



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 woman 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