



Clinical Trial Results Website

**Sponsor**

Novartis Pharmaceuticals

**Generic Drug Name**

KRP203

**Trial Indication(s)**

Patients undergoing allogeneic hematopoietic stem cell transplant for hematological malignancy

**Protocol Number**

CKRP203A2105

**Protocol Title**

A two-part, single- and two arm randomized, open-label study to evaluate the safety, tolerability, pharmacokinetics and efficacy (in Part 2 only) of KRP203 in patients undergoing stem cell transplant for hematological malignancies

**Clinical Trial Phase**

Phase 1b

**Phase of Drug Development**

PH I

**Study Start/End Dates**

Study Start Date: June 2013 (Actual)  
Primary Completion Date: August 2018 (Actual)  
Study Completion Date: August 2018 (Actual)

**Reason for Termination (If applicable)**

The study was terminated for strategic reasons unrelated to safety.

**Study Design/Methodology**

This was a multicenter, multinational two-part study to assess the safety and tolerability of KRP203 in subjects undergoing allogeneic HSCT for hematological malignancies.

**Part 1:** This part was open-label and single arm, which evaluated the safety of 3 mg KRP203 + CsA in 10 subjects. Part 1 comprised of a screening period (Days -50 to -2), Baseline (Day -1), treatment period from Day 1 to Day 111 with KRP203 and a follow-up period up to 365 days (from transplant). Subjects were admitted to the study site during the screening period (approximately 2 to 5 days before Baseline) and received the investigational product 3 mg KRP203 once daily from Day 1 until Day 111 along with cyclosporine A (CsA) given as standard of care (SOC) GvHD prophylaxis. Hematopoietic stem cell transplant (HSCT) was performed on Day 11.

**Part 2:** The second part of study was open-label, 2-arm and randomized which evaluated the safety, tolerability and efficacy of 1 mg KRP203 + CsA and 3 mg KRP203 + Tac treatment arm. Part 2 comprised of a screening period (Days -50 to -2), treatment period from Day 1 to Day 111 with KRP203 and follow-up visits. Hematopoietic stem cell transplant (HSCT) was performed on Day 11

**Centers**

8 centers in 3 countries: Switzerland(2), Germany(5), France(1)

**Objectives:****Primary Objective**

- To assess the safety and tolerability of KRP203 in subjects undergoing allogeneic HSCT for hematological malignancies

**Secondary Objectives**

- To determine the pharmacokinetic (PK) profile of KRP203 and its active metabolite KRP203-Phosphate in subjects undergoing allogeneic HSCT for hematological malignancies

- To assess GvHD-free, relapse free survival (GRFS) at 6 months after last treatment

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

Capsules of 1 mg KRP203 were provided and subjects randomized to 3 mg KRP203 dose were administered three capsules of 1 mg KRP203 taken orally once daily. KRP203 was co-administered with standard of care cyclosporine A or tacrolimus.

### **Statistical Methods**

No formal statistical inference was done for the analysis of the primary safety variable (incidence of AEs). KRP203 and KRP203-P blood concentration data were provided by descriptive summary statistics including mean (arithmetic and geometric), SD, CV (arithmetic and geometric). For Tmax and Tlag, median, minimum and maximum were presented

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

#### **Inclusion Criteria**

- Patients aged 18 to 65 years, inclusive
- Patients must have had a hematological malignancy that as per standard medical practice requires myeloablative conditioning (including short term myeloablative reduced intensity conditioning)
- Qualified for allogeneic hematopoietic stem cell transplant
- Karnofsky Performance status  $\geq 60\%$ .
- Suitable stem cell source available according to the graft selection
- algorithm using T-cell replete peripheral stem cells as a graft source

#### **Exclusion Criteria:**

- Resting heart rate below 55
- Significant cardiac disease (such as arrhythmia, heart failure) or any
- Significant condition which in the investigators opinion would have made the patient ineligible
  - o Previous allogeneic HSCT

o Any drug required that was not compatible with KRP203 (e.g. beta-blockers or anti-thymocyte globulin)

## **Participant Flow Table**

### **Overall Study**

<b>Arm/Group Description</b>	<b>Part 2:KRP203 1 mg + SOC CsA</b>	<b>Part 2: KRP203 3mg + SOC Tac</b>	<b>Part 1: KRP203 3 mg + CsA</b>	<b>Total</b>
	KRP203 1 mg for 111 days in addition to the standard treatment with cyclosporine A and methotrexate for GVHD prophylaxis	KRP203 3 mg dose for 111 days in addition to standard treatment with tacrolimus and methotrexate for GVHD prophylaxis	KRP203 3 mg + cyclosporine A (CsA) for 111 days	
<b>Started</b>	6	7	10	23
<b>Completed 1 year</b>	2	1	2	5
<b>Completed 2 years</b>	0	0	8	8
<b>Deaths after completion</b>	0	0	0	0
<b>Deaths after discontinuation</b>	0	3	0	3
<b>Completed study on Day 275</b>	1	0	0	1
<b>Completed</b>	3	1	10	14
<b>Not Completed</b>	3	6	0	9

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Adverse Event	1	2	0	3
Death	1	1	0	2
Withdrawal by Subject	1	3	0	4

**Baseline Characteristics**

	<b>Part 2:KRP203 1 mg + SOC CsA</b>	<b>Part 2: KRP203 3mg + SOC Tac</b>	<b>Part 1: KRP203 3 mg + CsA</b>	<b>Total</b>
<b>Arm/Group Description</b>	KRP203 1 mg for 111 days in addition to the standard treatment with cyclosporine A and methotrexate for GVHD prophylaxis	KRP203 3 mg dose for 111 days in addition to standard treatment with tacrolimus and methotrexate for GVHD prophylaxis	KRP203 3 mg + cyclosporine A (CsA) for 111 days	
<b>Number of Participants [units: participants]</b>	6	7	10	23
<b>Age, Customized (units: participants)</b>				
18 to 65	6	7	10	23
<b>Sex: Female, Male (units: )</b>				
Count of Participants (Not Applicable)				
Female	1	3	5	9
Male	5	4	5	14

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**Race/Ethnicity, Customized**

(units: )

Count of Participants (Not Applicable)

Caucasian	6	5	9	20
Asian	0	0	1	1
Other	0	2	0	2

**Primary Outcome Result(s)**
**Number of participants with Adverse Events from start of treatment until transplant**

(Time Frame: Baseline up to 111 days prior to transplant)

	<b>Part 2:KRP203 1 mg + SOC CsA</b>	<b>Part 2: KRP203 3mg + SOC Tac</b>	<b>Part 1: KRP203 3 mg + CsA</b>
<b>Arm/Group Description</b>	KRP203 1 mg for 111 days in addition to the standard treatment with cyclosporine A and methotrexate for GVHD prophylaxis	KRP203 3 mg dose for 111 days in addition to standard treatment with tacrolimus and methotrexate for GVHD prophylaxis	KRP203 3 mg + cyclosporine A (CsA) for 111 days
<b>Number of Participants Analyzed [units: participants]</b>	6	7	10

**Number of participants with Adverse Events from start of treatment until transplant**

(units: number of participants)

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Gastrointestinal disorders	6	4	6
Investigations	4	4	0
General disorders and admin site conditions	4	3	0
Nervous system disorders	1	2	1
Respiratory, thoracic and mediastinal disorders	2	1	1
Vascular disorders	1	2	1
Cardiac disorders	1	0	2
Infections and infestations	2	1	0
Metabolism and nutrition disorders	1	1	1
Psychiatric disorders	1	1	1
Skin and subcutaneous tissue disorders	1	1	1
Blood and lymphatic system disorders	1	1	0
Hepatobiliary disorders	0	0	1
Immune system disorders	1	0	0
Musculoskeletal and connective tissue disorders	1	0	0

**Number of participants with Adverse Events from transplant up to 30 days post transplant**

(Time Frame: Transplant up to 30 days post transplant)

	<b>Part 2: KRP203 1 mg + SOC CsA</b>	<b>Part 2: KRP203 3mg + SOC Tac</b>	<b>Part 1: KRP203 3 mg + CsA</b>
<b>Arm/Group Description</b>	KRP203 1 mg for 111 days	KRP203 3 mg dose for 111	KRP203 3 mg +

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	in addition to the standard treatment with cyclosporine A and methotrexate for GVHD prophylaxis	days in addition to standard treatment with tacrolimus and methotrexate for GVHD prophylaxis	cyclosporine A (CsA) for 111 days
<b>Number of Participants Analyzed [units: participants]</b>	6	7	10
<b>Number of participants with Adverse Events from transplant up to 30 days post transplant</b> (units: number of participants)			
Gastrointestinal disorders	5	6	7
Vascular disorders	4	5	3
Investigations	4	4	2
General disorders and admin site conditions	2	6	1
Metabolism and nutrition disorders	3	5	1
Nervous system disorders	3	3	3
Respiratory, thoracic and mediastinal disorders	1	3	4
Blood and lymphatic system disorders	4	2	0
Musculoskeletal and connective tissue disorders	3	2	1
Eye disorders	2	1	2
Infections and infestations	3	0	2



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Ear and labyrinth disorders	0	2	2
Immune system disorders	1	0	3
Cardiac disorders	0	3	0
Psychiatric disorders	1	2	0
Renal and urinary disorders	0	2	1
Skin and subcutaneous tissue disorders	1	2	0
Reproductive system and breast disorders	0	1	0

**Number of participants with Adverse Events from 30 days post transplant for up to 60 days post transplant**

(Time Frame: 30 days post transplant up to an additional 30 days)

<b>Arm/Group Description</b>	<b>Part 2:KRP203 1 mg + SOC CsA</b>	<b>Part 2: KRP203 3mg + SOC Tac</b>	<b>Part 1: KRP203 3 mg + CsA</b>
	KRP203 1 mg for 111 days in addition to the standard treatment with cyclosporine A and methotrexate for GVHD prophylaxis	KRP203 3 mg dose for 111 days in addition to standard treatment with tacrolimus and methotrexate for GVHD prophylaxis	KRP203 3 mg + cyclosporine A (CsA) for 111 days
<b>Number of Participants Analyzed [units: participants]</b>	6	7	10

**Number of participants with Adverse Events from 30 days post transplant for up to 60 days post transplant**

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(units: number of participants)

Immune system disorders	5	7	10
Infections and infestations	5	6	5
General disorders and admin site conditions	3	5	6
Gastrointestinal disorders	4	5	4
Skin and subcutaneous tissue disorders	5	6	2
Eye disorders	2	4	4
Investigations	4	3	3
Nervous system disorders	4	4	1
Respiratory, thoracic and mediastinal disorders	3	3	3
Blood and lymphatic system disorders	3	3	2
Metabolism and nutrition disorders	4	3	1
Musculoskeletal and connective tissue disorders	3	2	2
Vascular disorders	2	3	0
Psychiatric disorders	1	3	0
Renal and urinary disorders	2	1	1
Cardiac disorders	2	1	0
Neoplasms benign malignant and unspecified	0	1	2
Ear and labyrinth disorders	1	1	0
Endocrine disorders	0	1	1

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Injury, poisoning and procedural complications	0	2	0
Hepatobiliary disorders	0	1	0
Reproductive system and breast disorders	0	0	1

**Secondary Outcome Result(s)**
**AUCtau (area under the curve over a 24 hour dosing interval) for plasma of KRP203 and metabolite KRP203-P**

(Time Frame: Part 1: Day 1, 28; Part 2: Day 1, 25, 41)

	<b>Part 2: KRP203 1 mg + SOC CsA</b>	<b>Part 2: KRP203 3mg + SOC Tac</b>	<b>Part 1: KRP203 3 mg + CsA</b>
<b>Arm/Group Description</b>	KRP203 1 mg for 111 days in addition to the standard treatment with cyclosporine A and methotrexate for GVHD prophylaxis	KRP203 3 mg dose for 111 days in addition to standard treatment with tacrolimus and methotrexate for GVHD prophylaxis	KRP203 3 mg + cyclosporine A (CsA) for 111 days
<b>Number of Participants Analyzed [units: participants]</b>	6	7	10
<b>AUCtau (area under the curve over a 24 hour dosing interval) for plasma of KRP203 and metabolite KRP203-P</b>			
(units: h.ng/mL)			
Geometric Mean (Geometric Coefficient of Variation)			
KRP203 Day 1	6.49 (68.1%)	13.3	12.1 (20.4%)

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KRP203 Day 25	40.3 (41.2%)	66.1 (27.1%)	
KRP203 Day 28			139 (34.8%)
KRP203 Day 41	57.7 (18.3%)	105	
KRP203 - P Day 1	9.79 (95.0%)		16.0 (30.0%)
KRP203 - P Day 25	69.6 (47.3%)	123 (37.4%)	
KRP203 - P Day 28			297 (24.0%)
KRP203 - P Day 41	138 (35.7%)	173	

**Cmax (maximum blood drug concentration) for KRP203 and metabolite KRP203-P**

(Time Frame: Part 1: Day 1, 28; Part 2: Day 1, 25, 41)

	<b>Part 2: KRP203 1 mg + SOC CsA</b>	<b>Part 2: KRP203 3mg + SOC Tac</b>	<b>Part 1: KRP203 3 mg + CsA</b>
<b>Arm/Group Description</b>	KRP203 1 mg for 111 days in addition to the standard treatment with cyclosporine A and methotrexate for GVHD prophylaxis	KRP203 3 mg dose for 111 days in addition to standard treatment with tacrolimus and methotrexate for GVHD prophylaxis	KRP203 3 mg + cyclosporine A (CsA) for 111 days
<b>Number of Participants Analyzed [units: participants]</b>	6	7	10

**Cmax (maximum blood drug concentration) for KRP203 and metabolite KRP203-P**

(units: ng/mL)

Geometric Mean (Geometric Coefficient of Variation)

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KRP203 Day 1	0.237 (45.6%)	0.701	0.609 (21.7%)
KRP203 Day 25	1.86 (26.5%)	3.45 (28.9%)	
KRP203 Day 28			7.24 (38.4%)
KRP203 Day 41	2.69 (14.8%)	5.04	
KRP203 - P Day 1	0.356 (56.0%)	0.997	0.834 (22.1%)
KRP203 - P Day 25	3.59 (50.8%)	6.27 (34.0%)	
KRP203 - P Day 28			18.7 (43.4%)
KRP203 - P Day 41	7.53 (22.5%)	8.17	

**Tmax (time to reach maximum blood drug concentration) for KRP203 and metabolite KRP203-P**

(Time Frame: Part 1: Day 1, 28; Part 2: Day 1, 25, 41)

<b>Arm/Group Description</b>	<b>Part 2: KRP203 1 mg + SOC CsA</b>	<b>Part 2: KRP203 3mg + SOC Tac</b>	<b>Part 1: KRP203 3 mg + CsA</b>
	KRP203 1 mg for 111 days in addition to the standard treatment with cyclosporine A and methotrexate for GVHD prophylaxis	KRP203 3 mg dose for 111 days in addition to standard treatment with tacrolimus and methotrexate for GVHD prophylaxis	KRP203 3 mg + cyclosporine A (CsA) for 111 days
<b>Number of Participants Analyzed [units: participants]</b>	6	7	10

**Tmax (time to reach maximum blood drug concentration) for KRP203 and metabolite KRP203-P**

(units: h)

Median (Full Range)

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KRP203 Day 1	3.02 (2.98 to 8.08)	2.97 (2.97 to 2.97)	9.95 (6.00 to 23.9)
KRP203 Day 25	5.51 (0 to 10.0)	6.03 (3.00 to 11.9)	
KRP203 Day 28			6.00 (2.83 to 12.0)
KRP203 Day 41	5.99 (5.97 to 6.02)	6.00 (6.00 to 6.00)	
KRP203 - P Day 1	9.93 (6.00 to 228)	11.9 (11.9 to 11.9)	12.0 (8.00 to 24.1)
KRP203 - P Day 25	4.50 (0 to 6.00)	6.00 (0 to 7.92)	
KRP203 - P Day 28			5.83 (2.95 to 23.9)
KRP203 - P Day 41	3.03 (3.00 to 5.97)	8.00 (8.00 to 8.00)	

**Tlag (lag time between drug intake and first quantifiable concentration) for KRP203 and metabolite KRP203-P**

(Time Frame: Part 1: Day 1; Part 2: Day 1)

<b>Arm/Group Description</b>	<b>Part 2: KRP203 1 mg + SOC CsA</b>	<b>Part 2: KRP203 3mg + SOC Tac</b>	<b>Part 1: KRP203 3 mg + CsA</b>
	KRP203 1 mg for 111 days in addition to the standard treatment with cyclosporine A and methotrexate for GVHD prophylaxis	KRP203 3 mg dose for 111 days in addition to standard treatment with tacrolimus and methotrexate for GVHD prophylaxis	KRP203 3 mg + cyclosporine A (CsA) for 111 days

<b>Number of Participants Analyzed [units: participants]</b>	2	1	6
<b>Tlag (lag time between drug intake and first quantifiable concentration) for KRP203 and metabolite KRP203-P</b> (units: h) Median (Full Range)			
KRP203 Day 1	0.500 (0 to 0.750)	0.500 (0.500 to 0.500)	0.417 (0 to 0.633)
KRP203 - P Day 1	0.500 (0 to 0.750)	0.500 (0.500 to 0.500)	0.500 (0.417 to 0.633)

**Percentage of participants who were GVHD-free (graft versus host disease), relapse free and survived 6 months after last treatment**

(Time Frame: Last treatment up to 6 months)

<b>Arm/Group Description</b>	<b>Part 2:KRP203 1 mg + SOC CsA</b>	<b>Part 2: KRP203 3mg + SOC Tac</b>	<b>Part 1: KRP203 3 mg + CsA</b>
	KRP203 1 mg for 111 days in addition to the standard treatment with cyclosporine A and methotrexate for GVHD prophylaxis	KRP203 3 mg dose for 111 days in addition to standard treatment with tacrolimus and methotrexate for GVHD prophylaxis	KRP203 3 mg + cyclosporine A (CsA) for 111 days
<b>Number of Participants Analyzed [units: participants]</b>	6	7	10

**Percentage of participants who were GVHD-free (graft versus host disease), relapse free and survived 6 months after last treatment**

(units: percentage of participants)

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50                      28.6                      70

## Safety Results

### All-Cause Mortality

	<b>Before transplant KRP203 1mg + CsA N = 6</b>	<b>Before transplant KRP203 3mg + Tac N = 7</b>	<b>Before transplant KRP203 3mg + CsA N = 10</b>	<b>Until transplant + 30D KRP203 1mg + CsA N = 6</b>	<b>Until transplant + 30D KRP203 3mg + Tac N = 7</b>	<b>Until transplant + 30D KRP203 3mg + CsA N = 10</b>	<b>After transplant + 30D KRP203 1mg + CsA N = 6</b>	<b>After transplant + 30D KRP203 3mg + Tac N = 7</b>	<b>After transplant + 30D KRP203 3mg + CsA N = 10</b>
<b>Arm/Group Description</b>	Before transplant KRP203 1mg + CsA	Before transplant KRP203 3mg + Tac	Before transplant KRP203 3mg + CsA	Until transplant + 30D KRP203 1mg + CsA	Until transplant + 30D KRP203 3mg + Tac	Until transplant + 30D KRP203 3mg + CsA	After transplant + 30D KRP203 1mg + CsA	After transplant + 30D KRP203 3mg + Tac	After transplant + 30D KRP203 3mg + CsA
<b>Total participants affected</b>	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	4 (57.14%)	2 (20.00%)



**Serious Adverse Events by System Organ Class**

Time Frame	Adverse Events and Serious Adverse Events were collected for the maximum actual duration of treatment exposure and follow up for a participant per the protocol for treatment-emergent adverse events up to approximately 1.3 years								
Source Vocabulary for Table Default	MedDRA (21.0)								
Assessment Type for Table Default	Systematic Assessment								
Arm/Group Description	Before transplant KRP203 1mg + CsA N = 6	Before transplant KRP203 3mg + Tac N = 7	Before transplant KRP203 3mg + CsA N = 10	Until transplant + 30D KRP203 1mg + CsA N = 6	Until transplant + 30D KRP203 3mg + Tac N = 7	Until transplant + 30D KRP203 3mg + CsA N = 10	After transplant + 30D KRP203 1mg + CsA N = 6	After transplant + 30D KRP203 3mg + Tac N = 7	After transplant + 30D KRP203 3mg + CsA N = 10
	Before transplant KRP203 1mg + CsA	Before transplant KRP203 3mg + Tac	Before transplant KRP203 3mg + CsA	Until transplant + 30D KRP203 1mg + CsA	Until transplant + 30D KRP203 3mg + Tac	Until transplant + 30D KRP203 3mg + CsA	After transplant + 30D KRP203 1mg + CsA	After transplant + 30D KRP203 3mg + Tac	After transplant + 30D KRP203 3mg + CsA
<b>Total participants affected</b>	0 (0.00%)	0 (0.00%)	1 (10.00%)	1 (16.67%)	0 (0.00%)	2 (20.00%)	3 (50.00%)	6 (85.71%)	4 (40.00%)
<b>Blood and lymphatic system disorders</b>									
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%)	1 (14.29%)	0 (0.00%)
<b>Cardiac disorders</b>									
Angina unstable	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>Eye disorders</b>									
Blepharitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cystoid macular oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)

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Macular ischaemia	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%)
Retinal ischaemia	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%)
<b>Gastrointestinal disorders</b>									
Diarrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (28.57%)	1 (10.00%)
Diarrhoea haemorrhagic	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%)
Vomiting	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>General disorders and administration site conditions</b>									
General physical health deterioration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	1 (10.00%)
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%)	1 (10.00%)
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%)	1 (10.00%)
<b>Hepatobiliary disorders</b>									
Hepatic failure	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>Immune system disorders</b>									
Acute graft versus host disease in intestine	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	2 (33.33%)	1 (14.29%)	1 (10.00%)
Acute 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%)	1 (14.29%)	0 (0.00%)
Chronic graft versus host disease	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%)
Chronic graft versus host disease in intestine	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%)

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Graft versus host disease in gastrointestinal tract	0 (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>Infections and infestations</b>										
Enterococcal 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%)	1 (10.00%)
Infection	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%)
Mastoiditis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Progressive multifocal leukoencephalopathy	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%)
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%)	1 (14.29%)	0 (0.00%)
<b>Investigations</b>										
Weight increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>										
Acute myeloid leukaemia recurrent	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Hodgkin's 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 (14.29%)	0 (0.00%)
Parathyroid tumour benign	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Thyroid cancer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
<b>Renal and urinary disorders</b>										
Renal impairment	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
<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%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

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Dyspnoea exertional	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Pneumonia aspiration	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%)
Pneumonitis	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%)
<b>Skin and subcutaneous tissue disorders</b>									
Rash maculo-papular	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>Vascular disorders</b>									
Deep vein thrombosis	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%)

**Other Adverse Events by System Organ Class**

<b>Time Frame</b>	Adverse Events and Serious Adverse Events were collected for the maximum actual duration of treatment exposure and follow up for a participant per the protocol for treatment-emergent adverse events up to approximately 1.3 years
<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>	0%

	Before transplant KRP203 1mg + CsA N = 6	Before transplant KRP203 3mg + Tac N = 7	Before transplant KRP203 3mg + CsA N = 10	Until transplant + 30D KRP203 1mg + CsA N = 6	Until transplant + 30D KRP203 3mg + Tac N = 7	Until transplant + 30D KRP203 3mg + CsA N = 10	After transplant + 30D KRP203 1mg + CsA N = 6	After transplant + 30D KRP203 3mg + Tac N = 7	After transplant + 30D KRP203 3mg + CsA N = 10
<b>Arm/Group Description</b>	Before transplant KRP203 1mg + CsA	Before transplant KRP203 3mg + Tac	Before transplant KRP203 3mg + CsA	Until transplant + 30D	Until transplant + 30D	Until transplant + 30D	After transplant + 30D	After transplant + 30D	After transplant + 30D KRP203 3mg + CsA

				KRP203 1mg + CsA	KRP203 3mg + Tac	KRP203 3mg + CsA	KRP203 1mg + CsA	KRP203 3mg + Tac	
<b>Total participants affected</b>	6 (100.00%)	7 (100.00%)	6 (60.00%)	6 (100.00%)	7 (100.00%)	9 (90.00%)	6 (100.00%)	7 (100.00%)	10 (100.00%)
<b>Blood and lymphatic system disorders</b>									
Anaemia	0 (0.00%)	1 (14.29%)	0 (0.00%)	2 (33.33%)	1 (14.29%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Eosinophilia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Febrile neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhagic anaemia	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%)
Immune thrombocytopenic purpura	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%)
Leukopenia	1 (16.67%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)
Neutrophilia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Pancytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	1 (10.00%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (50.00%)	2 (28.57%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)
Thrombotic microangiopathy	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%)
<b>Cardiac disorders</b>									
Bradycardia	0 (0.00%)	0 (0.00%)	2 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Extrasystoles	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Palpitations	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%)
Sinus arrest	1 (16.67%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinus tachycardia	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%)
Stress cardiomyopathy	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%)
Tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Ear and labyrinth disorders**

Deafness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Middle ear inflammation	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%)
Presbycusis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Vertigo	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)

**Endocrine disorders**

Adrenal insufficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Androgen deficiency	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%)

**Eye disorders**

Blepharitis	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%)
Cataract	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%)
Dry eye	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)
Erythema of eyelid	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%)
Eyelid oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	2 (20.00%)
Lacrimation increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Macular ischaemia	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%)
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%)	1 (10.00%)
Optic disc haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Photophobia	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%)
Retinal detachment	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Retinal exudates	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	1 (10.00%)
Retinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

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Retinal ischaemia	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%)
Vision blurred	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)
Visual acuity reduced	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Gastrointestinal disorders</b>									
Abdominal distension	1 (16.67%)	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	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (28.57%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Abdominal pain upper	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ascites	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Constipation	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Diarrhoea	0 (0.00%)	2 (28.57%)	0 (0.00%)	2 (33.33%)	2 (28.57%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	2 (20.00%)
Dry mouth	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Duodenal ulcer	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%)
Dyspepsia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Dysphagia	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%)
Enterocolitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flatulence	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (28.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	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%)	2 (28.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intra-abdominal haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Large intestine polyp	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Malabsorption	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%)
Mouth ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Nausea	4 (66.67%)	3 (42.86%)	2 (20.00%)	1 (16.67%)	2 (28.57%)	2 (20.00%)	3 (50.00%)	1 (14.29%)	2 (20.00%)
Odynophagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stomatitis	1 (16.67%)	1 (14.29%)	0 (0.00%)	4 (66.67%)	5 (71.43%)	1 (10.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)
Subileus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Swollen tongue	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tongue coated	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Toothache	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vomiting	2 (33.33%)	1 (14.29%)	3 (30.00%)	2 (33.33%)	3 (42.86%)	6 (60.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)
<b>General disorders and 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%)	1 (14.29%)	0 (0.00%)
Catheter site erythema	1 (16.67%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Catheter site haematoma	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site pain	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site vesicles	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest pain	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%)
Face oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	2 (28.57%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Generalised oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
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%)	1 (10.00%)
Localised oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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%)	1 (14.29%)	0 (0.00%)
Oedema peripheral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (28.57%)	1 (10.00%)	3 (50.00%)	3 (42.86%)	4 (40.00%)
Pyrexia	1 (16.67%)	1 (14.29%)	0 (0.00%)	1 (16.67%)	4 (57.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)



**Hepatobiliary disorders**

Hepatic cyst	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ocular icterus	0 (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%)

**Immune system disorders**

Acute 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 (14.29%)
Acute graft versus host disease in intestine	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	3 (30.00%)	0 (0.00%)	1 (14.29%)	3 (30.00%)
Acute graft versus host disease in liver	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)
Acute graft versus host disease in skin	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (10.00%)	2 (33.33%)	3 (42.86%)	3 (30.00%)
Allergy to immunoglobulin therapy	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chronic graft versus host disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	2 (28.57%)	7 (70.00%)
Chronic graft versus host disease in intestine	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	2 (20.00%)
Chronic graft versus host disease in liver	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (50.00%)	1 (14.29%)	5 (50.00%)
Chronic 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%)	2 (28.57%)	3 (30.00%)
Graft versus host disease in eye	0 (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%)
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%)	1 (14.29%)

**Infections and infestations**

**Clinical Trial Results Website**

Bacteraemia	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%)
Campylobacter infection	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%)
Clostridium difficile infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	1 (10.00%)
Conjunctivitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Corona 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%)	1 (10.00%)
Cytomegalovirus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (42.86%)	1 (10.00%)
Epstein-Barr virus infection	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%)
Escherichia urinary tract infection	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fungal sepsis	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%)
Furuncle	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%)
Gastroenteritis	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%)
Gastrointestinal infection	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%)
Herpes simplex	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%)
Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	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%)	1 (10.00%)
Mucosal 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 (10.00%)
Nasopharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)
Oral candidiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (50.00%)	2 (28.57%)	0 (0.00%)
Oral herpes	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Otitis externa	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%)
Paronychia	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	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%)	1 (14.29%)	0 (0.00%)

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Pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	1 (10.00%)
Rhinovirus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	1 (10.00%)
Sinusitis	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%)
Upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	1 (10.00%)
Urinary tract infection	1 (16.67%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)
Urinary tract infection staphylococcal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral infection	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%)
Viral 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%)	1 (10.00%)
<b>Injury, poisoning and procedural complications</b>									
Fall	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%)
Laceration	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%)
Periorbital haematoma	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%)
Tooth injury	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>Investigations</b>									
Alanine aminotransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (66.67%)	2 (28.57%)	1 (10.00%)
Aspartate aminotransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (50.00%)	0 (0.00%)	1 (10.00%)
BK polyomavirus test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

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Blood albumin decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (28.57%)	0 (0.00%)
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%)	0 (0.00%)	1 (10.00%)
Blood bilirubin 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 (10.00%)
Blood cholesterol increased	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%)
Blood creatinine increased	2 (33.33%)	1 (14.29%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	1 (10.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Blood magnesium decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood potassium decreased	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Blood triglycerides increased	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%)
B-lymphocyte count 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%)	1 (10.00%)
CD4 lymphocytes 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%)	1 (10.00%)
C-reactive protein increased	1 (16.67%)	1 (14.29%)	0 (0.00%)	2 (33.33%)	2 (28.57%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	1 (10.00%)
Enterobacter test positive	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)
Immunosuppressant drug level increased	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neisseria test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pantoea agglomerans test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

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Platelet count decreased	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%)
Staphylococcus test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Streptococcus test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
T-lymphocyte count 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%)	1 (10.00%)
Weight 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%)	1 (10.00%)
Weight increased	3 (50.00%)	3 (42.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Metabolism and nutrition disorders</b>									
Cachexia	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%)
Decreased appetite	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (28.57%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	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%)	1 (14.29%)	0 (0.00%)
Folate deficiency	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%)
Hyperglycaemia	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%)
Hyperkalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Hypernatraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertriglyceridaemia	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperuricaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Hypoalbuminaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Hypocalcaemia	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)
Hypokalaemia	1 (16.67%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	2 (33.33%)	1 (14.29%)	0 (0.00%)
Hypomagnesaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	2 (28.57%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Hyponatraemia	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%)
Malnutrition	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)

**Musculoskeletal and  
connective tissue  
disorders**

Arthralgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)
Back pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	2 (28.57%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)
Bone pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	2 (28.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intervertebral disc protrusion	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%)
Muscular weakness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (28.57%)	0 (0.00%)
Myalgia	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%)
Myopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)
Osteopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	1 (10.00%)
Pain in extremity	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Polymyositis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Spinal osteoarthritis	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%)
Tendonitis	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%)

**Nervous system  
disorders**

Dizziness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Dysgeusia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Dyskinesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	0 (0.00%)	1 (14.29%)	1 (10.00%)	1 (16.67%)	3 (42.86%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Leukoencephalopathy	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%)
Paraesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral nerve lesion	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%)
Peripheral sensory neuropathy	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%)

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Peroneal nerve palsy	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%)
Polyneuropathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Restless legs syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sciatica	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%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tremor	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	1 (16.67%)	0 (0.00%)	1 (10.00%)
<b>Psychiatric disorders</b>									
Agitation	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Apathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Delirium	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	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%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)
Disorientation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Insomnia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (28.57%)	0 (0.00%)
Restlessness	0 (0.00%)	1 (14.29%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sleep disorder	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Renal and urinary disorders</b>									
Chronic kidney disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Dysuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	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%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)
<b>Reproductive system and breast disorders</b>									
Ovarian 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%)	1 (10.00%)

Vulvovaginal pruritus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Respiratory, thoracic and mediastinal disorders</b>									
Asthma	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cough	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	1 (10.00%)
Dyspnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	2 (28.57%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	0 (0.00%)
Epistaxis	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (28.57%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hiccups	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Laryngeal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	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%)	1 (14.29%)	0 (0.00%)
Nasal dryness	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	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%)	1 (14.29%)	2 (20.00%)	1 (16.67%)	1 (14.29%)	1 (10.00%)
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%)	1 (10.00%)
<b>Skin and subcutaneous tissue disorders</b>									
Acne	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Alopecia	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%)
Dry skin	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%)
Eczema	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%)
Erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	1 (10.00%)
Generalised erythema	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%)
Papule	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	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%)	1 (16.67%)	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%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Rash	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (50.00%)	1 (14.29%)	2 (20.00%)



**Clinical Trial Results Website**

Rash generalised	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (14.29%)	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%)	2 (28.57%)	0 (0.00%)
Rash maculo-papular	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 atrophy	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%)
Stasis dermatitis	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%)
Urticaria	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Vascular disorders</b>									
Capillary leak syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Deep vein thrombosis	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%)
Haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertension	1 (16.67%)	1 (14.29%)	1 (10.00%)	4 (66.67%)	4 (57.14%)	1 (10.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)
Hypotension	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subclavian vein thrombosis	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%)
Venous thrombosis limb	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%)
Withdrawal hypertension	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%)

**Conclusion:**

In this pilot study, KRP203 demonstrated an acceptable safety and tolerability profile in patients undergoing allogeneic hematopoietic stem cell transplant (HSCT) for hematological malignancies.



Clinical Trial Results Website

**Date of Clinical Trial Report**

23-Apr-2019