Protocol Registration Receipt
05/22/2014

Grantor: CDER IND/IDE Number: 65,177 Serial Number:

A Study to Determine the Efficacy and Safety of Albiglutide as Compared With Liraglutide.

This study has been completed.

Sponsor:	GlaxoSmithKline
Collaborators:	
Information provided by (Responsible Party):	GlaxoSmithKline
ClinicalTrials.gov Identifier:	NCT01128894

Purpose

This open-label study examines the efficacy and safety of albiglutide as compared with liraglutide in subjects with type 2 diabetes.

Condition	Intervention	Phase
Diabetes Mellitus	Biological/Vaccine: albiglutide Drug: liraglutide	Phase 3

Study Type: Interventional

Study Design: Treatment, Parallel Assignment, Open Label, Randomized, Safety/Efficacy Study

Official Title: A Randomized, Open-Label, Parallel-Group, Multicenter Study to Determine the Efficacy and Safety of Albiglutide as Compared With Liraglutide in Subjects With Type 2 Diabetes Mellitus

Further study details as provided by GlaxoSmithKline:

Primary Outcome Measure:

- Mean Change From Baseline in Glycosylated Hemoglobin (HbA1c) at Week 32 [Time Frame: Baseline and Week 32] [Designated as safety issue: No]
  HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. The Baseline HbA1c value is defined as the last non-missing value before the start of treatment. Change from Baseline in HbA1c was calculated as the value at Week 32 minus the value at Baseline. The analysis was performed using an Analysis of Covariance (ANCOVA) model with treatment group, region, history of prior myocardial infarction (yes versus no), and age category (<65 years versus ≥65 years) as factors and Baseline HbA1c as a continuous covariate. The last observation carried forward (LOCF) method was used to impute missing data, in which the last non-missing post-Baseline on-treatment measurement was used to impute the missing measurement. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing.

Secondary Outcome Measures:

- Mean Change From Baseline in HbA1c at Weeks 4, 6, 12, 18 and 26 [Time Frame: Baseline, Weeks 4, 6, 12, 18 and 26] [Designated as safety issue: No]
  HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. The Baseline HbA1c value is defined as the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. The LOCF method was used to impute missing data, in which the last non-missing post-Baseline on-treatment measurement was used to impute the missing measurement. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing. Participants were considered in the treatment week if they had received at least one dose in that treatment week.
- Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Week 32 [Time Frame: Baseline and Week 32] [Designated as safety issue: No]
  The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. The Baseline FPG value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline value minus the value at Baseline. The analysis was performed using an Analysis of Covariance (ANCOVA) model with treatment group, region, Baseline HbA1c category, history of prior myocardial infarction (yes versus no), and age category (<65 years versus ≥65 years) as factors and Baseline FPG as a continuous covariate. The LOCF method was used to impute missing data, in which the last non-missing post-Baseline on-treatment measurement was used to impute the missing measurement. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing. Participants were considered in the treatment week if they had received at least one dose in that treatment week.
- Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Weeks 1, 2, 3, 4, 6, 12, 18 and 26 [Time Frame: Baseline, Weeks 1, 2, 3, 4, 6, 12, 18 and 26] [Designated as safety issue: No]
  The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. The Baseline FPG value is the last non-missing

value before the start of treatment. Change from Baseline was calculated as the post-Baseline value minus the value at Baseline. The LOCF method was used to impute missing data, in which the last non-missing post-Baseline on-treatment measurement was used to impute the missing measurement. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing. Participants were considered in the treatment week if they had received at least one dose in that treatment week.

