Clinical trial results:
An open-label study of the safety and tolerability of repeated administration of a 200-mcg Dose of IPP-201101 Plus Standard of Care in Patients With Systemic Lupus Erythematosus

Summary

EudraCT number	2017-004060-35
Trial protocol	HU
Global end of trial date	05 February 2019

Results information

Result version number	v1 (current)
This version publication date	15 August 2020
First version publication date	15 August 2020

Trial information

Trial identification

Sponsor protocol code	IPP-201101/006

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03427151
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Immupharma
Sponsor organisation address	5, rue du Rhône, Mulhouse, France, 68100
Public contact	Robert Zimmer , ImmuPharma, 00 618221650, robert.zimmer@immupharma.com
Scientific contact	Robert Zimmer , ImmuPharma, 00 618221650, robert.zimmer@immupharma.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	05 September 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 February 2019
Global end of trial reached?	Yes
Global end of trial date	05 February 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate the safety and tolerability of a 200-mcg dose every 4 weeks for 24 weeks of IPP-201101 in patients with systemic lupus erythematosus (SLE) who had participated in the main study IP-005.

Protection of trial subjects:

Pregnant and lactating womam was excluded. To prevent a risk of pregnancy, a test was done at each visit.
Patients in age were asked to use adequate contraception to prevent the risk of pregnancy.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 January 2018
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	Mauritius: 23
Country: Number of subjects enrolled	United States: 11
Country: Number of subjects enrolled	Czech Republic: 9
Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Hungary: 14
Worldwide total number of subjects	62
EEA total number of subjects	28

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)	61
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Among other inclusion criteria, main inclusion criteria was that patients were eligible if they have previously participated into the phase III IP-005 study.

Pre-assignment

Screening details:

inclusion criteria were similar to phase III IP-005 study as the study IP-006 is a long term follow up study.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

As it is an extension study from IP-005, it is an open label study

Arms

Arm title	IPP-201101

Arm description: -

Arm type	Experimental
Investigational medicinal product name	IPP-201101
Investigational medicinal product code	
Other name	Lupuzor
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

200 mcg in 1ml of reconstituted solution

Number of subjects in period 1	IPP-201101
Started	62
Completed	55
Not completed	7
Consent withdrawn by subject	4
Lack of efficacy	2
Protocol deviation	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	62	62	
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)	61	61	
From 65-84 years	1	1	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	46.50		
standard deviation	± 12.74	-	
Gender categorical Units: Subjects			
Female	58	58	
Male	4	4	

End points

End points reporting groups

Reporting group title	IPP-201101
Reporting group description: -	
Subject analysis set title	safety analysis set
Subject analysis set type	Full analysis
Subject analysis set description:	
The safety analysis set includes all patients who received one or more doses of IPP-201101 in the extension phase	
Subject analysis set title	Full analysis set
Subject analysis set type	Full analysis
Subject analysis set description:	
It includes all patients who received one or more doses of IPP-201101 in the extension phase.	

Primary: Safety

End point title	Safety[1]
End point description:	
The primary objective of this study extension is to evaluate the safety and tolerability of a 200-mcg dose every 4 weeks for 24 weeks of IPP-201101 in patients with systemic lupus erythematosus (SLE) who had participated in the main study IP-005	
End point type	Primary
End point timeframe:	
7 months	

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: It is a descriptive analysis

End point values	IPP-201101	safety analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	62	62		
Units: adverse event	55	55		

Statistical analyses

No statistical analyses for this end point

Secondary: the effect of IPP-201101 in the Clinical SLEDAI-2K total score

End point title	the effect of IPP-201101 in the Clinical SLEDAI-2K total score
End point description:	
The Clinical SLEDAI has been evaluated at Visit 1 and final Visit. The Clinical SLEDAI is calculated with the SLEDAI 2K score irrespective of anti-dsDNA and complement (C3, C4). The loss of 4 points was considered as a response.	
End point type	Secondary
End point timeframe:	
at week 28	

End point values	IPP-201101	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	62	62		
Units: patients				
number (not applicable)	22	22		

Statistical analyses

No statistical analyses for this end point

Secondary: remission of the disease

End point title	remission of the disease
End point description: Remission of the disease is defined as a reduction of Clinical SLEDAI 2K score to 0.	
End point type	Secondary
End point timeframe: at week 28	

End point values	IPP-201101	Full analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	62	62		
Units: patient				
number (not applicable)	20	20		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 7 months	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21

Reporting groups	
Reporting group title	Safety group

Reporting group description: -

Serious adverse events	Safety group		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 62 (3.23%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Gastrointestinal disorders			
Gastritis			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
SLE flare			
subjects affected / exposed	1 / 62 (1.61%)		
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	Safety group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	32 / 62 (51.61%)		
Investigations			
Urine protein/creatinine ratio increased			

subjects affected / exposed occurrences (all)	4 / 62 (6.45%) 4		
General disorders and administration site conditions Injection site pain subjects affected / exposed occurrences (all)	 6 / 62 (9.68%) 7		
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	 9 / 62 (14.52%) 16		
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	 5 / 62 (8.06%) 5		
Musculoskeletal and connective tissue disorders Systemic lupus erythematosus subjects affected / exposed occurrences (all)	 4 / 62 (6.45%) 4		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	 4 / 62 (6.45%) 6		

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