



Clinical trial results:

A randomized (1:1), double-blind, parallel, placebo-controlled exploratory pilot study to evaluate the safety, pharmacokinetics and efficacy of systemic (po) application of MP1032 in patients with moderate to severe chronic plaque psoriasis

Summary

EudraCT number	2015-005159-28
Trial protocol	DE
Global end of trial date	29 December 2016

Results information

Result version number	v1 (current)
This version publication date	02 November 2017
First version publication date	02 November 2017
Summary attachment (see zip file)	MP1032-CT02 Study Synopsis (Synopsis CT02.pdf)

Trial information

Trial identification

Sponsor protocol code	MP1032-CT02
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02908347
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MetrioPharm AG
Sponsor organisation address	Bleicherweg 45, Zurich, Switzerland, 8002
Public contact	Corporate Communications, MetrioPharm Deutschland GmbH, +49 3033 84 395 40, invest@metriopharm.com
Scientific contact	Clinical Disclosure Office, MetrioPharm Deutschland GmbH, +49 3033 84 395 36,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	02 June 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 December 2016
Global end of trial reached?	Yes
Global end of trial date	29 December 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and pharmacokinetics (PK) of orally administered 100 mg MP1032 twice a day (bid) when taken for 42 days by patients with moderate to severe chronic plaque psoriasis

Protection of trial subjects:

Safety assessments used in this study included standard measurements that are used routinely in clinical studies of investigational drugs, such as assessment of AEs, physical examinations, vital signs, ECGs, and clinical laboratory evaluations.

To ease pain and itching and to prevent phototoxic reactions non-medicated emollients, moisturizers and sunscreens were allowed. Use of low potency topical steroids for critical areas such as the face, genitalia, and scalp were allowed until 24 hours prior to randomization.

Background therapy:

Apart from the following exceptions there was no background therapy:

- Non-medicated emollients, moisturizers and sunscreens were allowed.
- Use of low potency topical steroids for critical areas such as the face, genitalia, and scalp were allowed until 24 hours prior to randomization.

In some cases prior and/or concomitant medication which was not excluded by inclusion/exclusion criteria was given to treat conditions other than psoriasis.

Evidence for comparator:

In this Phase 2a trial MP1032 has been compared with placebo only.

Actual start date of recruitment	17 May 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 46
Worldwide total number of subjects	46
EEA total number of subjects	46

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	45
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

in total 46 patients were enrolled after screening and randomized.

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
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Arm title	MP1032
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Arm description:

Treatment group - 100 mg MP1032 b.i.d.

Arm type	Experimental
Investigational medicinal product name	MP1032 Hard Gelatine Capsules 50 mg
Investigational medicinal product code	MP1032
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

2 capsules of "MP1032 Hard Gelatine Capsules 50 mg", i.e. 100 mg MP1032, were administered twice daily over 42 consecutive days

Arm title	Placebo
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Arm description:

Placebo group - Placebo b.i.d.

Arm type	Placebo
Investigational medicinal product name	Placebo to MP1032 Hard Gelatine Capsules 50 mg
Investigational medicinal product code	Placebo
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

2 capsules of "MP1032 Hard Gelatine Capsules 50 mg (Placebo)" twice daily over 42 consecutive days

Number of subjects in period 1	MP1032	Placebo
Started	23	23
End of Treatment	22	22
Completed	22	22
Not completed	1	1

Adverse event, non-fatal	-	1
Lost to follow-up	1	-

Baseline characteristics

Reporting groups

Reporting group title	overall trial
Reporting group description: -	

Reporting group values	overall trial	Total	
Number of subjects	46	46	
Age categorical			
Units: Subjects			
Adults (18-64 years)	45	45	
From 65-84 years	1	1	
Gender categorical			
Units: Subjects			
Female	11	11	
Male	35	35	

Subject analysis sets

Subject analysis set title	MP1032completed / PK analysis set
Subject analysis set type	Per protocol

Subject analysis set description:

This subset includes all patients from the MP1032 group who provided plasma for PK purposes and completed the study.

Subject analysis set title	AUC_2h subgroup 1
Subject analysis set type	Per protocol

Subject analysis set description:

Patients were grouped into the following AUC subgroups according to AUC2h values estimated using the linear-logarithmic trapezoidal method on Day 1:

- Group 1: 6 patients with lowest AUCs;
- Group 2: 5 patients with the next highest AUCs;
- Group 3: 6 patients with the next highest AUCs;
- Group 4: 5 patients with the highest AUCs.

Subject analysis set title	AUC_2h subgroup 2
Subject analysis set type	Per protocol

Subject analysis set description:

Patients were grouped into the following AUC subgroups according to AUC2h values estimated using the linear-logarithmic trapezoidal method on Day 1:

- Group 1: 6 patients with lowest AUCs;
- Group 2: 5 patients with the next highest AUCs;
- Group 3: 6 patients with the next highest AUCs;
- Group 4: 5 patients with the highest AUCs.

Subject analysis set title	AUC_2h subgroup 3
Subject analysis set type	Per protocol

Subject analysis set description:

Patients were grouped into the following AUC subgroups according to AUC2h values estimated using the linear-logarithmic trapezoidal method on Day 1:

- Group 1: 6 patients with lowest AUCs;
- Group 2: 5 patients with the next highest AUCs;
- Group 3: 6 patients with the next highest AUCs;
- Group 4: 5 patients with the highest AUCs.

Subject analysis set title	AUC_2h subgroup 4
Subject analysis set type	Per protocol

Subject analysis set description:

Patients were grouped into the following AUC subgroups according to AUC_{2h} values estimated using the linear-logarithmic trapezoidal method on Day 1:

Group 1: 6 patients with lowest AUCs;

Group 2: 5 patients with the next highest AUCs;

Group 3: 6 patients with the next highest AUCs;

Group 4: 5 patients with the highest AUCs.

Subject analysis set title	Placebo completed
Subject analysis set type	Per protocol

Subject analysis set description:

This subset includes all patients from the Placebo group who provided plasma for PK purposes and completed the study.

Subject analysis set title	AUC _t subgroup 1
Subject analysis set type	Per protocol

Subject analysis set description:

Patients were grouped into the following AUC subgroups according to AUC_t values estimated using the linear-logarithmic trapezoidal method on Day 1:

Group 1: 6 patients with lowest AUCs;

Group 2: 5 patients with the next highest AUCs;

Group 3: 6 patients with the next highest AUCs;

Group 4: 5 patients with the highest AUCs.

Subject analysis set title	AUC _t subgroup 2
Subject analysis set type	Per protocol

Subject analysis set description:

Patients were grouped into the following AUC subgroups according to AUC_t values estimated using the linear-logarithmic trapezoidal method on Day 1:

Group 1: 6 patients with lowest AUCs;

Group 2: 5 patients with the next highest AUCs;

Group 3: 6 patients with the next highest AUCs;

Group 4: 5 patients with the highest AUCs.

Subject analysis set title	AUC _t subgroup 3
Subject analysis set type	Per protocol

Subject analysis set description:

Patients were grouped into the following AUC subgroups according to AUC_t values estimated using the linear-logarithmic trapezoidal method on Day 1:

Group 1: 6 patients with lowest AUCs;

Group 2: 5 patients with the next highest AUCs;

Group 3: 6 patients with the next highest AUCs;

Group 4: 5 patients with the highest AUCs.

Subject analysis set title	AUC _t subgroup 4
Subject analysis set type	Per protocol

Subject analysis set description:

Patients were grouped into the following AUC subgroups according to AUC_t values estimated using the linear-logarithmic trapezoidal method on Day 1:

Group 1: 6 patients with lowest AUCs;

Group 2: 5 patients with the next highest AUCs;

Group 3: 6 patients with the next highest AUCs;

Group 4: 5 patients with the highest AUCs.

Reporting group values	MP1032completed / PK analysis set	AUC _{2h} subgroup 1	AUC _{2h} subgroup 2
Number of subjects	22	6	5
Age categorical Units: Subjects			
Adults (18-64 years)	21	6	5
From 65-84 years	1	0	0
Gender categorical Units: Subjects			
Female	5	0	0

Male	17	6	5
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Reporting group values	AUC_2h subgroup 3	AUC_2h subgroup 4	Placebo completed
Number of subjects	6	5	22
Age categorical Units: Subjects			
Adults (18-64 years)	6	4	22
From 65-84 years	0	1	0
Gender categorical Units: Subjects			
Female	3	2	6
Male	3	3	16

Reporting group values	AUC_t subgroup 1	AUC_t subgroup 2	AUC_t subgroup 3
Number of subjects	6	5	6
Age categorical Units: Subjects			
Adults (18-64 years)	6	5	6
From 65-84 years	0	0	0
Gender categorical Units: Subjects			
Female	0	0	3
Male	6	6	3

Reporting group values	AUC_t subgroup 4		
Number of subjects	5		
Age categorical Units: Subjects			
Adults (18-64 years)	4		
From 65-84 years	1		
Gender categorical Units: Subjects			
Female	2		
Male	3		

End points

End points reporting groups

Reporting group title	MP1032
Reporting group description:	
Treatment group - 100 mg MP1032 b.i.d.	
Reporting group title	Placebo
Reporting group description:	
Placebo group - Placebo b.i.d.	
Subject analysis set title	MP1032completed / PK analysis set
Subject analysis set type	Per protocol
Subject analysis set description:	
This subset includes all patients from the MP1032 group who provided plasma for PK purposes and completed the study.	
Subject analysis set title	AUC_2h subgroup 1
Subject analysis set type	Per protocol
Subject analysis set description:	
Patients were grouped into the following AUC subgroups according to AUC2h values estimated using the linear-logarithmic trapezoidal method on Day 1:	
Group 1: 6 patients with lowest AUCs;	
Group 2: 5 patients with the next highest AUCs;	
Group 3: 6 patients with the next highest AUCs;	
Group 4: 5 patients with the highest AUCs.	
Subject analysis set title	AUC_2h subgroup 2
Subject analysis set type	Per protocol
Subject analysis set description:	
Patients were grouped into the following AUC subgroups according to AUC2h values estimated using the linear-logarithmic trapezoidal method on Day 1:	
Group 1: 6 patients with lowest AUCs;	
Group 2: 5 patients with the next highest AUCs;	
Group 3: 6 patients with the next highest AUCs;	
Group 4: 5 patients with the highest AUCs.	
Subject analysis set title	AUC_2h subgroup 3
Subject analysis set type	Per protocol
Subject analysis set description:	
Patients were grouped into the following AUC subgroups according to AUC2h values estimated using the linear-logarithmic trapezoidal method on Day 1:	
Group 1: 6 patients with lowest AUCs;	
Group 2: 5 patients with the next highest AUCs;	
Group 3: 6 patients with the next highest AUCs;	
Group 4: 5 patients with the highest AUCs.	
Subject analysis set title	AUC_2h subgroup 4
Subject analysis set type	Per protocol
Subject analysis set description:	
Patients were grouped into the following AUC subgroups according to AUC2h values estimated using the linear-logarithmic trapezoidal method on Day 1:	
Group 1: 6 patients with lowest AUCs;	
Group 2: 5 patients with the next highest AUCs;	
Group 3: 6 patients with the next highest AUCs;	
Group 4: 5 patients with the highest AUCs.	
Subject analysis set title	Placebo completed
Subject analysis set type	Per protocol
Subject analysis set description:	
This subset includes all patients from the Placebo group who provided plasma for PK purposes and completed the study.	
Subject analysis set title	AUC_t subgroup 1
Subject analysis set type	Per protocol

Subject analysis set description:

Patients were grouped into the following AUC subgroups according to AUCt values estimated using the linear-logarithmic trapezoidal method on Day 1:

Group 1: 6 patients with lowest AUCs;

Group 2: 5 patients with the next highest AUCs;

Group 3: 6 patients with the next highest AUCs;

Group 4: 5 patients with the highest AUCs.

Subject analysis set title	AUC_t subgroup 2
Subject analysis set type	Per protocol

Subject analysis set description:

Patients were grouped into the following AUC subgroups according to AUCt values estimated using the linear-logarithmic trapezoidal method on Day 1:

Group 1: 6 patients with lowest AUCs;

Group 2: 5 patients with the next highest AUCs;

Group 3: 6 patients with the next highest AUCs;

Group 4: 5 patients with the highest AUCs.

Subject analysis set title	AUC_t subgroup 3
Subject analysis set type	Per protocol

Subject analysis set description:

Patients were grouped into the following AUC subgroups according to AUCt values estimated using the linear-logarithmic trapezoidal method on Day 1:

Group 1: 6 patients with lowest AUCs;

Group 2: 5 patients with the next highest AUCs;

Group 3: 6 patients with the next highest AUCs;

Group 4: 5 patients with the highest AUCs.

Subject analysis set title	AUC_t subgroup 4
Subject analysis set type	Per protocol

Subject analysis set description:

Patients were grouped into the following AUC subgroups according to AUCt values estimated using the linear-logarithmic trapezoidal method on Day 1:

Group 1: 6 patients with lowest AUCs;

Group 2: 5 patients with the next highest AUCs;

Group 3: 6 patients with the next highest AUCs;

Group 4: 5 patients with the highest AUCs.

Primary: MP1032 safety evaluation - TEAEs

End point title	MP1032 safety evaluation - TEAEs ^[1]
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End point description:

Number of Treatment Emergent Adverse Events (TEAEs) reported

End point type	Primary
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End point timeframe:

overall study participation

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive statistics have been performed for this endpoint.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: TEAEs				
All TEAEs	27	32		
Serious TEAEs	0	0		
Severe TEAEs	0	1		
Related TEAEs	6	9		
TEAEs leading to Withdrawal	0	1		
TEAEs leading to Death	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: MP1032 safety evaluation - Patients with TEAEs

End point title MP1032 safety evaluation - Patients with TEAEs^[2]

End point description:

End point type Primary

End point timeframe:

overall study participation

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive statistics have been performed for this endpoint.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: Patients				
All TEAEs	14	15		
Serious TEAEs	0	0		
Severe TEAEs	0	1		
Related TEAEs	5	5		
TEAEs leading to Withdrawal	0	1		
TEAEs leading to Death	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Occurrence of related TEAEs by SOC

End point title Occurrence of related TEAEs by SOC^[3]

End point description:

End point type Primary

End point timeframe:

overall study

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive statistics have been performed for this endpoint.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: TEAEs				
All related TEAEs	6	9		
Gastrointestinal Disorders	0	3		
General Disorders - Administration Site Conditions	2	0		
Infections and Infestations	2	3		
Nervous System Disorders	0	1		
Skin and Subcutaneous Tissue Disorders	2	2		

Statistical analyses

No statistical analyses for this end point

Primary: Patients with related TEAEs by SOC

End point title	Patients with related TEAEs by SOC ^[4]
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End point description:

End point type	Primary
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End point timeframe:

overall study

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive statistics have been performed for this endpoint.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: Patients				
Patients with at least one related TEAE	5	5		
Gastrointestinal Disorders	0	2		
General Disorders - Administration Site Conditions	2	0		
Infections and Infestations	2	3		
Nervous System Disorders	0	1		
Skin and Subcutaneous Tissue Disorders	1	2		

Statistical analyses

No statistical analyses for this end point

Primary: MP1032 Plasma Concentrations at Nominal Time Points

End point title	MP1032 Plasma Concentrations at Nominal Time Points ^[5]
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End point description:

For study Day 1 - 2 hours 6 of 22 patients had BLQ values. For descriptive statistics values of these patients have been set to zero.

For Study Day 43 AM and SD have not been calculated as majority (18 of 22) of measurements was not quantifiable (BLQ). Thus - due to technical reasons - values were set to zero for the purpose of this data table.

End point type	Primary
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End point timeframe:

Study Day 1: 15 min, 30 min, 1 and 2 hours after IMP administration,
Study Day 15, 29 and 43 (i.e. 1 Day after last treatment) any time after previous IMP administration

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive statistics have been performed for this endpoint.