- Number of Participants Who Achieved HbA1c Response Level of <6.5% and <7.0% at Week 32 [Time Frame: Week 32] [Designated as safety issue: No]
  Number of participants who achieved HbA1c response levels of <6.5% and <7.0% at Week 32 were assessed. The last observation carried forward (LOCF) method was used to impute missing data, in which the last non-missing post-Baseline on-treatment measurement was used to impute the missing measurement. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing.
- Time to Hyperglycemia Rescue at Week 32 [Time Frame: Week 32] [Designated as safety issue: No]
  Participants who experienced persistent hyperglycemia (high blood glucose) could have qualified for hyperglycemia rescue. The conditions for hyperglycemia rescue were as follows: fasting plasma glucose (FPG) >=280 milligram/decilitre (mg/dL) >= Week 2 and < Week 4, FPG >=250 mg/dL >= Week 4 and <Week 12, HbA1c ≥8.5% and ≤0.5% reduction from Baseline- >= Week 12 and <Week 26, or HbA1c ≥8.5% >= Week 26. Time to hyperglycemia rescue is defined as the time between the date of the first dose of study medication and the date of hyperglycemia rescue plus one day, or the time between the date of the first dose of study medication and the date of the last visit during the active treatment period plus one day for participants not requiring rescue. This time was divided by 7 to express the result in weeks. All times extending beyond Week 32 relevant to hyperglycemia rescue were censored at Week 32.
- Mean Change From Baseline in Body Weight at Week 32 [Time Frame: Baseline and Week 32] [Designated as safety issue: No]
  The Baseline value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the value at Week 32 minus the value at Baseline. The analysis was performed using an Analysis of Covariance (ANCOVA) model with treatment group, region, Baseline HbA1c category, history of prior myocardial infarction (yes versus no), and age category (<65 years versus ≥65 years) as factors and Baseline weight as a continuous covariate. The LOCF method was used to impute missing data, in which the last non-missing post-Baseline on-treatment measurement was used to impute the missing measurement. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing. Weight values obtained after hyperglycemia rescue were treated as missing and replaced with pre-rescue values.

Enrollment: 841
Study Start Date: May 2010
Study Completion Date: September 2011
Primary Completion Date: September 2011

Arms	Assigned Interventions
Experimental: albiglutide weekly albiglutide subcutaneous injection	Biological/Vaccine: albiglutide albiglutide weekly subcutaneous injection

Arms	Assigned Interventions
Active Comparator: liraglutide liraglutide daily subcutaneous injection, starting at 0.6mg, then up-titrating to 1.2mg then 1.8mg in accordance with prescribing information.	Drug: liraglutide liraglutide daily subcutaneous injection, starting at 0.6mg, then up-titrating to 1.2mg then 1.8mg in accordance with prescribing information.

This randomized, open-label, multicenter, 2 parallel-group study evaluates the efficacy and safety of a weekly subcutaneously injected dose of albiglutide as compared with liraglutide. Subjects with a historical diagnosis of type 2 diabetes mellitus and whose glycemia is inadequately controlled on their current regimen of metformin, thiazolidinedione, sulfonylurea, or any combination of these oral antidiabetics will be recruited into the study.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both

Inclusion Criteria:

- Diagnosis of type 2 diabetes mellitus and experiencing inadequate glycemic control on their current regimen of metformin, TZD, SU, or any combination of these oral antidiabetic medications
- BMI >/=20kg/m2 and </=45 kg/m2
- Fasting C-peptide >/=0.8 ng/mL (>/=0.26 nmol/L)
- HbA1c between 7.0% and 10.0%, inclusive
- Female subjects of childbearing potential must be practicing adequate contraception.

Exclusion Criteria:

- History of cancer
- History of treated diabetic gastroparesis
- Current biliary disease or history of pancreatitis
- History of significant GI surgery
- Recent clinically significant cardiovascular and/or cerebrovascular disease
- Hypertension
- History of human immunodeficiency virus infection
- History of or current liver disease or acute symptomatic infection with hepatitis B or hepatitis C

- History of alcohol or substance abuse
- Female subject is pregnant, lactating, or <6 weeks postpartum
- Known allergy to any GLP 1 analogue, liraglutide, other study medications' excipients, excipients of albiglutide, or Baker's yeast
- History of type 1 diabetes mellitus
- Contraindications (as per the prescribing information) for the use of either background or potential randomized study medications (e.g., liraglutide)
- Receipt of any investigational drug or liraglutide within the 30 days or 5 half lives, whichever is longer, before Screening or a history of receipt of an investigational antidiabetic drug within the 3 months before randomization or receipt of albiglutide in previous studies
- History or family history of thyroid disease

Contacts and Locations

Locations

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Investigators

Study Director:	GSK Clinical Trials	GlaxoSmithKline

More Information

Responsible Party: GlaxoSmithKline
Study ID Numbers: 114179
Health Authority: United States: Food and Drug Administration

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Study Results

Participant Flow

Pre-Assignment Details

Eligible participants entered into 2 weeks of Prescreening and Screening; 4 weeks of Run-in/stabilization; a 32-week Treatment Period for evaluation of efficacy and safety and 8 weeks of post treatment Follow-up. A total of 1764 participants were screened, 841 were randomized and 812 received at least one dose of study treatment.

