Protocol Registration Receipt
09/29/2014

Grantor: CBER IND/IDE Number: 65,177 Serial Number: TBD

A Multi-center, Placebo-controlled Study to Evaluate the Safety of GSK716155 and Its Effects on Myocardial Metabolism, Myocardial Function, and Exercise Capacity in Patients With NYHA Class II/III Congestive Heart Failure

This study has been completed.

Sponsor:	GlaxoSmithKline
Collaborators:	
Information provided by (Responsible Party):	GlaxoSmithKline
ClinicalTrials.gov Identifier:	NCT01357850

Purpose

This exploratory proof of concept study will be conducted in patients with stable New York Heart Association (NYHA) Class II-III heart failure. The focus of the efficacy endpoints is to test the hypothesis that GSK716155 administration will increase glucose uptake and utilization in the myocardium, resulting in increased myocardial efficiency and increased exercise capacity. A positive result, defined as either statistically significant effects on one or more of the efficacy endpoints or as an overall signal suggesting a clinically relevant effect on myocardial physiology, would provide evidence for potential progression into further development in a chronic heart failure population.

Condition	Intervention	Phase
Heart Failure, Congestive	Drug: GSK716155 Drug: Placebo	Phase 2

Study Type: Interventional
Study Design: Basic Science, Parallel Assignment, Double Blind (Subject, Caregiver, Investigator), Randomized, Safety/Efficacy Study
Official Title: A Multi-center, Placebo-controlled Study to Evaluate the Safety of GSK716155 and Its Effects on Myocardial Metabolism, Myocardial Function, and Exercise Capacity in Patients With NYHA Class II/III Congestive Heart Failure

Further study details as provided by GlaxoSmithKline:

Primary Outcome Measure:

- Change From Baseline in Myocardial Glucose Utilization as Assessed by [18F]Fluoro-2-deoxy-glucose Positron Emission Tomography (FDG-PET) Imaging [Time Frame: Baseline and Week 13] [Designated as safety issue: No]

  FDG-PET imaging was performed at Baseline and Week 13 to assess myocardial glucose uptake. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Based on analysis using a mixed effects analysis of variance (ANOVA) model, fitting terms for treatment, visit and interaction of treatment and visit, with participants as random effects.
- Change From Baseline in Myocardial Efficiency (Work Performed/Myocardial Oxygen Consumption [MVO2]) Assessed at Rest [Time Frame: Baseline and Week 13] [Designated as safety issue: No]

  MVO2 was estimated by measuring the rate of myocardial clearance of 11C-activity which represents overall myocardial oxidative flux through the TCA cycle. Cardiac work was measured by echocardiography and cardiac efficiency index was calculated as work (by echocardiography) divided by MVO2. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Based on analysis using a mixed effects ANOVA model, fitting terms for treatment, visit and interaction of treatment and visit, with participants as random effects.
- Change From Baseline in Peak Oxygen Uptake (Peak VO2) as Assessed by Bicycle Cardiopulmonary Exercise Testing [Time Frame: Baseline and Week 13] [Designated as safety issue: No]

  Peak VO2 was measured at Baseline and Week 13. Participants performed a maximal exercise test limited by dyspnea or fatigue on a cycle ergometer. After a rest period, the workloads were increased in a step fashion by 25 watts every 3 minutes. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Based on analysis using a mixed effects ANOVA model, fitting terms for treatment, visit and interaction of treatment and visit, with participants as random effects.

Secondary Outcome Measures:

- Change From Baseline in Left Ventricular Ejection Fraction (LVEF) as Assessed by Echocardiogram [Time Frame: Baseline and Week 13] [Designated as safety issue: No]

  Echocardiography was performed at Baseline and Week 13 using pulse-wave, continuous-wave, and tissue Doppler. Change from Baseline was

calculated as the post-Baseline value minus the Baseline value.

- Change From Baseline in Left Ventricular (LV) Volumes in Systole and Diastole as Assessed by Echocardiogram [Time Frame: Baseline and Week 13] [Designated as safety issue: No]

  Echocardiography was performed at Baseline and Week 13 using pulse-wave, continuous-wave and tissue Doppler. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.

- Change From Baseline in LV and RV Function Assessed by Cardiac Magnetic Resonance (CMR) (LVEF), Myocardial Strain Assessed by Myocardial Tagging Indices [Time Frame: Baseline and Week 13] [Designated as safety issue: No]

  Non-contrast CMR to assess left ventricular (LV) and right ventricular (RV) ejection fraction, volume, mass, and strain was performed following a period of rest after exercise testing at Baseline and after the Week 13 treatment phase. A 3Tesla magnetic resonance imagine (MRI) examination was performed including sequences for evaluation of LV structure and function. Only those participants available at the specified time points were analyzed. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.

- Change From Baseline in LV and RV Function Assessed by CMR (LV and RV Volumes in Systole and Diastole), Myocardial Strain Assessed by Myocardial Tagging Indices [Time Frame: Baseline and Week 13] [Designated as safety issue: No]

  Non-contrast CMR to assess LV and RV ejection fraction, volume, mass, and strain was performed following a period of rest after exercise testing at Baseline and after the Week 13 treatment phase. A 3Tesla magnetic resonance imagine (MRI) examination was performed including sequences for evaluation of LV structure and function. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.

- Change From Baseline in LV and RV Function Assessed by CMR (LV Mass), Myocardial Strain Assessed by Myocardial Tagging Indices [Time Frame: Baseline and Week 13] [Designated as safety issue: No]

  Non-contrast CMR to assess left/right ventricular ejection fraction, volume, mass, and strain was performed following a period of rest after exercise testing at Baseline and after the Week 13 treatment phase. A 3Tesla magnetic resonance imagine (MRI) examination was performed including sequences for evaluation of LV structure and function. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.

- Change From Baseline in Cardiac Energetics (PCr/ATP) Measured by 31P Magnetic Resonance Spectroscopy (MRS) [Time Frame: Baseline and Week 13] [Designated as safety issue: No]

  Participants underwent a CMR scan performed on a 3 Tesla MR system at Baseline and Week 13 to assess cardiac mass, volumes (global function and dilatation), strain and torsion, cardiac and liver lipid content and cardiac energy metabolism. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.

- Change From Baseline in Cardiac and Liver Fat by Proton Spectroscopy (1H MRS) [Time Frame: Baseline and Week 13] [Designated as safety issue: No]

  Change in Baseline in cardiac and liver fat by proton spectroscopy was planned at Baseline and Week 13. The protocol allowed for sites to perform all or only efficacy assessments, depending on site designation, capability and feasibility. No sites that enrolled participants into this study were able to perform this outcome measure.

- Change From Baseline in Exercise Capacity Assessed by 6-minute Walk Test [Time Frame: Baseline and Week 13] [Designated as safety issue: No]

  The six minute walk test was performed at Baseline and Week 13. All participantss were given standardized instructions and the distance walked was measured. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.

- Change From Baseline in Serum N-terminal Fragment Brain Natriuretic Peptide (NT-BNP) Level [Time Frame: Change from Baseline at Week 13] [Designated as safety issue: No]

Baseline is defined as the last available assessment on or prior to the first dose of study medication. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.