End point values	MP1032 completed / PK analysis set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: ng/mL				
arithmetic mean (standard deviation)				
Day 1 - 15 min	190.3 (± 153.537)			
Day 1 - 30 min	162.861 (± 64.674)			
Day 1 - 1 hour	56.875 (± 30.8)			
Day 1 - 2 hours	8.677 (± 6.629)			
Day 15	211.545 (± 151.406)			
Day 29	199.652 (± 149.857)			
Day 43 (EOT)	0 (± 0)			

Statistical analyses

No statistical analyses for this end point

Primary: Summary of Day 1 PK Parameters - C max

End point title	Summary of Day 1 PK Parameters - C max ^[6]
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End point description:

C max = maximum plasma concentration

End point type	Primary
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End point timeframe:

Study Day 1 - 15 min, 30 min, 1 hour and 2 hours after administration

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive statistics have been performed for this endpoint.

End point values	MP1032completed / PK analysis set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: ng/mL				
arithmetic mean (standard deviation)	235.585 (± 124.726)			

Statistical analyses

No statistical analyses for this end point

Primary: Summary of Day 1 PK Parameters - t max

End point title	Summary of Day 1 PK Parameters - t max ^[7]
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End point description:

t max = time of occurrence of C max

End point type	Primary
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End point timeframe:

Study Day 1 - 15 min, 30 min, 1 hour and 2 hours after administration

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive statistics have been performed for this endpoint.

End point values	MP1032completed / PK analysis set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: hours				
median (full range (min-max))	0.25 (0.25 to 1.02)			

Statistical analyses

No statistical analyses for this end point

Primary: Summary of Day 1 PK Parameters - AUC 2h (lin-log)

End point title	Summary of Day 1 PK Parameters - AUC 2h (lin-log) ^[8]
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End point description:

AUC 2h = area under the plasma concentration-time curve from time zero to 2 hours

End point type	Primary
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End point timeframe:

Study Day 1 - 15 min, 30 min, 1 hour and 2 hours after administration

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive statistics have been performed for this endpoint.

End point values	MP1032completed / PK analysis set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: h*ng/mL				
arithmetic mean (standard deviation)	142.212 (\pm 61.874)			

Statistical analyses

No statistical analyses for this end point

Primary: Summary of Day 1 PK Parameters - AUC 2h (lin-lin)

End point title	Summary of Day 1 PK Parameters - AUC 2h (lin-lin) ^[9]
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End point description:

AUC 2h = area under the plasma concentration-time curve from time zero to 2 hours

End point type	Primary
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End point timeframe:

Study Day 1 - 15 min, 30 min, 1 hour and 2 hours after administration

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive statistics have been performed for this endpoint.

End point values	MP1032completed / PK analysis set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: h*ng/mL				
arithmetic mean (standard deviation)	154.161 (\pm 67.048)			

Statistical analyses

No statistical analyses for this end point

Primary: Summary of Day 1 PK Parameters - AUC t (lin-log)

End point title	Summary of Day 1 PK Parameters - AUC t (lin-log) ^[10]
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End point description:

AUC t = area under the plasma concentration-time curve from time zero to the last quantifiable concentration

End point type	Primary
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End point timeframe:

Study Day 1 - 15 min, 30 min, 1 hour and 2 hours after administration

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive statistics have been performed for this endpoint.

End point values	MP1032completed / PK analysis set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: h*ng/mL				
arithmetic mean (standard deviation)	139.497 (\pm 63.598)			

Statistical analyses

No statistical analyses for this end point

Primary: Summary of Day 1 PK Parameters - AUC t (lin-lin)

End point title	Summary of Day 1 PK Parameters - AUC t (lin-lin) ^[11]
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End point description:

AUC t = area under the plasma concentration-time curve from time zero to the last quantifiable concentration

End point type	Primary
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End point timeframe:

Study Day 1 - 15 min, 30 min, 1 hour and 2 hours after administration

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive statistics have been performed for this endpoint.

End point values	MP1032completed / PK analysis set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: h*ng/mL				
arithmetic mean (standard deviation)	151.448 (\pm 68.868)			

Statistical analyses

No statistical analyses for this end point

Primary: Summary of Day 1 PK Parameters - t last

End point title	Summary of Day 1 PK Parameters - t last ^[12]
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End point description:

t last = time of last quantifiable concentration

End point type	Primary
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End point timeframe:

Study Day 1 - 15 min, 30 min, 1 hour and 2 hours after administration

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive statistics have been performed for this endpoint.

End point values	MP1032completed / PK analysis set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: hours				
median (full range (min-max))	1.99 (1 to 2.05)			

Statistical analyses

No statistical analyses for this end point

Primary: AUC (lin-log) by subgroups

End point title AUC (lin-log) by subgroups^[13]

End point description:

End point type Primary

End point timeframe:

Study Day 1 - 15 min, 30 min, 1 hour and 2 hours after administration

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive statistics have been performed for this endpoint.

End point values	AUC_2h subgroup 1	AUC_2h subgroup 2	AUC_2h subgroup 3	AUC_2h subgroup 4
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	5	6	5
Units: h*ng/mL				
median (full range (min-max))	84.699 (63.87 to 103.92)	114.1 (108.97 to 123.74)	137.246 (124.9 to 166.22)	218.482 (206.25 to 289.74)

End point values	AUC_t subgroup 1	AUC_t subgroup 2	AUC_t subgroup 3	AUC_t subgroup 4
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	5	6	5
Units: h*ng/mL				
median (full range (min-max))	75.934 (63.87 to 103.92)	114.1 (108.97 to 122.12)	134.561 (123.13 to 166.09)	218.482 (206.83 to 289.74)

Statistical analyses

No statistical analyses for this end point

Secondary: PASI Score - Observed Values - Day 1 (Baseline)

End point title	PASI Score - Observed Values - Day 1 (Baseline)
End point description: PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.	
End point type	Secondary
End point timeframe: PASI-Scoring took place on Site visits: baseline (Day 1), Day 29, Day 43 (End of Treatment), and at 2 Follow-Up visits.	

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: PASI Score				
arithmetic mean (standard deviation)	16.03 (\pm 7.203)	17.25 (\pm 7.458)		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI Score - Observed Values Day 43 (End of Treatment)

End point title	PASI Score - Observed Values Day 43 (End of Treatment)
End point description: PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.	
End point type	Secondary
End point timeframe: PASI-Scoring took place on Site visits: baseline (Day 1), Day 29, Day 43 (End of Treatment), and at 2 Follow-Up visits.	

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: PASI Score				
arithmetic mean (standard deviation)	14.03 (\pm 9.509)	14.69 (\pm 8.532)		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI Score - Observed Values - Day 57 (Follow-Up 1)

End point title	PASI Score - Observed Values - Day 57 (Follow-Up 1)
End point description:	
PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.	
End point type	Secondary
End point timeframe:	
PASI-Scoring took place on Site visits: baseline (Day 1), Day 29, Day 43 (End of Treatment), and at 2 Follow-Up visits.	

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	23		
Units: PASI Score				
arithmetic mean (standard deviation)	15.28 (\pm 10.681)	15.97 (\pm 8.837)		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI Score - Observed Values - Day 71 (Follow-Up 2)

End point title	PASI Score - Observed Values - Day 71 (Follow-Up 2)
End point description:	
PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.	
End point type	Secondary
End point timeframe:	
PASI-Scoring took place on Site visits: baseline (Day 1), Day 29, Day 43 (End of Treatment), and at 2 Follow-Up visits.	

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	23		
Units: PASI Score				
arithmetic mean (standard deviation)	15.21 (\pm 10.03)	16.09 (\pm 9.363)		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI Score - Change from Baseline / Treatment Difference (Day 43)

End point title	PASI Score - Change from Baseline / Treatment Difference (Day 43)
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End point description:

PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.

End point type	Secondary
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End point timeframe:

PASI-Scoring took place on Site visits: baseline (Day 1), Day 29, Day 43 (End of Treatment), and at 2 Follow-Up visits.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: PASI Score				
arithmetic mean (standard deviation)	-2 (\pm 3.994)	-2.56 (\pm 5.025)		

Statistical analyses

Statistical analysis title	Treatment Difference at Day 43
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Statistical analysis description:

LS means, difference and CI are estimated using an ANCOVA model with Baseline as covariate and treatment as a factor. p-value was calculated using the nonparametric Wilcoxon 2-sample test.

Comparison groups	Placebo v MP1032
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8785
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)
Point estimate	0.64

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.09
upper limit	3.36

Secondary: PASI30 at Day 29

End point title	PASI30 at Day 29
End point description: PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.	
End point type	Secondary
End point timeframe: Number of Patients who had an at least 30% reduction in PASI score on Day 29 compared to Baseline.	

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	23		
Units: Patients	6	6		

Statistical analyses

Statistical analysis title	PASI30 at Day 29 - Treatment Difference
Comparison groups	Placebo v MP1032
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Fisher exact

Secondary: PASI30 at Day 29 - Responder Frequency

End point title	PASI30 at Day 29 - Responder Frequency
End point description: PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.	
End point type	Secondary
End point timeframe: Number of Patients who had an at least 30% reduction in PASI score on Day 29 compared to Baseline.	

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	23		
Units: percent				
number (not applicable)	27.27	26.09		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI30 at Day 43

End point title	PASI30 at Day 43
End point description:	PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.
End point type	Secondary
End point timeframe:	Number of Patients who had an at least 30% reduction in PASI score on Day 43 compared to Baseline.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: Patients	8	5		

Statistical analyses

Statistical analysis title	PASI30 at Day 43 - Treatment Difference
Comparison groups	MP1032 v Placebo
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5136
Method	Fisher exact

Secondary: PASI30 at Day 43 - Responder Frequency

End point title	PASI30 at Day 43 - Responder Frequency
End point description:	PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.
End point type	Secondary

End point timeframe:

Frequency of Patients who had an at least 30% reduction in PASI score on Day 43 compared to Baseline.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: percent				
number (not applicable)	34.78	21.74		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI50 at Day 29

End point title	PASI50 at Day 29
End point description: PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.	
End point type	Secondary
End point timeframe: Number of Patients who had an at least 50% reduction in PASI score on Day 29 compared to Baseline.	

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	23		
Units: Patients	2	2		

Statistical analyses

Statistical analysis title	PASI50 at Day 29 - Treatment Difference
Comparison groups	MP1032 v Placebo
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Fisher exact

Secondary: PASI50 at Day 29 - Responder Frequency

End point title	PASI50 at Day 29 - Responder Frequency
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End point description:

PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.

End point type	Secondary
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End point timeframe:

Frequency of Patients who had an at least 50% reduction in PASI score on Day 29 compared to Baseline.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	23		
Units: percent				
number (not applicable)	9.09	8.7		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI50 at Day 43

End point title	PASI50 at Day 43
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End point description:

PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.

End point type	Secondary
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End point timeframe:

Number of Patients who had an at least 50% reduction in PASI score on Day 43 compared to Baseline.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: Patients	3	4		

Statistical analyses

Statistical analysis title	PASI50 at Day 43 - Treatment Difference
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Comparison groups	MP1032 v Placebo
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Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Fisher exact

Secondary: PASI50 at Day 43 - Responder Frequency

End point title	PASI50 at Day 43 - Responder Frequency
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End point description:

PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.

End point type	Secondary
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End point timeframe:

Frequency of Patients who had an at least 50% reduction in PASI score on Day 43 compared to Baseline.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: percent				
number (not applicable)	13.04	17.39		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI percentage change at Day 29

End point title	PASI percentage change at Day 29
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End point description:

PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.

End point type	Secondary
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End point timeframe:

The PASI percentage change in % at Day 29 is calculated as $\text{PASI of (Day 29 - Baseline)} / \text{Baseline} * 100$.

End point values	MP1032 completed / PK analysis set	AUC_2h subgroup 1	AUC_2h subgroup 2	AUC_2h subgroup 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	6	5	6
Units: percent				
arithmetic mean (standard deviation)	-18.24 (±)	-6.61 (±)	-14.74 (±)	-35.46 (±)

24.069)	25.575)	24.96)	22.891)
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End point values	AUC_2h subgroup 4	Placebo completed	AUC_t subgroup 1	AUC_t subgroup 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	22	6	5
Units: percent				
arithmetic mean (standard deviation)	-15.03 (\pm 16.422)	-14.57 (\pm 21.5)	-6.61 (\pm 25.575)	-27.07 (\pm 33.055)

End point values	AUC_t subgroup 3	AUC_t subgroup 4		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	5		
Units: percent				
arithmetic mean (standard deviation)	-25.18 (\pm 19.510)	-15.03 (\pm 16.422)		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI percentage change at Day 43

End point title	PASI percentage change at Day 43
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End point description:

PASI is a total score computed over 4 body regions with 4 assessments ranging from 0 (no symptoms) to 4 (very marked). The total score ranges from 0 to 72.

End point type	Secondary
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End point timeframe:

The PASI percentage change in % at Day 43 is calculated as PASI of (Day 43 - Baseline)/Baseline*100.

End point values	MP1032 completed / PK analysis set	AUC_2h subgroup 1	AUC_2h subgroup 2	AUC_2h subgroup 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	6	5	6
Units: percent				
arithmetic mean (standard deviation)	-17.83 (\pm 29.853)	3.06 (\pm 23.42)	-21.82 (\pm 38.572)	-38.31 (\pm 28.353)

End point values	AUC_2h	Placebo	AUC_t	AUC_t
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	subgroup 4	completed	subgroup 1	subgroup 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	22	6	5
Units: percent				
arithmetic mean (standard deviation)	-14.32 (\pm 13.466)	-15.56 (\pm 27.181)	3.06 (\pm 23.42)	-35.88 (\pm 42.928)

End point values	AUC_t subgroup 3	AUC_t subgroup 4		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	5		
Units: percent				
arithmetic mean (standard deviation)	-26.59 (\pm 24.922)	-14.32 (\pm 13.466)		

Statistical analyses

No statistical analyses for this end point

Secondary: PGA Score observed Day 1 (Baseline)

End point title	PGA Score observed Day 1 (Baseline)
End point description:	PGA is the physician's global assessment of the severity of psoriasis using a 7-point scale from 0 (clear) to 6 (severe).
End point type	Secondary
End point timeframe:	PGA (physicians global assessment) score has been evaluated on Day 1 (Baseline), Day 29, Day 43 (End of Treatment) and on two Follow-Up Visits.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: PGA score				
arithmetic mean (standard deviation)	4.2 (\pm 0.8)	4.4 (\pm 0.73)		

Statistical analyses

No statistical analyses for this end point

Secondary: PGA Score observed - Day 43 (End of Treatment)

End point title	PGA Score observed - Day 43 (End of Treatment)
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End point description:

PGA is the physician's global assessment of the severity of psoriasis using a 7-point scale from 0 (clear) to 6 (severe).

End point type	Secondary
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End point timeframe:

PGA (physicians global assessment) score has been evaluated on Day 1 (Baseline), Day 29, Day 43 (End of Treatment) and on two Follow-Up Visits.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: PGA Score				
arithmetic mean (standard deviation)	3.9 (± 1.32)	4.0 (± 1.11)		

Statistical analyses

No statistical analyses for this end point

Secondary: PGA Score - Change from Baseline at Day 43

End point title	PGA Score - Change from Baseline at Day 43
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End point description:

PGA is the physician's global assessment of the severity of psoriasis using a 7-point scale from 0 (clear) to 6 (severe).

End point type	Secondary
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End point timeframe:

PGA (physicians global assessment) score has been evaluated on Day 1 (Baseline), Day 29, Day 43 (End of Treatment) and on two Follow-Up Visits.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: PGA Score				
arithmetic mean (standard deviation)	-0.3 (± 0.98)	-0.4 (± 0.89)		

Statistical analyses

No statistical analyses for this end point

Secondary: DLQI observed values - Day 1 (Baseline)

End point title	DLQI observed values - Day 1 (Baseline)
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End point description:

DLQI is a total score computed from answers to 10 questions, with each answer scored from 0 (not at all) to 3 (very much). The total score ranges from 0 to 30.

End point type	Secondary
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End point timeframe:

DLQI (dermatology life quality index) score has been evaluated on Day 1 (Baseline), Day 29, Day 43 (End of Treatment) and on two Follow-Up Visits.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: DLQI Score				
arithmetic mean (standard deviation)	8.2 (± 3.68)	8.6 (± 5.92)		

Statistical analyses

No statistical analyses for this end point

Secondary: DLQI Observed Values - Day 43 (End of Treatment)

End point title	DLQI Observed Values - Day 43 (End of Treatment)
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End point description:

DLQI is a total score computed from answers to 10 questions, with each answer scored from 0 (not at all) to 3 (very much). The total score ranges from 0 to 30.

End point type	Secondary
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End point timeframe:

DLQI (dermatology life quality index) score has been evaluated on Day 1 (Baseline), Day 29, Day 43 (End of Treatment) and on two Follow-Up Visits.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: DLQI Score				
arithmetic mean (standard deviation)	7.1 (± 4.66)	7.3 (± 5.59)		

Statistical analyses

No statistical analyses for this end point

Secondary: DLQI Change from Baseline at Day 43

End point title	DLQI Change from Baseline at Day 43
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End point description:

DLQI is a total score computed from answers to 10 questions, with each answer scored from 0 (not at all) to 3 (very much). The total score ranges from 0 to 30.

End point type	Secondary
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End point timeframe:

DLQI (dermatology life quality index) score has been evaluated on Day 1 (Baseline), Day 29, Day 43 (End of Treatment) and on two Follow-Up Visits.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: DLQI Score				
arithmetic mean (standard deviation)	-1 (± 3.91)	-1.3 (± 3.51)		

Statistical analyses

No statistical analyses for this end point

Secondary: EQ-5D 5L Observed Values - Day 1 (Baseline)

End point title	EQ-5D 5L Observed Values - Day 1 (Baseline)
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End point description:

EQ-5D (VAS) is a total score which records the patients' self-rated health status with the scale numbered 0 to 100 (0=worst imaginable, 100=best imaginable).

End point type	Secondary
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End point timeframe:

EQ-5D 5L (VAS) score has been evaluated on Day 1 (Baseline), Day 29, Day 43 (End of Treatment) and on two Follow-Up Visits.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: VAS Score				
arithmetic mean (standard deviation)	73.7 (± 16.58)	76 (± 11.25)		

Statistical analyses

No statistical analyses for this end point

Secondary: EQ-5D 5L observed values - Day 43 (End of Treatment)

End point title	EQ-5D 5L observed values - Day 43 (End of Treatment)
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End point description:

EQ-5D (VAS) is a total score which records the patients' self-rated health status with the scale numbered 0 to 100 (0=worst imaginable, 100=best imaginable).

End point type	Secondary
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End point timeframe:

EQ-5D 5L (VAS) score has been evaluated on Day 1 (Baseline), Day 29, Day 43 (End of Treatment) and on two Follow-Up Visits.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: VAS Score				
arithmetic mean (standard deviation)	74.8 (± 14.62)	76.2 (± 12.48)		

Statistical analyses

No statistical analyses for this end point

Secondary: EQ-5D 5L Change from Baseline at Day 43

End point title	EQ-5D 5L Change from Baseline at Day 43
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End point description:

EQ-5D (VAS) is a total score which records the patients' self-rated health status with the scale numbered 0 to 100 (0=worst imaginable, 100=best imaginable).

End point type	Secondary
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End point timeframe:

EQ-5D 5L (VAS) score has been evaluated on Day 1 (Baseline), Day 29, Day 43 (End of Treatment) and on two Follow-Up Visits.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: VAS Score				
arithmetic mean (standard deviation)	1.1 (± 8.14)	0.1 (± 10.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: mNAPSI Observed Values - Day 1 (Baseline)

End point title	mNAPSI Observed Values - Day 1 (Baseline)
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End point description:

mNAPSI score is a total score computed from answers to 7 questions, 3 of which can be answered with a score ranging from 0 to 3, and 4 of which can be answered with a score ranging from 0 to 1. The total score ranges from 0 to 13.

End point type	Secondary
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End point timeframe:

mNAPSI (modified nail psoriasis severity index) score has been evaluated on Day 1 (Baseline), Day 29, Day 43 (End of Treatment) and on two Follow-Up Visits.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17 ^[14]	15 ^[15]		
Units: mNAPSI Score				
arithmetic mean (standard deviation)	3.5 (± 1.37)	4.9 (± 1.49)		

Notes:

[14] - Only evaluated in patients with psoriatic nail disease.

[15] - Only evaluated in patients with psoriatic nail disease.

Statistical analyses

No statistical analyses for this end point

Secondary: mNAPSI Observed Values - Day 43 (End of Treatment)

End point title	mNAPSI Observed Values - Day 43 (End of Treatment)
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End point description:

mNAPSI score is a total score computed from answers to 7 questions, 3 of which can be answered with a score ranging from 0 to 3, and 4 of which can be answered with a score ranging from 0 to 1. The total score ranges from 0 to 13.

End point type	Secondary
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End point timeframe:

mNAPSI (modified nail psoriasis severity index) score has been evaluated on Day 1 (Baseline), Day 29, Day 43 (End of Treatment) and on two Follow-Up Visits.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17 ^[16]	15 ^[17]		
Units: mNAPSI Score				
arithmetic mean (standard deviation)	2.8 (± 1.64)	4.8 (± 1.78)		

Notes:

[16] - Only evaluated in patients with psoriatic nail disease.

[17] - Only evaluated in patients with psoriatic nail disease.

Statistical analyses

No statistical analyses for this end point

Secondary: mNAPSI Change from Baseline at Day 43

End point title	mNAPSI Change from Baseline at Day 43
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End point description:

mNAPSI score is a total score computed from answers to 7 questions, 3 of which can be answered with a score ranging from 0 to 3, and 4 of which can be answered with a score ranging from 0 to 1. The total score ranges from 0 to 13.

End point type	Secondary
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End point timeframe:

mNAPSI (modified nail psoriasis severity index) score has been evaluated on Day 1 (Baseline), Day 29, Day 43 (End of Treatment) and on two Follow-Up Visits.

End point values	MP1032	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17 ^[18]	15 ^[19]		
Units: mNAPSI Score				
arithmetic mean (standard deviation)	-0.8 (± 1.48)	-0.1 (± 0.92)		

Notes:

[18] - Only evaluated in patients with psoriatic nail disease.

[19] - Only evaluated in patients with psoriatic nail disease.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse event reporting extended from the signing of the ICF until the last follow-up visit.

Adverse event reporting additional description:

In the following, treatment emergent adverse events (TEAEs) are summarized by system organ class (SOC) and preferred term (PT). For further details (e.g. severity and causality) please refer to the endpoint section.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.1
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Reporting groups

Reporting group title	MP1032
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Reporting group description:

Treatment group - 100 mg MP1032 b.i.d.

Reporting group title	Placebo
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Reporting group description:

Placebo group - Placebo b.i.d.

Serious adverse events	MP1032	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 23 (0.00%)	0 / 23 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	MP1032	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 23 (60.87%)	15 / 23 (65.22%)	
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	

Injury, poisoning and procedural complications Injury subjects affected / exposed occurrences (all) Muscle strain subjects affected / exposed occurrences (all) Skin abrasion subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1 0 / 23 (0.00%) 0 1 / 23 (4.35%) 1	0 / 23 (0.00%) 0 1 / 23 (4.35%) 1 0 / 23 (0.00%) 0	
Vascular disorders Haematoma subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 23 (0.00%) 0	
Nervous system disorders Headache subjects affected / exposed occurrences (all) Migraine subjects affected / exposed occurrences (all) Sciatica subjects affected / exposed occurrences (all)	6 / 23 (26.09%) 6 0 / 23 (0.00%) 0 1 / 23 (4.35%) 1	2 / 23 (8.70%) 2 1 / 23 (4.35%) 3 0 / 23 (0.00%) 0	
General disorders and administration site conditions Influenza like illness subjects affected / exposed occurrences (all) Feeling drunk subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1 1 / 23 (4.35%) 1	0 / 23 (0.00%) 0 0 / 23 (0.00%) 0	
Ear and labyrinth disorders Tympanic membrane perforation subjects affected / exposed occurrences (all) Ear pain	1 / 23 (4.35%) 1	0 / 23 (0.00%) 0	

subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 23 (0.00%) 0	
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 23 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	2 / 23 (8.70%)	1 / 23 (4.35%)	
occurrences (all)	2	1	
Epigastric discomfort			
subjects affected / exposed	1 / 23 (4.35%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	1 / 23 (4.35%)	1 / 23 (4.35%)	
occurrences (all)	1	1	
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	1 / 23 (4.35%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Pruritus			
subjects affected / exposed	1 / 23 (4.35%)	1 / 23 (4.35%)	
occurrences (all)	2	1	
Pruritus generalised			
subjects affected / exposed	0 / 23 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Psoriasis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Skin reaction			
subjects affected / exposed	0 / 23 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Skin ulcer			
subjects affected / exposed	0 / 23 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Renal and urinary disorders			

Leukocyturia subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 23 (4.35%) 1	
Haematuria subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 23 (4.35%) 2	
Musculoskeletal and connective tissue disorders			
Back pain subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	1 / 23 (4.35%) 1	
Myalgia subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 23 (4.35%) 1	
Psoriatic arthropathy subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 23 (4.35%) 1	
Infections and infestations			
Nasopharyngitis subjects affected / exposed occurrences (all)	5 / 23 (21.74%) 5	6 / 23 (26.09%) 8	
Oral herpes subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 23 (4.35%) 1	
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 23 (4.35%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 April 2016	Protocol Version 1.1 was the first protocol version to receive approval.
03 May 2016	Protocol Version 1.2: Amendments: 1. The chapter of determination on sample size was adapted, since the primary objectives of the study do not require any confirmatory statistical testing. The sample size was determined to have to represent a large enough exploratory sample. 2. The premature termination criteria were adapted and the following termination criteria were added: termination upon decision of the Sponsor, the Investigator, the CA or the IEC, because of safety concerns, ethical issues and severe non-compliance.
04 August 2016	Protocol Version 1.2: Amendments: 1. Change of inclusion criterion #3 to allow inclusion of patients with a BMI between 18.5 and 34.9 kg/m ² . 2. Increase of the number of clinical trial sites from 2 to 5 to ensure that sufficient backup sites are in place to compensate for any enrollment rate that is slower than the predicted one. 3. Clarification on adequate contraception measures that are considered acceptable. 4. Clarification on the definition of "post-menopausal women". 5. Inclusion of the definition "sterile women". 6. The Drug product section of the IMPD was amended to introduce a shelf life extension plan.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported