Clinical trial results:
A Phase II, Multicenter, Double-blind, Placebo-controlled, Efficacy and Safety Study of Two Oral Doses (150 mg bid / 300 mg bid) of MP1032 in Male and Female Patients with Moderate-to-Severe Chronic Plaque Psoriasis

Summary

EudraCT number	2017-003484-36
Trial protocol	DE PL
Global end of trial date	12 June 2019

Results information

Result version number	v1 (current)
This version publication date	04 June 2020
First version publication date	04 June 2020
Summary attachment (see zip file)	MP1032-CT04 Synopsis (20200424 MP1032-CT04_Synopsis_V2.pdf)

Trial information

Trial identification

Sponsor protocol code	MP1032-CT04

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03706209
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MetrioPharm AG
Sponsor organisation address	Bleicherweg 10, Zürich, Switzerland, 80002
Public contact	Clinical Trials Group, MetrioPharm Deutschland GmbH, +49 30338439502, info@metriopharm.com
Scientific contact	Clinical Trials Group, MetrioPharm Deutschland GmbH, +49 30338439502, info@metriopharm.com

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	13 August 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 June 2019
Global end of trial reached?	Yes
Global end of trial date	12 June 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this trial is to evaluate the clinical efficacy and safety of two oral doses of MP1032 (150 mg bid and 300 mg bid) when taken for 12 weeks by patients with moderate-to-severe chronic plaque psoriasis

Protection of trial subjects:

The trial design consisted of a 28 day screening period, a 12 week treatment period, and subsequently a 28 day follow up (FU) period. Each patient had 6 planned visits and additional unscheduled visits as needed. Safety parameters were monitored from the signing of the ICF until the last FU Visit. Safety was assessed through physical examination, vital signs and safety laboratory. A serum pregnancy test was done for all women at Screening Visit followed by 2 subsequent urine pregnancy tests.
PK samples were collected in a subgroup at five selected trial sites. Patients who discontinued early from the trial should, if possible, have had an Early Termination Visit. This visit should have taken place as soon as possible after the patient stopped taking IMP.

Any medication other than the IMP, was considered a concomitant medication. All medications taken in the 6 weeks before the first dose had to be recorded as concomitant. Medication to treat stable diseases as well as medication to treat AEs were allowed during the course of the trial.

Measures were taken concerning treatment compliance. Criteria that might have warranted the discontinuation of an individual patient from study or even the termination of the whole study had been in place.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 February 2018
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: 41
Country: Number of subjects enrolled	Poland: 114
Worldwide total number of subjects	155
EEA total number of subjects	155

Notes:

Subjects enrolled per age group

In utero	0

Preterm newborn - gestational age < 37 wk	0
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)	147
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

About 150 patients were planned to be randomized to receive either 150 mg or 300 mg MP1032 or placebo orally twice daily for 12 weeks.
Treatment allocation was based on a blinded 1:1:1 ratio (50:50:50 patients). Finally 155 patients were randomized in the ratio 48:52:55 (300mg/150mg/placebo) using an Interactive Web Response System (IWRS).

Pre-assignment

Screening details:

204 patients were screened. 155 were randomized to treatment groups within a maximum time frame of 28 days after screening visit (assessment of demographic, efficacy and safety data), 22 failed screening, i.e. did not meet the inclusion criteria or met any exclusion criteria, 27 were not randomized for further associated reasons.

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 150mg

Arm description:

Treatment Group - 150mg MP1032 b.i.d.

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

Dosage and administration details:

3 capsules of "MP1032 Hard Gelantine Capsules 50 mg", i.e. 150 mg MP1032, were administered twice daily over 84 consecutive days.

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

Dosage and administration details:

3 capsules of " Placebo to MP1032 Hard Gelatine Capsules 50mg", were administered twice daily over 84 consecutive days

Arm title	Placebo

Arm description:

Placebo

Arm type	Placebo

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

Dosage and administration details:

6 capsules of " Placebo to MP1032 Hard Gelatine Capsules 50mg", were administered twice daily over 84 consecutive days

Arm title	MP1032 300mg

Arm description:

Treatment Group - 300mg MP1032 b.i.d.

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

Dosage and administration details:

6 capsules of "MP1032 Hard Gelantine Capsules 50 mg", i.e. 300 mg MP1032, were administered twice daily over 84 consecutive days.

Number of subjects in period 1	MP1032 150mg	Placebo	MP1032 300mg
Started	52	55	48
Completed	34	38	37
Not completed	18	17	11
Consent withdrawn by subject	17	12	8
Randomized by Mistake	-	1	-
Patient took prohibited medication	-	1	-
Adverse event, non-fatal	1	1	-
Non-Compliance with study drug	-	1	1
Lost to follow-up	-	1	2

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	155	155	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	147	147	
From 65-84 years	8	8	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	48	48	
Male	107	107	

Subject analysis sets	
Subject analysis set title	SES
Subject analysis set type	Safety analysis

Subject analysis set description:

The safety-evaluation-set (SES) included all patients who received any trial medication at least once; all safety analyses will be based on the SES.

Subject analysis set title	FAS
Subject analysis set type	Full analysis

Subject analysis set description:

The full-analysis-set (FAS) included all randomized patients who received at least one dose of IMP and had at least one post-baseline assessment. The ITT analysis was based on the FAS. The FAS was considered primary analysis set for the efficacy analysis.

Subject analysis set title	PKS
Subject analysis set type	Per protocol

Subject analysis set description:

The pharmacokinetics evaluation set (PKS) includes all patients without any protocol deviations that could have interfered with the administration of the treatment or the evaluation of systemic concentrations of MP1032, who received at least one dose of IMP and who had any completed determination of MP1032 levels were included in the PKS.

Subject analysis set title	VCS
Subject analysis set type	Per protocol

Subject analysis set description:

The valid-cases-set (VCS) included all patients from the FAS, who completed the assessments of the co-primary endpoints without any protocol violation interfering with the precise evaluation of treatment efficacy and with sufficient exposure to IMP.

Subject analysis set title	PASI ≤ 15 (FAS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This subgroup comprises all subjects out of the FAS set who had a baseline PASI score ≤ 15.
Several study specific categories had been created for subgroup analyses including centers, age, sex, BMI, years of psoriasis, smoking, baseline PGA, baseline PASI and baseline CRP.
However, only subgroups that showed relevant results are herewith provided as subject analysis set.

Subject analysis set title	Age > 40 (FAS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This subgroup comprises all subjects out of the FAS set who were older than 40 years.
Several study specific categories had been created for subgroup analyses including centers, age, sex, BMI, years of psoriasis, smoking, baseline PGA, baseline PASI and baseline CRP.
However, only subgroups that showed relevant results are herewith provided as subject analysis set.

Subject analysis set title	BMI ≥ 30 (FAS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This subgroup comprises all subjects out of the FAS set who had a body mass index ≥ 30.
Several study specific categories had been created for subgroup analyses including centers, age, sex, BMI, years of psoriasis, smoking, baseline PGA, baseline PASI and baseline CRP.
However, only subgroups that showed relevant results are herewith provided as subject analysis set.

Reporting group values	SES	FAS	PKS
Number of subjects	154	151	23
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	146	143	23
From 65-84 years	8	8	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	48	46	7
Male	106	105	16

Reporting group values	VCS	PASI ≤ 15 (FAS)	Age > 40 (FAS)
Number of subjects	102	97	79
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0

Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	98	94	71
From 65-84 years	4	3	8
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	32	32	23
Male	70	65	56

Reporting group values	BMI ≥ 30 (FAS)		
Number of subjects	41		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
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)	40		
From 65-84 years	1		
85 years and over	0		
Gender categorical Units: Subjects			
Female	12		
Male	29		

End points

End points reporting groups

Reporting group title	MP1032 150mg
Reporting group description:	
Treatment Group - 150mg MP1032 b.i.d.	
Reporting group title	Placebo
Reporting group description:	
Placebo	
Reporting group title	MP1032 300mg
Reporting group description:	
Treatment Group - 300mg MP1032 b.i.d.	
Subject analysis set title	SES
Subject analysis set type	Safety analysis
Subject analysis set description:	
The safety-evaluation-set (SES) included all patients who received any trial medication at least once; all safety analyses will be based on the SES.	
Subject analysis set title	FAS
Subject analysis set type	Full analysis
Subject analysis set description:	
The full-analysis-set (FAS) included all randomized patients who received at least one dose of IMP and had at least one post-baseline assessment. The ITT analysis was based on the FAS. The FAS was considered primary analysis set for the efficacy analysis.	
Subject analysis set title	PKS
Subject analysis set type	Per protocol
Subject analysis set description:	
The pharmacokinetics evaluation set (PKS) includes all patients without any protocol deviations that could have interfered with the administration of the treatment or the evaluation of systemic concentrations of MP1032, who received at least one dose of IMP and who had any completed determination of MP1032 levels were included in the PKS.	
Subject analysis set title	VCS
Subject analysis set type	Per protocol
Subject analysis set description:	
The valid-cases-set (VCS) included all patients from the FAS, who completed the assessments of the co-primary endpoints without any protocol violation interfering with the precise evaluation of treatment efficacy and with sufficient exposure to IMP.	
Subject analysis set title	PASI ≤ 15 (FAS)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
This subgroup comprises all subjects out of the FAS set who had a baseline PASI score ≤ 15. Several study specific categories had been created for subgroup analyses including centers, age, sex, BMI, years of psoriasis, smoking, baseline PGA, baseline PASI and baseline CRP. However, only subgroups that showed relevant results are herewith provided as subject analysis set.	

Subject analysis set title	Age > 40 (FAS)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
This subgroup comprises all subjects out of the FAS set who were older than 40 years. Several study specific categories had been created for subgroup analyses including centers, age, sex, BMI, years of psoriasis, smoking, baseline PGA, baseline PASI and baseline CRP. However, only subgroups that showed relevant results are herewith provided as subject analysis set.	

Subject analysis set title	BMI ≥ 30 (FAS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This subgroup comprises all subjects out of the FAS set who had a body mass index ≥ 30.
Several study specific categories had been created for subgroup analyses including centers, age, sex, BMI, years of psoriasis, smoking, baseline PGA, baseline PASI and baseline CRP.
However, only subgroups that showed relevant results are herewith provided as subject analysis set.

Primary: PASI 75 responders - week 12 (EoT)

End point title	PASI 75 responders - week 12 (EoT)

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician's assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

The number of responders corresponds to the number of patients with an improvement of at least 75% in the PASI score at End-of-Treatment compared to baseline.

End point type	Primary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: patients				
Responder	4	1	4	9
Non-Responder	46	53	43	142

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - EoT
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.161
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	4.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	35.97

Statistical analysis title	MP1032 300mg bid vs placebo - EoT
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.111
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	5.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	55.43

Primary: PGA improvement - week 12 (EoT)

End point title	PGA improvement - week 12 (EoT)

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

The number of responders corresponds to the number of patients with an improvement of 1 or more points on the 7-points PGA scale at End-of-Treatment compared to baseline.

End point type	Primary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: Patients				
Responder	14	10	14	38
Non-Responder	36	44	33	113

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - EoT
Comparison groups	Placebo v MP1032 150mg

Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.222
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	4.25

Statistical analysis title	MP1032 300mg bid vs placebo - EoT
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.182
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	4.91

Secondary: PASI 50 responders - week 12 (EoT)

End point title	PASI 50 responders - week 12 (EoT)

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician’s assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

The number of responders corresponds to the number of patients with an improvement of at least 50% in the PASI score at End-of-Treatment compared to baseline.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: patients	8	6	10	24

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - EoT
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.47
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	4.52

Statistical analysis title	MP1032 300mg bid vs placebo - EoT
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.136
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	7.82

Secondary: PASI 75 Responders - weeks 4 and 8

End point title	PASI 75 Responders - weeks 4 and 8

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician’s assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

The number of responders corresponds to the number of patients with an improvement of at least 75%

in the PASI score in the respective weeks compared to baseline.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: patients				
week 4	0	2	1	3
week 8	2	1	1	4

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - 4 weeks
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.178 [1]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Confidence interval	
level	95 %
sides	2-sided

Notes:

[1] - As data were too sparse neither OR nor CI have been computed.

Statistical analysis title	MP1032 150mg bid vs placebo - 8 weeks
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.474
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.21
upper limit	28.05

Statistical analysis title	MP1032 300mg bid vs placebo - 4 weeks
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.718
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.05
upper limit	7.48

Statistical analysis title	MP1032 300mg bid vs placebo - 8 weeks
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.867
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.08
upper limit	19.05

Secondary: PASI 75 responders - week 16 (FU)

End point title	PASI 75 responders - week 16 (FU)

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician’s assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

The number of responders corresponds to the number of patients with an improvement of at least 75% in the PASI score at the Follow-Up visit compared to baseline.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	38	44	40	122
Units: patients	4	2	5	11

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - FU
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.375
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	12.84

Statistical analysis title	MP1032 300mg bid vs placebo - FU
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.116
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	4.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	27.08

Secondary: PASI 50 responders - weeks 4 and 8

End point title	PASI 50 responders - weeks 4 and 8

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician’s assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

The number of responders corresponds to the number of patients with an improvement of at least 50% in the PASI score in the respective weeks compared to baseline.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: patients				
week 4	2	5	7	14
week 8	5	7	9	21

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - 4 weeks
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.287
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.08
upper limit	2.27

Statistical analysis title	MP1032 150mg bid vs placebo - 8 weeks
Comparison groups	MP1032 150mg v Placebo

Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.719
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.25
upper limit	2.63

Statistical analysis title	MP1032 300mg bid vs placebo - 4 weeks
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.332
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	6.4

Statistical analysis title	MP1032 300mg bid vs placebo - 8 weeks
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.357
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	5.32

Secondary: PASI 50 responders - week 16 (FU)

End point title	PASI 50 responders - week 16 (FU)

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician’s assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

The number of responders corresponds to the number of patients with an improvement of at least 50% in the PASI score at the Follow-Up visit compared to baseline.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	38	44	40	122
Units: patients	8	6	10	24

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - FU
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.355
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	5.72

Statistical analysis title	MP1032 300mg bid vs placebo - FU
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.198
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.22

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	7.37

Secondary: PASI ANCOVA for change from baseline - weeks 4, 8 and 12 (EoT)

End point title	PASI ANCOVA for change from baseline - weeks 4, 8 and 12 (EoT)

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician’s assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

Displayed are changes in the PASI score of the respective weeks compared to baseline in the different arms in patients of the FAS subject analysis set.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	54	47	
Units: PASI				
arithmetic mean (standard error)				
week 4	-0.3 (± 0.7)	-0.6 (± 0.7)	-1.7 (± 0.7)	
week 8	0.2 (± 0.9)	-0.8 (± 0.8)	-1.8 (± 0.9)	
week 12	0.1 (± 1.0)	-0.1 (± 1.0)	-1.1 (± 1.0)	

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - 4 weeks

Statistical analysis description:

Estimates and treatment comparison of least square means using an ANCOVA model, with treatment arm and (pooled) analysis center as factors and baseline outcome as covariate.

Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.757
Method	ANCOVA
Parameter estimate	least square means
Point estimate	0.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	2.3
Variability estimate	Standard error of the mean
Dispersion value	1

Statistical analysis title	MP1032 150mg bid vs placebo - 8 weeks

Statistical analysis description:

Estimates and treatment comparison of least square means using an ANCOVA model, with treatment arm and (pooled) analysis center as factors and baseline outcome as covariate.

Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.412
Method	ANCOVA
Parameter estimate	least square means
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	3.4
Variability estimate	Standard error of the mean
Dispersion value	1.2

Statistical analysis title	MP1032 150mg bid vs placebo - EoT

Statistical analysis description:

Estimates and treatment comparison of least square means using an ANCOVA model, with treatment arm and (pooled) analysis center as factors and baseline outcome as covariate.

Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.894
Method	ANCOVA
Parameter estimate	least square means
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	3
Variability estimate	Standard error of the mean
Dispersion value	1.4

Statistical analysis title	MP1032 300mg bid vs placebo - 4 weeks

Statistical analysis description:

Estimates and treatment comparison of least square means using an ANCOVA model, with treatment arm and (pooled) analysis center as factors and baseline outcome as covariate.

Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.267
Method	ANCOVA
Parameter estimate	least square means
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	0.9
Variability estimate	Standard error of the mean
Dispersion value	1

Statistical analysis title	MP1032 300mg bid vs placebo - 8 weeks

Statistical analysis description:

Estimates and treatment comparison of least square means using an ANCOVA model, with treatment arm and (pooled) analysis center as factors and baseline outcome as covariate.

Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.401
Method	ANCOVA
Parameter estimate	least square means
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	1.4
Variability estimate	Standard error of the mean
Dispersion value	1.2

Statistical analysis title	MP1032 300mg bid vs placebo - EoT

Statistical analysis description:

Estimates and treatment comparison of least square means using an ANCOVA model, with treatment arm and (pooled) analysis center as factors and baseline outcome as covariate.

Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.456
Method	ANCOVA
Parameter estimate	least square means
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.8
upper limit	1.7
Variability estimate	Standard error of the mean
Dispersion value	1.4

Secondary: PASI ANCOVA for change from baseline - week 16 (FU)

End point title	PASI ANCOVA for change from baseline - week 16 (FU)

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician's assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

Displayed are changes in the PASI score of the respective weeks compared to baseline in the different arms in patients of the FAS subject analysis set.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	38	44	40	
Units: PASI				
arithmetic mean (standard error)	-0.3 (± 1.3)	-0.8 (± 1.2)	-0.8 (± 1.2)	

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - FU

Statistical analysis description:

Estimates and treatment comparison of least square means using an ANCOVA model, with treatment arm and (pooled) analysis center as factors and baseline outcome as covariate.

Comparison groups	MP1032 150mg v Placebo

Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.801
Method	ANCOVA
Parameter estimate	Estimated Mean
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	3.9
Variability estimate	Standard error of the mean
Dispersion value	1.7

Statistical analysis title	MP1032 300mg bid vs placebo - FU

Statistical analysis description:

Estimates and treatment comparison of least square means using an ANCOVA model, with treatment arm and (pooled) analysis center as factors and baseline outcome as covariate.

Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.957
Method	ANCOVA
Parameter estimate	Estimated Mean
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	3.3
Variability estimate	Standard error of the mean
Dispersion value	1.7

Secondary: PGA improvement - weeks 4 and 8

End point title	PGA improvement - weeks 4 and 8

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

The number of responders corresponds to the number of patients with an improvement of 1 or more points on the 7-points PGA scale in the respective weeks compared to baseline.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: patients				
week 4	11	9	13	33
week 8	12	14	16	42

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - 4 weeks
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.45
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	3.8

Statistical analysis title	MP1032 150mg bid vs placebo - 8 weeks
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.884
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	2.18

Statistical analysis title	MP1032 300mg bid vs placebo - 4 weeks

Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.186
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	5.26

Statistical analysis title	MP1032 300mg bid vs placebo - 8 weeks
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.384
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	3.64

Secondary: PGA improvement - week 16 (FU)

End point title	PGA improvement - week 16 (FU)

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

The number of responders corresponds to the number of patients with an improvement of 1 or more points on the 7-points PGA scale at the Follow-Up visit compared to baseline.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	38	44	40	122
Units: patients	14	12	13	39

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - FU
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.311
Method	Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	4.26

Statistical analysis title	MP1032 300mg bid vs placebo - FU
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.699
Method	Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	3.17

Secondary: PGA descriptive statistics - day 1 (baseline) - week 12 (EoT)

End point title	PGA descriptive statistics - day 1 (baseline) - week 12 (EoT)

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: PGA				
arithmetic mean (standard deviation)				
Day 1	4.1 (± 0.7)	4.1 (± 0.7)	4.2 (± 0.7)	4.1 (± 0.7)
week 4	3.9 (± 0.9)	4.0 (± 1.0)	3.9 (± 0.9)	3.9 (± 0.9)
week 4 - change from baseline	-0.1 (± 0.7)	-0.1 (± 0.6)	-0.3 (± 0.6)	-0.2 (± 0.6)
week 8	4.0 (± 1.1)	3.9 (± 1.1)	3.8 (± 1.1)	3.9 (± 1.1)
week 8 - change from baseline	-0.1 (± 0.9)	-0.2 (± 0.8)	-0.4 (± 0.8)	-0.2 (± 0.9)
week 12	4.0 (± 1.3)	4.1 (± 1.0)	3.8 (± 1.2)	4.0 (± 1.2)
week 12 - change from baseline	-0.1 (± 1.1)	-0.0 (± 0.8)	-0.4 (± 1.0)	-0.1 (± 0.9)

Statistical analyses

No statistical analyses for this end point

Secondary: PGA descriptive statistics - week 16 (FU)

End point title	PGA descriptive statistics - week 16 (FU)

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	38	44	40	122
Units: PGA				
arithmetic mean (standard deviation)				
week 16	3.8 (± 1.3)	3.9 (± 1.1)	3.8 (± 1.3)	3.8 (± 1.3)
week 16 - change from baseline	-0.2 (± 1.1)	-0.1 (± 0.7)	-0.4 (± 1.1)	-0.3 (± 1.0)

Statistical analyses

No statistical analyses for this end point

Secondary: PGA change from baseline - weeks 4, 8 and 12 (EoT)

End point title	PGA change from baseline - weeks 4, 8 and 12 (EoT)

End point description:

The PGA (Physician's global assessment) provides an overall evaluation of the severity of the disease. The 7-point's assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: PGA				
arithmetic mean (standard deviation)				
week 4	-0.1 (± 0.7)	-0.1 (± 0.6)	-0.3 (± 0.6)	-0.2 (± 0.6)
week 8	-0.1 (± 0.9)	-0.2 (± 0.8)	-0.4 (± 0.8)	-0.2 (± 0.9)
week 12	-0.1 (± 1.1)	-0.0 (± 0.8)	-0.4 (± 1.0)	-0.1 (± 0.9)

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - 4 weeks
Comparison groups	Placebo v MP1032 150mg
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.671
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0

Statistical analysis title	MP1032 150mg bid vs placebo - 8 weeks
Comparison groups	MP1032 150mg v Placebo

Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.542
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0

Statistical analysis title	MP1032 150mg bid vs placebo - EoT
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.992
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0

Statistical analysis title	MP1032 300mg bid vs placebo - 4 weeks
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.183
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Variability estimate	Standard error of the mean
Dispersion value	0

Statistical analysis title	MP1032 300mg bid vs placebo - 8 weeks
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.328
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0

Statistical analysis title	MP1032 300mg bid vs placebo - EoT
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.143
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0

Secondary: PGA change from baseline - week 16 (FU)

End point title	PGA change from baseline - week 16 (FU)

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	38	44	40	122
Units: PGA				
arithmetic mean (standard deviation)	-0.2 (± 1.1)	-0.1 (± 0.7)	-0.4 (± 1.1)	-0.3 (± 1.0)

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - FU
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.921
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0

Statistical analysis title	MP1032 300mg bid vs placebo - FU
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.488
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0

Secondary: PGA frequency Counts - day 1 (baseline)

End point title	PGA frequency Counts - day 1 (baseline)

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: patients				
0 - Clear	0	0	0	0
1 - Almost Clear	0	0	0	0
2 - Mild	1	0	0	1
3 - Mild to moderate	8	11	8	27
4 - Moderate	28	27	24	79
5 - Moderate to severe	13	15	14	42
6 - Severe	0	1	1	2

Statistical analyses

No statistical analyses for this end point

Secondary: PGA frequency counts - week 4

End point title	PGA frequency counts - week 4

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: patients				
0 - Clear	0	0	0	0
1 - Almost clear	0	0	0	0
2 - Mild	2	5	2	9
3 - Mild to moderate	15	10	13	38
4 - Moderate	19	20	21	60
5 - Moderate to severe	12	19	10	41
6 - Severe	2	0	1	3

Statistical analyses

No statistical analyses for this end point

Secondary: PGA frequency counts - week 12 (EoT)

End point title	PGA frequency counts - week 12 (EoT)

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	122
Units: patients				
0 - Clear	0	0	0	0
1 - Almost clear	1	0	1	2
2 - Mild	6	4	7	17
3 - Mild to moderate	10	11	9	30
4 - Moderate	15	18	15	48
5 - Moderate to severe	12	18	13	43
6 - Severe	6	3	2	11

Statistical analyses

No statistical analyses for this end point

Secondary: PGA frequency counts - week 16 (FU)

End point title	PGA frequency counts - week 16 (FU)

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	38	44	40	122
Units: patients				
0 - Clear	0	0	0	0
1 - Almost clear	2	1	3	6
2 - Mild	4	4	4	12
3 - Mild to moderate	10	10	8	28
4 - Moderate	9	14	11	34
5 - Moderate to severe	10	13	12	35
6 - Severe	3	2	2	7

Statistical analyses

No statistical analyses for this end point

Secondary: BSA descriptive statistics - day 1 (baseline) - week 12 (EoT)

End point title	BSA descriptive statistics - day 1 (baseline) - week 12 (EoT)

End point description:

The BSA (Body Surface Area) provides information on the total surface area of the body affected with psoriasis plaques in percent (%).

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: BSA (%)				
arithmetic mean (standard deviation)				
Day 1	19 (± 8.8)	17.5 (± 6.3)	19.2 (± 10.5)	18.5 (± 8.6)
week 4	19.7 (± 12.4)	17.1 (± 7.1)	18.3 (± 11.9)	18.3 (± 10.6)
week 4 - change from baseline	0.7 (± 8.3)	-0.4 (± 3.1)	-0.9 (± 6.3)	-0.2 (± 6.2)
week 8	20.4 (± 12.9)	16.6 (± 7.9)	18.6 (± 14.7)	18.5 (± 12.1)
week 8 - change from baseline	1.4 (± 9.5)	-0.9 (± 3.9)	-0.6 (± 9)	-0.1 (± 7.8)

week 12	20.2 (± 13)	17.3 (± 8.7)	19.7 (± 17.2)	19.0 (± 13.2)
week 12 - change from baseline	1.2 (± 9.4)	-0.2 (± 5.3)	0.5 (± 11.3)	0.5 (± 8.8)

Statistical analyses

No statistical analyses for this end point

Secondary: BSA descriptive statistics - week 16 (FU)

End point title	BSA descriptive statistics - week 16 (FU)

End point description:

The BSA (Body Surface Area) provides information on the total surface area of the body affected with psoriasis plaques in percent (%).

End point type	Secondary

End point timeframe:

Day1, Week 4, Week 8, Week 12 (EoT), Week 16 (Follow Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	38	44	40	122
Units: BSA (%)				
arithmetic mean (standard deviation)				
week 16	20.9 (± 15.5)	15.5 (± 6.4)	20.2 (± 19.8)	18.7 (± 14.8)
week 16 - change from baseline	0.6 (± 12.8)	-1.1 (± 4.1)	0.4 (± 13.4)	-0.1 (± 10.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to PASI 75 - weeks 4, 8, 12 (EoT) and 16 (FU)

End point title	Time to PASI 75 - weeks 4, 8, 12 (EoT) and 16 (FU)

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician’s assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

The number of responders corresponds to the number of patients that reached an improvement of at least 75% in the PASI score in the respective week.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: patients				
week 4	0	2	1	3
week 8	2	0	0	2
week 12 (EoT)	3	1	3	7
week 16 (FU)	0	1	2	3

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	= 0.572
Method	Logrank

Notes:

[2] - Kaplan-Meier estimate of the median time (day) to reach the PASI 75 criterion was not computed since data were too sparse.

Statistical analysis title	MP1032 300mg bid vs placebo
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	= 0.4494
Method	Logrank

Notes:

[3] - Kaplan-Meier estimate of the median time (day) to reach the PASI 75 criterion was not computed since data were too sparse.

Secondary: Time to PASI 50 - weeks 4, 8, 12 (EoT) and 16 (FU)

End point title	Time to PASI 50 - weeks 4, 8, 12 (EoT) and 16 (FU)

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician’s assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

The number of responders corresponds to the number of patients that reached an improvement of at least 50% in the PASI score in the respective week.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: patients				
week 4	2	5	7	14
week 8	4	2	3	9
week 12 (EOT)	4	2	3	9
week 16 (FU)	1	2	3	6

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7922
Method	Logrank

Statistical analysis title	MP1032 300mg bid vs placebo
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1425
Method	Logrank

Secondary: PASI descriptive statistics - day 1 (baseline) - week 12 (EoT)

End point title	PASI descriptive statistics - day 1 (baseline) - week 12 (EoT)

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician's assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: PASI				
arithmetic mean (standard deviation)				
Day 1	14.7 (± 2.8)	13.8 (± 2.5)	14.2 (± 2.7)	14.2 (± 2.7)
week 4	14.5 (± 7.1)	13.1 (± 4.6)	12.4 (± 5.5)	13.3 (± 5.8)
week 4 - change from baseline	-0.2 (± 6.3)	-0.7 (± 4.1)	-1.8 (± 4.2)	-0.8 (± 5.0)
week 8	15.1 (± 8.1)	12.8 (± 5.4)	12.3 (± 7.8)	13.4 (± 7.2)
week 8 - change from baseline	0.4 (± 7.4)	-1 (± 4.9)	-1.9 (± 6.4)	-0.8 (± 6.3)
week 12	15 (± 9.1)	13.5 (± 6)	13 (± 9)	13.8 (± 8.1)
week 12 - change from baseline	0.3 (± 8.4)	-0.3 (± 5.5)	-1.2 (± 7.6)	-0.4 (± 7.2)

Statistical analyses

No statistical analyses for this end point

Secondary: PASI descriptive statistics - week 16 (FU)

End point title	PASI descriptive statistics - week 16 (FU)

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician’s assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	38	44	40	122
Units: PASI				
arithmetic mean (standard deviation)				
week 16	15.1 (± 9.3)	12.3 (± 5.1)	13.6 (± 11)	13.6 (± 8.7)
week 16 - change from baseline	0.3 (± 9)	-1.2 (± 4.7)	-0.7 (± 9.6)	-0.6 (± 7.9)

Statistical analyses

No statistical analyses for this end point

Secondary: PASI 75 responders - week 12 (EoT)

End point title	PASI 75 responders - week 12 (EoT)

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician's assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

The number of responders corresponds to the number of patients with an improvement of at least 75% in the PASI score compared to baseline.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	VCS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	32	34	36	102
Units: patients	3	1	3	7

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - EoT
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.294
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	25.39

Statistical analysis title	MP1032 300mg bid vs placebo - EoT
Comparison groups	Placebo v MP1032 300mg

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.291
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	4.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.31
upper limit	53.14

Secondary: PGA improvement - week 12 (EoT)

End point title	PGA improvement - week 12 (EoT)

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

The number of responders corresponds to the number of patients with an improvement of 1 or more points on the 7-points PGA scale compared to baseline.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	VCS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	32	34	36	102
Units: patients	9	8	13	30

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - EoT
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.617
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.31

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	3.77

Statistical analysis title	MP1032 300mg bid vs placebo - EoT
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.319
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	5

Secondary: Pharmacokinetics – Day 1: Cmax

End point title	Pharmacokinetics – Day 1: Cmax[4]

End point description:

Non-compartment parameters:
- Cmax is the maximum MP1032 concentration observed.
- tmax is the time point (effective) at which the maximum concentration (Cmax) was observed.
- AUC(0,t) is the area under the concentration-time curve up to the last quantifiable sample drawn.

End point type	Secondary

End point timeframe:

Plasma samples were taken predose, and 15 minutes, 30 minutes, 1 hour, and 2 hours after the first dose.

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Placebo patients are not part of the PK analysis. However, respective plasma sampling has been performed in placebo patients as the study was blinded.

End point values	MP1032 150mg	MP1032 300mg	PKS	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	6	8	14	
Units: ng/mL				
arithmetic mean (standard deviation)	388 (± 146.3)	612.4 (± 467.3)	516.2 (± 373.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics – Day 1: Tmax

End point title	Pharmacokinetics – Day 1: Tmax[5]

End point description:

Non-compartment parameters:
- Cmax is the maximum MP1032 concentration observed.
- tmax is the time point (effective) at which the maximum concentration (Cmax) was observed.
- AUC(0,t) is the area under the concentration-time curve up to the last quantifiable sample drawn.

End point type	Secondary

End point timeframe:

Plasma samples were taken predose, and 15 minutes, 30 minutes, 1 hour, and 2 hours after the first dose.

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Placebo patients are not part of the PK analysis. However, respective plasma sampling has been performed in placebo patients as the study was blinded.

End point values	MP1032 150mg	MP1032 300mg	PKS	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	6	8	14	
Units: min				
median (full range (min-max))	15 (13 to 30)	22.5 (15 to 60)	15 (13 to 60)	

Statistical analyses

No statistical analyses for this end point

Secondary: Extent of exposure - dosed capsules

End point title	Extent of exposure - dosed capsules

End point description:

Total number of dosed capsules = 6 * # planned applications - # missed capsules + # overdose capsules.
Average number of capsules per application = # dosed capsules / # applications.
Average number of capsules per day = # dosed capsules / days of treatment.

End point type	Secondary

End point timeframe:

overal trial

End point values	MP1032 150mg	Placebo	MP1032 300mg	SES
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	51	55	47	153
Units: Capsules				
arithmetic mean (standard deviation)				
Total number of dosed capsules	821.9 (± 304.3)	872.2 (± 248.3)	920.6 (± 214.2)	870.3 (± 260.4)
Average number of capsules per application	6.00 (± 0.02)	6.00 (± 0)	6.00 (± 0.01)	6.00 (± 0.01)
Average number of capsules per day	11.48 (± 1.40)	11.79 (± 0.25)	11.85 (± 0.20)	11.71 (± 0.84)

End point values	SES			
Subject group type	Subject analysis set			
Number of subjects analysed	153			
Units: Capsules				
arithmetic mean (standard deviation)				
Total number of dosed capsules	870.3 (± 260.4)			
Average number of capsules per application	6.00 (± 0.01)			
Average number of capsules per day	11.71 (± 0.84)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sufficient extent of exposure

End point title	Sufficient extent of exposure

End point description:

Exposure was regarded as sufficient if the patient took at least 80% of planned applications wherein % Exposure was calculated as 100 * # dosed capsules / (84 * 2 * 6).

End point type	Secondary

End point timeframe:

overall trial

End point values	MP1032 150mg	Placebo	MP1032 300mg	SES
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	51	55	47	153
Units: patients				
Insufficient	16	15	8	39
Sufficient	35	40	39	114

Statistical analyses

No statistical analyses for this end point

Secondary: Extent of exposure - treatment duration

End point title	Extent of exposure - treatment duration

End point description:

Treatment duration = date of last dose - date of first dose + 1.

End point type	Secondary

End point timeframe:

overall trial

End point values	MP1032 150mg	Placebo	MP1032 300mg	SES
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	51	55	48	154
Units: days				
arithmetic mean (standard deviation)	70.7 (± 24.1)	73.9 (± 21.0)	76.1 (± 21.1)	73.6 (± 22.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Overview on AEs - Incidence of TEAEs

End point title	Overview on AEs - Incidence of TEAEs

End point description:

End point type	Secondary

End point timeframe:

Overall Trial - Explicit inquiry on Day1, Week 4, Week 8, Week 12 (EoT), Week 16 (Follow Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	SES
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	51	55	48	154
Units: patients				
All TEAEs	22	33	15	70
Serious TEAEs	0	3	0	3
TEAEs leading to study discontinuation	2	5	0	7

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - TEAEs
Comparison groups	Placebo v MP1032 150mg
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1193
Method	Fisher exact

Statistical analysis title	MP1032 300mg bid vs placebo - TEAEs
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0054
Method	Fisher exact

Statistical analysis title	MP1032 150mg bid vs placebo - serious TEAEs
Comparison groups	Placebo v MP1032 150mg
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2439
Method	Fisher exact

Statistical analysis title	MP1032 300mg bid vs placebo - serious TEAEs
Comparison groups	Placebo v MP1032 300mg

Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2461
Method	Fisher exact

Statistical analysis title	MP1032 300mg bid vs placebo - discontinued
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0593
Method	Fisher exact

Statistical analysis title	MP1032 150mg bid vs placebo - discontinued
Comparison groups	Placebo v MP1032 150mg
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4395
Method	Fisher exact

Secondary: TEAEs by SOCs

End point title	TEAEs by SOCs

End point description:

Only PTs occuring in ≥5% of the patients in total were considered for this overview.

End point type	Secondary

End point timeframe:

Overall Trial - Explicit inquiry on Day1, Week 4, Week 8, Week 12 (EoT), Week 16 (Follow Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	SES
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	51	55	48	154
Units: patients				
Infections and infestations	11	14	8	33
Skin and subcutaneous tissue disorders	3	10	4	17
Gastrointestinal disorders	5	7	2	14
Nervous system disorders	2	2	4	8

Statistical analyses

No statistical analyses for this end point

Secondary: Overview on AEs - incidence of TEAEs by intensity

End point title	Overview on AEs - incidence of TEAEs by intensity

End point description:

End point type	Secondary

End point timeframe:

Overall Trial - Explicit inquiry on Day1, Week 4, Week 8, Week 12 (EoT), Week 16 (Follow Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	SES
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	51	55	48	154
Units: patients				
Severe	2	4	0	6
Moderate	7	15	4	26
Mild	13	14	11	38

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0507
Method	Fisher exact

Statistical analysis title	MP1032 300mg bid vs placebo
Comparison groups	Placebo v MP1032 300mg

Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0005
Method	Fisher exact

Secondary: Overview on AEs - incidence of TEAEs by relation to the IMP

End point title	Overview on AEs - incidence of TEAEs by relation to the IMP

End point description:

End point type	Secondary

End point timeframe:

Overall Trial - Explicit inquiry on Day1, Week 4, Week 8, Week 12 (EoT), Week 16 (Follow Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	SES
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	51	55	48	154
Units: patients				
Certain	0	0	0	0
Probable	1	1	0	2
Possible	4	8	2	14
Unlikely	6	14	5	25
Not related	11	10	8	29

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0504
Method	Fisher exact

Statistical analysis title	MP1032 300mg bid vs placebo
Comparison groups	Placebo v MP1032 300mg

Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0013
Method	Fisher exact

Secondary: Overview on AEs - incidence of TEAEs by causality with the IMP

End point title	Overview on AEs - incidence of TEAEs by causality with the IMP

End point description:

End point type	Secondary

End point timeframe:

Overall Trial - Explicit inquiry on Day1, Week 4, Week 8, Week 12 (EoT), Week 16 (Follow Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	SES
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	51	55	48	154
Units: patients				
Related	5	9	2	16
Not related	17	24	13	54

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.098
Method	Fisher exact

Statistical analysis title	MP1032 300mg bid vs placebo
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0032
Method	Fisher exact

Secondary: PASI ANCOVA for change from baseline - weeks 4, 8 and 12 (EoT) - Score

End point title	PASI ANCOVA for change from baseline - weeks 4, 8 and 12 (EoT) - Score

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician's assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

Displayed are changes in the PASI score of the respective weeks compared to baseline in the different arms in patients of the FAS subject analysis set, wherein this subgroup analysis only considers patients with a PASI ≤ 15 at baseline.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	37	31	
Units: PASI				
arithmetic mean (standard error)				
week 4	-1.3 (± 0.7)	-0.8 (± 0.6)	-2.0 (± 0.7)	
week 8	-0.6 (± 0.9)	-1.3 (± 0.8)	-3.2 (± 0.9)	
week 12	-0.8 (± 0.9)	-0.6 (± 0.8)	-3.0 (± 0.9)	

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - 4 weeks
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.575
Method	ANCOVA
Parameter estimate	least square means
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	1.3
Variability estimate	Standard error of the mean
Dispersion value	0.9

Statistical analysis title	MP1032 150mg bid vs placebo - 8 weeks
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.574
Method	ANCOVA
Parameter estimate	least square means
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	2.9
Variability estimate	Standard error of the mean
Dispersion value	1.1

Statistical analysis title	MP1032 150mg bid vs placebo - EoT
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.858
Method	ANCOVA
Parameter estimate	least square means
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	2.2
Variability estimate	Standard error of the mean
Dispersion value	1.2

Statistical analysis title	MP1032 300mg bid vs placebo - 4 weeks
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.177
Method	ANCOVA
Parameter estimate	least square means
Point estimate	-1.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	0.6
Variability estimate	Standard error of the mean
Dispersion value	0.9

Statistical analysis title	MP1032 300mg bid vs placebo - 8 weeks
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.086
Method	ANCOVA
Parameter estimate	least square means
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	0.3
Variability estimate	Standard error of the mean
Dispersion value	1.1

Statistical analysis title	MP1032 300mg bid vs placebo - EoT
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.048
Method	ANCOVA
Parameter estimate	least square means
Point estimate	-2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.7
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	1.2

Secondary: PASI ANCOVA for change from baseline - week 16 (FU) - Score	
End point title	PASI ANCOVA for change from baseline - week 16 (FU) - Score

End point description:

The PASI (psoriasis area severity index) is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. It is a physician's assessment of psoriasis that is a therapeutic standard in clinical studies for this disease.

Displayed are changes in the PASI score of the respective weeks compared to baseline in the different arms in patients of the FAS subject analysis set, wherein this subgroup analysis only considers patients with a PASI ≤ 15 at baseline.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	23	32	25	
Units: PASI				
arithmetic mean (standard error)	1.1 (± 1.3)	-1.2 (± 1.1)	-2.9 (± 1.2)	

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - FU
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.183
Method	ANCOVA
Parameter estimate	least square means
Point estimate	2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	5.6
Variability estimate	Standard error of the mean
Dispersion value	1.7

Statistical analysis title	MP1032 300mg bid vs placebo - FU
Comparison groups	Placebo v MP1032 300mg

Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.297
Method	ANCOVA
Parameter estimate	least square means
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.9
upper limit	1.5
Variability estimate	Standard error of the mean
Dispersion value	1.6

Secondary: PGA change from baseline - weeks 4, 8 and 12 (EoT) - age

End point title	PGA change from baseline - weeks 4, 8 and 12 (EoT) - age

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

Subgroup-Analysis only considering patients older than 40 years at baseline.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	Age > 40 (FAS)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	25	28	26	79
Units: PGA				
arithmetic mean (standard deviation)				
week 4	0 (± 0.8)	0 (± 0.5)	-0.3 (± 0.6)	-0.1 (± 0.7)
week 8	0.1 (± 1.0)	0 (± 0.9)	-0.4 (± 0.9)	-0.1 (± 0.9)
week 12	0 (± 1.3)	0.2 (± 0.7)	-0.4 (± 1.0)	-0.1 (± 1.0)

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - 4 weeks
Comparison groups	MP1032 150mg v Placebo

Number of subjects included in analysis	53
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.549
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0

Statistical analysis title	MP1032 150mg bid vs placebo - 8 weeks
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	53
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.783
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0

Statistical analysis title	MP1032 150mg bid vs placebo - EoT
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	53
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.766
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	0

Variability estimate	Standard error of the mean
Dispersion value	0.26

Statistical analysis title	MP1032 300mg bid vs placebo - 4 weeks
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.049
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0

Statistical analysis title	MP1032 300mg bid vs placebo - 8 weeks
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.095
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0.26

Statistical analysis title	MP1032 300mg bid vs placebo - EoT
Comparison groups	Placebo v MP1032 300mg

Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.046
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0.26

Secondary: PGA change from baseline - week 16 (FU) - age

End point title	PGA change from baseline - week 16 (FU) - age

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

Subgroup-Analysis only considering patients older than 40 years at baseline.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	Age > 40 (FAS)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	18	23	23	64
Units: PGA				
arithmetic mean (standard deviation)	-0.3 (± 1.4)	0 (± 0.6)	-0.3 (± 1.1)	-0.2 (± 1.1)

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - FU
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	41
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.97
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	1
Variability estimate	Standard error of the mean
Dispersion value	0.51

Statistical analysis title	MP1032 300mg bid vs placebo - FU
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.52
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0.26

Secondary: PGA change from baseline - weeks 4, 8 and 12 (EoT) - BMI

End point title	PGA change from baseline - weeks 4, 8 and 12 (EoT) - BMI

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

Subgroup-Analysis only considering patients with a body mass index (BMI) of at least 30.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	BMI ≥ 30 (FAS)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	11	20	10	41
Units: PGA				
arithmetic mean (standard deviation)				
week 4	0.2 (± 1.1)	-0.1 (± 0.4)	-0.3 (± 0.5)	-0.1 (± 0.7)
week 8	0.5 (± 1.0)	-0.3 (± 0.6)	-0.6 (± 0.7)	-0.1 (± 0.8)

week 12	0.5 (± 1.3)	0 (± 0.7)	-0.6 (± 0.8)	0.0 (± 1.0)

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - 4 weeks
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.69
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0

Statistical analysis title	MP1032 150mg bid vs placebo - 8 weeks
Comparison groups	MP1032 150mg v Placebo
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.028
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	1
Variability estimate	Standard error of the mean
Dispersion value	0.26

Statistical analysis title	MP1032 150mg bid vs placebo - EoT
Comparison groups	MP1032 150mg v Placebo

Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.075
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	1
Variability estimate	Standard error of the mean
Dispersion value	0.26

Statistical analysis title	MP1032 300mg bid vs placebo - 4 weeks
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.402
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0

Statistical analysis title	MP1032 300mg bid vs placebo - 8 weeks
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.221
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	0

Variability estimate	Standard error of the mean
Dispersion value	0.26

Statistical analysis title	MP1032 300mg bid vs placebo - EoT
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.112
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0.26

Secondary: PGA change from baseline - week 16 (FU) - BMI	
End point title	PGA change from baseline - week 16 (FU) - BMI
End point description:	
The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease. Subgroup-Analysis only considering patients with a body mass index (BMI) of at least 30.	
End point type	Secondary
End point timeframe:	
Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)	

End point values	MP1032 150mg	Placebo	MP1032 300mg	BMI ≥ 30 (FAS)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	9	17	9	35
Units: PGA				
arithmetic mean (standard deviation)	0.1 (± 1.2)	-0.1 (± 0.9)	-0.4 (± 0.9)	-0.1 (± 1.0)

Statistical analyses

Statistical analysis title	MP1032 150mg bid vs placebo - FU
Comparison groups	Placebo v MP1032 150mg
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.427
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	1
Variability estimate	Standard error of the mean
Dispersion value	0.51

Statistical analysis title	MP1032 300mg bid vs placebo - FU
Comparison groups	Placebo v MP1032 300mg
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.457
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Hodges-Lehmann using location shift
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	0
Variability estimate	Standard error of the mean
Dispersion value	0.26

Secondary: Extent of exposure - applications	
End point title	Extent of exposure - applications
End point description:	
Total number of applications = # planned applications - # missed applications +# overdose applications.	
End point type	Secondary
End point timeframe:	
Day1, Week 4, Week 8, Week 12 (EoT), Week 16 (Follow Up)	

End point values	MP1032 150mg	Placebo	MP1032 300mg	SES
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	51	55	47	153
Units: Application				
arithmetic mean (standard deviation)	137.0 (± 50.7)	145.4 (± 41.4)	153.4 (± 35.7)	145.0 (± 43.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics – Day 1: AUC(0,t)

End point title	Pharmacokinetics – Day 1: AUC(0,t)[6]

End point description:

Non-compartment parameters:
- Cmax is the maximum MP1032 concentration observed.
- tmax is the time point (effective) at which the maximum concentration (Cmax) was observed.
- AUC(0,t) is the area under the concentration-time curve up to the last quantifiable sample drawn.

End point type	Secondary

End point timeframe:

Plasma samples were taken predose, and 15 minutes, 30 minutes, 1 hour, and 2 hours after the first dose.

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Placebo patients are not part of the PK analysis. However, respective plasma sampling has been performed in placebo patients as the study was blinded.

End point values	MP1032 150mg	MP1032 300mg	PKS	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	6	8	14	
Units: ng/mL*min				
arithmetic mean (standard deviation)	15585.3 (± 5757.4)	26543.8 (± 16592.3)	21847.3 (± 13880.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: PGA Frequency counts - week 8

End point title	PGA Frequency counts - week 8

End point description:

The PGA (Physician’s global assessment) provides an overall evaluation of the severity of the disease. The 7-point’s assessment of psoriasis is a therapeutic standard in clinical studies for this disease.

End point type	Secondary

End point timeframe:

Scoring took place on Site visits: Day1 (Baseline), Week 4, Week 8, Week 12 (End-of-Treatment), Week 16 (Follow-Up)

End point values	MP1032 150mg	Placebo	MP1032 300mg	FAS
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	50	54	47	151
Units: patients				
0 - Clear	0	0	0	0
1 - Almost clear	0	1	1	2
2 - Mild	5	6	5	16
3 - Mild to moderate	11	10	11	32
4 - Moderate	17	17	18	52
5 - Moderate to severe	14	19	9	42
6 - Severe	3	1	3	7

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From Screening to last follow up visit (week 16)	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.1
Reporting groups	
Reporting group title	MP1032 300mg
Reporting group description: -	
Reporting group title	MP1032 150mg
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	MP1032 300mg	MP1032 150mg	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	3 / 55 (5.45%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Biceps tendon rupture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Malum perforans			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exacerbation of psoriasis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	MP1032 300mg	MP1032 150mg	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 48 (31.25%)	22 / 51 (43.14%)	32 / 55 (58.18%)
Vascular disorders			
Hypertension worsened			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Blood pressure high			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Hypertension arterial			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	2 / 55 (3.64%)
occurrences (all)	0	0	2
Venous insufficiency			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Chest tightness			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Immune system disorders			
Drug allergy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			

Sniffles			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Sinus pain			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Sore throat			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	1	0	1
Investigations			
AST increased			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	1 / 55 (1.82%)
occurrences (all)	0	1	1
ALT increased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Radius fracture			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Postoperative pain			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Subcutaneous hematoma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	1 / 55 (1.82%)
occurrences (all)	0	1	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Headache			

subjects affected / exposed	2 / 48 (4.17%)	1 / 51 (1.96%)	1 / 55 (1.82%)
occurrences (all)	2	1	1
Migraine			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Sciatica			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
taste disorder			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Diabetic polyneuropathy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Tingling feet/hands			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	2 / 55 (3.64%)
occurrences (all)	0	0	2
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Redness of eyes			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Ocular congestion			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Eye redness			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Heartburn			

subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Lower abdominal pain			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Stomach pain			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 48 (0.00%)	2 / 51 (3.92%)	3 / 55 (5.45%)
occurrences (all)	0	2	3
Stools watery			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Feces soft			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	2 / 55 (3.64%)
occurrences (all)	0	0	2
Increased stool frequency			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Hypochondrium pain right			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Gastrointestinal discomfort			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Diarrhea			
subjects affected / exposed	1 / 48 (2.08%)	1 / 51 (1.96%)	1 / 55 (1.82%)
occurrences (all)	1	1	1
Stomach ache			

subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Exacerbation of psoriasis			
subjects affected / exposed	1 / 48 (2.08%)	3 / 51 (5.88%)	3 / 55 (5.45%)
occurrences (all)	1	3	3
Plaque psoriasis			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	1	0	1
Pruritus aggravated			
subjects affected / exposed	2 / 48 (4.17%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	2	0	1
Pustular psoriasis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Skin rash			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Diabetic foot			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Pain of skin			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Exanthematic drug eruption			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Psoriasis aggravated			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Psoriatic plaque			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Glycosuria			

subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Ketonuria			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Microscopic hematuria			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Renal calculus			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis aggravated			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Muscle tension			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Bone pain			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Low back pain			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Joint pain			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Infections and infestations			
Acute osteomyelitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Ascariasis			

subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Cold sores			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Common cold			
subjects affected / exposed	4 / 48 (8.33%)	4 / 51 (7.84%)	7 / 55 (12.73%)
occurrences (all)	4	4	7
Cystitis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Diverticulitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Facial abscess			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Folliculitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Herpes zoster			
subjects affected / exposed	1 / 48 (2.08%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	1	1	0
Infected skin atheroma			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Pyoderma			
subjects affected / exposed	1 / 48 (2.08%)	0 / 51 (0.00%)	2 / 55 (3.64%)
occurrences (all)	1	0	2
Quinsy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Tonsillitis			

subjects affected / exposed	0 / 48 (0.00%)	1 / 51 (1.96%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 48 (4.17%)	4 / 51 (7.84%)	2 / 55 (3.64%)
occurrences (all)	2	4	2
Urinary tract infection			
subjects affected / exposed	0 / 48 (0.00%)	2 / 51 (3.92%)	1 / 55 (1.82%)
occurrences (all)	0	2	1
Metabolism and nutrition disorders			
Hypertriglyceridemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 51 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 October 2018	There are 3 changes in the protocol amendment. 1. The name from the responsible person for SAE notifications was changed. 2. The address from the PK samples was changed. 3. The number of PK sites for Germany and Poland was changed

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported