Clinical trial results:
A Phase 4 Open-Label Study Evaluating the Absorption and Systemic Pharmacokinetics of Topically Applied IDP-110 Gel (ACANYA™ Gel) in Subjects with Acne Vulgaris

Summary

EudraCT number	2010-022678-15
Trial protocol	DE
Global end of trial date	02 October 2011

Results information

Result version number	v1 (current)
This version publication date	04 January 2020
First version publication date	04 January 2020

Trial information

Trial identification

Sponsor protocol code	DPSI IDP-110-P4 01

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Dow Pharmaceutical Sciences, Inc
Sponsor organisation address	1330 Redwood Way, Petaluma, United States, 94954-7121
Public contact	Clinical Trial Manager, Dow Pharmaceuticals, 707 793-2600,
Scientific contact	Clinical Trial Manager, Dow Pharmaceuticals, 707 793-2600,

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	02 October 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 October 2011
Global end of trial reached?	Yes
Global end of trial date	02 October 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety, systemic exposure and pharmacokinetics of clindamycin in IDP-110 Gel (clindamycin phosphate 1.2% and benzoyl peroxide 2.5%) in subjects with moderate or severe acne vulgaris during once daily topical application of IDP-110 Gel for 30 days.

Protection of trial subjects:

The clinical trial was performed in accordance with the currently valid declaration of Helsinki as well as German regulations. The ICH guideline for GCP (January 1997) was observed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 January 2011
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: 3
Country: Number of subjects enrolled	United States: 20
Worldwide total number of subjects	23
EEA total number of subjects	3

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)	23
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Ten to 11 male or female Caucasian and 5 to 6 male or female non-Caucasian subjects aged 18 years or older who met the inclusion criteria were to be enrolled in this study.

Period 1

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

Arms

Arm title	IDP-110 Gel

Arm description: -

Arm type	Experimental
Investigational medicinal product name	ACANYA® Gel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

applied once a day for 30 days

Number of subjects in period 1[1]	IDP-110 Gel
Started	16
Completed	16

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: There were 23 subjects enrolled and 16 subjects treated.

Baseline characteristics

Reporting groups	
Reporting group title	IDP-110 Gel

Reporting group description: -

Reporting group values	IDP-110 Gel	Total	
Number of subjects	16	16	
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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	25.4		
standard deviation	± 5.9	-	
Gender categorical Units: Subjects			
Female	12	12	
Male	4	4	
Clindamycin Concentration Units: Subjects			
Concentration lower than quantification	16	16	

End points

End points reporting groups

Reporting group title	IDP-110 Gel

Reporting group description: -

Primary: Maximum concentration at Day 30

End point title	Maximum concentration at Day 30[1]

End point description:

End point type	Primary

End point timeframe:

30 days

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: No formal statistical analyses were conducted for this study.

End point values	IDP-110 Gel			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: ng/dL				
arithmetic mean (standard deviation)	1.22 (± 0.879)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 30 days	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	14
Reporting groups	
Reporting group title	IDP-110 Gel

Reporting group description: -

Serious adverse events	IDP-110 Gel		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	IDP-110 Gel		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 16 (43.75%)		
Injury, poisoning and procedural complications			
Joint sprain			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 16 (12.50%)		
occurrences (all)	2		
General disorders and administration site conditions			
Application site dryness			
subjects affected / exposed	3 / 16 (18.75%)		
occurrences (all)	3		
Musculoskeletal and connective tissue			

disorders Pain in extremity subjects affected / exposed occurrences (all)	 1 / 16 (6.25%) 1		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	 2 / 16 (12.50%) 2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 December 2010	Required statement of the EC was included that ACANYA™ Gel had no marketing authorization in Germany. Furthermore, the name of the Chief Medical Officer had changed.
27 July 2011	To include the investigative site in the United States.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported