



## 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

|                  |             |
|------------------|-------------|
| <b>Arm title</b> | 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.

|                                       |             |
|---------------------------------------|-------------|
| <b>Number of subjects in period 1</b> | 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<br>(gestational age < 37 wks) |               | 0     |  |
| Newborns (0-27 days)                                  |               | 0     |  |
| Infants and toddlers (28 days-23<br>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 <sup>[1]</sup> |
|-----------------|--|

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 <sup>[2]</sup> |  |  |  |
| 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

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

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

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

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### Dictionary used

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

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|                    |   |
|--------------------|---|
| Dictionary version | 0 |
|--------------------|---|

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

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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

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported