Clinical trial results:
A double-blind, randomised, placebo-controlled clinical study to evaluate the efficacy and safety of N-Acetyl-GED-0507-34-LEVO gel, 1 and 2%, applied once daily for 12 weeks in patients with mild to moderate facial acne vulgaris

Summary

EudraCT number	2016-000540-33
Trial protocol	HU CZ SK
Global end of trial date	26 January 2017

Results information

Result version number	v1 (current)
This version publication date	10 June 2022
First version publication date	10 June 2022
Summary attachment (see zip file)	Clinical Summary Results (Clinical Summary Results_prtoGED0507ACNE0106.pdf)

Trial information

Trial identification

Sponsor protocol code	GED-0507-ACN-01-16

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	PPM SERVICES SA
Sponsor organisation address	Viale Serfontana 10, Morbio Inferiore,, Switzerland, 6834
Public contact	Angelo Vaccani, CROSS Reserach, +41 916300510, angelo.vaccani@croalliance.com
Scientific contact	Angelo Vaccani, CROSS Reserach, +41 916300510, angelo.vaccani@croalliance.com
Sponsor organisation name	PPM Services S.A.
Sponsor organisation address	Viale Serfontana 10, Morbio Inferiore, Switzerland, CH-6834
Public contact	Dr Salvatore Bellinvia (Sponsor medical officer), PPM Services S.A., 0041 916969710, sbellinvia@ppmservices.ch
Scientific contact	Dr Salvatore Bellinvia (Sponsor medical officer), PPM Services S.A., +41 91 69 61 712, sbellinvia@ppmservices.ch

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No	No

1901/2006 apply to this trial?	
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	26 January 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 January 2017
Global end of trial reached?	Yes
Global end of trial date	26 January 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of the study is to evaluate the efficacy and the local and systemic safety of 1% and 2% N-Acetyl-GED-0507-34-Levo gel, in comparison to the matching placebo gel, applied once daily for 12 weeks in patients with mild to moderate facial acne vulgaris

Protection of trial subjects:

Data verification was required and it was performed by direct comparison with source documents, always giving due consideration to data protection and medical confidentiality. In this respect the Investigator have assured support to the monitors at all times.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	01 July 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Slovakia: 49
Country: Number of subjects enrolled	Czech Republic: 49
Country: Number of subjects enrolled	Hungary: 49
Worldwide total number of subjects	147
EEA total number of subjects	147

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)	18
Adults (18-64 years)	129
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The recruitment took place in the following countries: Hungary, Czech Republic and Slovakia.
Date of first enrolment is 4th July 2016 (first randomized patient)
Date of last completed 26th January 2017 (last visit of the last patient)

Pre-assignment

Screening details:

N. 155 patients have been screened for the study and 147 patients receiving double-blind medication with a total of 6 screening failure patients

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	IMP 1%

Arm description:

N-ACETYL-GED-0507-34-LEVO GEL 1%

Arm type	Experimental
Investigational medicinal product name	N-ACETYL-GED-0507-34-LEVO GEL 1%
Investigational medicinal product code	N-ACETYL-GED-0507-34-LEVO GEL
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

1% daily dosage for 12 weeks

Arm title	IMP 2%

Arm description:

N-ACETYL-GED-0507-34-LEVO GEL 2%

Arm type	Experimental
Investigational medicinal product name	N-ACETYL-GED-0507-34-LEVO GEL 2%
Investigational medicinal product code	N-ACETYL-GED-0507-34-LEVO GEL
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

2% daily dosage for 12 weeks

Investigational medicinal product name	Placebo
Investigational medicinal product code	Placebo
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

PLACEBO daily for 12 weeks

Arm title	Placebo
Arm description: Placebo	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	Placebo
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:
placebo daily use for 12 weeks

Number of subjects in period 1	IMP 1%	IMP 2%	Placebo
Started	50	50	47
Completed	46	50	42
Not completed	4	0	5
Adverse event, non-fatal	-	-	1
Progressive Disease	-	-	1
Withdrawal by Parent/Guardian	2	-	-
Withdrawal by Subject	1	-	2
Lost to follow-up	-	-	1
Lack of efficacy	1	-	-

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	147	147	
Age categorical			
Age ranged from 14.0 to 30.0 years.			
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)	18	18	
Adults (18-64 years)	129	129	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
age ranged from 14.0 to 30.0 years.			
Units: years			
arithmetic mean	21.2		
standard deviation	± 3.65	-	
Gender categorical			
Units: Subjects			
Female	85	85	
Male	62	62	

End points

End points reporting groups

Reporting group title	IMP 1%
Reporting group description: N-ACETYL-GED-0507-34-LEVO GEL 1%	
Reporting group title	IMP 2%
Reporting group description: N-ACETYL-GED-0507-34-LEVO GEL 2%	
Reporting group title	Placebo
Reporting group description: Placebo	

Primary: Efficacy inflammatory lesions

End point title	Efficacy inflammatory lesions

End point description:

In the whole study period (follow-up included), for all the three analysis sets the inflammatory lesion number showed a decrease over time in the mean value. By considering Intention To Treat Set, after 12 weeks of treatment the percent changes from baseline were -45.2 for N-Acetyl-GED-0507-34-Levo 1% group, -57.2 for 2% and -28.7 for placebo. Results from pairwise two-sided multiple comparison analysis were statistically significant for N-Acetyl-GED-0507-34-Levo 2% vs placebo (p=0.0003) and N-Acetyl-GED-0507-34-Levo 1% vs placebo (p= 0.0329) but not for N-Acetyl-GED-0507-34-Levo 2% vs N-Acetyl-GED-0507-34-Levo 1% (p=0.1085). Similar patterns were observed both in the mITT set and in Sub-Group Analysis N1 Set.

End point type	Primary

End point timeframe:

12 weeks

End point values	IMP 1%	IMP 2%	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	50	47	
Units: -100-0				
number (not applicable)	-45.2	-57.2	-28.7	

Statistical analyses

Statistical analysis title	Statistical

Statistical analysis description:

The statistical analysis was performed using SAS® version 9.3 – SAS Institute Inc, Cary, NC, USA and carried out according to ICH guidelines ICH E9: "Statistical Principles for Clinical Trials" (CPMP/ICH/363/96 September 1998). All statistical tests were carried out at a significant level (alpha level) of 0.05, two tailed.

Comparison groups	IMP 1% v IMP 2% v Placebo

Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	< 0.05
Method	ANCOVA

Notes:

[1] - In addition to the descriptive analysis, an Ancova model, with baseline value as covariate and treatment as fixed factor was applied to test the null hypothesis H0: “The mean score on the changes from baseline are identical among treatment groups” (both for INF, non-INF, and TOT Les counts). Additional analysis with the ranked change (absolute or percent) in lesion count was performed with an ANCOVA model, by using ranked baseline count as covariate and treatment as factor.

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Overall	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20

Reporting groups	
Reporting group title	TEAEs

Reporting group description: -

Serious adverse events	TEAEs		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 147 (1.36%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Investigations			
Laboratory test abnormal			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pneumothorax spontaneous			
subjects affected / exposed	1 / 147 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	TEAEs		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	72 / 147 (48.98%)		
Nervous system disorders			
Headache			

subjects affected / exposed occurrences (all)	21 / 147 (14.29%) 21		
General disorders and administration site conditions APPLICATION SITE DRYNESS subjects affected / exposed occurrences (all) Application site exfoliation subjects affected / exposed occurrences (all) Application site erythema subjects affected / exposed occurrences (all)	 19 / 147 (12.93%) 19 11 / 147 (7.48%) 11 11 / 147 (7.48%) 11		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	 3 / 147 (2.04%) 3		
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	 4 / 147 (2.72%) 4		
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all)	 7 / 147 (4.76%) 7		
Infections and infestations Viral upper respiratory tract infection subjects affected / exposed occurrences (all) Influenza subjects affected / exposed occurrences (all)	 7 / 147 (4.76%) 7 3 / 147 (2.04%) 3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported