Protocol Registration Receipt
07/24/2014

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

A Study of the Efficacy and Safety of Albiglutide in Subjects With Type 2 Diabetes With Renal Impairment.

This study has been completed.

Sponsor:	GlaxoSmithKline
Collaborators:	GlaxoSmithKline
Information provided by (Responsible Party):	GlaxoSmithKline
ClinicalTrials.gov Identifier:	NCT01098539

Purpose

This randomized, double-blind, active-controlled study evaluates the efficacy and safety of a weekly dose of albiglutide as compared with sitagliptin. Subjects who are renally impaired with a historical diagnosis of type 2 diabetes mellitus and whose glycemia is inadequately controlled on their current regimen of diet and exercise or their antidiabetic therapy of metformin, thiazolidinedione, sulfonylurea, or any combination of these oral antidiabetic medications will be recruited into the study.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Biological/Vaccine: albiglutide Drug: sitagliptin	Phase 3

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Safety/Efficacy Study
Official Title: A Randomized, Double-Blind, Active-Controlled, Parallel-Group, Multicenter Study to Determine the Efficacy and Safety of Albiglutide as Compared With Sitagliptin in Subjects With Type 2 Diabetes Mellitus With Renal Impairment

Further study details as provided by GlaxoSmithKline:

Primary Outcome Measure:

- Change From Baseline in Glycosylated Hemoglobin (HbA1c) at Week 26 [Time Frame: Baseline; Week 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 in HbA1c was calculated as the value at Week 26 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, 8, 12, 16, and 20: LOCF [Time Frame: Baseline; Weeks 4, 8, 12, 16, and 20] [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 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 analyzed in a particular treatment week if they had received at least one dose in that treatment week.
- Mean Change From Baseline in HbA1c at Weeks 4, 8, 12, 16, 20, 26, 36, 48, and Week 52: Observed Cases [Time Frame: Baseline; Weeks 4, 8, 12, 16, 20, 26, 36, 48, and 52] [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 post-Baseline value minus the Baseline value. The Observed Cases (OC) method (no imputation of missing data) was used. If a participant had missing

observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing. Participants were analyzed in a particular treatment week if they had received at least one dose in that treatment week.

- Change From Baseline in Fasting Plasma Glucose (FPG) at Week 26 [Time Frame: Baseline; Week 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 define as the last non-missing value before the start of treatment. Change from Baseline in FBG 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 analyzed in a particular treatment week if they had received at least one dose in that treatment week. Based on ANCOVA: Change = treatment + Baseline FPG + renal impairment + prior myocardial infarction history + age category + region.

- Mean Change From Baseline in FPG at Weeks 4, 8, 12, 16, 20, and 26: LOCF [Time Frame: Baseline; Weeks 4, 8, 12, 16, 20, 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 in FBG 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 analyzed in a particular 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, 8, 12, 16, 20, 26, 36, 48, and Week 52: OC [Time Frame: Baseline; Weeks 1, 2, 3, 4, 8, 12, 16, 20, 26, 36, 48, Week 52] [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 defined as the last non-missing value prior to treatment. Change from Baseline in FBG was calculated as the post-Baseline value minus the Baseline value. The OC method (no imputation of missing data) was used. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing. Participants were analyzed in a particular treatment week if they had received at least one dose in that treatment week.

- Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5% and <7.0% at Week 26: LOCF [Time Frame: Week 26] [Designated as safety issue: No]

  The number of participants who acheieved the HbA1c treatment goal (i.e., the number of participants who achieved HbA1c <7% and <6.5% at Week 26) was assessed. 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.

- Number of Participants Who Achieved a Clinically Meaningful Improvement in the HbA1c Response Level of >=1.0%, >=1.5%, and >=2.0% at Week 26: LOCF [Time Frame: Week 26] [Designated as safety issue: No]

  The number of participants who a clinically meaningful improvement from Baseline in the HbA1c response level of >=1.0%, >=1.5%, and >=2.0% at Week 26 were assessed. 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.

- Number of Participants Who Achieved a Clinically Meaningful HbA1c Response Level of <6.5% and <7.0% at Week 52: OC [Time Frame: Week 52] [Designated as safety issue: No]

  The number of participants who acheieved the HbA1c treatment goal (i.e., number of participants who achieved HbA1c <7% and <6.5% at Week 26) was assessed. The OC method (no imputation of missing data) was used. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing.
- Number of Participants Who Achieved a Clinically Meaningful Improvement in the HbA1c Response Level of >=1.0%, >=1.5%, and >=2.0% at Week 52: OC [Time Frame: Week 52] [Designated as safety issue: No]

  The number of participants who a clinically meaningful improvement from Baseline in the HbA1c response level of >=1.0%, >=1.5%, and >=2.0% at Week 52 assessed. The OC method (no imputation of missing data) was used. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing.
- Number of Participants With the Indicated Time to Hyperglycemic Rescue Through Week 52 [Time Frame: Week 2 to Week 52] [Designated as safety issue: No]

  Hyperglycemic rescue was defined as meeting one of the following criteria, confirmed by a second sample drawn within 7 days and analyzed by the central laboratory: for the Week 2 to Week 4 visit, a single FPG value >=280 milligrams per deciliter (mg/dL); for the >Week 4 and <Week 12 visits, a single FPG value >=250 mg/dL and previous titration for >=4 weeks; for the >=Week 12 and <Week 26 visits, HbA1c >=8.5% and a <=0.5% reduction from Baseline and previous titration for >=4 weeks; for the >=Week 26 and <Week 48 visits, HbA1c >=8.5% and previous titration for >=4 weeks; for the >=Week 48 and <Week 52 visits, HbA1c >=8.0% and previous titration for >=4 weeks. Time to hyperglycemia rescue is the time between the date of first dose and the date of hyperglycemia rescue plus 1 day, or the time between the date of first dose and the date of last visit during active treatment period plus 1 day for participants not requiring rescue.
- Time to Hyperglycemic Rescue Through Week 52 [Time Frame: Week 2 to Week 52] [Designated as safety issue: No]

  Hyperglycemic rescue was defined as meeting one of the following criteria, confirmed by a second sample drawn within 7 days and analyzed by the central laboratory: for the Week 2 to Week 4 visit, a single FPG value >=280 milligrams per deciliter (mg/dL); for the >Week 4 and <Week 12 visits, a single FPG value >=250 mg/dL and previous titration for >=4 weeks; for the >=Week 12 and <Week 26 visits, HbA1c >=8.5% and a <=0.5% reduction from Baseline and previous titration for >=4 weeks; for the >=Week 26 and <Week 48 visits, HbA1c >=8.5% and previous titration for >=4 weeks; for the >=Week 48 and <Week 52 visits, HbA1c >=8.0% and previous titration for >=4 weeks. Time to hyperglycemia rescue is the time between the date of first dose and the date of hyperglycemia rescue plus 1 day, or the time between the date of first dose and the date of last visit during active treatment period plus 1 day for participants not requiring rescue. This time is divided by 7 to express the result in weeks.
- Change From Baseline in Body Weight at Week 26: LOCF [Time Frame: Baseline; Week 26] [Designated as safety issue: No]

  Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight. The Baseline weight value is defined as the last non-missing value prior to treatment. This analysis used the LOCF method for missing post-Baseline weight values. Weight values obtained after hyperglycemia rescue werre treated as missing and were replaced with pre-rescue values. Based on ANCOVA: Change = treatment + Baseline weight + renal impairment + prior myocardial infarction history + age category + region.
- Change From Baseline in Body Weight Through Week 26: LOCF [Time Frame: Baseline; Week 1, Week 2 , Week 3, Week 4, Week 8, Week 12, Week 16, Week 20, and Week 26] [Designated as safety issue: No]

  Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight. The Baseline weight value is defined as the last

non-missing value prior to treatment. This analysis used the LOCF method for missing post-Baseline weight values. Weight values obtained after hyperglycemia rescue werre treated as missing and were replaced with pre-rescue values.

- Change From Baseline in Body Weight Through Week 52: OC [Time Frame: Baseline; Week 1, Week 2 , Week 3, Week 4, Week 8, Week 12, Week 16, Week 20, Week 26, Week 36, Week 48, and Week 52] [Designated as safety issue: No]

  Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight. The Baseline weight value is defined as the last non-missing value prior to treatment. This analysis used observed weight values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.

- Plasma Concentrations (Conc.) of Albiglutide at Week 8 and Week 16 [Time Frame: Week 8 Pre-dose (immediately prior to dose), Week 8 Post-dose (at least 2 days after a dose of medication), Week 16 Pre-dose (immediately prior to dose), and Week 16 Post-dose (at least 2 days after previous dose of albiglutide)] [Designated as safety issue: No]

  Sparse population pharmacokinetic (PK) data were collected for population PK and PK/pharmacodynamic (PD) analyses. Participants (par.) who received albiglutide were initiated on a 30 mg weekly dosing regimen. Beginning at Week 4, uptitration of albiglutide was allowed based on glycemic parameters. As such, albiglutide plasma conc. achieved at each sampling time represent a mixed population of par. who received either 30 mg or 50 mg weekly for various durations. The PK and PK/PD of albiglutide were characterized using a population modeling approach. Mean albiglutide plasma conc. observed at Weeks 8 and 16 are presented. Par. came to the clinic at Weeks 8 and 16 without taking albiglutide/matching placebo. The pre-dose PK sample was taken immediately prior to dosing. The Week 8 post-dose sample was taken between Weeks 8 and 10, >=2 days after a dose of medication. The Week 16 post-dose PK sample was taken any time between Weeks 16 and 20, >=2 days after the previous dose of albiglutide.

Enrollment: 507
Study Start Date: May 2010
Study Completion Date: May 2012
Primary Completion Date: May 2012

Arms	Assigned Interventions
Active Comparator: albiglutide albiglutide weekly subcutaneous injection + sitagliptin matching placebo	Biological/Vaccine: albiglutide albiglutide weekly subcutaneous injection + sitagliptin matching placebo
Active Comparator: sitagliptin albiglutide matching placebo + sitagliptin	Drug: sitagliptin albiglutide matching placebo + sitagliptin (25mg, 50mg or 100mg depending on level of renal impairment)

This randomized, double-blind, active-controlled, 2 parallel-group, multicenter study evaluates the efficacy and safety of a weekly subcutaneously injected dose

of albiglutide as compared with sitagliptin. Subjects who are renally impaired with a historical diagnosis of type 2 diabetes mellitus and whose glycemia is inadequately controlled on their current regimen of diet and exercise or their antidiabetic therapy of metformin, thiazolidinedione, sulfonylurea, or any combination of these oral antidiabetic medications will be recruited into the study.

Eligibility

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

Inclusion Criteria:

- Renally impaired with a historical diagnosis of type 2 diabetes mellitus and is experiencing inadequate glycemic control on their current regime of diet and exercise or their antidiabetic therapy of metformin, TZD, SU, or any combination of these oral antidiabetic medications
- BMI >/=20 kg/m2 and </=45 kg/m2
- Fasting C-peptide >/=0.8 ng/mL (>/=0.26 nmol/L)
- HbA1c between 7.0% and 10.0%, inclusive.

Exclusion Criteria:

- History of cancer
- History of treated diabetic gastroparesis
- Current biliary disease or history of pancreatitis
- History of significant gastrointestinal surgery
- Recent clinically significant cardiovascular and/or cerebrovascular disease
- History of human immunodeficiency virus infection
- Abnormal liver function or acute symptomatic infection with hepatitis B or hepatitis C
- Female subject is pregnant (confirmed by laboratory testing), lactating, or <6 weeks postpartum
- Known allergy to any GLP 1 analogue, sitagliptin, other study medications' excipients, excipients of albiglutide, or Baker's yeast
- Receipt of any investigational drug or sitagliptin 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

Contacts and Locations

Locations

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South Africa

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Somerset West, South Africa, 07129

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Tygerberg, South Africa, 7505

GSK Investigational Site

Port Elizabeth, Eastern Cape, South Africa, 6014

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Johannesburg, Gauteng, South Africa, 2193

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GSK Investigational Site
Plymouth, United Kingdom, PL6 8BX
GSK Investigational Site
Swansea, United Kingdom, SA6 6NL
GSK Investigational Site
Coventry, West Midlands, United Kingdom, CV2 2DX

Investigators

Study Director:	GSK Clinical Trials	GlaxoSmithKline

More Information

Responsible Party:	GlaxoSmithKline
Study ID Numbers:	114130
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 Pre-screening and Screening; 4 weeks of Run-in/stabilization; 52-week Treatment Period for evaluation of efficacy and safety and 8 weeks of post treatment Follow-up. A total of 771 participants were screened, 507 were randomized and 495 received at least one dose of study treatment.

Reporting Groups

	Description
Albiglutide 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Overall Study

	Albiglutide 30 mg	Sitagliptin 100 mg
Started	249	246
Completed	198	178
Not Completed	51	68
Adverse Event	26	26

	Albiglutide 30 mg	Sitagliptin 100 mg
Protocol Violation	1	4
Noncompliance	3	5
Lost to Follow-up	4	4
Withdrawal by Subject	12	26
Physician Decision	5	3

Baseline Characteristics

Reporting Groups

	Description
Albiglutide 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of

	Description
	the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Baseline Measures

	Albiglutide 30 mg	Sitagliptin 100 mg	Total
Number of Participants	249	246	495
Age, Continuous [units: Years] Mean (Standard Deviation)	63.2 (8.37)	63.5 (9.02)	63.3 (8.69)
Gender, Male/Female [units: Participants]			
Female	113	116	229
Male	136	130	266
Race/Ethnicity, Customized [units: Participants]			
African American/African Heritage	36	42	78
American Indian or Alaskan Native	16	16	32
Asian - Central/South Asian Heritage	45	33	78
Asian - East Asian Heritage	26	29	55
Asian - South East Asian Heritage	13	14	27

	Albiglutide 30 mg	Sitagliptin 100 mg	Total
Native Hawaiian or Other Pacific Islander	1	0	1
White - Arabic/North African Heritage	0	1	1
White - White/Caucasian/European Heritage	112	111	223

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline in Glycosylated Hemoglobin (HbA1c) at Week 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 in HbA1c was calculated as the value at Week 26 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; Week 26
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 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	242	236
Change From Baseline in Glycosylated Hemoglobin (HbA1c) at Week 26 [units: Percentage of HbA1c in the blood] Least Squares Mean (Standard Error)	-0.83 (0.062)	-0.52 (0.063)

Statistical Analysis 1 for Change From Baseline in Glycosylated Hemoglobin (HbA1c) at Week 26

Groups	Albiglutide 30 mg, Sitagliptin 100 mg
Non-Inferiority/Equivalence Test	Yes
Method	t-test, 1 sided
P-Value	<0.0001
Median Difference (Final Values)	-0.32
95% Confidence Interval	-0.49 to -0.15

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

[Not specified.]

The p-value was from a 1-sided t test to test whether the difference of LS means (albiglutide – sitagliptin) was less than or equal to the prespecified noninferiority margin of 0.4%.

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, 8, 12,

	16, and 20: LOCF
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 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 analyzed in a particular treatment week if they had received at least one dose in that treatment week.
Time Frame	Baseline; Weeks 4, 8, 12, 16, and 20
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 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration

	Description
	rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	246	240
Mean Change From Baseline in HbA1c at Weeks 4, 8, 12, 16, and 20: LOCF [units: Percentage of HbA1c in the blood] Mean (Standard Deviation)		
Week 4, n=237, 234	-0.43 (0.460)	-0.37 (0.512)
Week 8, n=242, 236	-0.60 (0.663)	-0.52 (0.785)
Week 12, n=242, 236	-0.69 (0.840)	-0.56 (0.989)
Week 16, n=242, 236	-0.75 (0.886)	-0.56 (1.103)
Week 20, n=242, 236	-0.79 (0.890)	-0.54 (1.083)

3. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in HbA1c at Weeks 4, 8, 12, 16, 20, 26, 36, 48, and Week 52: Observed Cases
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 post-Baseline value minus the Baseline value. The Observed Cases (OC) method (no imputation of missing data) was used. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing. Participants were analyzed in a particular treatment week if they had received at least one dose in that treatment week.
Time Frame	Baseline; Weeks 4, 8, 12, 16, 20, 26, 36, 48, and 52
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 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration

	Description
	rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	246	240
Mean Change From Baseline in HbA1c at Weeks 4, 8, 12, 16, 20, 26, 36, 48, and Week 52: Observed Cases [units: Percentage of HbA1c in the blood] Mean (Standard Deviation)		
Week 4, n=233, 228	-0.43 (0.463)	-0.37 (0.512)
Week 8, n=222, 213	-0.63 (0.677)	-0.56 (0.794)
Week 12, n=224, 216	-0.71 (0.832)	-0.62 (0.940)
Week 16, n=218, 209	-0.75 (0.885)	-0.63 (1.085)
Week 20, n=207, 196	-0.86 (0.852)	-0.71 (0.931)
Week 26, n=202, 178	-0.93 (0.806)	-0.80 (0.887)

	Albiglutide 30 mg	Sitagliptin 100 mg
Week 36, n=192, 155	-1.01 (0.808)	-0.82 (1.014)
Week 48, n=172, 139	-1.01 (0.884)	-0.89 (0.977)
Week 52, n=157, 118	-1.04 (0.796)	-1.03 (0.883)

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG) at Week 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 define as the last non-missing value before the start of treatment. Change from Baseline in FBG 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 analyzed in a particular treatment week if they had received at least one dose in that treatment week. Based on ANCOVA: Change = treatment + Baseline FPG + renal impairment + prior myocardial infarction history + age category + region.
Time Frame	Baseline; Week 26
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the specified time points were analyzed.

Reporting Groups

	Description
Albiglutide 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	244	240
Change From Baseline in Fasting Plasma Glucose (FPG) at Week 26 [units: Millimoles per liter (mmol/L)] Least Squares Mean (Standard Error)	-1.42 (0.183)	-0.22 (0.184)

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in FPG at Weeks 4, 8, 12, 16, 20, and 26: LOCF
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 in FBG 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 analyzed in a particular treatment week if they had received at least one dose in that treatment week.
Time Frame	Baseline; Weeks 4, 8, 12, 16, 20, 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 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and

	Description
	continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	246	240
Mean Change From Baseline in FPG at Weeks 4, 8, 12, 16, 20, and 26: LOCF [units: Millimoles per liter (mmol/L)] Mean (Standard Deviation)		
Week 4, n=244, 240	-1.47 (3.054)	-0.84 (2.670)
Week 8, n=244, 240	-1.19 (3.115)	-0.82 (3.169)
Week 12, n=244, 240	-1.35 (2.930)	-0.81 (3.214)
Week 16, n=244, 240	-1.34 (3.070)	-0.49 (3.440)
Week 20, n=244, 240	-1.37 (3.198)	-0.62 (3.257)

6. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Weeks 1, 2, 3, 4, 8, 12, 16, 20, 26, 36, 48, and Week 52: OC
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 defined as the last non-missing value prior to treatment. Change from Baseline in FBG was calculated as the post-Baseline value minus the Baseline value. The OC method (no imputation of missing data) was used. If a participant had missing observation(s) immediately after Baseline, the Baseline observation was not carried forward and was left as missing. Participants were analyzed in a particular treatment week if they had received at least one dose in that treatment week.
Time Frame	Baseline; Weeks 1, 2, 3, 4, 8, 12, 16, 20, 26, 36, 48, Week 52
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 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

	Description
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	246	240
Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Weeks 1, 2, 3, 4, 8, 12, 16, 20, 26, 36, 48, and Week 52: OC [units: Millimoles per liter (mmol/L)] Mean (Standard Deviation)		
Week 1, n=219, 217	-0.82 (2.572)	-0.93 (2.207)
Week 2, n=226, 223	-1.28 (2.569)	-0.66 (2.319)
Week 3, n=230, 219	-1.25 (3.168)	-0.88 (2.136)
Week 4, n=231, 226	-1.55 (2.859)	-0.76 (2.569)
Week 8, n=221, 210	-1.24 (2.896)	-0.74 (2.877)

	Albiglutide 30 mg	Sitagliptin 100 mg
Week 12, n=224, 216	-1.46 (2.623)	-0.88 (2.723)
Week 16, n=214, 204	-1.41 (2.796)	-0.55 (3.023)
Week 20, n=207, 191	-1.51 (2.859)	-1.00 (2.474)
Week 26, n=200, 177	-1.54 (2.507)	-0.58 (2.673)
Week 36, n=186, 149	-1.42 (2.788)	-0.92 (2.628)
Week 48, n=165, 140	-1.08 (2.720)	-0.58 (2.725)
Week 52, n=149, 114	-1.06 (2.850)	-0.96 (2.281)

7. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5% and <7.0% at Week 26: LOCF
Measure Description	The number of participants who acheieved the HbA1c treatment goal (i.e., the number of participants who achieved HbA1c <7% and <6.5% at Week 26) was assessed. 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.
Time Frame	Week 26
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Albiglutide 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	242	236
Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5% and <7.0% at Week 26: LOCF		

	Albiglutide 30 mg	Sitagliptin 100 mg
[units: Participants]		
HbA1c <6.5%	37	29
HbA1c <7.0%	103	72

8. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved a Clinically Meaningful Improvement in the HbA1c Response Level of >=1.0%, >=1.5%, and >=2.0% at Week 26: LOCF
Measure Description	The number of participants who a clinically meaningful improvement from Baseline in the HbA1c response level of >=1.0%, >=1.5%, and >=2.0% at Week 26 were assessed. 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.
Time Frame	Week 26
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Albiglutide 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration

	Description
	to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	242	236
Number of Participants Who Achieved a Clinically Meaningful Improvement in the HbA1c Response Level of >=1.0%, >=1.5%, and >=2.0% at Week 26: LOCF [units: Participants]		
HbA1c >=1.0%	102	77

	Albiglutide 30 mg	Sitagliptin 100 mg
HbA1c >=1.5%	49	38
HbA1c >=2.0%	26	17

9. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved a Clinically Meaningful HbA1c Response Level of <6.5% and <7.0% at Week 52: OC
Measure Description	The number of participants who acheieved the HbA1c treatment goal (i.e., number of participants who achieved HbA1c <7% and <6.5% at Week 26) was assessed. The OC method (no imputation of missing data) was used. 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 52
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Albiglutide 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching

	Description
	placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	157	118
Number of Participants Who Achieved a Clinically Meaningful HbA1c Response Level of <6.5% and <7.0% at Week 52: OC [units: Participants]		
HbA1c <6.5%	44	27
HbA1c <7.0%	98	61

10. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved a Clinically Meaningful Improvement in the HbA1c Response Level of >=1.0%, >=1.5%, and >=2.0% at Week 52: OC
Measure Description	The number of participants who a clinically meaningful improvement from Baseline in the HbA1c response level of >=1.0%, >=1.5%, and >=2.0% at Week 52 assessed. The OC method (no imputation of missing data) was used. 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 52
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Albiglutide 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week

	Description
	52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	157	118
Number of Participants Who Achieved a Clinically Meaningful Improvement in the HbA1c Response Level of >=1.0%, >=1.5%, and >=2.0% at Week 52: OC [units: Participants]		
HbA1c >=1.0%	79	65
HbA1c >=1.5%	43	30
HbA1c >=2.0%	20	15

11. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Time to Hyperglycemic Rescue Through Week 52
Measure Description	Hyperglycemic rescue was defined as meeting one of the following

	criteria, confirmed by a second sample drawn within 7 days and analyzed by the central laboratory: for the Week 2 to Week 4 visit, a single FPG value >=280 milligrams per deciliter (mg/dL); for the >Week 4 and <Week 12 visits, a single FPG value >=250 mg/dL and previous titration for >=4 weeks; for the >=Week 12 and <Week 26 visits, HbA1c >=8.5% and a <=0.5% reduction from Baseline and previous titration for >=4 weeks; for the >=Week 26 and <Week 48 visits, HbA1c >=8.5% and previous titration for >=4 weeks; for the >=Week 48 and <Week 52 visits, HbA1c >=8.0% and previous titration for >=4 weeks. Time to hyperglycemia rescue is the time between the date of first dose and the date of hyperglycemia rescue plus 1 day, or the time between the date of first dose and the date of last visit during active treatment period plus 1 day for participants not requiring rescue.
Time Frame	Week 2 to Week 52
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Albiglutide 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin

	Description
	100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	246	240
Number of Participants With the Indicated Time to Hyperglycemic Rescue Through Week 52 [units: Participants]		
Week 2	0	2
Week 4	0	2
Week 8	1	3
Week 12	2	5
Week 16	5	6
Week 20	9	14
Week 26	15	29
Week 36	25	47

	Albiglutide 30 mg	Sitagliptin 100 mg
Week 48	33	53
Week 52	44	68

12. Secondary Outcome Measure:

Measure Title	Time to Hyperglycemic Rescue Through Week 52
Measure Description	Hyperglycemic rescue was defined as meeting one of the following criteria, confirmed by a second sample drawn within 7 days and analyzed by the central laboratory: for the Week 2 to Week 4 visit, a single FPG value >=280 milligrams per deciliter (mg/dL); for the >Week 4 and <Week 12 visits, a single FPG value >=250 mg/dL and previous titration for >=4 weeks; for the >=Week 12 and <Week 26 visits, HbA1c >=8.5% and a <=0.5% reduction from Baseline and previous titration for >=4 weeks; for the >=Week 26 and <Week 48 visits, HbA1c >=8.5% and previous titration for >=4 weeks; for the >=Week 48 and <Week 52 visits, HbA1c >=8.0% and previous titration for >=4 weeks. Time to hyperglycemia rescue is the time between the date of first dose and the date of hyperglycemia rescue plus 1 day, or the time between the date of first dose and the date of last visit during active treatment period plus 1 day for participants not requiring rescue. This time is divided by 7 to express the result in weeks.
Time Frame	Week 2 to Week 52
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Albiglutide 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	246	240
Time to Hyperglycemic Rescue Through Week 52 [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.

13. Secondary Outcome Measure:

Measure Title	Change From Baseline in Body Weight at Week 26: LOCF
Measure Description	Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight. The Baseline weight value is defined as the last non-missing value prior to treatment. This analysis used the LOCF method for missing post-Baseline weight values. Weight values obtained after hyperglycemia rescue werre treated as missing and were replaced with pre-rescue values. Based on ANCOVA: Change = treatment + Baseline weight + renal impairment + prior myocardial infarction history + age category + region.
Time Frame	Baseline; Week 26
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the specified time points were analyzed.

Reporting Groups

	Description
Albiglutide 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and

	Description
	continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	244	240
Change From Baseline in Body Weight at Week 26: LOCF [units: Kilograms] Least Squares Mean (Standard Error)	-0.79 (0.192)	-0.19 (0.194)

14. Secondary Outcome Measure:

Measure Title	Change From Baseline in Body Weight Through Week 26: LOCF
Measure Description	Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight. The Baseline weight value is defined as the

	last non-missing value prior to treatment. This analysis used the LOCF method for missing post-Baseline weight values. Weight values obtained after hyperglycemia rescue werre treated as missing and were replaced with pre-rescue values.
Time Frame	Baseline; Week 1, Week 2 , Week 3, Week 4, Week 8, Week 12, Week 16, Week 20, and Week 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 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant’s severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of

