



Clinical trial results:

Albiglutide Versus Placebo as Add-on to Intensified Basal-Bolus Insulin Therapy in Subjects With Type 2 Diabetes Mellitus

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2014-001969-27 |
| Trial protocol | HU DE GB |
| Global end of trial date | 09 June 2017 |

Results information

| | |
|-----------------------------------|---|
| Result version number | v1 (current) |
| This version publication date | 30 December 2018 |
| First version publication date | 30 December 2018 |
| Summary attachment (see zip file) | Cancelled before Active Statement (Cancelled before Active Statement GLP111892.doc) |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | GLP111892 |
|-----------------------|-----------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | GlaxoSmithKline |
| Sponsor organisation address | 980 Great West Road, Brentford, United Kingdom, Middlesex |
| Public contact | GSK Response Center, GlaxoSmithKline, 1 866-435-7343, |
| Scientific contact | GSK Response Center, GlaxoSmithKline, 1 866-435-7343, |

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 | 09 June 2017 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 09 June 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of once-weekly albiglutide in providing similar (or better) glycemic control with less hypoglycemia when added to a regimen of intensified basal-bolus insulin therapy compared with intensified basal-bolus insulin therapy alone in subjects with T2DM.

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 09 June 2017 |
| 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: 99999 |
| Worldwide total number of subjects | 99999 |
| EEA total number of subjects | 99999 |

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) | 99999 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial

Pre-assignment

Screening details:

NA

Period 1

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

Arms

| | |
|-----------|-------------|
| Arm title | Albiglutide |
|-----------|-------------|

Arm description:

Subjects would have received Albiglutide 30 mg (with forced uptitration to albiglutide 50 mg at Week 4).

| | |
|--|------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Albiglutide |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects were planned to receive once-weekly subcutaneous injections of albiglutide 30 mg (with forced uptitration to albiglutide 50 mg at Week 4) in addition to intensification of background basal-bolus insulin therapy (with or without metformin) according to predefined titration algorithms.

| Number of subjects in period 1 | Albiglutide |
|--------------------------------|-------------|
| Started | 99999 |
| Completed | 99999 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|---------------|
| Reporting group title | Overall Study |
|-----------------------|---------------|

Reporting group description: -

| Reporting group values | Overall Study | Total | |
|---|---------------|-------|--|
| Number of subjects | 99999 | 99999 | |
| 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 | 0 | | |
| standard deviation | ± 0 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 99999 | 99999 | |
| Male | 0 | 0 | |

End points

End points reporting groups

| | |
|--|-------------|
| Reporting group title | Albiglutide |
| Reporting group description: | |
| Subjects would have received Albiglutide 30 mg (with forced uptitration to albiglutide 50 mg at Week 4). | |

Primary: 1.Percentage of subjects with severe or documented symptomatic hypoglycemia through Week 26

| | |
|-----------------|--|
| End point title | 1.Percentage of subjects with severe or documented symptomatic hypoglycemia through Week 26 ^[1] |
|-----------------|--|

End point description:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

99999

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 subjects were enrolled in the trial hence results are not available

| End point values | Albiglutide | | | |
|-----------------------------|----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 99999 ^[2] | | | |
| Units: Not available | 99999 | | | |

Notes:

[2] - 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

All adverse events occurring during the course of the clinical trial were to be collected.

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

Dictionary used

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

| | |
|--------------------|---|
| Dictionary version | 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: No subjects were enrolled in the trial hence results are not available

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