Reporting Groups

	Description
Albiglutide 50 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously (SC) from Baseline until Week 6 with up-titration to 50 mg weekly at Week 6.
Liraglutide 1.8 mg	Participants received liraglutide 0.6 mg once daily (OD) SC from Baseline until Week 1. From Week 1 to Week 2 the dose was increased to 1.2 mg. At Week 2, the dose was increased to 1.8 mg.

Overall Study

	Albiglutide 50 mg	Liraglutide 1.8 mg
Started	404	408
Completed	346	340
Not Completed	58	68
Adverse Event	31	41
Protocol Violation	2	1
Noncompliance	4	5
Lost to Follow-up	8	8
Withdrawal by Subject	10	12
Physician Decision	2	1
Conflicting HbA1c Results at Screening	1	0

Baseline Characteristics

Reporting Groups

	Description
Albiglutide 50 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously (SC) from Baseline until Week 6 with up-titration to 50 mg weekly at Week 6.
Liraglutide 1.8 mg	Participants received liraglutide 0.6 mg once daily (OD) SC from Baseline until Week 1. From Week 1 to Week 2 the dose was increased to 1.2 mg. At Week 2, the dose was increased to 1.8 mg.

Baseline Measures

	Albiglutide 50 mg	Liraglutide 1.8 mg	Total
Number of Participants	404	408	812
Age, Continuous [units: Years] Mean (Standard Deviation)	55.4 (10.11)	55.8 (9.95)	55.6 (10.03)
Gender, Male/Female [units: Participants]			
Female	213	190	403
Male	191	218	409
Race/Ethnicity, Customized [units: Participants]			
African American/African Heritage	47	29	76
American Indian or Alaskan Native	30	37	67
Asian - Central/South Asian Heritage	3	9	12
Asian - East Asian Heritage	26	18	44
Asian - Japanese Heritage	0	3	3
Asian - South East Asian Heritage	17	19	36
Native Hawaiian or Other Pacific Islander	0	2	2
White - Arabic/North African Heritage	5	6	11

	Albiglutide 50 mg	Liraglutide 1.8 mg	Total
White - White/Caucasian/European Heritage	276	285	561

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Mean Change From Baseline in Glycosylated Hemoglobin (HbA1c) at Week 32
Measure Description	HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. The Baseline HbA1c value is defined as the last non-missing value before the start of treatment. Change from Baseline in HbA1c was calculated as the value at Week 32 minus the value at Baseline. The analysis was performed using an Analysis of Covariance (ANCOVA) model with treatment group, region, history of prior myocardial infarction (yes versus no), and age category (<65 years versus ≥65 years) as factors and Baseline HbA1c as a continuous covariate. The last observation carried forward (LOCF) method was used to impute missing data, in which the last non-missing post-Baseline on-treatment measurement was used to impute the missing measurement. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing.
Time Frame	Baseline and Week 32
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population: all participants who received at least one dose of study medication and who had at least one post-Baseline assessment of the primary endpoint, HbA1c. Only those participants available at the indicated time point were assessed.

Reporting Groups

	Description
Albiglutide 50 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously (SC) from Baseline until Week 6 with up-titration to 50 mg weekly at Week 6.
Liraglutide 1.8 mg	Participants received liraglutide 0.6 mg once daily (OD) SC from Baseline until Week 1. From Week 1 to Week 2 the dose was increased to 1.2 mg. At Week 2, the dose was increased to 1.8 mg.

Measured Values

	Albiglutide 50 mg	Liraglutide 1.8 mg
Number of Participants Analyzed	398	402
Mean Change From Baseline in Glycosylated Hemoglobin (HbA1c) at Week 32 [units: Percentage of HbA1c in the blood] Least Squares Mean (Standard Error)	-0.78 (0.047)	-0.99 (0.046)

Statistical Analysis 1 for Mean Change From Baseline in Glycosylated Hemoglobin (HbA1c) at Week 32

Groups	Albiglutide 50 mg, Liraglutide 1.8 mg
Non-Inferiority/Equivalence Test	Yes
Method	ANCOVA
P-Value	0.0846
Mean Difference (Final Values)	0.21

95% Confidence Interval	0.08 to 0.34

Additional details about the analysis, such as null hypothesis and power calculation:

[Not specified.]

The p-value was from a 1-sided t test testing whether or not the difference of least square means (albiglutide – liraglutide) was less than or equal to the prespecified noninferiority margin of 0.3%.

Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

[Not specified.]

Other relevant information, such as adjustments or degrees of freedom:

[Not specified.]

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in HbA1c at Weeks 4, 6, 12, 18 and 26
Measure Description	HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. The Baseline HbA1c value is defined as the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. The LOCF method was used to impute missing data, in which the last non-missing post-Baseline on-treatment measurement was used to impute the missing measurement. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing. Participants were considered in the treatment week if they had received at least one dose in that treatment week.
Time Frame	Baseline, Weeks 4, 6, 12, 18 and 26
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the ITT Population.

Reporting Groups

	Description
Albiglutide 50 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously (SC) from Baseline until Week 6 with up-titration to 50 mg weekly at Week 6.
Liraglutide 1.8 mg	Participants received liraglutide 0.6 mg once daily (OD) SC from Baseline until Week 1. From Week 1 to Week 2 the dose was increased to 1.2 mg. At Week 2, the dose was increased to 1.8 mg.

Measured Values

	Albiglutide 50 mg	Liraglutide 1.8 mg
Number of Participants Analyzed	402	403
Mean Change From Baseline in HbA1c at Weeks 4, 6, 12, 18 and 26 [units: Percentage of HbA1c in the blood] Mean (Standard Deviation)		
Week 4, n=387, 392	-0.52 (0.481)	-0.73 (0.447)
Week 6, n=398, 401	-0.66 (0.566)	-0.94 (0.569)
Week 12, n=398, 402	-0.88 (0.824)	-1.18 (0.798)
Week 18, n=398, 402	-0.87 (0.921)	-1.13 (0.904)
Week 26, n=398, 402	-0.79 (0.968)	-1.00 (0.969)

3. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Week 32
Measure Description	The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. The Baseline FPG value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline value minus the value at Baseline. The analysis was performed using an Analysis of Covariance (ANCOVA) model with treatment group, region, Baseline HbA1c category, history of prior myocardial infarction (yes versus no), and age category (<65 years versus ≥65 years) as factors and Baseline FPG as a continuous covariate. The LOCF method was used to impute missing data, in which the last non-missing post-Baseline on-treatment measurement was used to impute the missing measurement. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing. Participants were considered in the treatment week if they had received at least one dose in that treatment week.
Time Frame	Baseline and Week 32
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the indicated time point were assessed.

Reporting Groups

	Description
Albiglutide 50 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously (SC) from Baseline until Week 6 with up-titration to 50 mg weekly at Week 6.
Liraglutide 1.8 mg	Participants received liraglutide 0.6 mg once daily (OD) SC from Baseline until Week 1. From Week 1 to Week 2 the dose was

	Description
	increased to 1.2 mg. At Week 2, the dose was increased to 1.8 mg.

Measured Values

	Albiglutide 50 mg	Liraglutide 1.8 mg
Number of Participants Analyzed	400	402
Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Week 32 [units: Millimoles per liter (mmol/L)] Least Squares Mean (Standard Error)	-1.22 (0.115)	-1.68 (0.115)

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Weeks 1, 2, 3, 4, 6, 12, 18 and 26
Measure Description	The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. The Baseline FPG value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline value minus the value at Baseline. The LOCF method was used to impute missing data, in which the last non-missing post-Baseline on-treatment measurement was used to impute the missing measurement. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing. Participants were considered in the treatment week if they had received at least one dose in that treatment week.
Time Frame	Baseline, Weeks 1, 2, 3, 4, 6, 12, 18 and 26
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the ITT Population.