	Description
	the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	246	240
Change From Baseline in Body Weight Through Week 26: LOCF [units: Kilograms] Mean (Standard Deviation)		
Week 1, n=225, 225	-0.17 (1.215)	0.12 (1.237)
Week 2, n=241, 238	-0.21 (1.317)	-0.02 (1.423)
Week 3, n=244, 240	-0.25 (1.392)	0.01 (1.530)
Week 4, n=244, 240	-0.33 (1.456)	0.09 (1.806)
Week 8, n=244, 240	-0.58 (1.768)	0.02 (1.952)
Week 12, n=244, 240	-0.47 (2.055)	0.03 (2.254)
Week 16, n=244, 240	-0.63 (2.197)	-0.08 (2.564)
Week 20, n=244, 240	-0.69 (2.556)	-0.07 (2.878)

15. Secondary Outcome Measure:

Measure Title	Change From Baseline in Body Weight Through Week 52: OC

Measure Description	Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight. The Baseline weight value is defined as the last non-missing value prior to treatment. This analysis used observed weight values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.
Time Frame	Baseline; Week 1, Week 2 , Week 3, Week 4, Week 8, Week 12, Week 16, Week 20, Week 26, Week 36, Week 48, and Week 52
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 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant’s severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected

	Description
	subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	246	240
Change From Baseline in Body Weight Through Week 52: OC [units: Kilograms] Mean (Standard Deviation)		
Week 1, n=225, 225	-0.17 (1.215)	0.12 (1.237)
Week 2, n=232, 227	-0.21 (1.339)	-0.01 (1.438)
Week 3, n=236, 224	-0.24 (1.404)	0.03 (1.544)
Week 4, n=235, 230	-0.31 (1.466)	0.10 (1.827)
Week 8, n=226, 214	-0.61 (1.800)	0.05 (2.012)
Week 12, n=228, 219	-0.45 (2.091)	0.16 (2.193)
Week 16, n=223, 210	-0.68 (2.226)	0.07 (2.589)
Week 20, n=211, 198	-0.76 (2.619)	0.09 (2.976)
Week 26, n=202, 178	-0.87 (2.856)	-0.04 (3.465)
Week 36, n=190, 155	-0.92 (3.551)	0.01 (2.975)
Week 48, n=172, 140	-0.93 (3.829)	0.07 (3.349)
Week 52, n=157, 119	-0.82 (3.931)	0.31 (3.685)

16. Secondary Outcome Measure:

Measure Title	Plasma Concentrations (Conc.) of Albiglutide at Week 8 and Week 16
Measure Description	Sparse population pharmacokinetic (PK) data were collected for population PK and PK/pharmacodynamic (PD) analyses. Participants (par.) who received albiglutide were initiated on a 30 mg weekly dosing regimen. Beginning at Week 4, uptitration of albiglutide was allowed based on glycemic parameters. As such, albiglutide plasma conc. achieved at each sampling time represent a mixed population of par. who received either 30 mg or 50 mg weekly for various durations. The PK and PK/PD of albiglutide were characterized using a population modeling approach. Mean albiglutide plasma conc. observed at Weeks 8 and 16 are presented. Par. came to the clinic at Weeks 8 and 16 without taking albiglutide/matching placebo. The pre-dose PK sample was taken immediately prior to dosing. The Week 8 post-dose sample was taken between Weeks 8 and 10, >=2 days after a dose of medication. The Week 16 post-dose PK sample was taken any time between Weeks 16 and 20, >=2 days after the previous dose of albiglutide.
Time Frame	Week 8 Pre-dose (immediately prior to dose), Week 8 Post-dose (at least 2 days after a dose of medication), Week 16 Pre-dose (immediately prior to dose), and Week 16 Post-dose (at least 2 days after previous dose of albiglutide)
Safety Issue?	No

Analysis Population Description

ITT population. Only participants with data available at the indicated time points were analyzed.

Reporting Groups

	Description
Albiglutide 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Measured Values

	Albiglutide 30 mg	Sitagliptin 100 mg
Number of Participants Analyzed	228	0
Plasma Concentrations (Conc.) of Albiglutide at Week 8 and Week 16 [units: nanograms per milliliter (ng/mL)] Mean (Standard Deviation)		
Week 8, Pre-dose, n=223	3005.80	

	Albiglutide 30 mg	Sitagliptin 100 mg
	(1788.544)	
Week 8, Post-dose, n=220	3452.62 (1912.329)	
Week 16, Pre-dose, n=215	2994.15 (1759.161)	
Week 16, Post-dose, n=205	3583.06 (2239.026)	

Reported Adverse Events

Reporting Groups

	Description
Albiglutide 30 mg	Participants received albiglutide 30 milligrams (mg) once weekly subcutaneously from Baseline until Week 52, with optional up-titration to 50 mg if additional glycemic control was required. Albiglutide was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants also received sitagliptin matching placebo once daily orally. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.
Sitagliptin 100 mg	Participants with normal renal function (estimated glomerular filtration rate [eGFR] >89 milliliters per minute [mL/min]) received a sitagliptin 100 mg overcoated tablet once daily orally from Baseline until Week 52. The dose of sitagliptin was adjusted in a range of 25-100 mg based on the participant's severity of renal impairment using the modification of diet in renal disease (MDRD) formula. Participants also received albiglutide matching placebo once weekly subcutaneously from

	Description
	Baseline until Week 52. Albiglutide matching placebo was injected subcutaneously into the abdomen, on alternating right and left sides of the body. Participants who qualified for hyperglycemia rescue, on or after Week 2, continued in the study after rescue and continued to receive study treatment until study completion.

Time Frame

Serious adverse events (SAEs) and non-serious AEs were collected from the time of study participation consent through Week 60, or the final follow-up visit for participants who discontinued active participation in the study (up to Study Week 60).

Additional Description

On-therapy SAEs and non-serious AEs (events with a start date on or after the first day of study medication [SM] and within 56 days after the end of SM) were collected in members of the Safety Population, comprised of all randomly assigned study participants who received at least one dose of SM.

Serious Adverse Events

	Albiglutide 30 mg	Sitagliptin 100 mg
Total # participants affected/at risk	30/249 (12.05%)	33/246 (13.41%)
Blood and lymphatic system disorders		
Coagulopathy †[A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Cardiac disorders		

	Albiglutide 30 mg	Sitagliptin 100 mg
Acute myocardial infarction † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Angina pectoris † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Angina unstable † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Atrial fibrillation † [A]		
# participants affected/at risk	4/249 (1.61%)	1/246 (0.41%)
# events		
Atrial flutter † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Cardiac disorder † [A]		
# participants affected/at	1/249 (0.4%)	0/246 (0%)

	Albiglutide 30 mg	Sitagliptin 100 mg
risk		
# events		
Cardiac failure congestive † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Coronary artery disease † [A]		
# participants affected/at risk	1/249 (0.4%)	1/246 (0.41%)
# events		
Coronary artery occlusion † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Myocardial infarction † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Supraventricular tachycardia † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)

	Albiglutide 30 mg	Sitagliptin 100 mg
# events		
Ventricular tachycardia † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Endocrine disorders		
Goitre † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Eye disorders		
Retinal detachment † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Vitreous haemorrhage † [A]		
# participants affected/at risk	0/249 (0%)	2/246 (0.81%)
# events		
Gastrointestinal disorders		
Gastric ulcer haemorrhage †		

	Albiglutide 30 mg	Sitagliptin 100 mg
[A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Pancreatic pseudocyst † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Pancreatitis † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Pancreatitis necrotising † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
General disorders		
Chest discomfort † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Multi-organ failure † [A]		

	Albiglutide 30 mg	Sitagliptin 100 mg
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Non-cardiac chest pain †[A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Oedema peripheral †[A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Pain †[A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Sudden cardiac death †[A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Hepatobiliary disorders		
Cholecystitis †[A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)

	Albiglutide 30 mg	Sitagliptin 100 mg
# events		
Infections and infestations		
Bronchitis † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Gastroenteritis † [A]		
# participants affected/at risk	0/249 (0%)	3/246 (1.22%)
# events		
Infected skin ulcer † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Pneumonia † [A]		
# participants affected/at risk	1/249 (0.4%)	2/246 (0.81%)
# events		
Pneumonia necrotising † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		

	Albiglutide 30 mg	Sitagliptin 100 mg
Pyelonephritis acute † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Pyelonephritis chronic † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Sepsis † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Septic shock † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Urinary tract infection † [A]		
# participants affected/at risk	2/249 (0.8%)	0/246 (0%)
# events		
Injury, poisoning and procedural complications		
Radius fracture † [A]		

	Albiglutide 30 mg	Sitagliptin 100 mg
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Sternal fracture †[A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Metabolism and nutrition disorders		
Hypoglycaemia †[A]		
# participants affected/at risk	1/249 (0.4%)	1/246 (0.41%)
# events		
Hypokalaemia †[A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Musculoskeletal and connective tissue disorders		
Intervertebral disc disorder †[A]		
# participants affected/at	1/249 (0.4%)	0/246 (0%)

	Albiglutide 30 mg	Sitagliptin 100 mg
risk		
# events		
Osteoarthritis † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Spinal ligament ossification † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Spinal osteoarthritis † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Benign pancreatic neoplasm † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)

	Albiglutide 30 mg	Sitagliptin 100 mg
# events		
Brain neoplasm † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Breast cancer † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Breast cancer metastatic † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Malignant melanoma † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Pleural mesothelioma † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Prostate cancer † [A]		
# participants affected/at	1/249 (0.4%)	0/246 (0%)

	Albiglutide 30 mg	Sitagliptin 100 mg
risk		
# events		
Rectosigmoid cancer metastatic † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Renal cell carcinoma † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Nervous system disorders		
Cerebrovascular accident † [A]		
# participants affected/at risk	2/249 (0.8%)	1/246 (0.41%)
# events		
Cerebrovascular disorder † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		

	Albiglutide 30 mg	Sitagliptin 100 mg
Hypoxic-ischaemic encephalopathy † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Ischaemic stroke † [A]		
# participants affected/at risk	0/249 (0%)	3/246 (1.22%)
# events		
Subarachnoid haemorrhage † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Viith nerve paralysis † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Psychiatric disorders		
Mental status changes † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		

	Albiglutide 30 mg	Sitagliptin 100 mg
Renal and urinary disorders		
Haematuria † [A]		
# participants affected/at risk	2/249 (0.8%)	0/246 (0%)
# events		
Renal failure † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Renal impairment † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Reproductive system and breast disorders		
Prostatomegaly † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Uterine polyp † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)

	Albiglutide 30 mg	Sitagliptin 100 mg
# events		
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary Disease † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Haemoptysis † [A]		
# participants affected/at risk	1/249 (0.4%)	0/246 (0%)
# events		
Pulmonary hypertension † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Vascular disorders		
Arterial thrombosis limb † [A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# events		
Deep vein thrombosis † [A]		
# participants affected/at	0/249 (0%)	1/246 (0.41%)

	Albiglutide 30 mg	Sitagliptin 100 mg
risk		
# events		
Peripheral vascular disorder †[A]		
# participants affected/at risk	0/249 (0%)	1/246 (0.41%)
# 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 30 mg	Sitagliptin 100 mg
Total # participants affected/at risk	174/249 (69.88%)	162/246 (65.85%)
Blood and lymphatic system disorders		
Anaemia †[A]		
# participants affected/at risk	16/249 (6.43%)	10/246 (4.07%)
# events		
Ear and labyrinth disorders		
Vertigo †[A]		

	Albiglutide 30 mg	Sitagliptin 100 mg
# participants affected/at risk	3/249 (1.2%)	5/246 (2.03%)
# events		
Eye disorders		
Cataract †[A]		
# participants affected/at risk	9/249 (3.61%)	5/246 (2.03%)
# events		
Diabetic retinopathy †[A]		
# participants affected/at risk	12/249 (4.82%)	9/246 (3.66%)
# events		
Gastrointestinal disorders		
Constipation †[A]		
# participants affected/at risk	15/249 (6.02%)	6/246 (2.44%)
# events		
Diarrhoea †[A]		
# participants affected/at risk	25/249 (10.04%)	16/246 (6.5%)
# events		
Dyspepsia †[A]		

	Albiglutide 30 mg	Sitagliptin 100 mg
# participants affected/at risk	5/249 (2.01%)	9/246 (3.66%)
# events		
Gastritis † [A]		
# participants affected/at risk	5/249 (2.01%)	7/246 (2.85%)
# events		
Gastrooesophageal reflux disease † [A]		
# participants affected/at risk	3/249 (1.2%)	7/246 (2.85%)
# events		
Haemorrhoids † [A]		
# participants affected/at risk	6/249 (2.41%)	3/246 (1.22%)
# events		
Nausea † [A]		
# participants affected/at risk	12/249 (4.82%)	8/246 (3.25%)
# events		
General disorders		
Fatigue † [A]		
# participants affected/at	5/249 (2.01%)	2/246 (0.81%)

	Albiglutide 30 mg	Sitagliptin 100 mg
risk		
# events		
Injection site haematoma † [A]		
# participants affected/at risk	3/249 (1.2%)	6/246 (2.44%)
# events		
Injection site pruritus † [A]		
# participants affected/at risk	5/249 (2.01%)	0/246 (0%)
# events		
Injection site reaction † [A]		
# participants affected/at risk	10/249 (4.02%)	1/246 (0.41%)
# events		
Oedema peripheral † [A]		
# participants affected/at risk	13/249 (5.22%)	8/246 (3.25%)
# events		
Infections and infestations		
Bronchitis † [A]		
# participants affected/at	9/249 (3.61%)	7/246 (2.85%)

	Albiglutide 30 mg	Sitagliptin 100 mg
risk		
# events		
Gastroenteritis † [A]		
# participants affected/at risk	5/249 (2.01%)	3/246 (1.22%)
# events		
Influenza † [A]		
# participants affected/at risk	8/249 (3.21%)	7/246 (2.85%)
# events		
Nasopharyngitis † [A]		
# participants affected/at risk	14/249 (5.62%)	20/246 (8.13%)
# events		
Upper respiratory tract infection † [A]		
# participants affected/at risk	14/249 (5.62%)	23/246 (9.35%)
# events		
Urinary tract infection † [A]		
# participants affected/at risk	21/249 (8.43%)	20/246 (8.13%)
# events		

	Albiglutide 30 mg	Sitagliptin 100 mg
Metabolism and nutrition disorders		
Gout †[A]		
# participants affected/at risk	11/249 (4.42%)	7/246 (2.85%)
# events		
Hyperglycaemia †[A]		
# participants affected/at risk	2/249 (0.8%)	5/246 (2.03%)
# events		
Hyperkalaemia †[A]		
# participants affected/at risk	7/249 (2.81%)	2/246 (0.81%)
# events		
Hyperuricaemia †[A]		
# participants affected/at risk	8/249 (3.21%)	3/246 (1.22%)
# events		
Hypoglycaemia †[A]		
# participants affected/at risk	60/249 (24.1%)	39/246 (15.85%)
# events		
Musculoskeletal and		

	Albiglutide 30 mg	Sitagliptin 100 mg
connective tissue disorders		
Arthralgia †[A]		
# participants affected/at risk	9/249 (3.61%)	11/246 (4.47%)
# events		
Back pain †[A]		
# participants affected/at risk	6/249 (2.41%)	10/246 (4.07%)
# events		
Muscle spasms †[A]		
# participants affected/at risk	4/249 (1.61%)	6/246 (2.44%)
# events		
Pain in extremity †[A]		
# participants affected/at risk	7/249 (2.81%)	4/246 (1.63%)
# events		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Thyroid neoplasm †[A]		

	Albiglutide 30 mg	Sitagliptin 100 mg
# participants affected/at risk	5/249 (2.01%)	1/246 (0.41%)
# events		
Nervous system disorders		
Dizziness †[A]		
# participants affected/at risk	8/249 (3.21%)	5/246 (2.03%)
# events		
Headache †[A]		
# participants affected/at risk	8/249 (3.21%)	11/246 (4.47%)
# events		
Renal and urinary disorders		
Renal failure †[A]		
# participants affected/at risk	12/249 (4.82%)	10/246 (4.07%)
# events		
Renal impairment †[A]		
# participants affected/at risk	6/249 (2.41%)	8/246 (3.25%)
# events		

	Albiglutide 30 mg	Sitagliptin 100 mg
Respiratory, thoracic and mediastinal disorders		
Cough † [A]		
# participants affected/at risk	3/249 (1.2%)	5/246 (2.03%)
# events		
Oropharyngeal pain † [A]		
# participants affected/at risk	2/249 (0.8%)	5/246 (2.03%)
# events		
Vascular disorders		
Hypertension † [A]		
# participants affected/at risk	14/249 (5.62%)	19/246 (7.72%)
# events		
Hypotension † [A]		
# participants affected/at risk	3/249 (1.2%)	5/246 (2.03%)
# 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:

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