- Change From Baseline in Plasma Levels of Glucose, and Free Fatty Acids (FFA) [Time Frame: Baseline and Week 13] [Designated as safety issue: No]
  Blood samples for biomarker analysis of fasting levels of glucose and FFA were collected at Weeks 1, 7 and 13; glucose was also collected at Weeks 2, 4, 6, 8, 10, and 12. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
- Change From Baseline in Plasma Levels of Insulin [Time Frame: Baseline and Week 13] [Designated as safety issue: No]
  Blood samples for biomarker analysis of fasting levels of insulin were collected at Weeks 1, 7 and 13. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
- Change From Baseline in Quality of Life as Assessed by the Minnesota Living With Heart Failure Questionnaire [Time Frame: Baseline and Week 13] [Designated as safety issue: No]
  Minnesota living with heart failure questionnaire (MLHFQ) is a validated instrument to measure participant-reported quality of life at Baseline and Week 13. For each of 21 items, participants rated the effects of heart failure and its treatment on physical, socioeconomic and psychological aspects of their life. To measure the effects of symptoms, functional limitations, psychological distress on an individual's quality of life, the MLHF questionnaire asks each participant to indicate their response using a 6-point scale (ranging from 0 to 5, 0=no, 1=very little, and 5=very much). The min and max scores can range from 0 to 105. The likert scale measures the effect of heart failure and treatments for heart failure on an individual's ability to live as they want. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
- Number of Participants With Any Adverse Events (AEs) and Serious Adverse Events (SAEs) [Time Frame: Baseline and Week 13] [Designated as safety issue: No]
  An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. An SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or is a congenital anomaly/birth defect. Please refer to the AE/SAE section for further details.
- Number of Participants With Adverse Events by the Indicated Severity [Time Frame: Baseline and Week 13] [Designated as safety issue: No]
  An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. An SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or is a congenital anomaly/birth defect. Severity categories: Mild: an event that was easily tolerated by the participant, causing minimal discomfort and not interfering with everyday activities;Moderate: an event that was sufficiently discomforting to interfere with normal everyday activities; Severe: an event that prevents normal everyday activities.

Enrollment: 82
Study Start Date: September 2010
Study Completion Date: September 2012

Primary Completion Date: September 2012

Arms	Assigned Interventions
Experimental: GSK716155 (3.75mg) GSK716155 (3.75mg)	Drug: GSK716155 GSK716155
Experimental: GSK716155 (15mg) GSK716155 (15mg)	Drug: GSK716155 GSK716155
Experimental: GSK716155 (30mg) GSK716155 (30mg)	Drug: GSK716155 GSK716155
Placebo Comparator: GSK716155-matched placebo GSK716155-matcued placebo	Drug: Placebo Placebo

Eligibility

Ages Eligible for Study: 21 Years to 75 Years
Genders Eligible for Study: Both

Inclusion Criteria:

- Chronic dilated cardiomyopathy of ischemic or non-ischemic origin
- Clinically stable on optimal therapies for at least 3 months prior to screening/baseline visit.
- Left ventricular ejection fraction greater than or equal to 40% as assessed by any measurement in the previous 24 months.
- NYHA Class II/III heart failure for a minimum of 6 months prior to enrolment
- Male or female between 21 and 75 years of age inclusive, at the time of signing the informed consent. However the optimal age range for this study will be 40 to 65 years of age.
- A female subject is eligible to participate if she is of:

Non-childbearing potential defined as pre-menopausal females with a documented tubal ligation or hysterectomy; or postmenopausal defined as 12 months of spontaneous amenorrhea [in questionable cases a blood sample with simultaneous follicle stimulating hormone (FSH) > 40 MIU/ml and estradiol < 40 pg/ml (<140 pmol/L) is confirmatory].

Child-bearing potential and agrees to use one of the contraception methods listed in Section 8.1 for an appropriate period of time (as determined by the product label or investigator) prior to the start of dosing to sufficiently minimize the risk of pregnancy at that point. Female subjects must agree to use contraception until the follow-up visit ~28 days post-last dose.

- Capable of giving written informed consent, which includes compliance with the requirements and restrictions listed in the consent form.
- Confirmed QTcB or QTcF < 480 msec; or QTc < 500 msec in subjects with Bundle Branch Block.
- AST and ALT < 2xULN; alkaline phosphatase and bilirubin greater than or equal to 1.5xULN (isolated bilirubin >1.5xULN is acceptable if bilirubin is fractionated and direct bilirubin <35%).
- Subjects must be able to perform performance/exercise testing

Exclusion Criteria:

- A subject will not be eligible for inclusion in this study if any of the following criteria apply:
- Active ischemia manifest as a history of myocardial infarction or unstable angina in the past 12 months or a history of coronary revascularization (percutaneous coronary intervention and/or coronary artery bypass grafting) in the past 6 months.