Reporting Groups

	Description
Albiglutide 50 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously (SC) from Baseline until Week 6 with up-titration to 50 mg weekly at Week 6.
Liraglutide 1.8 mg	Participants received liraglutide 0.6 mg once daily (OD) SC from Baseline until Week 1. From Week 1 to Week 2 the dose was increased to 1.2 mg. At Week 2, the dose was increased to 1.8 mg.

Measured Values

	Albiglutide 50 mg	Liraglutide 1.8 mg
Number of Participants Analyzed	402	403
Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Weeks 1, 2, 3, 4, 6, 12, 18 and 26 [units: Millimoles per liter (mmol/L)] Mean (Standard Deviation)		
Week 1, n=386, 381	-0.98 (1.939)	-1.62 (2.116)
Week 2, n= 399, 398	-1.33 (2.194)	-2.25 (2.296)
Week 3, n= 400, 402	-1.61 (2.067)	-2.43 (2.470)
Week 4, n= 400, 402	-1.52 (2.148)	-2.45 (2.381)
Week 6, n= 400, 402	-1.25 (2.317)	-2.11 (2.451)
Week 12, n= 400, 402	-1.73 (2.526)	-2.10 (2.590)

	Albiglutide 50 mg	Liraglutide 1.8 mg
Week 18, n= 400, 402	-1.44 (2.362)	-1.74 (2.704)
Week 26, n= 400, 402	-1.14 (2.694)	-1.64 (2.717)

5. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved HbA1c Response Level of <6.5% and <7.0% at Week 32
Measure Description	Number of participants who achieved HbA1c response levels of <6.5% and <7.0% at Week 32 were assessed. The last observation carried forward (LOCF) method was used to impute missing data, in which the last non-missing post-Baseline on-treatment measurement was used to impute the missing measurement. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing.
Time Frame	Week 32
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the indicated time point were assessed.

Reporting Groups

	Description
Albiglutide 50 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously (SC) from Baseline until Week 6 with up-titration to 50 mg weekly at Week 6.
Liraglutide 1.8 mg	Participants received liraglutide 0.6 mg once daily (OD) SC from

	Description
	Baseline until Week 1. From Week 1 to Week 2 the dose was increased to 1.2 mg. At Week 2, the dose was increased to 1.8 mg.

Measured Values

	Albiglutide 50 mg	Liraglutide 1.8 mg
Number of Participants Analyzed	398	402
Number of Participants Who Achieved HbA1c Response Level of <6.5% and <7.0% at Week 32 [units: Participants]		
HbA1c <6.5%	78	113
HbA1c <7.0%	168	208

6. Secondary Outcome Measure:

Measure Title	Time to Hyperglycemia Rescue at Week 32
Measure Description	Participants who experienced persistent hyperglycemia (high blood glucose) could have qualified for hyperglycemia rescue. The conditions for hyperglycemia rescue were as follows: fasting plasma glucose (FPG) >=280 milligram/decilitre (mg/dL) >= Week 2 and < Week 4, FPG >=250 mg/dL >= Week 4 and <Week 12, HbA1c ≥8.5% and ≤0.5% reduction from Baseline- >= Week 12 and <Week 26, or HbA1c ≥8.5% >= Week 26. Time to hyperglycemia rescue is defined as the time between the date of the first dose of study medication and the date of hyperglycemia rescue plus one day, or the time between the date of the first dose of study medication and the date of the last visit during the active treatment period plus one day for participants not requiring rescue. This time was divided by 7 to express the result in

	weeks. All times extending beyond Week 32 relevant to hyperglycemia rescue were censored at Week 32.
Time Frame	Week 32
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Albiglutide 50 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously (SC) from Baseline until Week 6 with up-titration to 50 mg weekly at Week 6.
Liraglutide 1.8 mg	Participants received liraglutide 0.6 mg once daily (OD) SC from Baseline until Week 1. From Week 1 to Week 2 the dose was increased to 1.2 mg. At Week 2, the dose was increased to 1.8 mg.

Measured Values

	Albiglutide 50 mg	Liraglutide 1.8 mg
Number of Participants Analyzed	402	403
Time to Hyperglycemia Rescue at Week 32 [units: Weeks] Median (95% Confidence Interval)	NA (NA to NA) [1]	NA (NA to NA) [2]

[1] There were too few events of hyperglycemia rescue (<50% of participants with events) to calculate the median and confidence interval.

[2] There were too few events of hyperglycemia rescue (<50% of participants with events) to calculate the median and confidence

interval.

7. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Body Weight at Week 32
Measure Description	The Baseline value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the value at Week 32 minus the value at Baseline. The analysis was performed using an Analysis of Covariance (ANCOVA) model with treatment group, region, Baseline HbA1c category, history of prior myocardial infarction (yes versus no), and age category (<65 years versus ≥65 years) as factors and Baseline weight as a continuous covariate. The LOCF method was used to impute missing data, in which the last non-missing post-Baseline on-treatment measurement was used to impute the missing measurement. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing. Weight values obtained after hyperglycemia rescue were treated as missing and replaced with pre-rescue values.
Time Frame	Baseline and Week 32
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the indicated time point were assessed.

Reporting Groups

	Description
Albiglutide 50 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously (SC) from Baseline until Week 6 with up-titration to 50 mg weekly at Week 6.

	Description
Liraglutide 1.8 mg	Participants received liraglutide 0.6 mg once daily (OD) SC from Baseline until Week 1. From Week 1 to Week 2 the dose was increased to 1.2 mg. At Week 2, the dose was increased to 1.8 mg.

Measured Values

	Albiglutide 50 mg	Liraglutide 1.8 mg
Number of Participants Analyzed	400	402
Mean Change From Baseline in Body Weight at Week 32 [units: Kilograms] Mean (Standard Deviation)	-0.62 (3.118)	-2.21 (4.147)

Reported Adverse Events

Reporting Groups

	Description
Albiglutide 50 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously (SC) from Baseline until Week 6 with up-titration to 50 mg weekly at Week 6.
Liraglutide 1.8 mg	Participants received liraglutide 0.6 mg once daily (OD) SC from Baseline until Week 1. From Week 1 to Week 2 the dose was increased to 1.2 mg. At Week 2, the dose was increased to 1.8 mg.

Time Frame

On-treatment serious adverse events (SAEs) and non-serious adverse events (AEs), defined as those events occurring while

participants were on treatment up until 56 days after the last dose (up to Week 40), are reported.

Additional Description

SAEs and AEs were collected in members of the Safety Population, comprised of all participants randomized to treatment, who received at least one dose of the study medication.

Serious Adverse Events

	Albiglutide 50 mg	Liraglutide 1.8 mg
Total # participants affected/at risk	20/404 (4.95%)	23/408 (5.64%)
Cardiac disorders		
Acute myocardial infarction †[A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Arteriosclerosis coronary artery †[A]		
# participants affected/at risk	1/404 (0.25%)	0/408 (0%)
# events		
Atrial fibrillation †[A]		
# participants affected/at risk	2/404 (0.5%)	2/408 (0.49%)
# events		
Atrial flutter †[A]		

	Albiglutide 50 mg	Liraglutide 1.8 mg
# participants affected/at risk	1/404 (0.25%)	0/408 (0%)
# events		
Cardiac failure congestive † [A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Coronary artery disease † [A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Coronary artery occlusion † [A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Myocardial infarction † [A]		
# participants affected/at risk	1/404 (0.25%)	1/408 (0.25%)
# events		
Ear and labyrinth disorders		

	Albiglutide 50 mg	Liraglutide 1.8 mg
Vertigo †[A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Endocrine disorders		
Hyperthyroidism †[A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Eye disorders		
Retinal detachment †[A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Gastrointestinal disorders		
Colitis †[A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Pancreatitis †[A]		
# participants affected/at	0/404 (0%)	1/408 (0.25%)

	Albiglutide 50 mg	Liraglutide 1.8 mg
risk		
# events		
General disorders		
Chest pain †[A]		
# participants affected/at risk	1/404 (0.25%)	2/408 (0.49%)
# events		
Ileus †[A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Non-cardiac chest pain †[A]		
# participants affected/at risk	1/404 (0.25%)	1/408 (0.25%)
# events		
Pyrexia †[A]		
# participants affected/at risk	1/404 (0.25%)	0/408 (0%)
# events		
Sudden death †[A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)

	Albiglutide 50 mg	Liraglutide 1.8 mg
# events		
Hepatobiliary disorders		
Hepatitis † [A]		
# participants affected/at risk	1/404 (0.25%)	0/408 (0%)
# events		
Infections and infestations		
Cellulitis † [A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Encephalitis herpes † [A]		
# participants affected/at risk	1/404 (0.25%)	0/408 (0%)
# events		
Gastroenteritis † [A]		
# participants affected/at risk	2/404 (0.5%)	0/408 (0%)
# events		
Influenza † [A]		
# participants affected/at risk	1/404 (0.25%)	0/408 (0%)

	Albiglutide 50 mg	Liraglutide 1.8 mg
# events		
Osteomyelitis † [A]		
# participants affected/at risk	1/404 (0.25%)	0/408 (0%)
# events		
Pneumonia viral † [A]		
# participants affected/at risk	1/404 (0.25%)	0/408 (0%)
# events		
Tracheobronchitis † [A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Urinary tract infection † [A]		
# participants affected/at risk	1/404 (0.25%)	0/408 (0%)
# events		
Viral infection † [A]		
# participants affected/at risk	1/404 (0.25%)	0/408 (0%)
# events		
Injury, poisoning and procedural complications		

	Albiglutide 50 mg	Liraglutide 1.8 mg
Burns first degree †[A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Subdural haematoma †[A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Thoracic vertebral fracture †[A]		
# participants affected/at risk	1/404 (0.25%)	0/408 (0%)
# events		
Investigations		
Blood amylase increased †[A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Lipase increased †[A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		

	Albiglutide 50 mg	Liraglutide 1.8 mg
Musculoskeletal and connective tissue disorders		
Osteoarthritis † [A]		
# participants affected/at risk	1/404 (0.25%)	2/408 (0.49%)
# events		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Transitional cell carcinoma † [A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Nervous system disorders		
Cerebral infarction † [A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Convulsion † [A]		

	Albiglutide 50 mg	Liraglutide 1.8 mg
# participants affected/at risk	0/404 (0%)	2/408 (0.49%)
# events		
Ischaemic stroke † [A]		
# participants affected/at risk	1/404 (0.25%)	0/408 (0%)
# events		
Presyncope † [A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Transient ischaemic attack † [A]		
# participants affected/at risk	2/404 (0.5%)	0/408 (0%)
# events		
Psychiatric disorders		
Anxiety † [A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Renal and urinary disorders		

	Albiglutide 50 mg	Liraglutide 1.8 mg
Renal colic †[A]		
# participants affected/at risk	1/404 (0.25%)	0/408 (0%)
# events		
Renal failure acute †[A]		
# participants affected/at risk	1/404 (0.25%)	0/408 (0%)
# events		
Respiratory, thoracic and mediastinal disorders		
Asthma †[A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Pneumonia aspiration †[A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Pulmonary oedema †[A]		
# participants affected/at risk	0/404 (0%)	1/408 (0.25%)
# events		
Vascular disorders		

	Albiglutide 50 mg	Liraglutide 1.8 mg
Arteriosclerosis † [A]		
# participants affected/at risk	1/404 (0.25%)	1/408 (0.25%)
# events		

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 2%

	Albiglutide 50 mg	Liraglutide 1.8 mg
Total # participants affected/at risk	266/404 (65.84%)	289/408 (70.83%)
Blood and lymphatic system disorders		
Anaemia † [A]		
# participants affected/at risk	5/404 (1.24%)	10/408 (2.45%)
# events		
Gastrointestinal disorders		
Abdominal distension † [A]		
# participants affected/at risk	11/404 (2.72%)	8/408 (1.96%)
# events		

	Albiglutide 50 mg	Liraglutide 1.8 mg
Abdominal pain †[A]		
# participants affected/at risk	10/404 (2.48%)	11/408 (2.7%)
# events		
Abdominal pain upper †[A]		
# participants affected/at risk	11/404 (2.72%)	10/408 (2.45%)
# events		
Constipation †[A]		
# participants affected/at risk	17/404 (4.21%)	25/408 (6.13%)
# events		
Diarrhoea †[A]		
# participants affected/at risk	60/404 (14.85%)	55/408 (13.48%)
# events		
Dyspepsia †[A]		
# participants affected/at risk	17/404 (4.21%)	25/408 (6.13%)
# events		
Flatulence †[A]		
# participants affected/at risk	10/404 (2.48%)	9/408 (2.21%)

	Albiglutide 50 mg	Liraglutide 1.8 mg
# events		
Gastrooesophageal reflux disease † [A]		
# participants affected/at risk	9/404 (2.23%)	14/408 (3.43%)
# events		
Nausea † [A]		
# participants affected/at risk	40/404 (9.9%)	119/408 (29.17%)
# events		
Vomiting † [A]		
# participants affected/at risk	20/404 (4.95%)	38/408 (9.31%)
# events		
General disorders		
Fatigue † [A]		
# participants affected/at risk	13/404 (3.22%)	10/408 (2.45%)
# events		
Injection site haematoma † [A]		
# participants affected/at risk	7/404 (1.73%)	9/408 (2.21%)

	Albiglutide 50 mg	Liraglutide 1.8 mg
# events		
Injection site reaction † [A]		
# participants affected/at risk	28/404 (6.93%)	5/408 (1.23%)
# events		
Oedema peripheral † [A]		
# participants affected/at risk	4/404 (0.99%)	10/408 (2.45%)
# events		
Infections and infestations		
Bronchitis † [A]		
# participants affected/at risk	11/404 (2.72%)	9/408 (2.21%)
# events		
Gastroenteritis † [A]		
# participants affected/at risk	7/404 (1.73%)	11/408 (2.7%)
# events		
Influenza † [A]		
# participants affected/at risk	7/404 (1.73%)	13/408 (3.19%)
# events		

	Albiglutide 50 mg	Liraglutide 1.8 mg
Nasopharyngitis †[A]		
# participants affected/at risk	24/404 (5.94%)	28/408 (6.86%)
# events		
Sinusitis †[A]		
# participants affected/at risk	12/404 (2.97%)	7/408 (1.72%)
# events		
Upper respiratory tract infection †[A]		
# participants affected/at risk	42/404 (10.4%)	45/408 (11.03%)
# events		
Urinary tract infection †[A]		
# participants affected/at risk	25/404 (6.19%)	23/408 (5.64%)
# events		
Injury, poisoning and procedural complications		
Contusion †[A]		
# participants affected/at risk	5/404 (1.24%)	9/408 (2.21%)
# events		

	Albiglutide 50 mg	Liraglutide 1.8 mg
Investigations		
Lipase increased †[A]		
# participants affected/at risk	22/404 (5.45%)	28/408 (6.86%)
# events		
Metabolism and nutrition disorders		
Decreased appetite †[A]		
# participants affected/at risk	12/404 (2.97%)	28/408 (6.86%)
# events		
Hypoglycaemia †[A]		
# participants affected/at risk	66/404 (16.34%)	83/408 (20.34%)
# events		
Musculoskeletal and connective tissue disorders		
Arthralgia †[A]		
# participants affected/at risk	16/404 (3.96%)	12/408 (2.94%)
# events		
Back pain †[A]		

	Albiglutide 50 mg	Liraglutide 1.8 mg
# participants affected/at risk	15/404 (3.71%)	19/408 (4.66%)
# events		
Nervous system disorders		
Dizziness †[A]		
# participants affected/at risk	10/404 (2.48%)	21/408 (5.15%)
# events		
Headache †[A]		
# participants affected/at risk	22/404 (5.45%)	22/408 (5.39%)
# events		
Respiratory, thoracic and mediastinal disorders		
Cough †[A]		
# participants affected/at risk	10/404 (2.48%)	12/408 (2.94%)
# events		
Vascular disorders		
Hypertension †[A]		
# participants affected/at risk	13/404 (3.22%)	15/408 (3.68%)

	Albiglutide 50 mg	Liraglutide 1.8 mg
# events		

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Limitations and Caveats:

Results Point of Contact:

Name/Official Title: GSK Response Center
Organization: GlaxoSmithKline
Phone: 866-435-7343
Email: