# 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 |

**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 |
| **Arm title** | MP1032 |

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 |

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<br>Units: Subjects | | | |
| Adults (18-64 years) | 45 | 45 | |
| From 65-84 years | 1 | 1 | |
| Gender categorical<br>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 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.

| **Reporting group values** | MP1032completed / PK analysis set | AUC_2h subgroup 1 | AUC_2h subgroup 2 |
|---|---|---|---|
| Number of subjects | 22 | 6 | 5 |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 21 | 6 | 5 |
| From 65-84 years | 1 | 0 | 0 |
| Gender categorical<br>Units: Subjects | | | |
| Female | 5 | 0 | 0 |

| | | | |
|---|---|---|---|
| Male | 17 | 6 | 5 |

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

| **Reporting group values** | AUC_t subgroup 4 | | |
|---|---|---|---|
| Number of subjects | 5 | | |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 4 | | |
| From 65-84 years | 1 | | |
| Gender categorical<br>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:<br>Group 1: 6 patients with lowest AUCs;<br>Group 2: 5 patients with the next highest AUCs;<br>Group 3: 6 patients with the next highest AUCs;<br>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:<br>Group 1: 6 patients with lowest AUCs;<br>Group 2: 5 patients with the next highest AUCs;<br>Group 3: 6 patients with the next highest AUCs;<br>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:<br>Group 1: 6 patients with lowest AUCs;<br>Group 2: 5 patients with the next highest AUCs;<br>Group 3: 6 patients with the next highest AUCs;<br>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:<br>Group 1: 6 patients with lowest AUCs;<br>Group 2: 5 patients with the next highest AUCs;<br>Group 3: 6 patients with the next highest AUCs;<br>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] |
|---|---|

End point description:

Number of Treatment Emergent Adverse Events (TEAEs) reported

| End point type | Primary |
|---|---|

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: Occurence of related TEAEs by SOC

| End point title | Occurence 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] |
|---|---|

End point description:

| End point type | Primary |
|---|---|

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] |
|---|---|

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 |
|---|---|

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** | MP1032completed / 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] |
|---|---|

End point description:

C max = maximum plasma concentration

| End point type | Primary |
|---|---|

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] |
|---|---|

End point description:

t max = time of occurence of C max

| End point type | Primary |
|---|---|

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] |
|---|---|

End point description:

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

| End point type | Primary |
|---|---|

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 (± 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] |
|---|---|

End point description:

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

| End point type | Primary |
|---|---|

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 (± 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] |
|---|---|

End point description:

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

| End point type | Primary |
|---|---|

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 (± 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] |
|---|---|

End point description:

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

| End point type | Primary |
|---|---|

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 (± 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] |
|---|---|

End point description:

t last = time of last quantifiable concentration

| End point type | Primary |
|---|---|

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 (± 7.203) | 17.25 (± 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 (± 9.509) | 14.69 (± 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 (± 10.681) | 15.97 (± 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 (± 10.03) | 16.09 (± 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) |
|---|---|

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) | -2 (± 3.994) | -2.56 (± 5.025) | | |

## Statistical analyses

| Statistical analysis title | Treatment Difference at Day 43 |
|---|---|

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 ssymptoms) 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 |
|---|---|

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 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 |
|---|---|

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 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 |
|---|---|
| Comparison groups | MP1032 v Placebo |

| | |
|---|---|
| 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 |

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 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 |

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:

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

| **End point values** | MP1032completed / 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) |

| 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 (± 16.422) | -14.57 (± 21.5) | -6.61 (± 25.575) | -27.07 (± 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 (± 19.510) | -15.03 (± 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 |
|---|---|

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:

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

| End point values | MP1032completed / 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 (± 29.853) | 3.06 (± 23.42) | -21.82 (± 38.572) | -38.31 (± 28.353) |

| End point values | AUC_2h | Placebo | AUC_t | AUC_t |
|---|---|---|---|---|

| | 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 (± 13.466) | -15.56 (± 27.181) | 3.06 (± 23.42) | -35.88 (± 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 (± 24.922) | -14.32 (± 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 (± 0.8) | 4.4 (± 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) |
|---|---|

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) | 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 |
|---|---|

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) | -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) |
|---|---|

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 |
|---|---|

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) |
|---|---|

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 |
|---|---|

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 |
|---|---|

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 |
|---|---|

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) |
|---|---|

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 |
|---|---|

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) |
|---|---|

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 |
|---|---|

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 |
|---|---|

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 |
|---|---|

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) |
|---|---|

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 |
|---|---|

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) |
|---|---|

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 |
|---|---|

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 |
|---|---|

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 |
|---|---|

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 |

| Dictionary used | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 18.1 |

| 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. | |

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

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 23 (4.35%) | 0 / 23 (0.00%) | |
| occurrences (all) | 1 | 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 | 0 / 23 (0.00%) | 1 / 23 (4.35%) | |
| occurrences (all) | 0 | 1 | |
| Haematuria | | | |
| subjects affected / exposed | 0 / 23 (0.00%) | 1 / 23 (4.35%) | |
| occurrences (all) | 0 | 2 | |
| Musculoskeletal and connective tissue disorders | | | |
| Back pain | | | |
| subjects affected / exposed | 1 / 23 (4.35%) | 1 / 23 (4.35%) | |
| occurrences (all) | 1 | 1 | |
| Myalgia | | | |
| subjects affected / exposed | 0 / 23 (0.00%) | 1 / 23 (4.35%) | |
| occurrences (all) | 0 | 1 | |
| Psoriatic arthropathy | | | |
| subjects affected / exposed | 0 / 23 (0.00%) | 1 / 23 (4.35%) | |
| occurrences (all) | 0 | 1 | |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 5 / 23 (21.74%) | 6 / 23 (26.09%) | |
| occurrences (all) | 5 | 8 | |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 23 (0.00%) | 1 / 23 (4.35%) | |
| occurrences (all) | 0 | 1 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 23 (0.00%) | 1 / 23 (4.35%) | |
| occurrences (all) | 0 | 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:<br>Amendments:<br>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.<br>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:<br>Amendments:<br>1. Change of inclusion criterion #3 to allow inclusion of patients with a BMI between 18.5 and 34.9 kg/m2.<br>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.<br>3. Clarification on adequate contraception measures that are considered acceptable.<br>4. Clarification on the definition of "post-menopausal women".<br>5. Inclusion of the definition "sterile women".<br>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