 mg</b>	<b>Solid tumors: HDM201 2A 7.5 mg</b>	<b>Solid tumors: HDM201 2A 15 mg</b>	<b>Solid tumors: HDM201 2A 20 mg</b>	<b>Solid tumors: HDM201 2C 15 mg</b>	<b>Solid tumors: HDM201 2C 20 mg</b>	<b>Solid tumors: HDM201 2C 25 mg</b>
<b>Arm/Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.
<b>Started</b>	1	2	4	4	4	5	8	6	5
<b>Completed</b>	0	0	0	0	0	0	0	0	0
<b>Not Completed</b>	1	2	4	4	4	5	8	6	5
Adverse Event	0	0	0	0	0	1	0	0	1
Disease progression	1	2	4	4	4	4	7	5	3
Protocol deviation	0	0	0	0	0	0	0	0	0
Subject/guardian decision	0	0	0	0	0	0	0	0	1
Physician Decision	0	0	0	0	0	0	0	1	0
Death	0	0	0	0	0	0	1	0	0



<b>Arm/Group Description</b>	<b>Hematological malignancies: HDM201 1A 250 mg</b> Regimen 1A. Dose: 250 mg HDM201 (RDE) in hematological malignancies.	<b>Hematological malignancies: HDM201 1A 350 mg</b> Regimen 1A. Dose: 350 mg HDM201 in hematological malignancies.	<b>Hematological malignancies: HDM201 1A 400 mg</b> Regimen 1A. Dose: 400 mg HDM201 in hematological malignancies.	<b>Hematological malignancies: HDM201 1B 120 mg</b> Regimen 1B. Dose: 120 mg HDM201 (RDE) in hematological malignancies.	<b>Hematological malignancies: HDM201 1B 150 mg</b> Regimen 1B. Dose: 150 mg HDM201 in hematological malignancies.	<b>Hematological malignancies: HDM201 2A 20 mg</b> Regimen 2A. Dose: 20 mg HDM201 in hematological malignancies.	<b>Hematological malignancies: HDM201 2A 30 mg</b> Regimen 2A. Dose: 30 mg HDM201 in hematological malignancies.	<b>Hematological malignancies: HDM201 2C 45 mg</b> Regimen 2C. Dose: 45 mg HDM201 (RDE) in hematological malignancies.	<b>Total</b> All participants in the study
<b>Started</b>	15	4	9	24	6	3	4	28	208
<b>Completed</b>	0	0	0	0	0	0	0	0	0
<b>Not Completed</b>	15	4	9	24	6	3	4	28	208
Adverse Event	1	1	0	2	0	0	2	3	18
Disease progression	11	3	3	12	5	2	1	16	146
Protocol deviation	0	0	0	0	0	0	0	0	1
Subject/guardian decision	1	0	1	3	0	1	0	3	15
Physician Decision	1	0	2	1	0	0	0	3	11
Death	1	0	3	6	1	0	1	3	17

**Baseline Characteristics**

	Solid tumors: HDM201 1A 12.5 mg	Solid tumors: HDM201 1A 25 mg	Solid tumors: HDM201 1A 50 mg	Solid tumors: HDM201 1A 100 mg	Solid tumors: HDM201 1A 200 mg	Solid tumors: HDM201 1A 250 mg	Solid tumors: HDM201 1A 350 mg	Solid tumors: HDM201 1A 250 mg + Eltrombopag	Solid tumors: HDM201 1B 120 mg	Solid tumors: HDM201 1B 150 mg	Solid tumors: HDM201 1B 200 mg	Solid tumors: HDM201 1B 150 mg + Eltrombopag
<b>Arm/Group Description</b>	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 + Eltrombopag in solid tumors.
<b>Number of Participants [units: participants]</b>	1	1	4	4	5	6	5	3	29	8	3	7
<b>Age Categorical</b> (units: participants) Count of Participants (Not Applicable)												
<=18 years	0	0	0	0	0	0	0	0	0	0	0	0
Between 18 and 65 years	1	0	2	1	4	4	3	3	18	7	1	6
>=65 years	0	1	2	3	1	2	2	0	11	1	2	1
<b>Sex: Female, Male</b> (units: participants) Count of Participants (Not Applicable)												
Female	0	1	3	2	4	3	4	2	13	4	1	3
Male	1	0	1	2	1	3	1	1	16	4	2	4
<b>Race/Ethnicity, Customized</b> (units: participants) Count of Participants (Not Applicable)												
Caucasian	0	1	1	3	3	4	2	2	16	2	3	5
Black	1	0	0	0	0	0	0	0	0	0	0	0

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Asian	0	0	3	1	1	1	2	0	10	3	0	2
Other	0	0	0	0	0	0	0	0	2	1	0	0
Missing	0	0	0	0	1	1	1	1	1	2	0	0

	Solid tumors: HDM201 2A 1 mg	Solid tumors: HDM201 2A 2 mg	Solid tumors: HDM201 2A 4 mg	Solid tumors: HDM201 2A 7.5 mg	Solid tumors: HDM201 2A 15 mg	Solid tumors: HDM201 2A 20 mg	Solid tumors: HDM201 2C 15 mg	Solid tumors: HDM201 2C 20 mg	Solid tumors: HDM201 2C 25 mg
<b>Arm/Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.
<b>Number of Participants [units: participants]</b>	1	2	4	4	4	5	8	6	5
<b>Age Categorical</b> (units: participants) Count of Participants (Not Applicable)									
<=18 years	0	0	0	0	0	0	0	0	0
Between 18 and 65 years	0	2	2	3	3	4	8	4	4
>=65 years	1	0	2	1	1	1	0	2	1
<b>Sex: Female, Male</b> (units: participants) Count of Participants (Not Applicable)									
Female	0	1	0	0	2	2	2	1	3
Male	1	1	4	4	2	3	6	5	2
<b>Race/Ethnicity, Customized</b> (units: participants) Count of Participants (Not Applicable)									
Caucasian	0	2	4	3	3	2	5	5	4

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Black	0	0	0	0	0	0	0	0	0
Asian	1	0	0	0	1	2	2	1	1
Other	0	0	0	0	0	0	0	0	0
Missing	0	0	0	1	0	1	1	0	0

	Hematological malignancies: HDM201 1A 250 mg	Hematological malignancies: HDM201 1A 350 mg	Hematological malignancies: HDM201 1A 400 mg	Hematological malignancies: HDM201 1B 120 mg	Hematological malignancies: HDM201 1B 150 mg	Hematological malignancies: HDM201 2A 20 mg	Hematological malignancies: HDM201 2A 30 mg	Hematological malignancies: HDM201 2C 45 mg	Total
<b>Arm/Group Description</b>	Regimen 1A. Dose: 250 mg HDM201 (RDE) in hematological malignancies.	Regimen 1A. Dose: 350 mg HDM201 in hematological malignancies.	Regimen 1A. Dose: 400 mg HDM201 in hematological malignancies.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in hematological malignancies.	Regimen 1B. Dose: 150 mg HDM201 in hematological malignancies.	Regimen 2A. Dose: 20 mg HDM201 in hematological malignancies.	Regimen 2A. Dose: 30 mg HDM201 in hematological malignancies.	Regimen 2C. Dose: 45 mg HDM201 (RDE) in hematological malignancies.	All participants in the study
<b>Number of Participants [units: participants]</b>	15	4	9	24	6	3	4	28	208
<b>Age Categorical</b> (units: participants) Count of Participants (Not Applicable)									
<=18 years	0	0	0	0	0	0	0	0	0
Between 18 and 65 years	4	2	3	7	1	3	1	9	110
>=65 years	11	2	6	17	5	0	3	19	98
<b>Sex: Female, Male</b> (units: participants) Count of Participants (Not Applicable)									
Female	8	1	3	7	5	0	0	11	86
Male	7	3	6	17	1	3	4	17	122

**Clinical Trial Results Website****Race/Ethnicity, Customized**

(units: participants)

Count of Participants (Not Applicable)

Caucasian	12	1	7	14	6	3	3	26	142
Black	1	1	1	0	0	0	0	0	4
Asian	0	0	1	0	0	0	0	1	33
Other	2	2	0	10	0	0	1	1	19
Missing	0	0	0	0	0	0	0	0	10

**Primary Outcome Result(s)**

**Incidence of Dose Limiting Toxicities (DLTs) during the first cycle of treatment**

(Time Frame: 3 weeks for regimen 1A and 2C, and 4 weeks for regimen 1B and 2A)

	<b>Solid tumors: HDM201 1A 12.5 mg</b>	<b>Solid tumors: HDM201 1A 25 mg</b>	<b>Solid tumors: HDM201 1A 50 mg</b>	<b>Solid tumors: HDM201 1A 100 mg</b>	<b>Solid tumors: HDM201 1A 200 mg</b>	<b>Solid tumors: HDM201 1A 250 mg</b>	<b>Solid tumors: HDM201 1A 350 mg</b>	<b>Solid tumors: HDM201 1A 250 mg + Eltrombopag</b>	<b>Solid tumors: HDM201 1B 120 mg</b>	<b>Solid tumors: HDM201 1B 150 mg</b>	<b>Solid tumors: HDM201 1B 200 mg</b>	<b>Solid tumors: HDM201 1B 150 mg + Eltrombopag</b>
<b>Arm/Group Description</b>	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 + Eltrombopag in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	1	1	4	4	5	6	5	3	9	8	3	5
<b>Incidence of Dose Limiting Toxicities (DLTs) during the first cycle of treatment (units: participants)</b>	Count of Participants (Not Applicable)											
	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (40%)	2 (66.67%)	0 (%)	1 (12.5%)	0 (%)	1 (20%)

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	<b>Solid tumors: HDM201 2A 1 mg</b>	<b>Solid tumors: HDM201 2A 2 mg</b>	<b>Solid tumors: HDM201 2A 4 mg</b>	<b>Solid tumors: HDM201 2A 7.5 mg</b>	<b>Solid tumors: HDM201 2A 15 mg</b>	<b>Solid tumors: HDM201 2A 20 mg</b>	<b>Solid tumors: HDM201 2C 15 mg</b>	<b>Solid tumors: HDM201 2C 20 mg</b>	<b>Solid tumors: HDM201 2C 25 mg</b>
<b>Arm/Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	1	2	3	4	4	5	8	6	5
<b>Incidence of Dose Limiting Toxicities (DLTs) during the first cycle of treatment</b> (units: participants) Count of Participants (Not Applicable)									
	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (40%)

	Hematological malignancies: HDM201 1A 250 mg	Hematological malignancies: HDM201 1A 350 mg	Hematological malignancies: HDM201 1A 400 mg	Hematological malignancies: HDM201 1B 120 mg	Hematological malignancies: HDM201 1B 150 mg	Hematological malignancies: HDM201 2A 20 mg	Hematological malignancies: HDM201 2A 30 mg	Hematological malignancies: HDM201 2C 45 mg
<b>Arm/Group Description</b>	Regimen 1A. Dose: 250 mg HDM201 (RDE) in hematological malignancies.	Regimen 1A. Dose: 350 mg HDM201 in hematological malignancies.	Regimen 1A. Dose: 400 mg HDM201 in hematological malignancies.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in hematological malignancies.	Regimen 1B. Dose: 150 mg HDM201 in hematological malignancies.	Regimen 2A. Dose: 20 mg HDM201 in hematological malignancies.	Regimen 2A. Dose: 30 mg HDM201 in hematological malignancies.	Regimen 2C. Dose: 45 mg HDM201 (RDE) in hematological malignancies.
<b>Number of Participants Analyzed [units: participants]</b>	14	4	7	6	6	3	4	9
<b>Incidence of Dose Limiting Toxicities (DLTs) during the first cycle of treatment</b>								
(units: participants)								
Count of Participants (Not Applicable)								
	3 (21.43%)	0 (%)	4 (57.14%)	0 (%)	1 (16.67%)	1 (33.33%)	0 (%)	1 (11.11%)



**Secondary Outcome Result(s)**

**Number of participants with dose reductions or dose delays**

(Time Frame: Up to 128 weeks (regimen 1A), 191 weeks (regimen 1B), 276 weeks (regimen 2A) and 89 weeks (regimen 2C).)

	<b>Solid tumors: HDM201 1A 12.5 mg</b>	<b>Solid tumors: HDM201 1A 25 mg</b>	<b>Solid tumors: HDM201 1A 50 mg</b>	<b>Solid tumors: HDM201 1A 100 mg</b>	<b>Solid tumors: HDM201 1A 200 mg</b>	<b>Solid tumors: HDM201 1A 250 mg</b>	<b>Solid tumors: HDM201 1A 350 mg</b>	<b>Solid tumors: HDM201 1A 250 mg + Eltrombopag</b>	<b>Solid tumors: HDM201 1B 120 mg</b>	<b>Solid tumors: HDM201 1B 150 mg</b>	<b>Solid tumors: HDM201 1B 200 mg</b>	<b>Solid tumors: HDM201 1B 150 mg + Eltrombopag</b>
<b>Arm/Group Description</b>	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors.	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 + Eltrombopag in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	1	1	4	4	5	6	5	3	29	8	3	7
<b>At least one dose reduction</b>	0 (%)	0 (%)	0 (%)	0 (%)	2 (40%)	3 (50%)	0 (%)	1 (33.33%)	7 (24.14%)	1 (12.5%)	1 (33.33%)	2 (28.57%)
<b>At least one dose delay</b>	1 (100%)	1 (100%)	4 (100%)	4 (100%)	5 (100%)	5 (83.33%)	5 (100%)	2 (66.67%)	28 (96.55%)	8 (100%)	3 (100%)	7 (100%)

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	<b>Solid tumors: HDM201 2A 1 mg</b>	<b>Solid tumors: HDM201 2A 2 mg</b>	<b>Solid tumors: HDM201 2A 4 mg</b>	<b>Solid tumors: HDM201 2A 7.5 mg</b>	<b>Solid tumors: HDM201 2A 15 mg</b>	<b>Solid tumors: HDM201 2A 20 mg</b>	<b>Solid tumors: HDM201 2C 15 mg</b>	<b>Solid tumors: HDM201 2C 20 mg</b>	<b>Solid tumors: HDM201 2C 25 mg</b>
<b>Arm/Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	1	2	4	4	4	5	8	6	5
At least one dose reduction	0 (%)	0 (%)	0 (%)	1 (25%)	2 (50%)	1 (20%)	1 (12.5%)	1 (16.67%)	1 (20%)
At least one dose delay	0 (%)	1 (50%)	3 (75%)	3 (75%)	4 (100%)	5 (100%)	8 (100%)	6 (100%)	5 (100%)

	<b>Hematological malignancies: HDM201 1A 250 mg</b>	<b>Hematological malignancies: HDM201 1A 350 mg</b>	<b>Hematological malignancies: HDM201 1A 400 mg</b>	<b>Hematological malignancies: HDM201 1B 120 mg</b>	<b>Hematological malignancies: HDM201 1B 150 mg</b>	<b>Hematological malignancies: HDM201 2A 20 mg</b>	<b>Hematological malignancies: HDM201 2A 30 mg</b>	<b>Hematological malignancies: HDM201 2C 45 mg</b>
<b>Arm/Group Description</b>	Regimen 1A. Dose: 250 mg HDM201 (RDE) in hematological malignancies.	Regimen 1A. Dose: 350 mg HDM201 in hematological malignancies.	Regimen 1A. Dose: 400 mg HDM201 in hematological malignancies.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in hematological malignancies.	Regimen 1B. Dose: 150 mg HDM201 in hematological malignancies.	Regimen 2A. Dose: 20 mg HDM201 in hematological malignancies.	Regimen 2A. Dose: 30 mg HDM201 in hematological malignancies.	Regimen 2C. Dose: 45 mg HDM201 (RDE) in hematological malignancies.
<b>Number of Participants Analyzed [units: participants]</b>	15	4	9	24	6	3	4	28
<b>At least one dose reduction</b>	2 (13.33%)	0 (%)	3 (33.33%)	0 (%)	1 (16.67%)	0 (%)	0 (%)	5 (17.86%)
<b>At least one dose delay</b>	7 (46.67%)	1 (25%)	4 (44.44%)	8 (33.33%)	2 (33.33%)	0 (%)	3 (75%)	15 (53.57%)

**Dose intensity**

(Time Frame: Up to 128 weeks (regimen 1A), 191 weeks (regimen 1B), 276 weeks (regimen 2A) and 89 weeks (regimen 2C).)

	Solid tumors: HDM201 1A 12.5 mg	Solid tumors: HDM201 1A 25 mg	Solid tumors: HDM201 1A 50 mg	Solid tumors: HDM201 1A 100 mg	Solid tumors: HDM201 1A 200 mg	Solid tumors: HDM201 1A 250 mg	Solid tumors: HDM201 1A 350 mg	Solid tumors: HDM201 1A 250 mg + Eltrombopag	Solid tumors: HDM201 1B 120 mg	Solid tumors: HDM201 1B 150 mg	Solid tumors: HDM201 1B 200 mg	Solid tumors: HDM201 1B 150 mg + Eltrombopag
<b>Arm/Group Description</b>	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 + Eltrombopag in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	1	1	4	4	5	6	5	3	29	8	3	7
<b>Dose intensity (units: mg/day) Median (Full Range)</b>	5.36 (5.36 to 5.36)	19.35 (19.35 to 19.35)	21.36 (18.75 to 25.00)	46.13 (37.50 to 50.00)	75.00 (42.86 to 100.00)	80.25 (61.81 to 250.00)	115.75 (68.69 to 140.00)	83.33 (55.92 to 250.00)	64.00 (42.51 to 120.00)	85.71 (73.68 to 98.82)	99.71 (65.38 to 110.24)	90.00 (63.36 to 144.83)

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	<b>Solid tumors: HDM201 2A 1 mg</b>	<b>Solid tumors: HDM201 2A 2 mg</b>	<b>Solid tumors: HDM201 2A 4 mg</b>	<b>Solid tumors: HDM201 2A 7.5 mg</b>	<b>Solid tumors: HDM201 2A 15 mg</b>	<b>Solid tumors: HDM201 2A 20 mg</b>	<b>Solid tumors: HDM201 2C 15 mg</b>	<b>Solid tumors: HDM201 2C 20 mg</b>	<b>Solid tumors: HDM201 2C 25 mg</b>
<b>Arm/Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	1	2	4	4	4	5	8	6	5
<b>Dose intensity (units: mg/day) Median (Full Range)</b>	1.00 (1.00 to 1.00)	1.64 (1.28 to 2.00)	2.65 (2.10 to 4.00)	5.48 (4.23 to 7.50)	8.39 (3.89 to 10.24)	11.00 (8.60 to 13.33)	9.62 (6.16 to 13.33)	10.63 (8.71 to 13.33)	12.39 (10.51 to 16.67)

	<b>Hematological malignancies: HDM201 1A 250 mg</b>	<b>Hematological malignancies: HDM201 1A 350 mg</b>	<b>Hematological malignancies: HDM201 1A 400 mg</b>	<b>Hematological malignancies: HDM201 1B 120 mg</b>	<b>Hematological malignancies: HDM201 1B 150 mg</b>	<b>Hematological malignancies: HDM201 2A 20 mg</b>	<b>Hematological malignancies: HDM201 2A 30 mg</b>	<b>Hematological malignancies: HDM201 2C 45 mg</b>
<b>Arm/Group Description</b>	Regimen 1A. Dose: 250 mg HDM201 (RDE) in hematological malignancies.	Regimen 1A. Dose: 350 mg HDM201 in hematological malignancies.	Regimen 1A. Dose: 400 mg HDM201 in hematological malignancies.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in hematological malignancies.	Regimen 1B. Dose: 150 mg HDM201 in hematological malignancies.	Regimen 2A. Dose: 20 mg HDM201 in hematological malignancies.	Regimen 2A. Dose: 30 mg HDM201 in hematological malignancies.	Regimen 2C. Dose: 45 mg HDM201 (RDE) in hematological malignancies.
<b>Number of Participants Analyzed [units: participants]</b>	15	4	9	24	6	3	4	28
<b>Dose intensity (units: mg/day) Median (Full Range)</b>	83.33 (39.91 to 250.00)	157.50 (120.93 to 175.00)	160.00 (92.23 to 400.00)	75.53 (39.07 to 120.00)	91.13 (53.79 to 150.00)	14.00 (13.33 to 20.00)	21.44 (13.41 to 30.00)	25.84 (8.11 to 64.00)

Clinical Trial Results Website

**Maximum observed plasma concentration (Cmax) of HDM201 (regimen 1A)**

(Time Frame: Pre-dose, 0.5, 1, 2, 3, 4, 8, 24 and 48 hours post-dose on Cycle 1 Day 1. On Cycle 2 Day 1, samples were taken up to 24 hours post-dose. The duration of each cycle was 3 weeks.)

	<b>HDM201 1A 12.5 mg</b>	<b>HDM201 1A 25 mg</b>	<b>HDM201 1A 50 mg</b>	<b>HDM201 1A 100 mg</b>	<b>HDM201 1A 200 mg</b>	<b>HDM201 1A 250 mg</b>	<b>HDM201 1A 350 mg</b>	<b>HDM201 1A 400 mg</b>
<b>Arm/Group Description</b>	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors and hematologic malignancies.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors and hematologic malignancies.	Regimen 1A. Dose: 400 mg HDM201 in hematologic malignancies.
<b>Number of Participants Analyzed [units: participants]</b>	1 (C1D1) 1 (C2D1)	1 (C1D1) 1 (C2D1)	4 (C1D1) 4 (C2D1)	4 (C1D1) 4 (C2D1)	5 (C1D1) 5 (C2D1)	21 (C1D1) 14 (C2D1)	9 (C1D1) 6 (C2D1)	9 (C1D1) 5 (C2D1)

**Maximum observed plasma concentration (Cmax) of HDM201 (regimen 1A)**

(units: ng/mL)

Geometric Mean (Geometric Coefficient of Variation)

Cycle 1 Day 1 (C1D1)	118.0	100.0	467.0 (13.0%)	663.3 (30.1%)	1168.8 (43.7%)	2015.7 (69.5%)	2258.8 (56.9%)	3750.4 (47.8%)
Cycle 2 Day 1 (C2D1)	121.0	126.0	499.9 (31.6%)	778.9 (14.8%)	1309.7 (63.0%)	1533.5 (44.1%)	2601.3 (58.6%)	3199.1 (15.7%)

**Clinical Trial Results Website**

**Maximum observed plasma concentration (Cmax) of HDM201 (regimen 1B)**

(Time Frame: Pre-dose, 0.5, 1, 2, 3, 4, 8, 24 and 48 hours post-dose on Cycle 1 Day 1. On Cycle 1 Day 8 and Cycle 2 Day 1, samples were taken up to 8 hours and 24 hours post-dose, respectively. The duration of each cycle was 4 weeks.)

	<b>HDM201 1B 120 mg (dose escalation phase)</b>	<b>HDM201 1B 120 mg (dose expansion phase)</b>	<b>HDM201 1B 150 mg</b>	<b>HDM201 1B 200 mg</b>
<b>Arm/Group Description</b>	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors and hematological malignancies.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors and hematological malignancies.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors and hematological malignancies.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	13 (C1D1) 14 (C1D8) 12 (C2D1)	38 (C1D1) 0 (C1D8) 0 (C2D1)	14 (C1D1) 12 (C1D8) 11 (C2D1)	3 (C1D1) 1 (C1D8) 3 (C2D1)

**Maximum observed plasma concentration (Cmax) of HDM201 (regimen 1B)**

(units: ng/mL)

Geometric Mean (Geometric Coefficient of Variation)

Cycle 1 Day 1 (C1D1)	1039.5 (51.5%)	1277.3 (34.0%)	1444.3 (27.8%)	2051.2 (82.2%)
Cycle 1 Day 8 (C1D8)	856.9 (74.7%)	-	1136.3 (48.1%)	1160.0
Cycle 2 Day 1 (C2D1)	851.6 (81.4%)	-	1430.5 (27.1%)	1421.1 (73.4%)



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**Maximum observed plasma concentration (C<sub>max</sub>) of HDM201 (regimen 2A)**

(Time Frame: Pre-dose, 0.5, 1, 2, 3, 4, 8 and 24 hours post-dose on Cycle 1 Day 1. On Cycle 1 Day 8 and Cycle 1 Day 14, samples were taken up to 8 hours post-dose. The duration of each cycle was 4 weeks.)

	HDM201 2A 1 mg	HDM201 2A 2 mg	HDM201 2A 4 mg	HDM201 2A 7.5 mg	HDM201 2A 15 mg	HDM201 2A 20 mg	HDM201 2A 30 mg
<b>Arm/Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors and hematological malignancies.	Regimen 2A. Dose: 30 mg HDM201 in hematological malignancies.
<b>Number of Participants</b>	1 (C1D1)	2 (C1D1)	4 (C1D1)	4 (C1D1)	4 (C1D1)	8 (C1D1)	4 (C1D1)
<b>Analyzed [units:</b>	1 (C1D8)	2 (C1D8)	4 (C1D8)	3 (C1D8)	4 (C1D8)	7 (C1D8)	3 (C1D8)
<b>participants]</b>	1 (C1D14)	2 (C1D14)	3 (C1D14)	3 (C1D14)	4 (C1D14)	7 (C1D14)	3 (C1D14)

**Maximum observed plasma concentration (C<sub>max</sub>) of HDM201 (regimen 2A)**

(units: ng/mL)

Geometric Mean (Geometric Coefficient of Variation)

Cycle 1 Day 1 (C1D1)	7.9	12.0 (23.7%)	17.6 (22.8%)	39.0 (43.9%)	91.5 (56.9%)	149.5 (20.3%)	176.9 (23.5%)
Cycle 1 Day 8 (C1D8)	15.5	18.8 (28.1%)	24.0 (26.4%)	48.1 (85.3%)	127.8 (22.4%)	183.5 (37.7%)	168.9 (28.9%)
Cycle 1 Day 14 (C1D14)	14.9	17.5 (4.9%)	25.6 (23.9%)	52.2 (79.9%)	106.0 (27.9%)	176.3 (32.0%)	156.7 (29.9%)

**Maximum observed plasma concentration (C<sub>max</sub>) of HDM201 (regimen 2C)**

(Time Frame: Pre-dose, 0.5, 1, 2, 3, 4, 8 and 24 hours post-dose on Cycle 1 Day 1. On Cycle 1 Day 7 and Cycle 2 Day 1, samples were taken up to 8 hours and 24 hours post-dose, respectively. The duration of each cycle was 3 weeks.)

	<b>HDM201 2C 15 mg</b>	<b>HDM201 2C 20 mg</b>	<b>HDM201 2C 25 mg</b>	<b>HDM201 2C 45 mg (dose escalation phase)</b>	<b>HDM201 2C 45 mg (dose expansion phase)</b>
<b>Arm/Group Description</b>	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.	Regimen 2C. Dose: 45 mg HDM201 (RDE) in hematological malignancies.	Regimen 2C. Dose: 45 mg HDM201 (RDE) in hematological malignancies.
<b>Number of Participants</b>	8 (C1D1)	6 (C1D1)	5 (C1D1)	8 (C1D1)	18 (C1D1)
<b>Analyzed [units: participants]</b>	7 (C1D7) 8 (C2D1)	5 (C1D7) 6 (C2D1)	5 (C1D7) 4 (C2D1)	5 (C1D7) 7 (C2D1)	0 (C1D7) 0 (C2D1)

**Maximum observed plasma concentration (C<sub>max</sub>) of HDM201 (regimen 2C)**

(units: ng/mL)

Geometric Mean (Geometric Coefficient of Variation)

Cycle 1 Day 1 (C1D1)	131.8 (64.9%)	156.6 (28.2%)	234.7 (27.5%)	425.3 (37.9%)	526.3 (33.3%)
Cycle 1 Day 7 (C1D7)	176.7 (64.1%)	197.6 (26.9%)	292.4 (43.8%)	433.2 (23.7%)	-
Cycle 2 Day 1 (C2D1)	117.6 (52.5%)	172.4 (33.2%)	211.5 (40.6%)	393.1 (26.3%)	-

**Area under the plasma concentration-time curve from time zero to the time of last quantifiable concentration point (AUClast) of HDM201 (regimen 1A)**

(Time Frame: Pre-dose, 0.5, 1, 2, 3, 4, 8, 24 and 48 hours post-dose on Cycle 1 Day 1. On Cycle 2 Day 1, samples were taken up to 24 hours post-dose. The duration of each cycle was 3 weeks.)

	HDM201 1A 12.5 mg	HDM201 1A 25 mg	HDM201 1A 50 mg	HDM201 1A 100 mg	HDM201 1A 200 mg	HDM201 1A 250 mg	HDM201 1A 350 mg	HDM201 1A 400 mg
<b>Arm/Group Description</b>	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors and hematologic malignancies.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors and hematologic malignancies.	Regimen 1A. Dose: 400 mg HDM201 in hematologic malignancies.
<b>Number of Participants Analyzed [units: participants]</b>	1 (C1D1) 1 (C2D1)	1 (C1D1) 1 (C2D1)	4 (C1D1) 4 (C2D1)	4 (C1D1) 3 (C2D1)	5 (C1D1) 5 (C2D1)	21 (C1D1) 13 (C2D1)	9 (C1D1) 6 (C2D1)	9 (C1D1) 4 (C2D1)

**Area under the plasma concentration-time curve from time zero to the time of last quantifiable concentration point (AUClast) of HDM201 (regimen 1A)**

(units: ng\*hr/mL)

Geometric Mean (Geometric Coefficient of Variation)

Cycle 1 Day 1 (C1D1)	1483.1	1773.6	8028.8 (25.6%)	14287.0 (58.5%)	26255.2 (56.2%)	41422.3 (71.2%)	55102.9 (34.4%)	81662.7 (42.3%)
Cycle 2 Day 1 (C2D1)	1359.7	1879.7	7178.2 (43.5%)	11675.2 (5.0%)	20070.6 (65.6%)	22887.0 (50.8%)	37768.7 (45.8%)	48124.6 (18.6%)

**Area under the plasma concentration-time curve from time zero to the time of last quantifiable concentration point (AUClast) of HDM201 (regimen 1B)**

(Time Frame: Pre-dose, 0.5, 1, 2, 3, 4, 8, 24 and 48 hours post-dose on Cycle 1 Day 1. On Cycle 1 Day 8 and Cycle 2 Day 1, samples were taken up to 8 hours and 24 hours post-dose, respectively. The duration of each cycle was 4 weeks.)

	<b>HDM201 1B 120 mg (dose escalation phase)</b>	<b>HDM201 1B 120 mg (dose expansion phase)</b>	<b>HDM201 1B 150 mg</b>	<b>HDM201 1B 200 mg</b>
<b>Arm/Group Description</b>	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors and hematological malignancies.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors and hematological malignancies.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors and hematological malignancies.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	13 (C1D1) 13 (C1D8) 10 (C2D1)	34 (C1D1) 0 (C1D8) 0 (C2D1)	14 (C1D1) 10 (C1D8) 9 (C2D1)	3 (C1D1) 1 (C1D8) 2 (C2D1)

**Area under the plasma concentration-time curve from time zero to the time of last quantifiable concentration point (AUClast) of HDM201 (regimen 1B)**

(units: ng\*hr/mL)

Geometric Mean (Geometric Coefficient of Variation)

Cycle 1 Day 1 (C1D1)	18481.7 (62.7%)	14761.1 (35.9%)	23727.1 (43.2%)	19303.0 (73.5%)
Cycle 1 Day 8 (C1D8)	5270.0 (53.4%)	-	6323.4 (36.7%)	4886.2
Cycle 2 Day 1 (C2D1)	11864.2 (83.4%)	-	17921.0 (29.2%)	14701.4 (78.2%)

**Area under the plasma concentration-time curve from time zero to the time of last quantifiable concentration point (AUC<sub>last</sub>) of HDM201 (regimen 2A)**

(Time Frame: Pre-dose, 0.5, 1, 2, 3, 4, 8 and 24 hours post-dose on Cycle 1 Day 1. On Cycle 1 Day 8 and Cycle 1 Day 14, samples were taken up to 8 hours post-dose. The duration of each cycle was 4 weeks.)

	<b>HDM201 2A 1 mg</b>	<b>HDM201 2A 2 mg</b>	<b>HDM201 2A 4 mg</b>	<b>HDM201 2A 7.5 mg</b>	<b>HDM201 2A 15 mg</b>	<b>HDM201 2A 20 mg</b>	<b>HDM201 2A 30 mg</b>
<b>Arm/Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors and hematological malignancies.	Regimen 2A. Dose: 30 mg HDM201 in hematological malignancies.
<b>Number of Participants Analyzed [units: participants]</b>	1 (C1D1) 1 (C1D8) 1 (C1D14)	2 (C1D1) 2 (C1D8) 2 (C1D14)	3 (C1D1) 4 (C1D8) 3 (C1D14)	4 (C1D1) 3 (C1D8) 3 (C1D14)	4 (C1D1) 3 (C1D8) 4 (C1D14)	7 (C1D1) 7 (C1D8) 7 (C1D14)	4 (C1D1) 3 (C1D8) 3 (C1D14)

**Area under the plasma concentration-time curve from time zero to the time of last quantifiable concentration point (AUC<sub>last</sub>) of HDM201 (regimen 2A)**

(units: ng\*hr/mL)

Geometric Mean (Geometric Coefficient of Variation)

	<b>HDM201 2A 1 mg</b>	<b>HDM201 2A 2 mg</b>	<b>HDM201 2A 4 mg</b>	<b>HDM201 2A 7.5 mg</b>	<b>HDM201 2A 15 mg</b>	<b>HDM201 2A 20 mg</b>	<b>HDM201 2A 30 mg</b>
Cycle 1 Day 1 (C1D1)	134.3	169.1 (31.5%)	215.3 (22.0%)	598.1 (49.8%)	1301.6 (71.0%)	2289.5 (29.6%)	2692.3 (41.9%)
Cycle 1 Day 8 (C1D8)	109.1	125.8 (18.8%)	140.1 (8.7%)	305.9 (79.5%)	783.2 (20.7%)	1132.4 (38.3%)	986.8 (45.7%)
Cycle 1 Day 14 (C1D14)	99.5	109.3 (6.0%)	155.0 (21.7%)	330.2 (87.4%)	688.8 (29.2%)	1044.7 (32.2%)	961.1 (23.9%)

**Area under the plasma concentration-time curve from time zero to the time of last quantifiable concentration point (AUClast) of HDM201 (regimen 2C)**

(Time Frame: Pre-dose, 0.5, 1, 2, 3, 4, 8 and 24 hours post-dose on Cycle 1 Day 1. On Cycle 1 Day 7 and Cycle 2 Day 1, samples were taken up to 8 hours and 24 hours post-dose, respectively. The duration of each cycle was 3 weeks.)

	<b>HDM201 2C 15 mg</b>	<b>HDM201 2C 20 mg</b>	<b>HDM201 2C 25 mg</b>	<b>HDM201 2C 45 mg (dose escalation phase)</b>	<b>HDM201 2C 45 mg (dose expansion phase)</b>
<b>Arm/Group Description</b>	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.	Regimen 2C. Dose: 45 mg HDM201 (RDE) in hematological malignancies.	Regimen 2C. Dose: 45 mg HDM201 (RDE) in hematological malignancies.
<b>Number of Participants Analyzed [units: participants]</b>	8 (C1D1) 7 (C1D7) 8 (C2D1)	6 (C1D1) 5 (C1D7) 5 (C2D1)	5 (C1D1) 5 (C1D7) 4 (C2D1)	7 (C1D1) 5 (C1D7) 7 (C2D1)	18 (C1D1) 0 (C1D7) 0 (C2D1)

**Area under the plasma concentration-time curve from time zero to the time of last quantifiable concentration point (AUClast) of HDM201 (regimen 2C)**

(units: ng\*hr/mL)

Geometric Mean (Geometric Coefficient of Variation)

Cycle 1 Day 1 (C1D1)	1549.2 (67.2%)	1962.2 (16.5%)	2667.7 (28.3%)	5234.6 (40.7%)	6353.9 (58.7%)
Cycle 1 Day 7 (C1D7)	933.7 (59.7%)	1037.7 (46.9%)	1662.8 (40.5%)	2285.4 (26.9%)	-
Cycle 2 Day 1 (C2D1)	1574.6 (51.0%)	2285.6 (38.1%)	2843.3 (37.7%)	4718.4 (32.3%)	-

**Time to reach maximum observed plasma concentration (Tmax) of HDM201 (all regimens)**

(Time Frame: Pre-dose, 0.5, 1, 2, 3, 4, 8 and 24 hours (and 48 hours for 1A and 1B only) post-dose on Cycle 1 Day 1.)

	HDM201 1A 12.5 mg	HDM201 1A 25 mg	HDM201 1A 50 mg	HDM201 1A 100 mg	HDM201 1A 200 mg	HDM201 1A 250 mg	HDM201 1A 350 mg	HDM201 1A 400 mg	HDM201 1B 120 mg (dose escalation phase)	HDM201 1B 120 mg (dose expansion phase)	HDM201 1B 150 mg	HDM201 1B 200 mg
<b>Arm/Group Description</b>	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors and hematologic malignancies.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors and hematologic malignancies.	Regimen 1A. Dose: 400 mg HDM201 in hematologic malignancies.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors and hematological malignancies.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors and hematological malignancies.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors and hematological malignancies.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	1	1	4	4	5	21	9	9	13	38	14	3
<b>Time to reach maximum observed plasma concentration (Tmax) of HDM201 (all regimens)</b>												
(units: hours)												
Median (Full Range)												
	3.2 (3.2 to 3.2)	2.1 (2.1 to 2.1)	3.0 (2.0 to 4.0)	3.5 (3.0 to 4.0)	3.0 (3.0 to 8.0)	3.0 (1.1 to 8.3)	3.0 (1.0 to 8.0)	3.0 (2.0 to 7.7)	2.1 (1.0 to 8.0)	2.0 (1.0 to 8.1)	2.0 (1.9 to 4.4)	2.1 (2.0 to 3.2)

	HDM201 2A 1 mg	HDM201 2A 2 mg	HDM201 2A 4 mg	HDM201 2A 7.5 mg	HDM201 2A 15 mg	HDM201 2A 20 mg	HDM201 2A 30 mg	HDM201 2C 15 mg	HDM201 2C 20 mg	HDM201 2C 25 mg	HDM201 2C 45 mg (dose escalation phase)	HDM201 2C 45 mg (dose expansion phase)
<b>Arm/Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors and hematological malignancies.	Regimen 2A. Dose: 30 mg HDM201 in hematological malignancies.	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.	Regimen 2C. Dose: 45 mg HDM201 (RDE) in hematological malignancies.	Regimen 2C. Dose: 45 mg HDM201 (RDE) in hematological malignancies.
<b>Number of Participants Analyzed [units: participants]</b>	1	2	4	4	4	8	4	8	6	5	8	18
<b>Time to reach maximum observed plasma concentration (Tmax) of HDM201 (all regimens)</b> (units: hours) Median (Full Range)	8.0 (8.0 to 8.0)	3.4 (2.8 to 4.0)	2.5 (2.0 to 3.9)	5.8 (4.0 to 8.0)	3.1 (2.9 to 4.0)	3.5 (2.0 to 8.0)	4.2 (3.0 to 24.0)	3.0 (1.9 to 4.0)	2.5 (2.0 to 7.9)	2.0 (1.0 to 2.9)	2.0 (1.0 to 4.2)	2.0 (1.0 to 24.1)



**Terminal elimination half-life (T1/2) of HDM201 (all regimens)**

(Time Frame: Pre-dose, 0.5, 1, 2, 3, 4, 8 and 24 hours (and 48 hours for 1A and 1B only) post-dose on Cycle 1 Day 1.)

	HDM201 1A 12.5 mg	HDM201 1A 25 mg	HDM201 1A 50 mg	HDM201 1A 100 mg	HDM201 1A 200 mg	HDM201 1A 250 mg	HDM201 1A 350 mg	HDM201 1A 400 mg	HDM201 1B 120 mg (dose escalation phase)	HDM201 1B 120 mg (dose expansion phase)	HDM201 1B 150 mg	HDM201 1B 200 mg
<b>Arm/Group Description</b>	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors and hematologic malignancies.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors and hematologic malignancies.	Regimen 1A. Dose: 400 mg HDM201 in hematologic malignancies.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors and hematological malignancies.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors and hematological malignancies.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors and hematological malignancies.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	1	1	4	3	4	18	7	8	11	29	14	3
<b>Terminal elimination half-life (T1/2) of HDM201 (all regimens)</b>												
(units: hours)												
Median (Full Range)												
	7.2 (7.2 to 7.2)	31.1 (31.1 to 31.1)	11.0 (9.4 to 17.3)	17.1 (13.0 to 19.7)	18.5 (5.4 to 34.3)	15.5 (7.7 to 36.7)	14.0 (8.6 to 24.9)	18.8 (8.5 to 42.8)	12.4 (8.3 to 43.9)	12.7 (4.7 to 21.8)	13.1 (6.2 to 25.3)	6.4 (6.2 to 7.0)

	HDM201 2A 1 mg	HDM201 2A 2 mg	HDM201 2A 4 mg	HDM201 2A 7.5 mg	HDM201 2A 15 mg	HDM201 2A 20 mg	HDM201 2A 30 mg	HDM201 2C 15 mg	HDM201 2C 20 mg	HDM201 2C 25 mg	HDM201 2C 45 mg (dose escalation phase)	HDM201 2C 45 mg (dose expansion phase)
<b>Arm/Group Description</b>	Regimen 2A, Dose: 1 mg HDM201 in solid tumors.	Regimen 2A, Dose: 2 mg HDM201 in solid tumors.	Regimen 2A, Dose: 4 mg HDM201 in solid tumors.	Regimen 2A, Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A, Dose: 15 mg HDM201 in solid tumors.	Regimen 2A, Dose: 20 mg HDM201 in solid tumors and hematologica l malignancies.	Regimen 2A, Dose: 30 mg HDM201 in hematological malignancies.	Regimen 2C, Dose: 15 mg HDM201 in solid tumors.	Regimen 2C, Dose: 20 mg HDM201 in solid tumors.	Regimen 2C, Dose: 25 mg HDM201 in solid tumors.	Regimen 2C, Dose: 45 mg HDM201 (RDE) in hematological malignancies.	Regimen 2C, Dose: 45 mg HDM201 (RDE) in hematological malignancies.
<b>Number of Participants Analyzed [units: participants]</b>	0	1	3	0	2	4	1	7	4	5	4	13
<b>Terminal elimination half-life (T1/2) of HDM201 (all regimens)</b> (units: hours) Median (Full Range)												
	-	14.8 (14.8 to 14.8)	14.3 (9.6 to 14.6)		14.2 (12.6 to 15.8)	15.8 (11.1 to 28.2)	19.2 (19.2 to 19.2)	11.5 (3.6 to 19.8)	12.7 (9.1 to 14.7)	14.7 (4.9 to 20.0)	11.7 (11.2 to 14.1)	11.0 (3.5 to 53.5)

**Fold change from baseline in GDF-15 values**

(Time Frame: Cycle 1 Day 1 (baseline) and Cycle 2 Day 2.)

	<b>Solid tumors: HDM201 1A 12.5 mg</b>	<b>Solid tumors: HDM201 1A 25 mg</b>	<b>Solid tumors: HDM201 1A 50 mg</b>	<b>Solid tumors: HDM201 1A 100 mg</b>	<b>Solid tumors: HDM201 1A 200 mg</b>	<b>Solid tumors: HDM201 1A 250 mg</b>	<b>Solid tumors: HDM201 1A 350 mg</b>	<b>Solid tumors: HDM201 1A 250 mg + Eltrombopag</b>	<b>Solid tumors: HDM201 1B 120 mg</b>	<b>Solid tumors: HDM201 1B 150 mg</b>	<b>Solid tumors: HDM201 1B 200 mg</b>	<b>Solid tumors: HDM201 1B 150 mg + Eltrombopag</b>
<b>Arm/Group Description</b>	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 + Eltrombopag in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	1	1	4	4	5	6	5	3	29	8	3	7
<b>Fold change from baseline in GDF-15 values</b> (units: no units) Median (Full Range)	1.5 (1.1 to 1.8)	1.6 (1.3 to 2.0)	11.8 (3.9 to 27.1)	8.9 (4.5 to 22.6)	26.0 (8.5 to 97.1)	24.9 (1.4 to 80.6)	33.6 (12.4 to 71.0)	9.7 (1.2 to 14.9)	15.0 (1.0 to 61.1)	19.4 (7.4 to 33.0)	8.0 (4.5 to 14.2)	17.1 (5.1 to 48.2)

**Clinical Trial Results Website**

	<b>Solid tumors: HDM201 2A 1 mg</b>	<b>Solid tumors: HDM201 2A 2 mg</b>	<b>Solid tumors: HDM201 2A 4 mg</b>	<b>Solid tumors: HDM201 2A 7.5 mg</b>	<b>Solid tumors: HDM201 2A 15 mg</b>	<b>Solid tumors: HDM201 2A 20 mg</b>	<b>Solid tumors: HDM201 2C 15 mg</b>	<b>Solid tumors: HDM201 2C 20 mg</b>	<b>Solid tumors: HDM201 2C 25 mg</b>
<b>Arm/Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	1	2	4	4	4	5	8	6	5
<b>Fold change from baseline in GDF-15 values</b> (units: no units) Median (Full Range)	1.5 (1.3 to 1.6)	0.8 (0.5 to 1.2)	1.8 (0.9 to 8.1)	2.2 (1.4 to 4.4)	2.6 (1.6 to 14.7)	5.3 (1.4 to 22.9)	3.3 (1.5 to 11.2)	6.0 (2.3 to 19.7)	6.0 (2.6 to 18.9)

	<b>Hematological malignancies: HDM201 1A 250 mg</b>	<b>Hematological malignancies: HDM201 1A 350 mg</b>	<b>Hematological malignancies: HDM201 1A 400 mg</b>	<b>Hematological malignancies: HDM201 1B 120 mg</b>	<b>Hematological malignancies: HDM201 1B 150 mg</b>	<b>Hematological malignancies: HDM201 2A 20 mg</b>	<b>Hematological malignancies: HDM201 2A 30 mg</b>	<b>Hematological malignancies: HDM201 2C 45 mg</b>
<b>Arm/Group Description</b>	Regimen 1A. Dose: 250 mg HDM201 (RDE) in hematological malignancies.	Regimen 1A. Dose: 350 mg HDM201 in hematological malignancies.	Regimen 1A. Dose: 400 mg HDM201 in hematological malignancies.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in hematological malignancies.	Regimen 1B. Dose: 150 mg HDM201 in hematological malignancies.	Regimen 2A. Dose: 20 mg HDM201 in hematological malignancies.	Regimen 2A. Dose: 30 mg HDM201 in hematological malignancies.	Regimen 2C. Dose: 45 mg HDM201 (RDE) in hematological malignancies.
<b>Number of Participants Analyzed [units: participants]</b>	15	4	9	24	6	3	4	28
<b>Fold change from baseline in GDF-15 values (units: no units) Median (Full Range)</b>	17.9 (1.0 to 37.8)	18.6 (0.6 to 23.2)	23.7 (0.7 to 45.5)	10.3 (0.9 to 35.7)	16.6 (1.8 to 40.4)	4.4 (2.7 to 8.4)	3.9 (0.9 to 11.1)	8.1 (0.2 to 36.5)

**Change from baseline in p21 values**

(Time Frame: Screening (baseline) and Cycle 2 Day 2.)

	Solid tumors: HDM201 1A 12.5 mg	Solid tumors: HDM201 1A 25 mg	Solid tumors: HDM201 1A 50 mg	Solid tumors: HDM201 1A 100 mg	Solid tumors: HDM201 1A 200 mg	Solid tumors: HDM201 1A 250 mg	Solid tumors: HDM201 1A 350 mg	Solid tumors: HDM201 1A 250 mg + Eltrombopag	Solid tumors: HDM201 1B 120 mg	Solid tumors: HDM201 1B 150 mg	Solid tumors: HDM201 1B 200 mg	Solid tumors: HDM201 1B 150 mg + Eltrombopag
<b>Arm/Group Description</b>	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 + Eltrombopag in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	0	0	0	0	2	1	0	0	0	0	0	0
<b>Change from baseline in p21 values</b> (units: no units) Median (Full Range)	-	-	-	-	70.0 (40.0 to 100.0)	-240.0 (-240.0 to -240.0)	-	-	-	-	-	-

**Clinical Trial Results Website**

	<b>Solid tumors: HDM201 2A 1 mg</b>	<b>Solid tumors: HDM201 2A 2 mg</b>	<b>Solid tumors: HDM201 2A 4 mg</b>	<b>Solid tumors: HDM201 2A 7.5 mg</b>	<b>Solid tumors: HDM201 2A 15 mg</b>	<b>Solid tumors: HDM201 2A 20 mg</b>	<b>Solid tumors: HDM201 2C 15 mg</b>	<b>Solid tumors: HDM201 2C 20 mg</b>	<b>Solid tumors: HDM201 2C 25 mg</b>
<b>Arm/Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	0	0	1	2	0	2	2	0	0
<b>Change from baseline in p21 values</b> (units: no units) Median (Full Range)	-	-	-70.0 (-70.0 to - 70.0)	2.5 (-20.0 to 25.0)	-	160.0 (85.0 to 235.0)	2.5 (-30.0 to 35.0)	-	-

**Number of participants with Best Overall Response (BOR) according to RECIST 1.1 (Solid Tumors)**

(Time Frame: From first dose of study treatment up to 132 weeks (regimen 1A), 195 weeks (regimen 1B), 280 weeks (regimen 2A) and 93 weeks (regimen 2C).)

	<b>Solid tumors: HDM201 1A 12.5 mg</b>	<b>Solid tumors: HDM201 1A 25 mg</b>	<b>Solid tumors: HDM201 1A 50 mg</b>	<b>Solid tumors: HDM201 1A 100 mg</b>	<b>Solid tumors: HDM201 1A 200 mg</b>	<b>Solid tumors: HDM201 1A 250 mg</b>	<b>Solid tumors: HDM201 1A 350 mg</b>	<b>Solid tumors: HDM201 1A 250 mg + Eltrombopag</b>	<b>Solid tumors: HDM201 1B 120 mg</b>	<b>Solid tumors: HDM201 1B 150 mg</b>	<b>Solid tumors: HDM201 1B 200 mg</b>	<b>Solid tumors: HDM201 1B 150 mg + Eltrombopag</b>
<b>Arm/Group Description</b>	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors.	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 + Eltrombopag in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	1	1	4	4	5	6	5	3	29	8	3	7

**Number of participants with Best Overall Response (BOR) according to RECIST 1.1 (Solid Tumors)**

(units: participants)

Count of Participants (Not Applicable)

<b>Complete Response (CR)</b>	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
<b>Partial Response (PR)</b>	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (16.67%)	0 (%)	0 (%)	3 (10.34%)	0 (%)	0 (%)	0 (%)
<b>Stable Disease (SD)</b>	0 (%)	1 (100%)	0 (%)	0 (%)	3 (60%)	3 (50%)	1 (20%)	0 (%)	10 (34.48%)	3 (37.5%)	2 (66.67%)	1 (14.29%)
<b>Progressive Disease (PD)</b>	1 (100%)	0 (%)	4 (100%)	3 (75%)	1 (20%)	2 (33.33%)	3 (60%)	2 (66.67%)	14 (48.28%)	5 (62.5%)	1 (33.33%)	3 (42.86%)
<b>Unknown</b>	0 (%)	0 (%)	0 (%)	1 (25%)	1 (20%)	0 (%)	1 (20%)	1 (33.33%)	2 (6.9%)	0 (%)	0 (%)	3 (42.86%)



Clinical Trial Results Website

	<b>Solid tumors: HDM201 2A 1 mg</b>	<b>Solid tumors: HDM201 2A 2 mg</b>	<b>Solid tumors: HDM201 2A 4 mg</b>	<b>Solid tumors: HDM201 2A 7.5 mg</b>	<b>Solid tumors: HDM201 2A 15 mg</b>	<b>Solid tumors: HDM201 2A 20 mg</b>	<b>Solid tumors: HDM201 2C 15 mg</b>	<b>Solid tumors: HDM201 2C 20 mg</b>	<b>Solid tumors: HDM201 2C 25 mg</b>
<b>Arm/Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	1	2	4	4	4	5	8	6	5
<b>Number of participants with Best Overall Response (BOR) according to RECIST 1.1 (Solid Tumors)</b> (units: participants) Count of Participants (Not Applicable)									
Complete Response (CR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Partial Response (PR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Stable Disease (SD)	0 (%)	0 (%)	0 (%)	2 (50%)	2 (50%)	3 (60%)	1 (12.5%)	4 (66.67%)	2 (40%)
Progressive Disease (PD)	1 (100%)	2 (100%)	3 (75%)	2 (50%)	2 (50%)	2 (40%)	6 (75%)	2 (33.33%)	2 (40%)
Unknown	0 (%)	0 (%)	1 (25%)	0 (%)	0 (%)	0 (%)	1 (12.5%)	0 (%)	1 (20%)

**Duration of Response (DOR) according to RECIST 1.1 (Solid Tumors)**

(Time Frame: From first dose of study treatment up to 132 weeks (regimen 1A), 195 weeks (regimen 1B), 280 weeks (regimen 2A) and 93 weeks (regimen 2C).)

Due to limited evidence of preliminary efficacy in solid tumors with only 4 Partial Responses observed, DOR could not be assessed.

**Progression-Free Survival (PFS) according to RECIST 1.1 (Solid Tumors)**

(Time Frame: From first dose of study treatment up to 132 weeks (regimen 1A), 195 weeks (regimen 1B), 280 weeks (regimen 2A) and 93 weeks (regimen 2C).)

	<b>Solid tumors: HDM201 1A 12.5 mg</b>	<b>Solid tumors: HDM201 1A 25 mg</b>	<b>Solid tumors: HDM201 1A 50 mg</b>	<b>Solid tumors: HDM201 1A 100 mg</b>	<b>Solid tumors: HDM201 1A 200 mg</b>	<b>Solid tumors: HDM201 1A 250 mg</b>	<b>Solid tumors: HDM201 1A 350 mg</b>	<b>Solid tumors: HDM201 1A 250 mg + Eltrombopag</b>	<b>Solid tumors: HDM201 1B 120 mg</b>	<b>Solid tumors: HDM201 1B 150 mg</b>	<b>Solid tumors: HDM201 1B 200 mg</b>	<b>Solid tumors: HDM201 1B 150 mg + Eltrombopag</b>	
<b>Arm/Group Description</b>	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.	Regimen 1B. Dose: 150 mg HDM201 + Eltrombopag in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	1	1	4	4	5	6	5	3	29	8	3	7	
<b>Progression-Free Survival (PFS) according to RECIST 1.1 (Solid Tumors)</b>													
(units: months)													
Median (95% Confidence Interval)													
	1.9 (n.a. to n.a.)	7.6 (n.a. to n.a.)	1.8 (1.0 to n.a.)	1.8 (1.4 to n.a.)	3.9 (1.1 to n.a.)	7.1 (1.2 to n.a.)	1.7 (1.4 to n.a.)	1.7 (0.9 to n.a.)	2.0 (1.7 to 3.7)	1.8 (1.4 to n.a.)	3.5 (1.9 to n.a.)	1.9 (0.4 to n.a.)	

**Clinical Trial Results Website**

	<b>Solid tumors: HDM201 2A 1 mg</b>	<b>Solid tumors: HDM201 2A 2 mg</b>	<b>Solid tumors: HDM201 2A 4 mg</b>	<b>Solid tumors: HDM201 2A 7.5 mg</b>	<b>Solid tumors: HDM201 2A 15 mg</b>	<b>Solid tumors: HDM201 2A 20 mg</b>	<b>Solid tumors: HDM201 2C 15 mg</b>	<b>Solid tumors: HDM201 2C 20 mg</b>	<b>Solid tumors: HDM201 2C 25 mg</b>
<b>Arm/Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.
<b>Number of Participants Analyzed [units: participants]</b>	1	2	4	4	4	5	8	6	5
<b>Progression-Free Survival (PFS) according to RECIST 1.1 (Solid Tumors)</b> (units: months) Median (95% Confidence Interval)									
	0.9 (n.a. to n.a.)	1.1 (1.0 to n.a.)	1.5 (0.5 to n.a.)	2.7 (1.1 to n.a.)	5.4 (1.4 to n.a.)	3.7 (1.2 to n.a.)	1.7 (1.0 to 2.7)	5.4 (1.4 to n.a.)	4.6 (1.6 to n.a.)

**Number of participants with Best Overall Response (BOR) according to Cheson 2003 (Acute myeloid leukemia)**

(Time Frame: From first dose of study treatment up to 40 weeks (regimen 1A), 39 weeks (regimen 1B), 26 weeks (regimen 2A) and 31 weeks (regimen 2C).)

	<b>Hematological malignancies: HDM201 1A 250 mg</b>	<b>Hematological malignancies: HDM201 1A 350 mg</b>	<b>Hematological malignancies: HDM201 1A 400 mg</b>	<b>Hematological malignancies: HDM201 1B 120 mg</b>	<b>Hematological malignancies: HDM201 1B 150 mg</b>	<b>Hematological malignancies: HDM201 2A 20 mg</b>	<b>Hematological malignancies: HDM201 2A 30 mg</b>	<b>Hematological malignancies: HDM201 2C 45 mg</b>
<b>Arm/Group Description</b>	Regimen 1A. Dose: 250 mg HDM201 (RDE) in hematological malignancies.	Regimen 1A. Dose: 350 mg HDM201 in hematological malignancies.	Regimen 1A. Dose: 400 mg HDM201 in hematological malignancies.	Regimen 1B. Dose: 120 mg HDM201 (RDE) in hematological malignancies.	Regimen 1B. Dose: 150 mg HDM201 in hematological malignancies.	Regimen 2A. Dose: 20 mg HDM201 in hematological malignancies.	Regimen 2A. Dose: 30 mg HDM201 in hematological malignancies.	Regimen 2C. Dose: 45 mg HDM201 (RDE) in hematological malignancies.
<b>Number of Participants Analyzed [units: participants]</b>	15	4	8	24	6	3	4	27

**Number of participants with Best Overall Response (BOR) according to Cheson 2003 (Acute myeloid leukemia)**

(units: participants)

Count of Participants (Not Applicable)

Complete Remission (CR)	1 (6.67%)	0 (%)	1 (12.5%)	1 (4.17%)	0 (%)	0 (%)	0 (%)	2 (7.41%)
Morphologic CR with incomplete blood count recovery (CRi)	2 (13.33%)	0 (%)	0 (%)	0 (%)	1 (16.67%)	0 (%)	0 (%)	4 (14.81%)
Treatment Failure (TF)	9 (60%)	3 (75%)	4 (50%)	15 (62.5%)	5 (83.33%)	3 (100%)	3 (75%)	16 (59.26%)
Unknown	0 (%)	0 (%)	0 (%)	2 (8.33%)	0 (%)	0 (%)	0 (%)	1 (3.7%)

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**Duration of Response (DOR) according to Cheson 2003 (Acute myeloid leukemia)**

(Time Frame: From first dose of study treatment up to 40 weeks (regimen 1A), 39 weeks (regimen 1B), 26 weeks (regimen 2A) and 31 weeks (regimen 2C).)

<b>HDM201 in hematological malignancies</b>	
<b>Arm/Group Description</b>	HDM201 (all regimens) in hematological malignancies
<b>Number of Participants Analyzed [units: participants]</b>	12
<b>Duration of Response (DOR) according to Cheson 2003 (Acute myeloid leukemia)</b> (units: days) Median (Full Range)	88.5 (22 to 152)

**Safety Results**

**All-Cause Mortality**

	HDM20 1 1A 12.5 mg N = 1	HDM20 1 1A 25 mg N = 1	HDM20 1 1A 50 mg N = 4	HDM20 1 1A 100 mg N = 4	HDM20 1 1A 200 mg N = 5	HDM201 1A 250 mg N = 21	HDM201 1A 250 mg + Eltrombopa g N = 3	HDM201 1A 350 mg N = 9	HDM201 1A 400 mg N = 9	HDM201 1B 120 mg N = 53	HDM201 1B 150 mg N = 14	HDM201 1B 150 mg + Eltrombopa g N = 7	HDM20 1 1B 200 mg N = 3
<b>Arm/ Group Description</b>	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors.	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors and hematologi- -cal malignan- cies.	Regimen 1A. Dose: 250 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors and hematologi- -cal malignan- cies.	Regimen 1A. Dose: 400 mg HDM201 in hematologi- -cal malignan- cies.	Regimen 1B. Dose: 120 mg HDM201 in solid tumors and hematologi- -cal malignan- cies.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors and hematologi- -cal malignan- cies.	Regimen 1B. Dose: 150 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.
<b>Total participant s affected</b>	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (20.00%)	3 (14.29%)	1 (33.33%)	1 (11.11%)	4 (44.44%)	13 (24.53%)	4 (28.57%)	2 (28.57%)	2 (66.67%)
	HDM201 2A 1 mg N = 1	HDM201 2A 2 mg N = 2	HDM201 2A 4 mg N = 4	HDM201 2A 7.5 mg N = 4	HDM201 2A 15 mg N = 4	HDM201 2A 20 mg N = 8	HDM201 2A 30 mg N = 4	HDM201 2C 15 mg N = 8	HDM201 2C 20 mg N = 6	HDM201 2C 25 mg N = 5	HDM201 2C 45 mg N = 28	<b>Total N = 208</b>	
<b>Arm/ Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors and hematologi- -cal malignan- cies.	Regimen 2A. Dose: 30 mg HDM201 in hematologi- -cal malignancies.	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.	Regimen 2C. Dose: 45 mg HDM201 in participants with hematological malignancies.	All participants	
<b>Total participants affected</b>	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)	2 (25.00%)	1 (16.67%)	0 (0.00%)	10 (35.71%)	48 (23.08%)	

### Serious Adverse Events by System Organ Class

<b>Time Frame</b>	From first dose of study treatment until last dose plus 30 days, up to maximum duration of 132 weeks (regimen 1A), 195 weeks (regimen 1B), 280 weeks (regimen 2A) and 93 weeks (regimen 2C).													
<b>Additional Description</b>	Any sign or symptom that occurs during the study treatment plus the 30 days post treatment.													
<b>Source Vocabulary for Table Default</b>	MedDRA (21.0)													
<b>Assessment Type for Table Default</b>	Systematic Assessment													
<b>Arm/Group Description</b>	<b>HDM20 1 1A 12.5 mg N = 1</b>	<b>HDM20 1 1A 25 mg N = 1</b>	<b>HDM201 1A 50 mg N = 4</b>	<b>HDM201 1A 100 mg N = 4</b>	<b>HDM201 1A 200 mg N = 5</b>	<b>HDM201 1A 250 mg N = 21</b>	<b>HDM201 1A 250 mg + Eltrombo pag N = 3</b>	<b>HDM201 1A 350 mg N = 9</b>	<b>HDM201 1A 400 mg N = 9</b>	<b>HDM201 1B 120 mg N = 53</b>	<b>HDM201 1B 150 mg N = 14</b>	<b>HDM201 1B 150 mg + Eltrombo pag N = 7</b>	<b>HDM201 1B 200 mg N = 3</b>	
	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors.	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors and hematological malignancies.	Regimen 1A. Dose: 250 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors and hematological malignancies.	Regimen 1A. Dose: 400 mg HDM201 in hematological malignancies.	Regimen 1B. Dose: 120 mg HDM201 in solid tumors and hematological malignancies.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors and hematological malignancies.	Regimen 1B. Dose: 150 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.	
<b>Total participants affected</b>	0 (0.00 %)	0 (0.00 %)	1 (25.0 %)	3 (75.0 %)	4 (80.0 %)	13 (61.9 %)	3 (100.0 %)	5 (55.5 %)	8 (88.8 %)	25 (47.1 %)	10 (71.4 %)	3 (42.86 %)	2 (66.6 %)	
<b>Blood And Lymphatic System Disorders</b>														
Anaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (5.66 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	

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Bone Marrow Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Disseminated Intravascular Coagulation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Febrile Bone Marrow Aplasia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.52%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (7.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Febrile Neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (19.05%)	0 (0.00%)	1 (11.11%)	3 (33.33%)	10 (18.87%)	2 (14.29%)	0 (0.00%)	0 (0.00%)
Leukocytosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (22.22%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	3 (33.33%)	3 (33.33%)	1 (1.89%)	3 (21.43%)	0 (0.00%)	0 (0.00%)
<b>Cardiac Disorders</b>													
Atrial Fibrillation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Coronary Artery Disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Left Ventricular Dysfunction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulseless Electrical Activity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)



**Clinical Trial Results Website**

Sinus Tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Endocrine Disorders</b>													
Adrenocortical Insufficiency Acute	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diabetes Insipidus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Eye Disorders</b>													
Macular Oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
<b>Gastrointestinal Disorders</b>													
Abdominal Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	2 (14.29%)	1 (14.29%)	0 (0.00%)
Abdominal Pain Upper	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diarrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal Obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ileus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Melaena	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

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Nausea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	1 (33.33%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Poor Dental Condition	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Proctalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Retroperitoneal Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Small Intestinal Obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>General Disorders And Administration Site Conditions</b>													
Asthenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
General Physical Health Deterioration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema Peripheral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (22.22%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Hepatobiliary Disorders**

**Clinical Trial Results Website**

Bile Duct Obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Hepatic Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Immune System Disorders</b>													
Chronic Graft Versus Host Disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Graft Versus Host Disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Graft Versus Host Disease In Skin	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Infections And Infestations</b>													
Abdominal Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aspergillus Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cellulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Device Related Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Ear Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Endocarditis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Enterocolitis Infectious	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Escherichia Bacteraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes Virus Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infectious Colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infective Glossitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.77%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Listeriosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lung Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenic Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Orchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pharyngeal Abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	3 (5.66%)	0 (0.00%)	1 (14.29%)	0 (0.00%)

**Clinical Trial Results Website**

Pneumonia Fungal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Retroperitoneal Abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinovirus Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.77%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Septic Shock	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinusitis Fungal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Staphylococcal Bacteraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Staphylococcal Sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tonsillitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary Tract Infection	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Injury, Poisoning And Procedural Complications</b>													
Acetabulum Fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Fall	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Femoral Neck Fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Femur Fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subarachnoid Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subdural Haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Transfusion Reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Investigations</b>													
Amylase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aspartate Aminotransferase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood Creatinine Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood Phosphorus Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
C-Reactive Protein Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eastern Cooperative Oncology Group Performance	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Status Worsened													
International Normalised Ratio Increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (14.29 %)	0 (0.00 %)
Lipase Increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (11.1 %)	1 (11.1 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)
Megakaryocytes Abnormal	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)
Neutrophil Count Decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (11.1 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)
Platelet Count Decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (4.76%)	0 (0.00%)	1 (11.1 %)	0 (0.00 %)	2 (3.77%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)
<b>Metabolism And Nutrition Disorders</b>													
Dehydration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)
Diabetes Mellitus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00 %)
Hyperuricaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (4.76%)	1 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)
Tumour Lysis Syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	7 (33.33 %)	0 (0.00%)	0 (0.00 %)	3 (33.3 %)	3 (5.66%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)
<b>Musculoskeletal And Connective Tissue Disorders</b>													
Arthritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)

**Clinical Trial Results Website**

Back Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Bone Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
<b>Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)</b>													
Tumour Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Nervous System Disorders</b>													
Cerebral Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Generalised Tonic-Clonic Seizure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ischaemic Stroke	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
<b>Product Issues</b>													
Device Occlusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)



**Clinical Trial Results Website**
**Renal And Urinary Disorders**

Acute Kidney Injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Renal Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary Retention	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary Tract Obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Reproductive System And Breast Disorders**

Prostatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
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**Respiratory, Thoracic And Mediastinal Disorders**

Dyspnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	1 (33.33%)
Epistaxis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoxia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lung Disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumothorax	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary Embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Pulmonary Mass	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary Oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tonsillar Inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Vascular Disorders</b>													
Hypotension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (40.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Microangiopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)

	HDM201 2A 1 mg N = 1	HDM201 2A 2 mg N = 2	HDM201 2A 4 mg N = 4	HDM201 2A 7.5 mg N = 4	HDM201 2A 15 mg N = 4	HDM201 2A 20 mg N = 8	HDM201 2A 30 mg N = 4	HDM201 2C 15 mg N = 8	HDM201 2C 20 mg N = 6	HDM201 2C 25 mg N = 5	HDM201 2C 45 mg N = 28	Total N = 208
<b>Arm/Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors and hematological malignancies.	Regimen 2A. Dose: 30 mg HDM201 in hematological malignancies.	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.	Regimen 2C. Dose: 45 mg HDM201 in participants with hematological malignancies.	All participants
<b>Total participants affected</b>	0 (0.00 %)	1 (50.00 %)	2 (50.00 %)	2 (50.00 %)	2 (50.00 %)	4 (50.00 %)	4 (100.00 %)	5 (62.50 %)	2 (33.33 %)	3 (60.00 %)	23 (82.14 %)	125 (60.10 %)
<b>Blood And Lymphatic System Disorders</b>												
Anaemia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	0 (0.00%)	2 (25.00 %)	0 (0.00%)	0 (0.00%)	1 (3.57%)	8 (3.85%)
Bone Marrow Failure	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Disseminated Intravascular Coagulation	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Febrile Bone Marrow Aplasia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	6 (2.88%)
Febrile Neutropenia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50 %)	3 (75.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	19 (67.86 %)	43 (20.67 %)
Leukocytosis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	4 (1.92%)
Leukopenia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)

### Clinical Trial Results Website

Neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (2.40%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	14 (6.73%)
<b>Cardiac Disorders</b>												
Atrial Fibrillation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Cardiac Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Coronary Artery Disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Left Ventricular Dysfunction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Pulseless Electrical Activity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Sinus Tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Endocrine Disorders</b>												
Adrenocortical Insufficiency Acute	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Diabetes Insipidus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (0.48%)
<b>Eye Disorders</b>												
Macular Oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Gastrointestinal Disorders</b>												

**Clinical Trial Results Website**

Abdominal Pain	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	9 (4.33%)
Abdominal Pain Upper	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Diarrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.44%)
Gastritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Gastrointestinal Obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	1 (0.48%)
Ileus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Melaena	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Nausea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.44%)
Poor Dental Condition	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (0.48%)
Proctalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (0.48%)
Retroperitoneal Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Small Intestinal Obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)

**General Disorders And**

**Clinical Trial Results Website**

<b>Administration Site Conditions</b>												
Asthenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Fatigue	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
General Physical Health Deterioration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (10.71%)	4 (1.92%)
Oedema Peripheral	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Pyrexia	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	5 (2.40%)
<b>Hepatobiliary Disorders</b>												
Bile Duct Obstruction	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Hepatic Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Hepatic Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Immune System Disorders</b>												
Chronic Graft Versus Host Disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Graft Versus Host Disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (0.48%)
Graft Versus Host Disease In Skin	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (0.48%)
<b>Infections And Infestations</b>												

**Clinical Trial Results Website**

Abdominal Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Aspergillus Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	2 (0.96%)
Bronchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Cellulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	3 (1.44%)
Device Related Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (0.48%)
Ear Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Endocarditis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (0.48%)
Enterocolitis Infectious	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Escherichia Bacteraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Herpes Virus Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Infectious Colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Infective Glossitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (0.48%)
Influenza	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.44%)
Listeriosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)

**Clinical Trial Results Website**

Lung Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Neutropenic Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Orchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Pharyngeal Abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (0.48%)
Pharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (0.48%)
Pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	6 (2.88%)
Pneumonia Fungal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Retroperitoneal Abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Rhinovirus Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	4 (1.92%)
Septic Shock	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Sinusitis Fungal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Skin Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Staphylococcal Bacteraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Staphylococcal Sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Tonsillitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (0.48%)



**Clinical Trial Results Website**

Urinary Tract Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.44%)	
Wound Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.48%)	
<b>Injury, Poisoning And Procedural Complications</b>													
Acetabulum Fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (0.48%)
Fall	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Femoral Neck Fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Femur Fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Subarachnoid Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Subdural Haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Transfusion Reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Investigations</b>													
Amylase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	1 (0.48%)	
Aspartate Aminotransferase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	2 (0.96%)	
Blood Creatinine Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	3 (1.44%)	

**Clinical Trial Results Website**

Blood Phosphorus Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
C-Reactive Protein Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Eastern Cooperative Oncology Group Performance Status Worsened	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
International Normalised Ratio Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Lipase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (3.57%)	4 (1.92%)	
Megakaryocytes Abnormal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	2 (0.96%)
Neutrophil Count Decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	3 (1.44%)	
Platelet Count Decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	6 (2.88%)	
<b>Metabolism And Nutrition Disorders</b>													
Dehydration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Diabetes Mellitus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Hyperuricaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)

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Tumour Lysis Syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	14 (6.73%)
<b>Musculoskeletal And Connective Tissue Disorders</b>													
Arthritis	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Back Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Bone Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Myalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)</b>													
Tumour Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Tumour Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Nervous System Disorders</b>													
Cerebral Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	2 (0.96%)
Generalised Tonic-Clonic Seizure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	1 (0.48%)
Ischaemic Stroke	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)

**Clinical Trial Results Website**

Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Product Issues</b>													
Device Occlusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Renal And Urinary Disorders</b>													
Acute Kidney Injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	8 (3.85%)
Renal Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (10.71%)	5 (2.40%)
Urinary Retention	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Urinary Tract Obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Reproductive System And Breast Disorders</b>													
Prostatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Respiratory, Thoracic And Mediastinal Disorders</b>													
Dyspnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	3 (1.44%)
Epistaxis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	3 (1.44%)
Hypoxia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (0.48%)

**Clinical Trial Results Website**

Lung Disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Pneumothorax	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Pulmonary Embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Pulmonary Mass	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Pulmonary Oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (0.48%)
Tonsillar Inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Vascular Disorders</b>												
Hypotension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (3.57%)	6 (2.88%)
Microangiopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)

### Other Adverse Events by System Organ Class

<b>Time Frame</b>	From first dose of study treatment until last dose plus 30 days, up to maximum duration of 132 weeks (regimen 1A), 195 weeks (regimen 1B), 280 weeks (regimen 2A) and 93 weeks (regimen 2C).													
<b>Additional Description</b>	Any sign or symptom that occurs during the study treatment plus the 30 days post treatment.													
<b>Source Vocabulary for Table Default</b>	MedDRA (21.0)													
<b>Assessment Type for Table Default</b>	Systematic Assessment													
<b>Frequent Event Reporting Threshold</b>	5%													
<b>Arm/Group Description</b>	<b>HDM201 1A 12.5 mg N = 1</b>	<b>HDM201 1A 25 mg N = 1</b>	<b>HDM201 1A 50 mg N = 4</b>	<b>HDM201 1A 100 mg N = 4</b>	<b>HDM201 1A 200 mg N = 5</b>	<b>HDM201 1A 250 mg N = 21</b>	<b>HDM201 1A 250 mg + Eltrombopag N = 3</b>	<b>HDM201 1A 350 mg N = 9</b>	<b>HDM201 1A 400 mg N = 9</b>	<b>HDM201 1B 120 mg N = 53</b>	<b>HDM201 1B 150 mg N = 14</b>	<b>HDM201 1B 150 mg + Eltrombopag N = 7</b>	<b>HDM201 1B 200 mg N = 3</b>	
	Regimen 1A. Dose: 12.5 mg HDM201 in solid tumors.	Regimen 1A. Dose: 25 mg HDM201 in solid tumors.	Regimen 1A. Dose: 50 mg HDM201 in solid tumors.	Regimen 1A. Dose: 100 mg HDM201 in solid tumors.	Regimen 1A. Dose: 200 mg HDM201 in solid tumors.	Regimen 1A. Dose: 250 mg HDM201 in solid tumors and hematological malignancies.	Regimen 1A. Dose: 250 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1A. Dose: 350 mg HDM201 in solid tumors and hematological malignancies.	Regimen 1A. Dose: 400 mg HDM201 in solid tumors and hematological malignancies.	Regimen 1B. Dose: 120 mg HDM201 in solid tumors and hematological malignancies.	Regimen 1B. Dose: 150 mg HDM201 in solid tumors and hematological malignancies.	Regimen 1B. Dose: 150 mg HDM201 + Eltrombopag in solid tumors.	Regimen 1B. Dose: 200 mg HDM201 in solid tumors.	
<b>Total participants affected</b>	1 (100.0%)	1 (100.0%)	3 (75.0%)	4 (100.0%)	5 (100.0%)	21 (100.0%)	3 (100.0%)	9 (100.0%)	9 (100.0%)	52 (98.1%)	14 (100.0%)	7 (100.0%)	3 (100.0%)	
<b>Blood And Lymphatic System Disorders</b>														
Anaemia	1 (100.0%)	0 (0.00%)	2 (50.0%)	1 (25.00%)	4 (80.00%)	12 (57.14%)	2 (66.67%)	7 (77.78%)	6 (66.67%)	32 (60.38%)	4 (28.57%)	4 (57.14%)	2 (66.67%)	
Febrile Neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	1 (11.11%)	3 (33.33%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	

**Clinical Trial Results Website**

Leukocytosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.52%)	0 (0.00%)	2 (22.22%)	0 (0.00%)	3 (5.66%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Leukopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (19.05%)	1 (33.33%)	4 (44.44%)	0 (0.00%)	9 (16.98%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Lymphadenopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (20.00%)	1 (4.76%)	2 (66.67%)	1 (11.11%)	0 (0.00%)	3 (5.66%)	2 (14.29%)	1 (14.29%)	1 (33.33%)
Neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	9 (42.86%)	1 (33.33%)	5 (55.56%)	3 (33.33%)	16 (30.19%)	5 (35.71%)	1 (14.29%)	0 (0.00%)
Pancytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	2 (40.00%)	9 (42.86%)	2 (66.67%)	4 (44.44%)	6 (66.67%)	21 (39.62%)	6 (42.86%)	1 (14.29%)	0 (0.00%)
Thrombocytosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
<b>Cardiac Disorders</b>													
Acute Myocardial Infarction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atrial Fibrillation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (4.76%)	0 (0.00%)	2 (22.22%)	1 (11.11%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atrial Flutter	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atrioventricular Block First Degree	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiovascular Disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diastolic Dysfunction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Palpitations	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pericardial Effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Pulmonary Valve Incompetence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (22.22%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Congenital, Familial And Genetic Disorders</b>													
Hydrocele	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Ear And Labyrinth Disorders</b>													
Ear Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoacusis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Motion Sickness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vertigo	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
<b>Eye Disorders</b>													
Amaurosis Fugax	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Conjunctival Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)



**Clinical Trial Results Website**

Eye Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Eyelid Oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intraocular Haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lacrimation Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vision Blurred	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Gastrointestinal Disorders</b>													
Abdominal Discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal Distension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (66.67%)	0 (0.00%)	0 (0.00%)	3 (5.66%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal Hernia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	4 (19.05%)	1 (33.33%)	1 (11.11%)	1 (11.11%)	8 (15.09%)	3 (21.43%)	1 (14.29%)	0 (0.00%)
Abdominal Pain Lower	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.77%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal Pain Upper	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	1 (11.11%)	4 (7.55%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Aerophagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal Incontinence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ascites	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Constipation	0 (0.00%)	1 (100.00%)	0 (0.00%)	1 (25.00%)	2 (40.00%)	2 (9.52%)	0 (0.00%)	2 (22.22%)	1 (11.11%)	10 (18.87%)	4 (28.57%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Diarrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	4 (80.00%)	6 (28.57%)	1 (33.33%)	3 (33.33%)	5 (55.56%)	12 (22.64%)	3 (21.43%)	1 (14.29%)	0 (0.00%)
Dry Mouth	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspepsia	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysphagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Gastritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastroesophageal Reflux Disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gingival Bleeding	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (22.22%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gingival Hypertrophy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Gingival Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhoids	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.52%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Lip Oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Melaena	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mouth Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	2 (3.77%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nausea	1 (100.00%)	1 (100.00%)	2 (50.00%)	3 (75.00%)	4 (80.00%)	11 (52.38%)	3 (100.00%)	6 (66.67%)	5 (55.56%)	29 (54.72%)	10 (71.43%)	5 (71.43%)	2 (66.67%)
Odynophagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	2 (3.77%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Oral Disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral Mucosal Eruption	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Oral Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pancreatic Steatosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rectal Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (14.29%)	0 (0.00%)
Small Intestinal Obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stomatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	2 (22.22%)	1 (1.89%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Toothache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Trichoglossia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vomiting	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	2 (40.00%)	6 (28.57%)	2 (66.67%)	4 (44.44%)	3 (33.33%)	23 (43.40%)	3 (21.43%)	3 (42.86%)	0 (0.00%)
<b>General Disorders And Administration Site Conditions</b>													
Asthenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (60.00%)	5 (23.81%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	13 (24.53%)	2 (14.29%)	1 (14.29%)	0 (0.00%)
Chest Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	2 (3.77%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Chills	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	2 (3.77%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Extravasation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Facial Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	1 (100.00%)	0 (0.00%)	2 (50.00%)	1 (25.00%)	2 (40.00%)	6 (28.57%)	3 (100.00%)	4 (44.44%)	1 (11.11%)	11 (20.75%)	4 (28.57%)	4 (57.14%)	2 (66.67%)
General Physical Health Deterioration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	1 (11.11%)	3 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Generalised Oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	2 (3.77%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza Like Illness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (4.76%)	1 (33.33%)	1 (11.11%)	0 (0.00%)	2 (3.77%)	1 (7.14%)	1 (14.29%)	0 (0.00%)
Malaise	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	4 (7.55%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Non-Cardiac Chest Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema Peripheral	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	4 (19.05%)	2 (66.67%)	3 (33.33%)	2 (22.22%)	9 (16.98%)	3 (21.43%)	0 (0.00%)	2 (66.67%)
Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)
Pyrexia	0 (0.00%)	0 (0.00%)	2 (50.00%)	1 (25.00%)	1 (20.00%)	3 (14.29%)	0 (0.00%)	3 (33.33%)	3 (33.33%)	11 (20.75%)	1 (7.14%)	2 (28.57%)	0 (0.00%)
<b>Hepatobiliary Disorders</b>													
Cholangitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cholelithiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

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Cholestasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperbilirubin aemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Jaundice	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
<b>Immune System Disorders</b>													
Anaphylactic Reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Graft Versus Host Disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Infections And Infestations</b>													
Atypical Pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bacteraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Balanitis Candida	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.77%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Candida Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Conjunctivitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Cystitis Viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

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Cytomegalovirus Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Emphysematous Pyelonephritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Folliculitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Fungal Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes Simplex	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes Virus Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes Zoster	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Laryngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lip Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Nasopharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenic Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oesophageal Candidiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Onychomycosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral Candidiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.77%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Oral Herpes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)
Orchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Paronychia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periodontitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (4.76%)	0 (0.00%)	1 (11.11%)	2 (22.22%)	1 (1.89%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Respiratory Tract Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	1 (7.14%)	0 (0.00%)	1 (33.33%)
Sinusitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Skin Candida	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Soft Tissue Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tongue Fungal Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper Respiratory Tract Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.77%)	0 (0.00%)	0 (0.00%)	1 (33.33%)

### Clinical Trial Results Website

Urinary Tract Infection	1 (100.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	2 (22.22%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Injury, Poisoning And Procedural Complications</b>													
Face Injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fall	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Scratch	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Skin Injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Transfusion Reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Investigations</b>													
Alanine Aminotransferase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (20.00%)	1 (4.76%)	1 (33.33%)	0 (0.00%)	1 (11.11%)	1 (1.89%)	2 (14.29%)	0 (0.00%)	0 (0.00%)
Ammonia Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Amylase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	2 (22.22%)	1 (11.11%)	3 (5.66%)	1 (7.14%)	0 (0.00%)	1 (33.33%)
Aspartate Aminotransferase Increased	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	1 (20.00%)	3 (14.29%)	1 (33.33%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)



**Clinical Trial Results Website**

Blood Alkaline Phosphatase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	2 (40.00%)	0 (0.00%)	2 (66.67%)	1 (11.11%)	2 (22.22%)	5 (9.43%)	2 (14.29%)	0 (0.00%)	0 (0.00%)
Blood Bilirubin Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (4.76%)	3 (100.00%)	1 (11.11%)	1 (11.11%)	4 (7.55%)	2 (14.29%)	0 (0.00%)	0 (0.00%)
Blood Creatine Phosphokinase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.77%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Blood Creatinine Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (60.00%)	2 (9.52%)	0 (0.00%)	1 (11.11%)	2 (22.22%)	3 (5.66%)	2 (14.29%)	0 (0.00%)	0 (0.00%)
Blood Lactate Dehydrogenase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.52%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (5.66%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood Phosphorus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Blood Phosphorus Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.52%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Blood Uric Acid Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
C-Reactive Protein Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.52%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ejection Fraction Decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Electrocardiogram Qt Prolonged	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gamma-Glutamyltransferase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	2 (9.52%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	4 (7.55%)	2 (14.29%)	0 (0.00%)	0 (0.00%)

### Clinical Trial Results Website

Heart Rate Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
International Normalised Ratio Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (40.00%)	0 (0.00%)	1 (33.33%)	1 (11.11%)	1 (11.11%)	5 (9.43%)	3 (21.43%)	0 (0.00%)	1 (33.33%)
Lymphocyte Count Decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (20.00%)	1 (4.76%)	1 (33.33%)	1 (11.11%)	0 (0.00%)	3 (5.66%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutrophil Count Decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.52%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	2 (3.77%)	2 (14.29%)	1 (14.29%)	1 (33.33%)
Ph Urine Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Platelet Count Decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (19.05%)	1 (33.33%)	1 (11.11%)	1 (11.11%)	10 (18.87%)	1 (7.14%)	2 (28.57%)	1 (33.33%)
Prothrombin Time Prolonged	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Weight Decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	1 (11.11%)	2 (22.22%)	3 (5.66%)	1 (7.14%)	1 (14.29%)	1 (33.33%)
Weight Increased	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (5.66%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
White Blood Cell Count Decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (40.00%)	3 (14.29%)	0 (0.00%)	2 (22.22%)	1 (11.11%)	8 (15.09%)	1 (7.14%)	2 (28.57%)	1 (33.33%)
<b>Metabolism And Nutrition Disorders</b>													
Decreased Appetite	1 (100.00%)	1 (100.00%)	2 (50.00%)	3 (75.00%)	1 (20.00%)	6 (28.57%)	0 (0.00%)	4 (44.44%)	3 (33.33%)	18 (33.96%)	5 (35.71%)	0 (0.00%)	1 (33.33%)

**Clinical Trial Results Website**

Dehydration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypercalcaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	1 (1.89%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Hyperglycaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	2 (22.22%)	1 (11.11%)	1 (1.89%)	2 (14.29%)	0 (0.00%)	0 (0.00%)
Hyperkalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	2 (40.00%)	3 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (9.43%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Hyperlipasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypernatraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperphosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.52%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	1 (1.89%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Hyperuricaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	2 (3.77%)	3 (21.43%)	1 (14.29%)	0 (0.00%)
Hypervolaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoalbuminaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (40.00%)	2 (9.52%)	1 (33.33%)	1 (11.11%)	0 (0.00%)	3 (5.66%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Hypocalcaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (20.00%)	4 (19.05%)	0 (0.00%)	1 (11.11%)	3 (33.33%)	5 (9.43%)	1 (7.14%)	0 (0.00%)	1 (33.33%)
Hypokalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	2 (40.00%)	4 (19.05%)	2 (66.67%)	1 (11.11%)	3 (33.33%)	12 (22.64%)	2 (14.29%)	0 (0.00%)	1 (33.33%)
Hypomagnesaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (40.00%)	5 (23.81%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.77%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyponatraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (40.00%)	1 (4.76%)	0 (0.00%)	2 (22.22%)	1 (11.11%)	1 (1.89%)	2 (14.29%)	0 (0.00%)	0 (0.00%)
Hypophosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (14.29%)	0 (0.00%)	0 (0.00%)	3 (33.33%)	6 (11.32%)	2 (14.29%)	0 (0.00%)	0 (0.00%)
Hypoproteinaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Iron Overload	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lactic Acidosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Tumour Lysis Syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.52%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	3 (5.66%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitamin B12 Deficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (40.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitamin D Deficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
<b>Musculoskeletal And Connective Tissue Disorders</b>													
Arthralgia	0 (0.00%)	1 (100.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	1 (11.11%)	1 (11.11%)	2 (3.77%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Back Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.52%)	1 (33.33%)	1 (11.11%)	0 (0.00%)	5 (9.43%)	1 (7.14%)	1 (14.29%)	0 (0.00%)
Bone Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flank Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Groin Pain	1 (100.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle Spasms	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscular Weakness	1 (100.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal Chest Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	1 (33.33%)

**Clinical Trial Results Website**

Musculoskeletal Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	6 (11.32%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Myalgia	1 (100.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (7.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neck Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Pain In Extremity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (4.76%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	5 (9.43%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Spondylolysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
<b>Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)</b>													
Chloroma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
<b>Nervous System Disorders</b>													
Altered State Of Consciousness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Balance Disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cognitive Disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Dizziness	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (20.00%)	3 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (5.66%)	2 (14.29%)	0 (0.00%)	0 (0.00%)
Dysaesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysgeusia	0 (0.00%)	1 (100.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	6 (11.32%)	0 (0.00%)	1 (14.29%)	1 (33.33%)
Headache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	8 (15.09%)	2 (14.29%)	0 (0.00%)	1 (33.33%)
Hypoaesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypotonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Lethargy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Migraine	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Neuralgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Paraesthesia	1 (100.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.52%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral Sensory Neuropathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Somnolence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Psychiatric Disorders</b>													
Affective Disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Anxiety	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (20.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.77%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Depression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Insomnia	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	6 (11.32%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mood Altered	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sleep Disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)

**Renal And Urinary Disorders**

Acute Kidney Injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	2 (3.77%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Azotaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	2 (3.77%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematuria	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	1 (7.14%)	0 (0.00%)	1 (33.33%)
Nocturia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pollakiuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Urinary Retention	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary Tract Obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Reproductive System And Breast Disorders**

### Clinical Trial Results Website

Benign Prostatic Hyperplasia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cervical Discharge	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema Genital	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pelvic Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pruritus Genital	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Testicular Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vaginal Ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Vulva Cyst	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
<b>Respiratory, Thoracic And Mediastinal Disorders</b>													
Cough	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	2 (40.00%)	5 (23.81%)	0 (0.00%)	2 (22.22%)	2 (22.22%)	3 (5.66%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Dysphonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	2 (22.22%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	2 (9.52%)	1 (33.33%)	1 (11.11%)	2 (22.22%)	5 (9.43%)	2 (14.29%)	1 (14.29%)	2 (66.67%)
Dyspnoea Exertional	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.52%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Epistaxis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	7 (13.21%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemoptysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	1 (7.14%)	0 (0.00%)	1 (33.33%)



**Clinical Trial Results Website**

Hiccups	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoxia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lung Infiltration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasal Congestion	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oropharyngeal Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pharyngeal Inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural Effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (22.22%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Pneumonitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Productive Cough	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Respiratory Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinorrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Skin And Subcutaneous Tissue Disorders</b>													
Alopecia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	1 (33.33%)	2 (22.22%)	1 (11.11%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood Blister	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Dermatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Dermatitis Acneiform	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Dry Skin	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (5.66%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ecchymosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Eczema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (14.29%)	0 (0.00%)
Erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperhidrosis	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (7.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Night Sweats	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain Of Skin	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Palmar-Plantar Erythrodysesthesia Syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Penile Ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Petechiae	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	2 (22.22%)	4 (7.55%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Pruritus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.77%)	2 (14.29%)	2 (28.57%)	1 (33.33%)
Purpura	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (5.66%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	2 (3.77%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Rash Erythematous	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash Macular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Rash Maculo-Papular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash Papular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin Burning Sensation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin Exfoliation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin Plaque	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Swelling Face	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Telangiectasia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urticaria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Vascular Disorders</b>													
Circulatory Collapse	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flushing	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (11.11%)	1 (1.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Hot Flush	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertension	1 (100.00%)	1 (100.00%)	1 (25.00%)	1 (25.00%)	0 (0.00%)	3 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Hypotension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)	0 (0.00%)	3 (33.33%)	1 (11.11%)	3 (5.66%)	1 (7.14%)	0 (0.00%)	0 (0.00%)
Thrombophlebitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (22.22%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)

	HDM201 2A 1 mg N = 1	HDM201 2A 2 mg N = 2	HDM201 2A 4 mg N = 4	HDM201 2A 7.5 mg N = 4	HDM201 2A 15 mg N = 4	HDM201 2A 20 mg N = 8	HDM201 2A 30 mg N = 4	HDM201 2C 15 mg N = 8	HDM201 2C 20 mg N = 6	HDM201 2C 25 mg N = 5	HDM201 2C 45 mg N = 28	Total N = 208
<b>Arm/Group Description</b>	Regimen 2A. Dose: 1 mg HDM201 in solid tumors.	Regimen 2A. Dose: 2 mg HDM201 in solid tumors.	Regimen 2A. Dose: 4 mg HDM201 in solid tumors.	Regimen 2A. Dose: 7.5 mg HDM201 in solid tumors.	Regimen 2A. Dose: 15 mg HDM201 in solid tumors.	Regimen 2A. Dose: 20 mg HDM201 in solid tumors and hematological malignancies.	Regimen 2A. Dose: 30 mg HDM201 in hematological malignancies.	Regimen 2C. Dose: 15 mg HDM201 in solid tumors.	Regimen 2C. Dose: 20 mg HDM201 in solid tumors.	Regimen 2C. Dose: 25 mg HDM201 in solid tumors.	Regimen 2C. Dose: 45 mg HDM201 in participants with hematological malignancies.	All participants
<b>Total participants affected</b>	1 (100.00%)	2 (100.00%)	4 (100.00%)	4 (100.00%)	4 (100.00%)	8 (100.00%)	3 (75.00%)	7 (87.50%)	6 (100.00%)	5 (100.00%)	27 (96.43%)	203 (97.60%)
<b>Blood And Lymphatic System Disorders</b>												
Anaemia	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	2 (50.00%)	6 (75.00%)	2 (50.00%)	3 (37.50%)	1 (16.67%)	1 (20.00%)	13 (46.43%)	107 (51.44%)
Febrile Neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	9 (32.14%)	15 (7.21%)
Leukocytosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (14.29%)	12 (5.77%)
Leukopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	2 (7.14%)	25 (12.02%)
Lymphadenopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Lymphopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (25.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	17 (8.17%)
Neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	10 (35.71%)	56 (26.92%)
Pancytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	3 (1.44%)

**Clinical Trial Results Website**

Thrombocytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)	2 (50.00%)	4 (50.00%)	1 (25.00%)	3 (37.50%)	1 (16.67%)	2 (40.00%)	11 (39.29%)	79 (37.98%)
Thrombocytosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	2 (0.96%)
<b>Cardiac Disorders</b>												
Acute Myocardial Infarction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Atrial Fibrillation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	7 (3.37%)
Atrial Flutter	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Atrioventricular Block First Degree	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Cardiovascular Disorder	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Diastolic Dysfunction	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Palpitations	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (3.57%)	4 (1.92%)
Pericardial Effusion	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Pulmonary Valve Incompetence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (3.57%)	7 (3.37%)
<b>Congenital, Familial And Genetic Disorders</b>												

**Clinical Trial Results Website**

Hydrocele	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%)
<b>Ear And Labyrinth Disorders</b>												
Ear Pain	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (12.50%) )	1 (25.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	2 (7.14%) )	5 (2.40%)
Hypoacusis	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (12.50%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	3 (1.44%)
Motion Sickness	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (25.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%)
Vertigo	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (12.50%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (3.57%) )	3 (1.44%)
<b>Eye Disorders</b>												
Amaurosis Fugax	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (25.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%)
Conjunctival Haemorrhage	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (3.57%) )	3 (1.44%)
Eye Pain	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%)
Eyelid Oedema	0 (0.00%) )	0 (0.00%) )	1 (25.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%)
Intraocular Haematoma	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%)
Lacrimation Increased	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%)
Vision Blurred	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (25.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%)
<b>Gastrointestinal Disorders</b>												

**Clinical Trial Results Website**

Abdominal Discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Abdominal Distension	1 (100.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	1 (12.50%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	10 (4.81%)
Abdominal Hernia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Abdominal Pain	1 (100.00%)	0 (0.00%)	1 (25.00%)	2 (50.00%)	2 (50.00%)	2 (25.00%)	1 (25.00%)	2 (25.00%)	1 (16.67%)	0 (0.00%)	3 (10.71%)	35 (16.83%)
Abdominal Pain Lower	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.44%)
Abdominal Pain Upper	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	12 (5.77%)
Aerophagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Anal Incontinence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	2 (0.96%)
Ascites	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Constipation	1 (100.00%)	2 (100.00%)	1 (25.00%)	2 (50.00%)	1 (25.00%)	1 (12.50%)	1 (25.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	6 (21.43%)	40 (19.23%)
Diarrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	2 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (20.00%)	10 (35.71%)	51 (24.52%)
Dry Mouth	0 (0.00%)	1 (50.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	8 (3.85%)
Dyspepsia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	5 (2.40%)
Dysphagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.92%)
Gastritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	3 (1.44%)



### Clinical Trial Results Website

Gastroesophageal Reflux Disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	3 (1.44%)
Gingival Bleeding	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Gingival Hypertrophy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Gingival Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Haemorrhoids	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	6 (2.88%)
Lip Oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Melaena	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Mouth Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	6 (2.88%)
Nausea	0 (0.00%)	1 (50.00%)	0 (0.00%)	2 (50.00%)	2 (50.00%)	5 (62.50%)	2 (50.00%)	4 (50.00%)	3 (50.00%)	3 (60.00%)	17 (60.71%)	121 (58.17%)
Odynophagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.44%)
Oral Disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.44%)
Oral Mucosal Eruption	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Oral Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (10.71%)	3 (1.44%)
Pancreatic Steatosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Rectal Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	4 (1.92%)

**Clinical Trial Results Website**

Small Intestinal Obstruction	1 (100.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Stomatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	6 (21.43%)	13 (6.25%)	
Toothache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	2 (0.96%)	
Trichoglossia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)	
Vomiting	1 (100.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)	1 (25.00%)	3 (37.50%)	1 (25.00%)	4 (50.00%)	1 (16.67%)	1 (20.00%)	10 (35.71%)	72 (34.62%)	
<b>General Disorders And Administration Site Conditions</b>													
Asthenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (12.50%)	1 (16.67%)	0 (0.00%)	4 (14.29%)	34 (16.35%)	
Chest Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	7 (3.37%)	
Chills	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	6 (2.88%)	
Extravasation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)	
Facial Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	2 (0.96%)	
Fatigue	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	4 (50.00%)	0 (0.00%)	2 (25.00%)	2 (33.33%)	2 (40.00%)	8 (28.57%)	61 (29.33%)	
General Physical Health Deterioration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (10.71%)	8 (3.85%)	
Generalised Oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	4 (1.92%)	
Influenza Like Illness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	8 (3.85%)	

**Clinical Trial Results Website**

Malaise	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (12.50%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	2 (7.14%) )	11 (5.29%) )
Non-Cardiac Chest Pain	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (20.00%) )	0 (0.00%) )	2 (0.96%) )
Oedema	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	2 (7.14%) )	3 (1.44%) )
Oedema Peripheral	0 (0.00%) )	1 (50.00%) )	1 (25.00%) )	1 (25.00%) )	1 (25.00%) )	0 (0.00%) )	0 (0.00%) )	1 (12.50%) )	0 (0.00%) )	0 (0.00%) )	9 (32.14%) )	40 (19.23%) )
Pain	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (3.57%) )	3 (1.44%) )
Pyrexia	0 (0.00%) )	1 (50.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	3 (37.50%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (20.00%) )	4 (14.29%) )	36 (17.31%) )
<b>Hepatobiliary Disorders</b>												
Cholangitis	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%) )
Cholelithiasis	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (16.67%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%) )
Cholestasis	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (25.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%) )
Hyperbilirubinaemia	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (25.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (3.57%) )	5 (2.40%) )
Jaundice	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%) )
<b>Immune System Disorders</b>												
Anaphylactic Reaction	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%) )
Graft Versus Host Disease	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (3.57%) )	3 (1.44%) )
<b>Infections And Infestations</b>												

**Clinical Trial Results Website**

Atypical Pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Bacteraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Balanitis Candida	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Bronchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.44%)
Candida Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Conjunctivitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Cystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	2 (0.96%)
Cystitis Viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Cytomegalovirus Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Emphysematous Pyelonephritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Folliculitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Fungal Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Gastrointestinal Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	2 (0.96%)
Herpes Simplex	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Herpes Virus Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)

**Clinical Trial Results Website**

Herpes Zoster	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Influenza	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	3 (1.44%)
Laryngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Lip Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Nasopharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	4 (1.92%)
Neutropenic Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Oesophageal Candidiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Onychomycosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Oral Candidiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	7 (3.37%)
Oral Herpes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (10.71%)	6 (2.88%)
Orchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Paronychia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Periodontitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Pharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (14.29%)	11 (5.29%)

**Clinical Trial Results Website**

Respiratory Tract Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	7 (3.37%)
Sinusitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	3 (1.44%)
Skin Candida	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Soft Tissue Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Tongue Fungal Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Upper Respiratory Tract Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.92%)
Urinary Tract Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	6 (2.88%)
Viral Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Wound Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Injury, Poisoning And Procedural Complications</b>												
Face Injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Fall	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	3 (1.44%)
Scratch	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Skin Injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Transfusion Reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (10.71%)	5 (2.40%)

**Clinical Trial Results Website**

**Investigations**

Alanine Aminotransferase Increased	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	2 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (10.71%)	14 (6.73%)
Ammonia Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Amylase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	2 (7.14%)	12 (5.77%)
Aspartate Aminotransferase Increased	0 (0.00%)	0 (0.00%)	2 (50.00%)	0 (0.00%)	2 (50.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	3 (10.71%)	18 (8.65%)
Blood Alkaline Phosphatase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (20.00%)	3 (10.71%)	20 (9.62%)
Blood Bilirubin Increased	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	5 (17.86%)	22 (10.58%)
Blood Creatine Phosphokinase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.92%)
Blood Creatinine Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)	1 (12.50%)	1 (25.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	4 (14.29%)	22 (10.58%)
Blood Lactate Dehydrogenase Increased	0 (0.00%)	1 (50.00%)	0 (0.00%)	2 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	10 (4.81%)
Blood Phosphorus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Blood Phosphorus Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.92%)
Blood Uric Acid Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	5 (2.40%)
C-Reactive Protein Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	6 (2.88%)

### Clinical Trial Results Website

Ejection Fraction Decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Electrocardiogram Qt Prolonged	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	4 (1.92%)
Gamma-Glutamyltransferase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	2 (7.14%)	14 (6.73%)
Heart Rate Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
International Normalised Ratio Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	3 (1.44%)
Lipase Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (3.57%)	16 (7.69%)
Lymphocyte Count Decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (20.00%)	2 (7.14%)	12 (5.77%)
Neutrophil Count Decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	4 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	2 (7.14%)	17 (8.17%)
Ph Urine Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Platelet Count Decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	4 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	2 (7.14%)	29 (13.94%)
Prothrombin Time Prolonged	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	2 (0.96%)
Weight Decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	3 (37.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	2 (7.14%)	18 (8.65%)
Weight Increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (2.40%)



**Clinical Trial Results Website**

White Blood Cell Count Decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	3 (10.71%)	27 (12.98%)
<b>Metabolism And Nutrition Disorders</b>												
Decreased Appetite	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	2 (50.00%)	2 (25.00%)	1 (25.00%)	2 (25.00%)	2 (33.33%)	2 (40.00%)	8 (28.57%)	65 (31.25%)
Dehydration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (17.86%)	7 (3.37%)
Hypercalcaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	4 (1.92%)
Hyperglycaemia	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (20.00%)	1 (3.57%)	12 (5.77%)
Hyperkalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	15 (7.21%)
Hyperlipasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Hypernatraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.44%)
Hyperphosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	7 (3.37%)
Hyperuricaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	3 (10.71%)	13 (6.25%)
Hypervolaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Hypoalbuminaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	3 (10.71%)	16 (7.69%)
Hypocalcaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	6 (21.43%)	23 (11.06%)
Hypokalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	10 (35.71%)	41 (19.71%)

**Clinical Trial Results Website**

Hypomagnesaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	12 (5.77%)
Hyponatraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	3 (10.71%)	14 (6.73%)
Hypophosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	7 (25.00%)	23 (11.06%)
Hypoproteinaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Iron Overload	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Lactic Acidosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Tumour Lysis Syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (10.71%)	11 (5.29%)
Vitamin B12 Deficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Vitamin D Deficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Musculoskeletal And Connective Tissue Disorders</b>												
Arthralgia	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	10 (4.81%)
Back Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (20.00%)	1 (3.57%)	16 (7.69%)
Bone Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Flank Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Groin Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.44%)

**Clinical Trial Results Website**

Muscle Spasms	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Muscular Weakness	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (2.40%)
Musculoskeletal Chest Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Musculoskeletal Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	7 (3.37%)
Myalgia	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	9 (4.33%)
Neck Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	3 (1.44%)
Pain In Extremity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (14.29%)	13 (6.25%)
Spondylolysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)</b>												
Chloroma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Tumour Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Tumour Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.44%)
<b>Nervous System Disorders</b>												
Altered State Of Consciousness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)

**Clinical Trial Results Website**

Balance Disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Cognitive Disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Dizziness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (14.29%)	15 (7.21%)
Dysaesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Dysgeusia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (20.00%)	1 (3.57%)	17 (8.17%)
Headache	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	1 (12.50%)	2 (50.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	7 (25.00%)	27 (12.98%)
Hypoaesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Hypotonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Lethargy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Migraine	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Neuralgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Paraesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	5 (2.40%)
Peripheral Sensory Neuropathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Somnolence	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	7 (3.37%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)

**Clinical Trial Results Website**

**Psychiatric Disorders**

Affective Disorder	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Anxiety	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (2.40%)
Depression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	4 (1.92%)
Insomnia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	12 (5.77%)
Mood Altered	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Sleep Disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	5 (2.40%)

**Renal And Urinary Disorders**

Acute Kidney Injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (10.71%)	7 (3.37%)
Azotaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Dysuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.92%)
Haematuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	5 (2.40%)
Nocturia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (3.57%)	2 (0.96%)
Pollakiuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	5 (2.40%)
Urinary Retention	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)

**Clinical Trial Results Website**

Urinary Tract Obstruction	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	2 (0.96%)
<b>Reproductive System And Breast Disorders</b>													
Benign Prostatic Hyperplasia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Cervical Discharge	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Oedema Genital	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Pelvic Pain	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Pruritus Genital	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Testicular Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Vaginal Ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Vulva Cyst	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Respiratory, Thoracic And Mediastinal Disorders</b>													
Cough	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	2 (25.00%)	0 (0.00%)	2 (25.00%)	1 (16.67%)	2 (40.00%)	7 (25.00%)	32 (15.38%)	
Dysphonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	5 (2.40%)	
Dyspnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (12.50%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	22 (10.58%)	

### Clinical Trial Results Website

Dyspnoea Exertional	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (2.40%)
Epistaxis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	6 (21.43%)	17 (8.17%)
Haemoptysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	6 (2.88%)
Hiccups	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Hypoxia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Lung Infiltration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	2 (0.96%)
Nasal Congestion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	3 (1.44%)
Oropharyngeal Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (3.57%)	5 (2.40%)
Pharyngeal Inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Pleural Effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	6 (2.88%)
Pneumonitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Productive Cough	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (3.57%)	4 (1.92%)
Pulmonary Haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Respiratory Failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Rhinorrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	4 (1.92%)

### Skin And Subcutaneous

**Clinical Trial Results Website**

<b>Tissue Disorders</b>												
Alopecia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (10.71%)	9 (4.33%)
Blood Blister	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Dermatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Dermatitis Acneiform	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Dry Skin	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	7 (3.37%)
Ecchymosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.44%)
Eczema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	4 (1.92%)
Hyperhidrosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (2.40%)
Night Sweats	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	2 (0.96%)
Pain Of Skin	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Palmar-Plantar Erythrodysesthesia Syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Penile Ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Petechiae	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (10.71%)	11 (5.29%)



**Clinical Trial Results Website**

Pruritus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	8 (3.85%)
Purpura	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.92%)
Rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	6 (2.88%)
Rash Erythematous	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	4 (1.92%)
Rash Macular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Rash Maculo-Papular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	4 (1.92%)
Rash Papular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Skin Burning Sensation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Skin Exfoliation	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Skin Plaque	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)	2 (0.96%)
Swelling Face	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.96%)
Telangiectasia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
Urticaria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)
<b>Vascular Disorders</b>													
Circulatory Collapse	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	2 (0.96%)
Embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.48%)

**Clinical Trial Results Website**

Flushing	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (25.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%)
Haematoma	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	3 (10.71%) )	6 (2.88%)
Hot Flush	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (0.48%)
Hypertension	0 (0.00%) )	0 (0.00%) )	1 (25.00%) )	1 (25.00%) )	2 (50.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (3.57%) )	13 (6.25%) )
Hypotension	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	1 (12.50%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	2 (7.14%) )	12 (5.77%) )
Thrombophlebitis	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	0 (0.00%) )	3 (1.44%)

**Conclusion:**

The primary objective of the study was to determine the MTD and/or identify the RDE of HDM201 with or without eltrombopag in one or more of the pre-defined regimens and indication groups. The study objectives of the study were met. Different RDEs have been defined in the first-in-human study: RDE 120 mg regimen 1B (Day 1, Day 8, 4-week cycle) in both solid tumors and hematological tumors; in addition, RDE 45 mg regimen 2C (Day 1-8, 4-week cycle), and RDE 250 mg regimen 1A (Q3W) in hematological tumors, only.

HDM201 has demonstrated a tolerable safety profile mainly characterized by bone marrow suppression and gastrointestinal (GI) toxicity. Whereas GI toxicity was of mild and moderate severity, hematological toxicity was of higher incidence and severity with a limited effect of eltrombopag on the mitigation of HDM201-induced thrombocytopenia. However, both toxicities were manageable in practice with hematological toxicity being very rarely dose limiting.

**Date of Clinical Trial Report**

23-Feb-2021