Clinical trial results:
Preliminary efficacy and safety of Apremilast in the treatment of acne conglobata: A phase II, single centre, open label, proof of concept study for the treatment of acne conglobata with the PDE-4 inhibitor Apremilast (APACCO-Study)

Summary

EudraCT number	2017-002612-14
Trial protocol	DE
Global end of trial date	17 February 2021

Results information

Result version number	v1 (current)
This version publication date	26 June 2022
First version publication date	26 June 2022

Trial information

Trial identification

Sponsor protocol code	TMP-0517

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04161456
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Fraunhofer Gesellschaft for its Institute Fraunhofer Institute for Molecular Biology and Applied Ecology (IME) - now ITMP
Sponsor organisation address	Theodor-Stern-Kai 7, Frankfurt, Germany, 60596
Public contact	Project Group TMP, Fraunhofer IME, Clinical Research, +49 630180208, clinical.research@ime.fraunhofer.de
Scientific contact	Project Group TMP, Fraunhofer IME, Clinical Research, +49 630180208, clinical.research@ime.fraunhofer.de

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	21 June 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 February 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study is to evaluate the proportion of subjects who achieve at least a 50% reduction in total number of inflammatory lesions at week 24

Protection of trial subjects:

Subjects were recruited based on inclusion and exclusion criteria, study visits were performed to ensure safety and well being and compliance of subjects

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 1
Worldwide total number of subjects	1
EEA total number of subjects	1

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)	1
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

16 patients planned, study start 22.08.2019 recruitment period planned for 6 months

Pre-assignment

Screening details:

Patient with acne conglobata were searched for inclusion. Intensive recruitment in known patient population, flyer and other advertisement still did not lead to enrolement.

Period 1

Period 1 title	treatment (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

design was a open-lable proof of concept study - no blinding was required

Arms

Arm title	treatment

Arm description:

apremilast was given with a starting titration and a maintenance dose of 30mg per day over a total period of 24 weeks

Arm type	Experimental
Investigational medicinal product name	Apremilast
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

30 mg twice daily, orally, with an initial titration schedule

Number of subjects in period 1	treatment
Started	1
Completed	0
Not completed	1
Lost to follow-up	1

Baseline characteristics

Reporting groups	
Reporting group title	treatment

Reporting group description: -

Reporting group values	treatment	Total	
Number of subjects	1	1	
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)	1	1	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	0	0	
Male	1	1	
Ethnicity			
Ethnicity of the one enroled subject is described			
Units: Subjects			
caucasian	1	1	
other	0	0	

End points

End points reporting groups

Reporting group title	treatment

Reporting group description:

apremilast was given with a starting titration and a maintenance dose of 30mg per day over a total period of 24 weeks

Primary: To evaluate the proportion of subjects who achieve at least a 50% reduction in total number of inflammatory lesions at week 24

End point title	To evaluate the proportion of subjects who achieve at least a 50% reduction in total number of inflammatory lesions at week 24[1]

End point description:

number of lesions at baseline were compared to number of lesions at week 24 after administration of IMP

End point type	Primary

End point timeframe:

baseline to week 24 after IMP administration

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: only on subject was enrolled and dropped out, so no statistical analysis was done and no value for primary endpoint can be provided.

End point values	treatment			
Subject group type	Reporting group			
Number of subjects analysed	1[2]			
Units: percentage				
percentage	0			

Notes:

[2] - only one subject was enrolled and has dropped out

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: baseline until end of study (28 weeks after start of treatment)	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	no coding
Dictionary version	na
Reporting groups	
Reporting group title	treatment
Reporting group description: adverse events are reported for the one included patient	

Serious adverse events	treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
Nervous system disorders			
headache			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
General disorders and administration site conditions			
belly ache			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
vermehrtes Durstgefühl			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			

schmerzende Haut subjects affected / exposed occurrences (all)	1 / 1 (100.00%) 1		

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

since only one of planned 16 patient could be enrolled no analysis of data was possible and non was done.

Notes: