



Clinical Trial Results Website

**Sponsor**

Novartis Pharmaceuticals

**Generic Drug Name**

CJM112

**Trial Indication(s)**

Moderate to severe inflammatory acne

**Protocol Number**

CCJM112X2203

**Protocol Title**

A randomized, subject and investigator blinded, placebo-controlled, multi-center study in parallel groups to assess the efficacy and safety of CJM112 in patients with moderate to severe inflammatory acne

**Clinical Trial Phase**

Phase 2

**Phase of Drug Development**

Phase II

**Study Start/End Dates**



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Study Start Date: December 2016 (Actual)  
Primary Completion Date: August 2018 (Actual)  
Study Completion Date: August 2018 (Actual)

#### **Reason for Termination (If applicable)**

The study was terminated early by the Sponsor, as the results met the pre-planned futility criterion at the pre-planned interim analyses (IA1).

#### **Study Design/Methodology**

Randomized, placebo controlled, patient and investigator blinded, multicenter, non-confirmatory, parallel group, proof of concept study in subjects with moderate to severe inflammatory acne

#### **Centers**

10 centers in 3 countries: Netherlands(3), Germany(4), United States(3)

#### **Objectives:**

##### **Primary:**

To assess the efficacy of CJM112 versus placebo on facial inflammatory lesion counts in patients with moderate to severe inflammatory acne

##### **Secondary:**

To assess the safety and tolerability of CJM112 in patients with moderate to severe inflammatory acne.

To assess the pharmacokinetics of CJM112 in patients with moderate to severe acne.

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

The investigational drug, CJM112 and matching placebo were prepared and supplied as individual patient packs to be administered via subcutaneous route at the Investigator site.

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Subjects were assigned to one of the following 3 treatment arms:

- CJM112 high dose (300mg) once a month for a total of up to 7 doses
- CJM112 low dose (75mg) once a month for a total of up to 7 doses
- Placebo once a month for a total of up to 3 doses, followed by re-randomization into either active treatment group for Extension Period 2 for a total of up to 4 active doses

**Statistical Methods**

The primary variable was the natural log transformed total inflammatory facial lesion counts at week 12. Bayesian model for repeated measurements was used to analyze the log transformed inflammatory facial lesion count.

**Efficacy criteria (only for primary endpoint)**

- there was at least 90% probability that the treatment effect of CJM112 at Week 12 is better than placebo, AND
- there was at least 50% probability that the treatment effect at Week 12 is at least 30% (hence less than -0.357 on the natural log scale) in favor of CJM112.

The 30% threshold was chosen based on a study showing around 30% difference in inflammatory facial lesion count at Week 12 between a standard care oral antibiotics and placebo.

**Futility criterion at IA1:**

- there was at least 60% probability that the treatment effect of CJM112 at Week 12 is worse than placebo.

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

Inclusion Criteria:

- Male and female subjects aged 18 to 45 years of age included, and otherwise in good health as determined by medical history, physical examination, vital signs, ECGs and laboratory tests at screening.
- Body weight between 50 and 120 kg, inclusive at screening.

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- Patients with papulo-pustular acne vulgaris with between 25 and 100 facial inflammatory lesions (papules, pustules and nodules), and presence of non-inflammatory lesions (open and closed comedones) in the face at screening and baseline, who have failed systemic therapy for inflammatory acne.
- No more than 5 facial inflammatory nodules at screening and baseline.
- Investigator's Global assessment (IGA) score of at least moderate (3) acne severity on the face at screening and baseline.

**Exclusion Criteria:**

- Appropriate wash out periods are required for investigational drugs, any oral/systemic treatment for acne, systemic or lesional injected (for acne) corticosteroids or systemic immunomodulators, any systemic hormonal treatments, previous treatment with biologics, oral retinoids (in particular isotretinoin) and any topical anti-acne treatment.
- Use of facial medium depth chemical peels (excluding home regimens) within 3 months prior to baseline.
- Any live vaccines (this includes nasal-spray flu vaccine) starting from 6 weeks before baseline.
- Any other forms of acne
- Any severe, progressive or uncontrolled medical or psychiatric condition or other factors at randomization that in the judgment of the investigator prevents the patient from participating in the study.
- History of hypersensitivity or allergy to the investigational compound/compound class being used in this study.
- Active systemic infections (other than common cold) during the 2 weeks prior to baseline.
- History of severe systemic Candida infections or evidence of Candidiasis in the 2 weeks prior to baseline.
- Evidence of active tuberculosis at screening. All patients will be tested for tuberculosis status using a blood test (QuantiFERON®-TB (Tuberculosis) Gold In-Tube). Patients with evidence of tuberculosis may enter the trial after adequate treatment has been started according to local regulations.
- Patients with known active Crohn's disease
- History of immunodeficiency diseases, including a positive HIV (ELISA and Western blot) test result at screening.
- A positive Hepatitis B surface antigen or Hepatitis C test result at screening
- Pregnant or nursing (lactating) women, where pregnancy is defined

