Protocol Registration Receipt
05/29/2014

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

Safety and Efficacy of Albiglutide in Type 2 Diabetes

This study has been completed.

Sponsor:	GlaxoSmithKline
Collaborators:	
Information provided by (Responsible Party):	GlaxoSmithKline
ClinicalTrials.gov Identifier:	NCT00849056

Purpose

The purpose of this study is to determine the safety, tolerability and efficacy of albiglutide in the treatment of type 2 diabetes.

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

Study Type: Interventional

Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Safety/Efficacy Study

Official Title: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Determine the Efficacy and Safety of Albiglutide When Used in Combination With Pioglitazone With or Without Metformin in Subjects With Type 2 Diabetes Mellitus

Further study details as provided by GlaxoSmithKline:

Primary Outcome Measure:

- Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at Week 52 [Time Frame: Baseline and Week 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 BL HbA1c value is defined as the last non-missing value before the start of treatment. Change from BL was calculated as the value at Week 52 minus the value at BL. Based on analysis of covariance (ANCOVA): change = treatment + BL HbA1c + prior myocardial infarction history + age category + region + current antidiabetic therapy. The last observation carried forward (LOCF) method was used to impute missing post-BL HbA1c values; the last non-missing post-BL on-treatment measurement was used to impute the missing measurement. HbA1c values obtained after hyperglycemic rescue were treated as missing and were replaced with pre-rescue values. One Intent-to-Treat (ITT) participant (par.) had all post-BL HbA1c measurements occur after hyperglycemic rescue. This par. is included in the ITT Population counts but did not contribute to this analysis.

Secondary Outcome Measures:

- Change From Baseline in HbA1c at Weeks 104 and 156 [Time Frame: Baseline and Weeks 104 and 156] [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. 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. This analysis used observed HbA1c values, excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.
- Time to Hyperglycemia Rescue [Time Frame: From the start of study medication until the end of the treatment (up to Week 156)] [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: FPG >=280 milligrams/deciliter (mg/dL) between >=Week 2 and <Week 4; FPG >=250 mg/dL between >=Week 4 and <Week 12; HbA1c >=8.5% and a <=0.5% reduction from Baseline between >=Week 12 and <Week 24; HbA1c >=8.5% between >=Week 24 and <Week 48; HbA1c >=8.0% between >= Week 48 and <Week 156. Participants could have been rescued at any time on or after Week 2. 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 1 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 1 day for participants not requiring rescue. This time was divided by 7 to express the result in weeks.
- Change From Baseline in Fasting Plasma Glucose (FPG) at Week 52 [Time Frame: Baseline and 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 the last non-missing value before the start of treatment. The LOCF method was used to impute missing post-Baseline FPG values. FPG values obtained after hyperglycemia rescue were treated as missing and replaced with pre-rescue values. Change from Baseline was calculated as the post-Baseline value minus the

Baseline value. Based on ANCOVA: change = treatment + Baseline weight + prior myocardial infarction history + age category + region + current antidiabetic therapy.

- Change From Baseline in Fasting Plasma Glucose (FPG) at Week 156 [Time Frame: Baseline and Week 156] [Designated as safety issue: No]
  The Baseline FPG value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline FPG minus the Baseline FPG.
- Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 52 [Time Frame: Week 52] [Designated as safety issue: No]
  The number of participants who achieved the HbA1c treatment goal (i.e., HbA1c response levels of <6.5%, <6.5%, and <7.0% at Week 52) were assessed.
- Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 156 [Time Frame: Week 156] [Designated as safety issue: No]
  The number of participants who achieved the HbA1c treatment goal (i.e., HbA1c response levels of <6.5%, <6.5%, and <7.0% at Week 156) were assessed.
- Change From Baseline in Body Weight at Week 52 [Time Frame: Baseline and Week 52] [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 post-Baseline weight minus the Baseline weight. The LOCF method was used to impute missing post-Baseline weight values. Weight values obtained after hyperglycemia rescue were treated as missing and replaced with prerescue values. Based on ANCOVA: change = treatment + Baseline weight + prior myocardial infarction history + age category + region + current antidiabetic therapy.
- Change From Baseline in Body Weight at Week 156 [Time Frame: Baseline and Week 156] [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 post-Baseline weight minus the Baseline weight.

Enrollment: 310
Study Start Date: January 2009
Study Completion Date: January 2013
Primary Completion Date: January 2013

Arms	Assigned Interventions
Placebo Comparator: placebo + pioglitazone (with or without metformin) Placebo albiglutide weekly injection + pioglitazone (with or without metformin)	Drug: placebo placebo weekly subcutaneous injection
Experimental: albiglutide + pioglitazone (with	Biological/Vaccine: albiglutide

Arms	Assigned Interventions
or without metformin) albiglutide weekly injection + pioglitazone (with or without meformin)	albiglutide weekly subcutaneous injection

Eligibility

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

Inclusion Criteria:

- type 2 diabetes
- BMI 20-45kg/m2

Exclusion Criteria:

- NYHA Class II to IV heart failure
- females who are pregnant, lactating, or less than 6 weeks post-partum

Contacts and Locations

Locations

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San Antonio, Texas, United States, 78229
GSK Investigational Site
San Antonio, Texas, United States, 78258
GSK Investigational Site
San Antonio, Texas, United States, 78205
GSK Investigational Site
San Antonio, Texas, United States, 78229
GSK Investigational Site
Schertz, Texas, United States, 78154
GSK Investigational Site
Sugar Land, Texas, United States, 77479
GSK Investigational Site
Sugarland, Texas, United States, 77479

United States, Utah

GSK Investigational Site
Bountiful, Utah, United States, 84010
GSK Investigational Site
Orem, Utah, United States, 84058
GSK Investigational Site
Salt Lake City, Utah, United States, 84107
GSK Investigational Site
Salt Lake City, Utah, United States, 84120

GSK Investigational Site

Salt Lake City, Utah, United States, 84107

GSK Investigational Site

West Jordan, Utah, United States, 84088

GSK Investigational Site

West Valley City, Utah, United States, 84120

United States, Vermont

GSK Investigational Site

South Burlington, Vermont, United States, 05403

United States, Virginia

GSK Investigational Site

Burke, Virginia, United States, 22015

GSK Investigational Site

Hampton, Virginia, United States, 23666

GSK Investigational Site

Manassas, Virginia, United States, 20110

GSK Investigational Site

Norfolk, Virginia, United States, 23502

GSK Investigational Site

Richmond, Virginia, United States, 23294

GSK Investigational Site

Suffolk, Virginia, United States

GSK Investigational Site

Weber City, Virginia, United States, 24290

United States, Washington

GSK Investigational Site

Federal Way, Washington, United States, 98003

GSK Investigational Site

Renton, Washington, United States, 98057

GSK Investigational Site

Richland, Washington, United States, 99352

GSK Investigational Site

Selah, Washington, United States, 98942

GSK Investigational Site

Spokane, Washington, United States, 99208

GSK Investigational Site

Spokane, Washington, United States, 99216

GSK Investigational Site

Tacoma, Washington, United States, 98405

United States, West Virginia

GSK Investigational Site

Lewisburg, West Virginia, United States, 24901

United States, Wisconsin

GSK Investigational Site

Milwaukee, Wisconsin, United States, 53226

India

GSK Investigational Site

Aurangabad, India, 431001

GSK Investigational Site

Pune, India, 411011

Korea, Republic of

GSK Investigational Site

Seongnam-si, Korea, Republic of, 463712

GSK Investigational Site

Suwon, Kyonggi-do, Korea, Republic of, 443-721

Peru

GSK Investigational Site

Trujillo, Peru

GSK Investigational Site

Arequipa, Arequipa, Peru, 54

GSK Investigational Site

El Agustino, Lima, Peru, 10

GSK Investigational Site

Huacho, Lima, Peru

GSK Investigational Site

Lima, Lima, Peru, 17

South Africa

GSK Investigational Site

Kempton Park, South Africa, 1619

GSK Investigational Site

Somerset West, South Africa, 07129

GSK Investigational Site

Port Elizabeth, Eastern Cape, South Africa, 6014

GSK Investigational Site

Phoenix, KwaZulu- Natal, South Africa, 4068

United Kingdom

GSK Investigational Site

Glasgow, United Kingdom, G45 9AW

GSK Investigational Site

Liverpool, United Kingdom, L9 7AL

GSK Investigational Site

London, United Kingdom, SE1 9NH

GSK Investigational Site

Canterbury, Kent, United Kingdom, CT1 3HX

GSK Investigational Site

Blackpool, Lancashire, United Kingdom, FY4 3AD

GSK Investigational Site

Sunbury-on-Thames, Middlesex, United Kingdom, TW16 6RH

GSK Investigational Site

Port Glasgow, Renfrewshire, United Kingdom, PA14 6HW

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:	112755
Health Authority:	United States: Food and Drug Administration

Participant Flow

Pre-Assignment Details

Participants (par.) who met eligibility criteria and completed a 4-week Run-in/Stabilization Period were then randomized to a 156-week Treatment Period, followed by 8 weeks of post-treatment follow-up. A total of 450 par. were screened; 310 par. were randomized, and 301 par. received >=1 treatment dose.

Reporting Groups

	Description
Placebo + Pioglitazone With or Without Metformin	Participants received matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 milligrams [mg]/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.
Albiglutide 30 mg + Pioglitazone With or Without Metformin	Participants received albiglutide 30 milligrams (mg) as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 mg/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.

Treatment Period (TP) (156 Weeks)

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Started	151	150
Completed	88	100
Not Completed	63	50
Adverse Event	13	11
Protocol Violation	3	6
Noncompliance	3	3
Lost to Follow-up	7	5
Withdrawal by Subject	31	18
Physician Decision	3	3
Termination of Study/Site by GSK	1	4
Calcitonin Out of Range	1	0
Pregnancy	1	0

Follow-up Period (FUP) (8 Weeks)

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Started	149 [1]	149 [2]
Completed	122	124
Not Completed	27	25
Adverse Event	1	3
Noncompliance	0	1
Lost to Follow-up	14	9
Withdrawal by Subject	9	7
Physician Decision	1	1
Termination of Study/Site by GSK	1	4
Early Termination	1	0

[1] Par. withdrawing from the TP could enter the FUP. Two par. did not participate in the FUP.

[2] Par. withdrawing from the TP could enter the FUP. One par. did not participate in the FUP.

Baseline Characteristics

Reporting Groups

	Description
Placebo + Pioglitazone With or Without Metformin	Participants received matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone

	Description
	(>=30 milligrams [mg]/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.
Albiglutide 30 mg + Pioglitazone With or Without Metformin	Participants received albiglutide 30 milligrams (mg) as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 mg/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.

Baseline Measures

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin	Total
Number of Participants	151	150	301
Age, Continuous [units: Years] Mean (Standard Deviation)	54.9 (9.40)	55.2 (9.98)	55.0 (9.67)
Gender, Male/Female [units: Participants]			
Female	63	58	121
Male	88	92	180

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin	Total
Race/Ethnicity, Customized [units: Participants]			
African American/African Heritage	20	19	39
American Indian or Alaskan Native	15	18	33
Asian - Central/South Asian Heritage	1	2	3
Asian - East Asian Heritage	2	3	5
Asian - Japanese Heritage	1	1	2
Asian - South East Asian Heritage	2	0	2
Native Hawaiian or other Pacific Islander	2	1	3
White - Arabic/North African Heritage	2	2	4
White - White/Caucasian/European Heritage	106	104	210

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at Week 52
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 BL HbA1c value is defined as the last non-missing value before the start of treatment. Change from BL was calculated as the value at Week 52 minus the value at BL. Based on analysis of covariance (ANCOVA): change = treatment + BL HbA1c + prior myocardial infarction history + age category + region + current antidiabetic therapy. The last observation carried forward (LOCF) method was used to impute missing post-BL HbA1c values; the last non-missing post-BL on-treatment measurement was used to impute the missing measurement. HbA1c values obtained after hyperglycemic rescue were treated as missing and were replaced with pre-rescue values. One Intent-to-Treat (ITT) participant (par.) had all post-BL HbA1c measurements occur after hyperglycemic rescue. This par. is included in the ITT Population counts but did not contribute to this analysis.
Time Frame	Baseline and Week 52
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population with LOCF: all randomized par. who received >=1 dose of study medication and who had a BL assessment and >=1 post-BL assessment of HbA1c. Only par. with a value at BL and at the specified visit were analyzed. Values were carried forward for par. who were rescued or discontinued from active treatment before Week 52.

Reporting Groups

	Description
Placebo + Pioglitazone With or Without Metformin	Participants received matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 milligrams [mg]/day, unless there was documented evidence

	Description
	that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.
Albiglutide 30 mg + Pioglitazone With or Without Metformin	Participants received albiglutide 30 milligrams (mg) as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 mg/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Number of Participants Analyzed	149	149
Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at Week 52 [units: Percentage of HbA1c in the blood] Least Squares Mean (Standard Error)	-0.05 (0.071)	-0.81 (0.071)

Statistical Analysis 1 for Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at Week 52

Groups	Placebo + Pioglitazone With or Without Metformin, Albiglutide 30 mg + Pioglitazone With or Without Metformin

Method	ANCOVA
P-Value	<0.0001
Mean Difference (Net)	-0.75
95% Confidence Interval	-0.95 to -0.56

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

[Not specified.]

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	Change From Baseline in HbA1c at Weeks 104 and 156
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. 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. This analysis used observed HbA1c values, excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.
Time Frame	Baseline and Weeks 104 and 156
Safety Issue?	No

Analysis Population Description

ITT Population with observed values. Only those participants with a value at Baseline and at the specified visit were analyzed (represented by n=X, X in the category titles).

Reporting Groups

	Description
Placebo + Pioglitazone With or Without Metformin	Participants received matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 milligrams [mg]/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.
Albiglutide 30 mg + Pioglitazone With or Without Metformin	Participants received albiglutide 30 milligrams (mg) as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 mg/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Number of Participants Analyzed	29	72
Change From Baseline in HbA1c at Weeks 104 and 156 [units: Percentage of HbA1c in the blood] Mean (Standard Deviation)		
Week 104, n= 29, 72	-0.72 (0.845)	-0.92 (1.038)

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Week 156, n=26, 54	-0.50 (0.805)	-0.87 (0.926)

3. Secondary Outcome Measure:

Measure Title	Time to Hyperglycemia Rescue
Measure Description	Participants who experienced persistent hyperglycemia (high blood glucose) could have qualified for hyperglycemia rescue. The conditions for hyperglycemia rescue were as follows: FPG >=280 milligrams/deciliter (mg/dL) between >=Week 2 and <Week 4; FPG >=250 mg/dL between >=Week 4 and <Week 12; HbA1c >=8.5% and a <=0.5% reduction from Baseline between >=Week 12 and <Week 24; HbA1c >=8.5% between >=Week 24 and <Week 48; HbA1c >=8.0% between >= Week 48 and <Week 156. Participants could have been rescued at any time on or after Week 2. 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 1 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 1 day for participants not requiring rescue. This time was divided by 7 to express the result in weeks.
Time Frame	From the start of study medication until the end of the treatment (up to Week 156)
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants with a value at Baseline and at the specified visit were analyzed.

Reporting Groups

	Description
Placebo + Pioglitazone With or Without Metformin	Participants received matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 milligrams [mg]/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.
Albiglutide 30 mg + Pioglitazone With or Without Metformin	Participants received albiglutide 30 milligrams (mg) as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 mg/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Number of Participants Analyzed	149	150
Time to Hyperglycemia Rescue [units: Weeks] Median (95% Confidence Interval)	52.86 (48.86 to 79.43)	NA (NA to NA) [1]

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

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG) at Week 52
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. The LOCF method was used to impute missing post-Baseline FPG values. FPG values obtained after hyperglycemia rescue were treated as missing and replaced with pre-rescue values. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Based on ANCOVA: change = treatment + Baseline weight + prior myocardial infarction history + age category + region + current antidiabetic therapy.
Time Frame	Baseline and Week 52
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population with LOCF. Only those participants with a value at Baseline and at the specified visit were analyzed. Values were carried forward for participants who were rescued or discontinued from active treatment before Week 52.

Reporting Groups

	Description
Placebo + Pioglitazone With or Without Metformin	Participants received matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 milligrams [mg]/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate.

	Description
	Participants did not receive investigational product during the Follow-up Period.
Albiglutide 30 mg + Pioglitazone With or Without Metformin	Participants received albiglutide 30 milligrams (mg) as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 mg/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Number of Participants Analyzed	149	149
Change From Baseline in Fasting Plasma Glucose (FPG) at Week 52 [units: Millimoles per liter (mmol/L)] Least Squares Mean (Standard Error)	0.35 (0.197)	-1.28 (0.197)

5. Secondary Outcome Measure:

Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG) at Week 156
Measure Description	The Baseline FPG value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the

	post-Baseline FPG minus the Baseline FPG.
Time Frame	Baseline and Week 156
Safety Issue?	No

Analysis Population Description

ITT Population with observed values. Only those participants with a value at Baseline and at the specified visit were analyzed. This analysis used observed FPG values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.

Reporting Groups

	Description
Placebo + Pioglitazone With or Without Metformin	Participants received matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 milligrams [mg]/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.
Albiglutide 30 mg + Pioglitazone With or Without Metformin	Participants received albiglutide 30 milligrams (mg) as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 mg/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Number of Participants Analyzed	25	54
Change From Baseline in Fasting Plasma Glucose (FPG) at Week 156 [units: Millimoles per liter (mmol/L)] Mean (Standard Deviation)	0.03 (1.950)	-1.26 (1.476)

6. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 52
Measure Description	The number of participants who achieved the HbA1c treatment goal (i.e., HbA1c response levels of <6.5%, <6.5%, and <7.0% at Week 52) were assessed.
Time Frame	Week 52
Safety Issue?	No

Analysis Population Description

ITT Population with LOCF. Only those participants with a value at Baseline and at the specified visit were analyzed. Values were carried forward for participants who were rescued or discontinued from active treatment before Week 52.

Reporting Groups

	Description
Placebo + Pioglitazone With	Participants received matching placebo as a subcutaneous injection

	Description
or Without Metformin	weekly via a fully disposable pen injector system and pioglitazone (>=30 milligrams [mg]/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.
Albiglutide 30 mg + Pioglitazone With or Without Metformin	Participants received albiglutide 30 milligrams (mg) as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 mg/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Number of Participants Analyzed	149	149
Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 52 [units: Participants]		
HbA1c <6.5%	8	37
HbA1c <7%	22	66

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
HbA1c <7.5%	44	96

7. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 156
Measure Description	The number of participants who achieved the HbA1c treatment goal (i.e., HbA1c response levels of <6.5%, <6.5%, and <7.0% at Week 156) were assessed.
Time Frame	Week 156
Safety Issue?	No

Analysis Population Description

ITT Population with observed values. Only those participants with a value at Baseline and at the specified visit were analyzed. This analysis used observed HbA1c values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.

Reporting Groups

	Description
Placebo + Pioglitazone With or Without Metformin	Participants received matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 milligrams [mg]/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate.

	Description
	Participants did not receive investigational product during the Follow-up Period.
Albiglutide 30 mg + Pioglitazone With or Without Metformin	Participants received albiglutide 30 milligrams (mg) as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 mg/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Number of Participants Analyzed	26	54
Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 156 [units: Participants]		
HbA1c <6.5%	7	20
HbA1c <7%	12	32
HbA1c <7.5%	17	44

8. Secondary Outcome Measure:

Measure Title	Change From Baseline in Body Weight at Week 52
Measure Description	The Baseline value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight. The LOCF method was used to impute missing post-Baseline weight values. Weight values obtained after hyperglycemia rescue were treated as missing and replaced with prerescue values. Based on ANCOVA: change = treatment + Baseline weight + prior myocardial infarction history + age category + region + current antidiabetic therapy.
Time Frame	Baseline and Week 52
Safety Issue?	No

Analysis Population Description

ITT Population with LOCF. Only those participants with a value at Baseline and at the specified visit were analyzed. Values were carried forward for participants who were rescued or discontinued from active treatment before Week 52.

Reporting Groups

	Description
Placebo + Pioglitazone With or Without Metformin	Participants received matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 milligrams [mg]/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.
Albiglutide 30 mg + Pioglitazone With or Without Metformin	Participants received albiglutide 30 milligrams (mg) as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 mg/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they

	Description
	were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Number of Participants Analyzed	149	149
Change From Baseline in Body Weight at Week 52 [units: Kilograms] Least Squares Mean (Standard Error)	0.45 (0.348)	0.28 (0.348)

9. Secondary Outcome Measure:

Measure Title	Change From Baseline in Body Weight at Week 156
Measure Description	The Baseline value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight.
Time Frame	Baseline and Week 156
Safety Issue?	No

Analysis Population Description

ITT Population with observed values. Only those participants who were available at the indicated time points were analyzed. This analysis used observed

body weight values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.

Reporting Groups

	Description
Placebo + Pioglitazone With or Without Metformin	Participants received matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 milligrams [mg]/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.
Albiglutide 30 mg + Pioglitazone With or Without Metformin	Participants received albiglutide 30 milligrams (mg) as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 mg/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Number of Participants Analyzed	26	55
Change From Baseline in Body Weight at Week 156 [units: Kilograms] Mean (Standard Deviation)	1.50 (6.939)	-0.16 (6.284)

Reported Adverse Events

Reporting Groups

	Description
Placebo + Pioglitazone With or Without Metformin	Participants received matching placebo as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 milligrams [mg]/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.
Albiglutide 30 mg + Pioglitazone With or Without Metformin	Participants received albiglutide 30 milligrams (mg) as a subcutaneous injection weekly via a fully disposable pen injector system and pioglitazone (>=30 mg/day, unless there was documented evidence that the participant could not tolerate that dose, in which case they were allowed 15 mg/day) with or without metformin as appropriate. Participants did not receive investigational product during the Follow-up Period.

Time Frame

On-treatment serious adverse events (SAEs) and non-serious AEs, defined as those events that had a start date on or after the first day of study medication and within 56 days after the end of study medication (up to Week 156), are reported.

Additional Description

SAEs and non-serious AEs are reported for members of the Safety Population, comprised of all participants who received at least one dose of study treatment.

Serious Adverse Events

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Total # participants affected/at risk	28/151 (18.54%)	15/150 (10%)
Cardiac disorders		
Acute myocardial infarction †[A]		
# participants affected/at risk	0/151 (0%)	2/150 (1.33%)
# events		
Angina unstable †[A]		
# participants affected/at risk	0/151 (0%)	1/150 (0.67%)
# events		
Aortic valve incompetence †[A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Atrial fibrillation †[A]		
# participants affected/at risk	0/151 (0%)	1/150 (0.67%)
# events		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Cardiac failure † [A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Cardiomyopathy † [A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Coronary artery disease † [A]		
# participants affected/at risk	2/151 (1.32%)	2/150 (1.33%)
# events		
Coronary artery stenosis † [A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Myocardial infarction † [A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Sick sinus syndrome †[A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Gastrointestinal disorders		
Colonic fistula †[A]		
# participants affected/at risk	0/151 (0%)	1/150 (0.67%)
# events		
Diabetic gastroparesis †[A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Gastric ulcer †[A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Gastrooesophageal reflux disease †[A]		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
# participants affected/at risk	0/151 (0%)	1/150 (0.67%)
# events		
Small intestinal obstruction †[A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
General disorders		
Chest pain †[A]		
# participants affected/at risk	3/151 (1.99%)	0/150 (0%)
# events		
Hepatobiliary disorders		
Cholecystitis †[A]		
# participants affected/at risk	0/151 (0%)	1/150 (0.67%)
# events		
Cholecystitis acute †[A]		
# participants affected/at	2/151 (1.32%)	0/150 (0%)

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
risk		
# events		
Infections and infestations		
Abscess limb † [A]		
# participants affected/at risk	1/151 (0.66%)	1/150 (0.67%)
# events		
Appendicitis perforated † [A]		
# participants affected/at risk	0/151 (0%)	1/150 (0.67%)
# events		
Cellulitis † [A]		
# participants affected/at risk	2/151 (1.32%)	1/150 (0.67%)
# events		
Diverticulitis † [A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Pneumonia † [A]		
# participants affected/at risk	0/151 (0%)	2/150 (1.33%)
# events		
Sinusitis † [A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Viral infection † [A]		
# participants affected/at risk	0/151 (0%)	1/150 (0.67%)
# events		
Vulval abscess † [A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Injury, poisoning and procedural complications		
Face injury † [A]		
# participants affected/at	1/151 (0.66%)	0/150 (0%)

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
risk		
# events		
Metabolism and nutrition disorders		
Obesity † [A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Musculoskeletal and connective tissue disorders		
Back pain † [A]		
# participants affected/at risk	2/151 (1.32%)	0/150 (0%)
# events		
Bursitis † [A]		
# participants affected/at risk	0/151 (0%)	1/150 (0.67%)
# events		
Osteoarthritis † [A]		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
# participants affected/at risk	1/151 (0.66%)	1/150 (0.67%)
# events		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast cancer stage I † [A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Lung cancer metastatic † [A]		
# participants affected/at risk	0/151 (0%)	1/150 (0.67%)
# events		
Metastases to liver † [A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Non-small cell lung cancer † [A]		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Prostate cancer metastatic † [A]		
# participants affected/at risk	0/151 (0%)	1/150 (0.67%)
# events		
Nervous system disorders		
Dizziness † [A]		
# participants affected/at risk	0/151 (0%)	1/150 (0.67%)
# events		
Pregnancy, puerperium and perinatal conditions		
Abortion spontaneous † [A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Psychiatric disorders		
Major depression † [A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Renal and urinary disorders		
Nephrolithiasis † [A]		
# participants affected/at risk	0/151 (0%)	1/150 (0.67%)
# events		
Renal colic † [A]		
# participants affected/at risk	0/151 (0%)	1/150 (0.67%)
# events		
Renal impairment † [A]		
# participants affected/at risk	1/151 (0.66%)	0/150 (0%)
# events		
Vascular disorders		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Deep vein thrombosis † [A]		
# participants affected/at risk	2/151 (1.32%)	0/150 (0%)
# 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%

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Total # participants affected/at risk	117/151 (77.48%)	126/150 (84%)
Blood and lymphatic system disorders		
Anaemia † [A]		
# participants affected/at risk	9/151 (5.96%)	6/150 (4%)
# events		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Cardiac disorders		
Angina pectoris † [A]		
# participants affected/at risk	4/151 (2.65%)	0/150 (0%)
# events		
Palpitations † [A]		
# participants affected/at risk	0/151 (0%)	4/150 (2.67%)
# events		
Ear and labyrinth disorders		
Ear pain † [A]		
# participants affected/at risk	4/151 (2.65%)	1/150 (0.67%)
# events		
Vertigo † [A]		
# participants affected/at risk	2/151 (1.32%)	5/150 (3.33%)
# events		
Eye disorders		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Cataract †[A]		
# participants affected/at risk	3/151 (1.99%)	7/150 (4.67%)
# events		
Diabetic retinopathy †[A]		
# participants affected/at risk	2/151 (1.32%)	7/150 (4.67%)
# events		
Presbyopia †[A]		
# participants affected/at risk	4/151 (2.65%)	2/150 (1.33%)
# events		
Refraction disorder †[A]		
# participants affected/at risk	4/151 (2.65%)	1/150 (0.67%)
# events		
Gastrointestinal disorders		
Abdominal pain †[A]		
# participants affected/at	8/151 (5.3%)	2/150 (1.33%)

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
risk		
# events		
Abdominal pain upper †[A]		
# participants affected/at risk	6/151 (3.97%)	6/150 (4%)
# events		
Constipation †[A]		
# participants affected/at risk	2/151 (1.32%)	5/150 (3.33%)
# events		
Diarrhoea †[A]		
# participants affected/at risk	16/151 (10.6%)	22/150 (14.67%)
# events		
Dyspepsia †[A]		
# participants affected/at risk	5/151 (3.31%)	4/150 (2.67%)
# events		
Gastritis †[A]		
# participants affected/at	3/151 (1.99%)	4/150 (2.67%)

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
risk		
# events		
Gastrooesophageal reflux disease †[A]		
# participants affected/at risk	1/151 (0.66%)	9/150 (6%)
# events		
Nausea †[A]		
# participants affected/at risk	18/151 (11.92%)	18/150 (12%)
# events		
Toothache †[A]		
# participants affected/at risk	4/151 (2.65%)	8/150 (5.33%)
# events		
Vomiting †[A]		
# participants affected/at risk	6/151 (3.97%)	8/150 (5.33%)
# events		
General disorders		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Fatigue †[A]		
# participants affected/at risk	7/151 (4.64%)	10/150 (6.67%)
# events		
Injection site haematoma †[A]		
# participants affected/at risk	4/151 (2.65%)	6/150 (4%)
# events		
Injection site haemorrhage †[A]		
# participants affected/at risk	1/151 (0.66%)	7/150 (4.67%)
# events		
Injection site reaction †[A]		
# participants affected/at risk	5/151 (3.31%)	8/150 (5.33%)
# events		
Injection stie pruritis †[A]		
# participants affected/at risk	5/151 (3.31%)	0/150 (0%)

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
# events		
Oedema peripheral †[A]		
# participants affected/at risk	16/151 (10.6%)	15/150 (10%)
# events		
Pyrexia †[A]		
# participants affected/at risk	4/151 (2.65%)	3/150 (2%)
# events		
Immune system disorders		
Seasonal allergy †[A]		
# participants affected/at risk	5/151 (3.31%)	5/150 (3.33%)
# events		
Infections and infestations		
Bronchitis †[A]		
# participants affected/at risk	15/151 (9.93%)	10/150 (6.67%)

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
# events		
Cellulitis † [A]		
# participants affected/at risk	4/151 (2.65%)	5/150 (3.33%)
# events		
Gastroenteritis † [A]		
# participants affected/at risk	2/151 (1.32%)	7/150 (4.67%)
# events		
Influenza † [A]		
# participants affected/at risk	2/151 (1.32%)	6/150 (4%)
# events		
Nasopharyngitis † [A]		
# participants affected/at risk	22/151 (14.57%)	12/150 (8%)
# events		
Pharyngitis † [A]		
# participants affected/at risk	7/151 (4.64%)	6/150 (4%)

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
# events		
Sinusitis † [A]		
# participants affected/at risk	9/151 (5.96%)	15/150 (10%)
# events		
Upper respiratory tract infection † [A]		
# participants affected/at risk	24/151 (15.89%)	24/150 (16%)
# events		
Urinary tract infection † [A]		
# participants affected/at risk	9/151 (5.96%)	17/150 (11.33%)
# events		
Injury, poisoning and procedural complications		
Contusion † [A]		
# participants affected/at risk	9/151 (5.96%)	12/150 (8%)
# events		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Laceration †[A]		
# participants affected/at risk	2/151 (1.32%)	7/150 (4.67%)
# events		
Ligament sprain †[A]		
# participants affected/at risk	4/151 (2.65%)	3/150 (2%)
# events		
Limb injury †[A]		
# participants affected/at risk	4/151 (2.65%)	2/150 (1.33%)
# events		
Meniscus lesion †[A]		
# participants affected/at risk	2/151 (1.32%)	4/150 (2.67%)
# events		
Muscle strain †[A]		
# participants affected/at risk	5/151 (3.31%)	2/150 (1.33%)
# events		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Procedural pain †[A]		
# participants affected/at risk	4/151 (2.65%)	3/150 (2%)
# events		
Metabolism and nutrition disorders		
Decreased appetite †[A]		
# participants affected/at risk	4/151 (2.65%)	3/150 (2%)
# events		
Dyslipidaemia †[A]		
# participants affected/at risk	8/151 (5.3%)	2/150 (1.33%)
# events		
Hypoglycaemia †[A]		
# participants affected/at risk	13/151 (8.61%)	25/150 (16.67%)
# events		
Musculoskeletal and connective tissue		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
disorders		
Arthralgia †[A]		
# participants affected/at risk	13/151 (8.61%)	15/150 (10%)
# events		
Back pain †[A]		
# participants affected/at risk	10/151 (6.62%)	13/150 (8.67%)
# events		
Bursitis †[A]		
# participants affected/at risk	4/151 (2.65%)	1/150 (0.67%)
# events		
Intervertebral disc protrusion †[A]		
# participants affected/at risk	4/151 (2.65%)	0/150 (0%)
# events		
Muscle spasms †[A]		
# participants affected/at	7/151 (4.64%)	4/150 (2.67%)

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
risk		
# events		
Musculoskeletal pain † [A]		
# participants affected/at risk	10/151 (6.62%)	13/150 (8.67%)
# events		
Myalgia † [A]		
# participants affected/at risk	3/151 (1.99%)	6/150 (4%)
# events		
Neck pain † [A]		
# participants affected/at risk	3/151 (1.99%)	5/150 (3.33%)
# events		
Osteoarthritis † [A]		
# participants affected/at risk	6/151 (3.97%)	11/150 (7.33%)
# events		
Pain in extremity † [A]		
# participants affected/at	11/151	7/150 (4.67%)

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
risk	(7.28%)	
# events		
Nervous system disorders		
Carpal tunnel syndrome †[A]		
# participants affected/at risk	6/151 (3.97%)	1/150 (0.67%)
# events		
Dizziness †[A]		
# participants affected/at risk	5/151 (3.31%)	10/150 (6.67%)
# events		
Headache †[A]		
# participants affected/at risk	18/151 (11.92%)	13/150 (8.67%)
# events		
Hypoaesthesia †[A]		
# participants affected/at risk	2/151 (1.32%)	4/150 (2.67%)
# events		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
Neuropathy peripheral † [A]		
# participants affected/at risk	6/151 (3.97%)	2/150 (1.33%)
# events		
Psychiatric disorders		
Anxiety † [A]		
# participants affected/at risk	6/151 (3.97%)	7/150 (4.67%)
# events		
Depression † [A]		
# participants affected/at risk	5/151 (3.31%)	4/150 (2.67%)
# events		
Insomnia † [A]		
# participants affected/at risk	4/151 (2.65%)	4/150 (2.67%)
# events		
Renal and urinary disorders		
Nephrolithiasis † [A]		

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
# participants affected/at risk	2/151 (1.32%)	5/150 (3.33%)
# events		
Renal cyst †[A]		
# participants affected/at risk	4/151 (2.65%)	0/150 (0%)
# events		
Respiratory, thoracic and mediastinal disorders		
Cough †[A]		
# participants affected/at risk	8/151 (5.3%)	10/150 (6.67%)
# events		
Oropharyngeal pain †[A]		
# participants affected/at risk	4/151 (2.65%)	4/150 (2.67%)
# events		
Sinus congestion †[A]		
# participants affected/at risk	4/151 (2.65%)	8/150 (5.33%)

	Placebo + Pioglitazone With or Without Metformin	Albiglutide 30 mg + Pioglitazone With or Without Metformin
# events		
Skin and subcutaneous tissue disorders		
Dry skin †[A]		
# participants affected/at risk	1/151 (0.66%)	4/150 (2.67%)
# events		
Pruritis †[A]		
# participants affected/at risk	1/151 (0.66%)	5/150 (3.33%)
# events		
Rash †[A]		
# participants affected/at risk	3/151 (1.99%)	4/150 (2.67%)
# events		
Vascular disorders		
Hypertension †[A]		
# participants affected/at risk	15/151 (9.93%)	17/150 (11.33%)
# 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:

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