



Clinical trial results:

A Global, Phase III, Double Blind, Randomized Controlled Study to Compare the Efficacy, Safety & Immunogenicity of LUBT010 with Lucentis® in Patients with Neovascular Age-Related Macular Degeneration.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2017-004409-42 |
| Trial protocol | HU BG |
| Global end of trial date | 09 March 2024 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v1 (current) |
| This version publication date | 24 March 2025 |
| First version publication date | 24 March 2025 |

Trial information

Trial identification

| | |
|-----------------------|----------------------|
| Sponsor protocol code | LRP/LUBT010/2016/008 |
|-----------------------|----------------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Lupin Limited |
| Sponsor organisation address | Taluka-Mulshi, Pune, India, |
| Public contact | Clinical Research Unit, Lupin Limited, neelamkardekar@lupin.com |
| Scientific contact | Clinical Research Unit, Lupin Limited, neelamkardekar@lupin.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 | 12 August 2024 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 09 March 2024 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the equivalence in efficacy of LUBT010 to Lucentis® in terms of visual acuity, in patients with neovascular AMD.

Protection of trial subjects:

Subjects were monitored onsite prior to and following each injection (for at least 60 minutes) to permit any early treatment and appropriate management if needed. If patient experienced red eye, sensitivity to light, pain or developed a change in vision they were instructed to seek immediate care from the study doctor or an ophthalmologist. Other medications that were considered necessary for the subject's welfare and that were not expected to interfere with the evaluation of the study medication could be given at the discretion of the Investigator, with the exceptions: • Any systemic treatment or ocular treatment with an investigational agent • Systemic anti-VEGF therapy.

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------------|
| Actual start date of recruitment | 29 September 2020 |
| 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 | Poland: 162 |
| Country: Number of subjects enrolled | Slovakia: 45 |
| Country: Number of subjects enrolled | Bulgaria: 25 |
| Country: Number of subjects enrolled | Hungary: 9 |
| Country: Number of subjects enrolled | India: 305 |
| Country: Number of subjects enrolled | Russian Federation: 19 |
| Country: Number of subjects enrolled | United States: 35 |
| Worldwide total number of subjects | 600 |
| EEA total number of subjects | 241 |

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) | 89 |
| From 65 to 84 years | 464 |
| 85 years and over | 47 |

Subject disposition

Recruitment

Recruitment details:

This study was conducted at a total of 78 study centers in 7 countries (Bulgaria, Hungary, India, Poland, the Russian Federation, Slovakia, and the United States of America).

Pre-assignment

Screening details:

Participants who meet the eligibility criteria were randomly assigned to one of the two treatments of this study.

Period 1

| | |
|------------------------------|--|
| Period 1 title | Overall Trial (complete study duration) (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Data analyst |

Blinding implementation details:

Double Blind

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|---------|
| Arm title | LUBT010 |
|------------------|---------|

Arm description:

LUBT010 (proposed ranibizumab biosimilar) Intravitreal injection of 0.05 mL (0.5mg).

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | LUBT010 (proposed ranibizumab biosimilar) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in vial |
| Routes of administration | Intravitreal use |

Dosage and administration details:

0.5 mg administered as intravitreal injection once every month.

| | |
|------------------|----------|
| Arm title | Lucentis |
|------------------|----------|

Arm description:

Lucentis Intravitreal injection of 0.05 mL (0.5mg)

| | |
|--|--------------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Lucentis |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in vial |
| Routes of administration | Intravitreal use |

Dosage and administration details:

0.5 mg administered as intravitreal injection once every month

| Number of subjects in period 1 | LUBT010 | Lucentis |
|---------------------------------------|---------|----------|
| Started | 299 | 301 |
| Completed | 256 | 269 |
| Not completed | 43 | 32 |
| Adverse event, serious fatal | 3 | 4 |
| Physician decision | 2 | - |
| Consent withdrawn by subject | 25 | 17 |
| Adverse event, non-fatal | 6 | 4 |
| Other | 3 | 1 |
| Lost to follow-up | 3 | 2 |
| Protocol deviation | 1 | 4 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|---------|
| Reporting group title | LUBT010 |
|-----------------------|---------|

Reporting group description:

LUBT010 (proposed ranibizumab biosimilar) Intravitreal injection of 0.05 mL (0.5mg).

| | |
|-----------------------|----------|
| Reporting group title | Lucentis |
|-----------------------|----------|

Reporting group description:

Lucentis Intravitreal injection of 0.05 mL (0.5mg)

| Reporting group values | LUBT010 | Lucentis | Total |
|---|---------|----------|-------|
| Number of subjects | 299 | 301 | 600 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 51 | 38 | 89 |
| From 65-84 years | 226 | 238 | 464 |
| 85 years and over | 22 | 25 | 47 |
| Age continuous Units: years | | | |
| arithmetic mean | 73.2 | 73.5 | |
| standard deviation | ± 8.75 | ± 7.9 | - |
| Gender categorical Units: Subjects | | | |
| Female | 151 | 146 | 297 |
| Male | 148 | 155 | 303 |

End points

End points reporting groups

| | |
|--|----------|
| Reporting group title | LUBT010 |
| Reporting group description: LUBT010 (proposed ranibizumab biosimilar) Intravitreal injection of 0.05 mL (0.5mg). | |
| Reporting group title | Lucentis |
| Reporting group description: Lucentis Intravitreal injection of 0.05 mL (0.5mg) | |

Primary: Mean change in best corrected visual acuity (BCVA) from baseline in the study eye at the end of 12 months, assessed with the ETDRS chart

| | |
|--|--|
| End point title | Mean change in best corrected visual acuity (BCVA) from baseline in the study eye at the end of 12 months, assessed with the ETDRS chart |
| End point description: The primary efficacy endpoint of change in BCVA from baseline in the study eye at the end of 12 months was analyzed using analysis of covariance (ANCOVA). | |
| End point type | Primary |
| End point timeframe: from baseline to 12 months | |

| End point values | LUBT010 | Lucentis | | |
|------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 295 | 296 | | |
| Units: BCVA letter score (Letters) | | | | |
| median (full range (min-max)) | 11 (-36 to 52) | 11 (-22 to 45) | | |

Statistical analyses

| | |
|--|----------------------------|
| Statistical analysis title | ANCOVA model |
| Statistical analysis description: To prove the products to be biosimilar, CI (90% for United States, 95% for the rest of the world) for the difference in mean change in BCVA from baseline in the study eye at the end of 12 months, within prespecified equivalence margin. | |
| Comparison groups | LUBT010 v Lucentis |
| Number of subjects included in analysis | 591 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[1] |
| P-value | > 0.05 ^[2] |
| Method | ANCOVA |
| Parameter estimate | Least Square Mean |
| Point estimate | 0.03 |

| | |
|----------------------|----------------------------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.82 |
| upper limit | 1.88 |
| Variability estimate | Standard error of the mean |

Notes:

[1] - Equivalence was met.

[2] - There was no statistical significance between LUBT010 and Lucentis.

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

AEs occurring during the study from date of informed consent until end of study visit.

Adverse event reporting additional description:

AEs (ocular or non-ocular) were recorded.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

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|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 26.0 |
|--------------------|------|

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: Details of safety analysis and split of serious adverse events and non-serious adverse events to be provided.

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