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as the state of a female after conception and until the termination of gestation, confirmed by a positive Human chorionic gonadotropin (HCG) laboratory test.  
 - WOCBP, defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception during dosing and for 13 weeks after stopping medication.

Other protocol-defined inclusion/exclusion criteria may apply.

**Participant Flow Table**

<b>Period 1</b>						
<b>Arm/Group Description</b>	<b>P1: CJM112 high dose / P2: CJM112 high dose</b>	<b>P1: CJM112 low dose / P2: CJM112 low dose</b>	<b>P1: Placebo / P2: CJM112 High Dose</b>	<b>P1: Placebo / P2: CJM112 Low Dose</b>	<b>P1: Placebo / P2: NA</b>	<b>Total</b>
	CJM112 high dose (300mg) in treatment period 1 (Day 1 - 85) ; CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	CJM112 low dose (75mg) in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85); CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85); Patients did not enter extension period 2	
<b>Started</b>	21	13	6	8	4	52
<b>Completed</b>	17	10	6	8	0	41
<b>Not Completed</b>	4	3	0	0	4	11
Study Terminated By Sponsor	2	1	0	0	1	4
Withdrawal by Subject	1	2	0	0	2	5

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Pregnancy	1	0	0	0	0	1
Adverse Event	0	0	0	0	1	1

**Period 2**

	<b>P1: CJM112 high dose / P2: CJM112 high dose</b>	<b>P1: CJM112 low dose / P2: CJM112 low dose</b>	<b>P1: Placebo / P2: CJM112 High Dose</b>	<b>P1: Placebo / P2: CJM112 Low Dose</b>	<b>P1: Placebo / P2: NA</b>	<b>Total</b>
<b>Arm/Group Description</b>	CJM112 high dose (300mg) in treatment period 1 (Day 1 - 85) ; CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	CJM112 low dose (75mg) in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85); CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85); Patients did not enter extension period 2	
<b>Started</b>	17	10	6	8	0	41
<b>Completed</b>	14	3	5	4	0	26
<b>Not Completed</b>	3	7	1	4	0	15
Adverse Event	0	1	0	0	0	1
Study Terminated By Sponsor	3	5	1	3	0	12
Withdrawal by Subject	0	1	0	0	0	1
Lost to Follow-up	0	0	0	1	0	1

**Baseline Characteristics**

	<b>P1: CJM112 high dose / P2: CJM112 high dose</b>	<b>P1: CJM112 low dose / P2: CJM112 low dose</b>	<b>P1: Placebo / P2: CJM112 High Dose</b>	<b>P1: Placebo / P2: CJM112 Low Dose</b>	<b>P1: Placebo / P2: NA</b>	<b>Total</b>
<b>Arm/Group Description</b>	CJM112 high dose (300mg) in treatment period 1 (Day 1 - 85) ; CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	CJM112 low dose (75mg) in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85); CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85); Patients did not enter extension period 2	
<b>Number of Participants [units: participants]</b>	21	13	6	8	4	52
<b>Age Continuous</b> (units: years) Mean ± Standard Deviation	23.8±4.19	25.5±5.99	22.5±3.21	25±4.66	23.75±4.35	24.3±4.62
<b>Sex: Female, Male</b> (units: Participants) Count of Participants (Not Applicable)						
Female	13	8	3	6	4	34
Male	8	5	3	2	0	18
<b>Race/Ethnicity, Customized</b> (units: Participants) Count of Participants (Not Applicable)						
White	18	10	5	8	4	45
Other	3	3	1	0	0	7

## Summary of Efficacy

### Primary Outcome Result(s)

#### **Total inflammatory facial lesion count at day 85**

(Time Frame: Day 85)

	<b>P1: CJM112 high dose / P2: CJM112 high dose</b>	<b>P1: CJM112 low dose / P2: CJM112 low dose</b>	<b>P1: Placebo / P2 CJM112 low dose or high dose</b>
<b>Arm/Group Description</b>	CJM112 high dose (300mg) in treatment period 1 (Day 1 - 85) ; CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	CJM112 low dose (75mg) in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85) ; CJM112 low dose or CJM112 high dose in extension period 2 (Day 86 - 169)
<b>Number of Participants Analyzed [units: participants]</b>	17	10	15
<b>Total inflammatory facial lesion count at day 85</b> (units: Lesions) Geometric Mean (90% Confidence Interval)	21.9 (16.58 to 29.14)	20.3 (13.76 to 29.66)	18.5 (13.51 to 25.13)

### **Statistical Analysis**



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<b>Groups</b>	P1: CJM112 high dose / P2: CJM112 high dose, P1: Placebo / P2 CJM112 low dose or high dose	
Non-Inferiority/Equivalence Test	Superiority	Comparison at end of Period 1 (P1): CJM112 versus Placebo.
Method	Other Bayesian model for repeated measurements	
Other Ratio of geometric means	1.18	Ratio of Geometric Means (CJM112 / Placebo) calculated. A value > 1 indicates a higher number of lesion counts in the CJM112 group. Bayesian analysis. The "credible interval" was calculated and presented under "confidence interval".
90 % Confidence Interval 2-Sided	0.79 to 1.81	

**Statistical Analysis**

<b>Groups</b>	P1: CJM112 low dose / P2: CJM112 low dose, P1: Placebo / P2 CJM112 low dose or high dose	
Non-Inferiority/Equivalence Test	Superiority	Comparison at end of Period 1 (P1): CJM112 versus Placebo.
Method	Other Bayesian model for repeated measurements	
Other Ratio of geometric means	1.10	Ratio of Geometric Means (CJM112 / Placebo) calculated. A value > 1

indicates a higher number of lesion counts in the CJM112 group. Bayesian analysis. The "credible interval" was calculated and presented under "confidence interval".

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90  
 % Confidence Interval      0.66 to 1.80  
 2-Sided

### **Secondary Outcome Result(s)**

#### **Number and severity of adverse events in Period 1**

(Time Frame: Day 1 to Day 85)

	<b>P1: CJM112 high dose / P2: CJM112 high dose</b>	<b>P1: CJM112 low dose / P2: CJM112 low dose</b>	<b>P1: Placebo / P2 CJM112 low dose or high dose</b>
<b>Arm/Group Description</b>	CJM112 high dose (300mg) in treatment period 1 (Day 1 - 85) ; CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	CJM112 low dose (75mg) in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85) ; CJM112 low dose or CJM112 high dose in extension period 2 (Day 86 - 169)
<b>Number of Participants Analyzed [units: participants]</b>	21	13	18

#### **Number and severity of adverse events in Period 1**

(units: Adverse Events)

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Number of AEs of mild intensity	27	25	20
Number of AEs of moderate intensity	5	7	9
Number of AEs of severe intensity	0	1	0

**Number and severity of adverse events in Period 2**

(Time Frame: Day 86 to Day 260)

<b>Arm/Group Description</b>	<b>P1: CJM112 high dose / P2: CJM112 high dose</b>	<b>P1: CJM112 low dose / P2: CJM112 low dose</b>	<b>P1: Placebo / P2: CJM112 high dose</b>	<b>P1: Placebo / P2: CJM112 low dose</b>
	CJM112 high dose (300mg) in treatment period 1 (Day 1 - 85) ; CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	CJM112 low dose (75mg) in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1; CJM112 high dose in extension period 2	Placebo in treatment period 1; CJM112 low dose in extension period 2
<b>Number of Participants Analyzed [units: participants]</b>	17	10	6	8
<b>Number and severity of adverse events in Period 2</b> (units: Adverse Events)				
Number of AEs of mild intensity	21	20	6	13
Number of AEs of moderate intensity	6	1	3	1
Number of AEs of severe intensity	1	1	0	0

**Pharmacokinetics (PK): Serum trough concentrations of CJM112 in Period 1**

(Time Frame: Day 1, Day 29, Day 57 and Day 85)

	<b>P1: CJM112 high dose / P2: CJM112 high dose</b>	<b>P1: CJM112 low dose / P2: CJM112 low dose</b>
<b>Arm/Group Description</b>	CJM112 high dose (300mg) in treatment period 1 (Day 1 - 85) ; CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	CJM112 low dose (75mg) in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)
<b>Number of Participants Analyzed [units: participants]</b>	21	12
<b>Pharmacokinetics (PK): Serum trough concentrations of CJM112 in Period 1</b> (units: ng/mL) Mean ± Standard Deviation		
Period 1 Day 1 (Pre Dose)	152 ± 663	0 ± 0
Period 1 Day 29 (Pre Dose)	8670 ± 3370	802 ± 961
Period 1 Day 57 (Pre Dose)	11500 ± 5020	1550 ± 1130
Period 1 Day 85 (Pre Dose)	17000 ± 8080	2040 ± 1570

**Pharmacokinetics (PK): Serum trough concentrations of CJM112 in Period 2**

(Time Frame: Day 85, Day 113, Day 141 and Day 169)

	<b>P1: CJM112 high dose / P2: CJM112 high dose</b>	<b>P1: CJM112 low dose / P2: CJM112 low dose</b>	<b>P1: Placebo / P2: CJM112 high dose</b>	<b>P1: Placebo / P2: CJM112 low dose</b>
<b>Arm/Group Description</b>	CJM112 high dose (300mg) in treatment period 1 (Day 1 - 85) ; CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	CJM112 low dose (75mg) in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1; CJM112 high dose in extension period 2	Placebo in treatment period 1; CJM112 low dose in extension period 2
<b>Number of Participants Analyzed [units: participants]</b>	21	12	6	8
<b>Pharmacokinetics (PK): Serum trough concentrations of CJM112 in Period 2</b> (units: ng/mL) Mean ± Standard Deviation				
Period 2 Day 85 (Pre Dose)	17000 ± 8080	2040 ± 1570	713 ± 1750	0 ± 0
Period 2 Day 113 (Pre Dose)	15900 ± 8140	1890 ± 634	8260 ± 5120	1430 ± 1190
Period 2 Day 141 (Pre Dose)	18700 ± 9450	3140 ± 2180	15700 ± 10700	3700 ± 1250
Period 2 Day 169 (Pre Dose)	19400 ± 9650	3890 ± 1890	16600 ± 6610	2890 ± 672

**Number of patients with clinically significant abnormal hematology laboratory parameters**  
(Time Frame: 38 Weeks)

<b>P1: CJM112 high dose / P2: CJM112 high dose</b>	<b>P1: CJM112 low dose / P2: CJM112 low dose</b>	<b>P1: Placebo / P2: CJM112 High Dose</b>	<b>P1: Placebo / P2: CJM112 Low Dose</b>	<b>P1: Placebo / P2: NA</b>
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<b>Arm/Group Description</b>	CJM112 high dose (300mg) in treatment period 1 (Day 1 - 85) ; CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	CJM112 low dose (75mg) in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85); CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85); Patients did not enter extension period 2
<b>Number of Participants Analyzed [units: participants]</b>	21	13	6	8	4
<b>Number of patients with clinically significant abnormal hematology laboratory parameters</b> (units: Participants) Count of Participants (Not Applicable)					
Period 1	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Period 2	0 (%)	0 (%)	0 (%)	0 (%)	(NaN%)

**Number of patients with clinically significant abnormal clinical chemistry laboratory parameters parameters**

(Time Frame: 38 Weeks)

<b>Arm/Group Description</b>	<b>P1: CJM112 high dose / P2: CJM112 high dose</b>	<b>P1: CJM112 low dose / P2: CJM112 low dose</b>	<b>P1: Placebo / P2: CJM112 High Dose</b>	<b>P1: Placebo / P2: CJM112 Low Dose</b>	<b>P1: Placebo / P2: NA</b>
CJM112 high dose (300mg) in treatment period 1 (Day 1 - 85) ; CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	CJM112 high dose (300mg) in treatment period 1 (Day 1 - 85) ; CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	CJM112 low dose (75mg) in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85); CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85); Patients did not enter extension period 2

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<b>Number of Participants Analyzed [units: participants]</b>	21	13	6	8	4
<b>Number of patients with clinically significant abnormal clinical chemistry laboratory parameters</b>					
(units: Participants)					
Count of Participants (Not Applicable)					
Period 1	3 (14.29%)	0 (%)	0 (%)	0 (%)	0 (%)
Period 2	0 (%)	3 (30%)	1 (16.67%)	1 (12.5%)	(NaN%)

**Number of patients with clinically significant abnormal urinalysis laboratory parameters**  
(Time Frame: 38 Weeks)

	<b>P1: CJM112 high dose / P2: CJM112 high dose</b>	<b>P1: CJM112 low dose / P2: CJM112 low dose</b>	<b>P1: Placebo / P2: CJM112 High Dose</b>	<b>P1: Placebo / P2: CJM112 Low Dose</b>	<b>P1: Placebo / P2: NA</b>
<b>Arm/Group Description</b>	CJM112 high dose (300mg) in treatment period 1 (Day 1 - 85) ; CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	CJM112 low dose (75mg) in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85); CJM112 high dose (300mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85) ; CJM112 low dose (75mg) in extension period 2 (Day 86 - 169)	Placebo in treatment period 1 (Day 1 - 85); Patients did not enter extension period 2
<b>Number of Participants Analyzed [units: participants]</b>	21	13	6	8	4
<b>Number of patients with clinically significant abnormal urinalysis laboratory parameters</b>					
(units: Participants)					
Count of Participants (Not Applicable)					
Period 1	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Period 2                      0                      0                      0                      0                      (NaN%)  
 (%)                      (%)                      (%)                      (%)

## Summary of Safety

### Safety Results

#### All-Cause Mortality

	Period 1: CJM112 high dose N = 21	Period 1: CJM112 low dose N = 13	Period 1: Placebo N = 18	Period 1: Pooled CJM112 N = 34	Period 2: CJM112 high dose/CJM112 high dose N = 17	Period 2: CJM112 low dose/CJM112 low dose N = 10	Period 2: Placebo/ CJM112 high dose N = 6	Period 2: Placebo/ CJM112 low dose N = 8	Period 2: Pooled CJM112 high dose N = 23	Period 2: Pooled CJM112 low dose N = 18
Arm/Group Description	Period 1: CJM112 high dose (300mg)	Period 1: CJM112 low dose (75mg)	Period 1: Placebo	Period 1: Pooled CJM112	CJM112 high dose (300mg) in treatment period 1; CJM112 high dose (300mg) in extension period 2	CJM112 low dose (75mg) in treatment period 1 ; CJM112 low dose (75mg) in extension period 2	Placebo in treatment period 1; CJM112 high dose (300mg) in extension period 2	Placebo in treatment period 1; CJM112 low dose (75mg) in extension period 2	Period 2: Pooled CJM112 high dose (300mg)	Period 2: Pooled CJM112 low dose (75mg)
<b>Total participants affected</b>	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

#### Serious Adverse Events by System Organ Class

**Time Frame**                      38 weeks



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**Source Vocabulary for Table Default** MedDRA (21.0)

**Assessment Type for Table Default** Systematic Assessment

	<b>Period 1: CJM112 high dose N = 21</b>	<b>Period 1: CJM112 low dose N = 13</b>	<b>Period 1: Placebo N = 18</b>	<b>Period 1: Pooled CJM112 N = 34</b>	<b>Period 2: CJM112 high dose/CJM112 high dose N = 17</b>	<b>Period 2: CJM112 low dose/CJM112 low dose N = 10</b>	<b>Period 2: Placebo/ CJM112 high dose N = 6</b>	<b>Period 2: Placebo/ CJM112 low dose N = 8</b>	<b>Period 2: Pooled CJM112 high dose N = 23</b>	<b>Period 2: Pooled CJM112 low dose N = 18</b>
<b>Arm/Group Description</b>	Period 1: CJM112 high dose (300mg)	Period 1: CJM112 low dose (75mg)	Period 1: Placebo	Period 1: Pooled CJM112	CJM112 high dose (300mg) in treatment period 1; CJM112 high dose (300mg) in extension period 2	CJM112 low dose (75mg) in treatment period 1 ; CJM112 low dose (75mg) in extension period 2	Placebo in treatment period 1; CJM112 high dose (300mg) in extension period 2	Placebo in treatment period 1; CJM112 low dose (75mg) in extension period 2	Period 2: Pooled CJM112 high dose (300mg)	Period 2: Pooled CJM112 low dose (75mg)
<b>Total participants affected</b>	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
<b>Hepatobiliary disorders</b>										
Cholelithiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)

**Other Adverse Events by System Organ Class**

**Time Frame** 38 weeks

**Source Vocabulary for Table Default** MedDRA (21.0)

**Assessment Type for Table Default** Systematic Assessment

**Frequent Event Reporting Threshold** 3%

<b>Arm/Group Description</b>	<b>Period 1: CJM112 high dose N = 21</b>	<b>Period 1: CJM112 low dose N = 13</b>	<b>Period 1: Placebo N = 18</b>	<b>Period 1: Pooled CJM112 N = 34</b>	<b>Period 2: CJM112 high dose/CJM112 2 high dose N = 17</b>	<b>Period 2: CJM112 low dose/CJM112 2 low dose N = 10</b>	<b>Period 2: Placebo/ CJM112 high dose N = 6</b>	<b>Period 2: Placebo/ CJM112 low dose N = 8</b>	<b>Period 2: Pooled CJM112 high dose N = 23</b>	<b>Period 2: Pooled CJM112 low dose N = 18</b>
	Period 1: CJM112 high dose (300mg)	Period 1: CJM112 low dose (75mg)	Period 1: Placebo	Period 1: Pooled CJM112	CJM112 high dose (300mg) in treatment period 1; CJM112 high dose (300mg) in extension period 2	CJM112 low dose (75mg) in treatment period 1 ; CJM112 low dose (75mg) in extension period 2	Placebo in treatment period 1; CJM112 high dose (300mg) in extension period 2	Placebo in treatment period 1; CJM112 low dose (75mg) in extension period 2	Period 2: Pooled CJM112 high dose (300mg)	Period 2: Pooled CJM112 low dose (75mg)
<b>Total participants affected</b>	16 (76.19 %)	11 (84.62 %)	10 (55.56 %)	27 (79.41 %)	10 (58.82%)	9 (90.00%)	5 (83.33 %)	5 (62.50 %)	15 (65.22 %)	14 (77.78 %)
<b>Blood and lymphatic system disorders</b>										
Increased tendency to bruise	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Cardiac disorders</b>										
Sinus arrest	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
Supraventricular extrasystoles	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
<b>Eye disorders</b>										

**Clinical Trial Results Website**

Blepharospasm	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 (4.35%)	0 (0.00%)
Dry eye	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 (5.56%)
Eye irritation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
Eye pruritus	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 (5.56%)
<b>Gastrointestinal disorders</b>										
Diarrhoea	1 (4.76%)	0 (0.00%)	2 (11.11%)	1 (2.94%)	1 (5.88%)	1 (10.00%)	1 (16.67%)	0 (0.00%)	2 (8.70%)	1 (5.56%)
Flatulence	0 (0.00%)	0 (0.00%)	1 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Frequent bowel movements	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Inguinal hernia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
Lip dry	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%)	1 (5.56%)
Nausea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
Toothache	1 (4.76%)	1 (7.69%)	0 (0.00%)	2 (5.88%)	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>										
Asthenia	0 (0.00%)	0 (0.00%)	1 (5.56%)	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%)	1 (7.69%)	1 (5.56%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza like illness	1 (4.76%)	0 (0.00%)	1 (5.56%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injection site bruising	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injection site reaction	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Non-cardiac chest pain	0 (0.00%)	0 (0.00%)	1 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sensation of foreign body	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
<b>Immune system disorders</b>										
Hypersensitivity	0 (0.00%)	0 (0.00%)	1 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seasonal allergy	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%)	1 (5.56%)
<b>Infections and infestations</b>										
Bacterial vaginosis	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchitis	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (2.94%)	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 (12.50%)	0 (0.00%)	1 (5.56%)
Cystitis	1 (4.76%)	1 (7.69%)	0 (0.00%)	2 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fungal skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
Gastroenteritis	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (2.94%)	1 (5.88%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	2 (8.70%)	0 (0.00%)
Gastroenteritis viral	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Helicobacter gastritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
Laryngitis	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasopharyngitis	3 (14.29%)	1 (7.69%)	1 (5.56%)	4 (11.76%)	2 (11.76%)	1 (10.00%)	0 (0.00%)	2 (25.00%)	2 (8.70%)	3 (16.67%)
Oral herpes	0 (0.00%)	0 (0.00%)	1 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pharyngitis	1 (4.76%)	1 (7.69%)	0 (0.00%)	2 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Sinusitis	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 (5.56%)
Tonsillitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
Tooth 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%)	1 (4.35%)	0 (0.00%)
Upper respiratory tract infection	1 (4.76%)	2 (15.38%)	0 (0.00%)	3 (8.82%)	1 (5.88%)	2 (20.00%)	1 (16.67%)	0 (0.00%)	2 (8.70%)	2 (11.11%)
Urinary tract infection	1 (4.76%)	1 (7.69%)	1 (5.56%)	2 (5.88%)	2 (11.76%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	2 (8.70%)	1 (5.56%)
Vulvovaginal mycotic infection	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.56%)
<b>Injury, poisoning and procedural complications</b>										
Concussion	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint dislocation	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 (4.35%)	0 (0.00%)
Ligament sprain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
Limb injury	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Road traffic accident	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sports injury	0 (0.00%)	0 (0.00%)	1 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Investigations</b>										
Alanine aminotransferase increased	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**

Aspartate aminotransferase 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 (5.56%)
Blood creatine phosphokinase increased	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	2 (20.00%)	1 (16.67%)	1 (12.50%)	1 (4.35%)	3 (16.67%)
Blood creatinine increased	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%)	1 (5.56%)
Blood triglycerides increased	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Glucose urine present	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
<b>Metabolism and nutrition disorders</b>										
Hypoglycaemia	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 (4.35%)	0 (0.00%)
Vitamin D deficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
<b>Musculoskeletal and connective tissue disorders</b>										
Arthritis	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.56%)
Back pain	0 (0.00%)	1 (7.69%)	1 (5.56%)	1 (2.94%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
Joint effusion	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%)	1 (5.56%)
Myalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	2 (11.11%)
Neck pain	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in extremity	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**
**Nervous system disorders**

Headache	1 (4.76%)	3 (23.08%)	1 (5.56%)	4 (11.76%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
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**Psychiatric disorders**

Depression	0 (0.00%)	0 (0.00%)	1 (5.56%)	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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**Renal and urinary disorders**

Micturition urgency	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.56%)
Pollakiuria	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.56%)
Proteinuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	3 (16.67%)

**Reproductive system and breast disorders**

Dysmenorrhoea	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
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**Respiratory, thoracic and mediastinal disorders**

Cough	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	0 (0.00%)	0 (0.00%)	1 (5.56%)	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%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
Oropharyngeal pain	1 (4.76%)	1 (7.69%)	0 (0.00%)	2 (5.88%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	2 (11.11%)
Rhinorrhoea	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Clinical Trial Results Website**
**Skin and  
subcutaneous  
tissue disorders**

Acne	0 (0.00%)	2 (15.38%)	0 (0.00%)	2 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dermal cyst	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dermatitis	0 (0.00%)	0 (0.00%)	1 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diffuse alopecia	0 (0.00%)	0 (0.00%)	1 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dry skin	2 (9.52%)	0 (0.00%)	2 (11.11%)	2 (5.88%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.56%)
Erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
Papule	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 (5.56%)
Pityriasis rosea	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pruritus	1 (4.76%)	0 (0.00%)	3 (16.67%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (4.35%)	0 (0.00%)
Psoriasis	0 (0.00%)	0 (0.00%)	1 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash maculo-papular	0 (0.00%)	0 (0.00%)	1 (5.56%)	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%)	1 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

**Other Relevant Findings**

NA

**Conclusion:**

The study was terminated early by the Sponsor, as the results met the pre-planned futility criterion at the pre-planned interim analyses (IA1).





**Clinical Trial Results Website**

Administration of monthly dose of CJM112 (high and low dose) over 12 weeks in Period 1 followed by Extension Period 2 was safe and well tolerated.

**Date of Clinical Trial Report**

28-Mar-2019