  -. High suspicion of active myocardial ischemia, in the opinion of the treating physician

- A positive pre-study Hepatitis B surface antigen or positive Hepatitis C antibody result within 3 months of screening
- History of drug/alcohol abuse.
- A positive test for HIV antibody.
- Calcitonin > 100 pg./mL
- Triglycerides > 850 mg/dL
- History of significant gastrointestinal surgery, including gastric bypass and banding, antrectomy, Roux-en-Y bypass, gastric vagotomy, small bowel resection, or surgeries thought to significantly affect upper gastrointestinal function.
- History of regular alcohol consumption within 6 months of the study defined as:

For UK: an average weekly intake of >21 units for males or >14 units for females. One unit is equivalent to 8 g of alcohol: a half-pint (~240 ml) of beer, 1 glass (125 ml) of wine or 1 (25 ml) measure of spirits.

For US: an average weekly intake of >14 drinks for males or >7 drinks for females. One drink is equivalent to 12 g of alcohol: 12 ounces (360 ml) of beer, 5 ounces (150 ml) of wine or 1.5 ounces (45 ml) of 80 proof distilled spirits.

- The subject has participated in a clinical trial and has received an investigational product within the following time period prior to the first dosing day in the current study: 30 days, 5 half-lives or twice the duration of the biological effect of the investigational product (whichever is longer).
- Exposure to more than four new chemical entities within 12 months prior to the first dosing day.
- Known allergy or history of sensitivity to albiglutide, any other GLP-1 analogue, , or Baker’s yeast.
- Where participation in the study would result in donation of blood or blood products in excess of 500 mL within a 56 day period.
- Pregnant females as determined by positive serum or urine hCG test at screening or prior to dosing.

- Lactating females.
- Unwillingness or inability to follow the procedures outlined in the protocol (e.g.. related to psychiatric disorder)
- Subject is mentally or legally incapacitated.
- Known diagnosis of diabetes mellitus, fasting glucose >140mg/dL, or HbA1c > 7%.
- Uncorrected thyroid disease manifest as an abnormal thyroid-stimulating hormone (TSH) (outside reference range at screening).
- Other medical problems with life expectancy less than 1yr.
- Other causes of cardiomyopathy or left ventricular dysfunction including:

Uncorrected primary obstructive or regurgitant valvular disease Restrictive cardiomyopathy due to amyloidosis, hemochromatosis, sarcoidosis or other cause Cardiac hypertrophy with wall thickness >1.5cm Alcohol-induced cardiomyopathy Women with heart failure during the 12 months following childbirth. Complex congenital heart disease Anthracycline induced cardiomyopathy

- Subjects with genetic disorders of skeletal muscle (e.g. Duchenne muscular dystrophy)
- Clinically significant pericardial disease.
- Listed as a status 1A or 1B on heart transplant waiting list.
- History of deep vein thrombosis or a known coagulation disorder
- History of pancreatitis
- History of or family history of medullary thyroid carcinoma
- History of or family history of multiple endocrine neoplasia type 2
- History of renal dysfunction with estimated GFR < 40 ml/min at screening
- Resting systolic blood pressure < 85 mmHg or >170 mmHg; or diastolic blood pressure >110 mgHg at screening.
- Inability of the patient to lie flat for a combined total of up to 4 hours to complete imaging assessments.
- No subjects will be enrolled at the single site performing the CMR sub-study who have contraindications to MRI scanning including, but not limited to:

Intracranial aneurysm clips with an appropriate operative conformation History of intra- orbital metal fragments Pacemakers or non-MR compatible heart valves Inner ear implants History of claustrophobia deemed significant by the investigator

Contacts and Locations

Locations

United States, Georgia

GSK Investigational Site

Savannah, Georgia, United States, 31405

United States, Louisiana

GSK Investigational Site

Metairie, Louisiana, United States, 70006

United States, Maine

GSK Investigational Site

Auburn, Maine, United States, 04210

United States, Maryland

GSK Investigational Site

Baltimore, Maryland, United States, 21287

United States, Michigan

GSK Investigational Site

Detroit, Michigan, United States, 48202

United States, Minnesota

GSK Investigational Site

Minneapolis, Minnesota, United States, 55407

United States, Missouri

GSK Investigational Site

St Louis, Missouri, United States, 63110

United States, New Jersey

GSK Investigational Site

Newark, New Jersey, United States, 7103

United States, New York

GSK Investigational Site

Stony Brook, New York, United States, 11794

United States, Ohio

GSK Investigational Site

Columbus, Ohio, United States, 43210

United States, Pennsylvania

GSK Investigational Site

New York, Pennsylvania, United States, 10032

GSK Investigational Site

Philadelphia, Pennsylvania, United States, 19104

United Kingdom

GSK Investigational Site

London, United Kingdom, W12 0HS

GSK Investigational Site

Oxford, United Kingdom, OX3 9DU

GSK Investigational Site

Cambridge, Cambridgeshire, United Kingdom, CB2 0QQ

Investigators

Study Director:	GSK Clinical Trials	GlaxoSmithKline

More Information

Responsible Party:	GlaxoSmithKline
Study ID Numbers:	112670
Health Authority:	United States: Food and Drug Administration Europe: European Medicines Agency

---

Study Results

Participant Flow

Pre-Assignment Details

Participants (par.) who met eligibility criteria and completed a 30 day Screening were then randomized to a 13-week Treatment Period, followed by a Follow-up visit 28 days post-treatment. The duration of the study was approximately 20 weeks from Screening to Follow-up. A total of 100 par. were planned, and 82 par. were randomized.

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 milligrams (mg) weekly injected

	Description
	subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Overall Study

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Started	30	12	13	27
Completed	29	12	13	27
Not Completed	1	0	0	0
Lost to Follow-up	1	0	0	0

Baseline Characteristics

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

	Description
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Baseline Measures

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg	Total
Number of Participants	30	12	13	27	82
Age, Continuous [units: Years] Mean (Standard Deviation)	55.6 (9.60)	51.3 (12.44)	57.2 (11.02)	58.2 (10.23)	56.1 (10.53)
Gender, Male/Female [units: Participants]					
Female	9	3	2	7	21
Male	21	9	11	20	61
Race/Ethnicity, Customized [units: Participants]					
African American/African Heritage	3	4	5	4	16
Native Hawaiian Or Other Pacific Islander	1	0	0	0	1
Asian - Central/South Asian Heritage	0	0	0	1	1
White - White/Caucasian/European	26	7	8	22	63

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg	Total
Heritage					
White - Arabic/North African Heritage	0	1	0	0	1

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline in Myocardial Glucose Utilization as Assessed by [18F]Fluoro-2-deoxy-glucose Positron Emission Tomography (FDG-PET) Imaging
Measure Description	FDG-PET imaging was performed at Baseline and Week 13 to assess myocardial glucose uptake. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Based on analysis using a mixed effects analysis of variance (ANOVA) model, fitting terms for treatment, visit and interaction of treatment and visit, with participants as random effects.
Time Frame	Baseline and Week 13
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population: all randomized participants who received >= 1 dose of study medication and had >= 1 on treatment assessment. Only those participants available at the specified time points were analyzed.

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected

	Description
	subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	10	4	4	11
Change From Baseline in Myocardial Glucose Utilization as Assessed by [18F]Fluoro-2-deoxy-glucose Positron Emission Tomography (FDG-PET) Imaging [units: micromoles per gram per minute] Least Squares Mean (95% Confidence Interval)	0.0185 (-0.0158 to 0.0528)	0.0103 (-0.0440 to 0.0646)	0.0369 (0.0042 to 0.0695)	0.0059 (-0.0268 to 0.0386)

Statistical Analysis 1 for Change From Baseline in Myocardial Glucose Utilization as Assessed by [18F]Fluoro-2-deoxy-glucose Positron Emission Tomography (FDG-PET) Imaging

Groups	Placebo, Albiglutide 3.75 mg
Method	ANOVA
P-Value	0.7873

Mean Difference (Final Values)	0.0119
95% Confidence Interval	-0.0768 to 0.1005

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.]

Statistical Analysis 2 for Change From Baseline in Myocardial Glucose Utilization as Assessed by [18F]Fluoro-2-deoxy-glucose Positron Emission Tomography (FDG-PET) Imaging

Groups	Placebo, Albiglutide 15 mg
Method	ANOVA
P-Value	0.0499
Mean Difference (Final Values)	0.0678
95% Confidence Interval	0.0000 to 0.1356

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.]

Statistical Analysis 3 for Change From Baseline in Myocardial Glucose Utilization as Assessed by [18F]Fluoro-2-deoxy-glucose Positron Emission Tomography (FDG-PET) Imaging

Groups	Placebo, Albiglutide 30 mg

Method	ANOVA
P-Value	0.1666
Mean Difference (Final Values)	0.0467
95% Confidence Interval	-0.0204 to 0.1137

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. Primary Outcome Measure:

Measure Title	Change From Baseline in Myocardial Efficiency (Work Performed/Myocardial Oxygen Consumption [MVO2]) Assessed at Rest
Measure Description	MVO2 was estimated by measuring the rate of myocardial clearance of 11C-activity which represents overall myocardial oxidative flux through the TCA cycle. Cardiac work was measured by echocardiography and cardiac efficiency index was calculated as work (by echocardiography) divided by MVO2. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Based on analysis using a mixed effects ANOVA model, fitting terms for treatment, visit and interaction of treatment and visit, with participants as random effects.
Time Frame	Baseline and Week 13
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	10	5	11	11
Change From Baseline in Myocardial Efficiency (Work Performed/Myocardial Oxygen Consumption [MVO2]) Assessed at Rest [units: millimeters of mercury/liter/minute2] Least Squares Mean (95% Confidence Interval)	-1051.90 (-3136.43 to 1032.63)	-1070.09 (-3846.14 to 1705.95)	-348.58 (-2278.39 to 1581.23)	-870.64 (-2771.39 to 1030.11)

Statistical Analysis 1 for Change From Baseline in Myocardial Efficiency (Work Performed/Myocardial Oxygen Consumption [MVO2]) Assessed at Rest

Groups	Placebo, Albiglutide 3.75 mg
Method	ANOVA
P-Value	0.9343
Mean Difference (Final Values)	134.89
95% Confidence Interval	-3172.05 to 3441.83

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.]

Statistical Analysis 2 for Change From Baseline in Myocardial Efficiency (Work Performed/Myocardial Oxygen Consumption [MVO2]) Assessed at Rest

Groups	Placebo, Albiglutide 15 mg
Method	ANOVA
P-Value	0.3375
Mean Difference (Final Values)	1278.77
95% Confidence Interval	-1398.13 to 3955.68

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.]

Statistical Analysis 3 for Change From Baseline in Myocardial Efficiency (Work Performed/Myocardial Oxygen Consumption [MVO2]) Assessed at Rest

Groups	Placebo, Albiglutide 30 mg
Method	ANOVA
P-Value	0.5582
Mean Difference (Final Values)	772.70
95% Confidence Interval	-1887.77 to 3433.17

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.]

3. Primary Outcome Measure:

Measure Title	Change From Baseline in Peak Oxygen Uptake (Peak VO2) as Assessed by Bicycle Cardiopulmonary Exercise Testing
Measure Description	Peak VO2 was measured at Baseline and Week 13. Participants performed a maximal exercise test limited by dyspnea or fatigue on a cycle ergometer. After a rest period, the workloads were increased in a step fashion by 25 watts every 3 minutes. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Based on analysis using a mixed effects ANOVA model, fitting terms for treatment, visit and interaction of treatment and visit, with participants as random effects.

Time Frame	Baseline and Week 13
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	29	12	13	26
Change From Baseline in Peak Oxygen Uptake (Peak VO2) as Assessed by Bicycle Cardiopulmonary Exercise Testing [units: Milliliters per kilogram per minute] Least Squares Mean (95% Confidence Interval)	-0.63 (-1.53 to 0.27)	0.05 (-1.35 to 1.45)	0.51 (-0.84 to 1.85)	0.88 (-0.07 to 1.83)

Statistical Analysis 1 for Change From Baseline in Peak Oxygen Uptake (Peak VO2) as Assessed by Bicycle Cardiopulmonary Exercise Testing

Groups	Placebo, Albiglutide 3.75 mg
Method	ANOVA
P-Value	0.2256
Median Difference (Final Values)	-2.06
95% Confidence Interval	-5.43 to 1.30

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.]

Statistical Analysis 2 for Change From Baseline in Peak Oxygen Uptake (Peak VO2) as Assessed by Bicycle Cardiopulmonary Exercise Testing

Groups	Placebo, Albiglutide 15 mg
Method	ANOVA
P-Value	0.5647
Mean Difference (Final Values)	-0.95
95% Confidence Interval	-4.22 to 2.32

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.]

Statistical Analysis 3 for Change From Baseline in Peak Oxygen Uptake (Peak VO2) as Assessed by Bicycle Cardiopulmonary Exercise Testing

Groups	Placebo, Albiglutide 30 mg
Method	ANOVA
P-Value	0.8942
Mean Difference (Final Values)	0.18
95% Confidence Interval	-2.44 to 2.79

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.]

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in Left Ventricular Ejection Fraction (LVEF) as Assessed by Echocardiogram
Measure Description	Echocardiography was performed at Baseline and Week 13 using pulse-wave, continuous-wave, and tissue Doppler. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
Time Frame	Baseline and Week 13

Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	28	11	13	27
Change From Baseline in Left Ventricular Ejection Fraction (LVEF) as Assessed by Echocardiogram [units: Percentage] Geometric Mean (Standard Error)	1.12 (1.06)	0.99 (2.21)	1.03 (1.64)	1.08 (1.08)

5. Secondary Outcome Measure:

Measure Title	Change From Baseline in Left Ventricular (LV) Volumes in Systole and Diastole as Assessed by Echocardiogram
Measure Description	Echocardiography was performed at Baseline and Week 13 using pulse-wave, continuous-wave and tissue Doppler. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
Time Frame	Baseline and Week 13
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	28	11	13	27
Change From Baseline in Left Ventricular (LV) Volumes in Systole and Diastole as Assessed by Echocardiogram [units: Milliliters] Geometric Mean (Standard Error)				
LV end-diastolic volume	0.9 (4.92)	1.0 (3.05)	1.0 (4.37)	1.0 (5.54)
LV end-systolic volume	0.9 (4.05)	1.0 (3.80)	1.0 (5.08)	0.9 (5.11)

6. Secondary Outcome Measure:

Measure Title	Change From Baseline in LV and RV Function Assessed by Cardiac Magnetic Resonance (CMR) (LVEF), Myocardial Strain Assessed by Myocardial Tagging Indices
Measure Description	Non-contrast CMR to assess left ventricular (LV) and right ventricular (RV) ejection fraction, volume, mass, and strain was performed following a period of rest after exercise testing at Baseline and after the Week 13 treatment phase. A 3Tesla magnetic resonance imagine (MRI) examination was performed including sequences for evaluation of LV structure and function. Only those participants available at the specified time points were analyzed. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
Time Frame	Baseline and Week 13
Safety Issue?	No

Analysis Population Description

CMR Substudy Population: all randomized participants who participated in the CMR substudy and had valid Baseline and/or Week 13 assessments for

>= 1 one of the imaging parameters of LV and RV function assessed by CMR (LVEF, LV and RV volumes in systole and diastole, LV mass), myocardial strain assessed by myocardial tagging indices.

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	5	1	2	7
Change From Baseline in LV and RV Function Assessed by Cardiac Magnetic Resonance (CMR) (LVEF), Myocardial Strain Assessed by Myocardial Tagging Indices [units: Percentage] Geometric Mean (Standard Error)	1.17 (1.64)	1.14 (NA) [1]	1.09 (4.0)	1.09 (1.90)

[1] Only one participant was analyzed in this treatment arm at this time point; therefore the mean and standard error cannot be

calculated.

7. Secondary Outcome Measure:

Measure Title	Change From Baseline in LV and RV Function Assessed by CMR (LV and RV Volumes in Systole and Diastole), Myocardial Strain Assessed by Myocardial Tagging Indices
Measure Description	Non-contrast CMR to assess LV and RV ejection fraction, volume, mass, and strain was performed following a period of rest after exercise testing at Baseline and after the Week 13 treatment phase. A 3Tesla magnetic resonance imagine (MRI) examination was performed including sequences for evaluation of LV structure and function. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
Time Frame	Baseline and Week 13
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously

	Description
	into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	5	1	2	7
Change From Baseline in LV and RV Function Assessed by CMR (LV and RV Volumes in Systole and Diastole), Myocardial Strain Assessed by Myocardial Tagging Indices [units: Milliliters] Geometric Mean (Standard Error)				
LV end-diastolic volume	0.99 (11.08)	1.02 (NA) [1]	0.96 (12.50)	0.95 (11.79)
LV end-systolic volume	0.90 (7.80)	0.89 (NA) [2]	0.94 (3.00)	0.89 (9.42)

[1] Only one participant was analyzed in this treatment arm at this time point; therefore the mean and standard error cannot be calculated.

[2] Only one participant was analyzed in this treatment arm at this time point; therefore the mean and standard error cannot be calculated.

8. Secondary Outcome Measure:

Measure Title	Change From Baseline in LV and RV Function Assessed by CMR (LV Mass), Myocardial Strain Assessed by

	Myocardial Tagging Indices
Measure Description	Non-contrast CMR to assess left/right ventricular ejection fraction, volume, mass, and strain was performed following a period of rest after exercise testing at Baseline and after the Week 13 treatment phase. A 3Tesla magnetic resonance imagine (MRI) examination was performed including sequences for evaluation of LV structure and function. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
Time Frame	Baseline and Week 13
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	5	1	2	7
Change From Baseline in LV and RV Function Assessed by CMR (LV Mass), Myocardial Strain Assessed by Myocardial Tagging Indices [units: Grams] Geometric Mean (Standard Error)	0.96 (7.99)	1.04 (NA) [1]	1.08 (1.50)	0.97 (10.65)

[1] Only one participant was analyzed in this treatment arm at this time point; therefore the mean and standard error cannot be calculated.

9. Secondary Outcome Measure:

Measure Title	Change From Baseline in Cardiac Energetics (PCr/ATP) Measured by 31P Magnetic Resonance Spectroscopy (MRS)
Measure Description	Participants underwent a CMR scan performed on a 3 Tesla MR system at Baseline and Week 13 to assess cardiac mass, volumes (global function and dilatation), strain and torsion, cardiac and liver lipid content and cardiac energy metabolism. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
Time Frame	Baseline and Week 13
Safety Issue?	No

Analysis Population Description

Magnetic Resonance Substudy Population (MRS): all randomized participants who participated in the MRS substudy and had valid Baseline and/or Week 13 assessments for either PCr/ATP via 31P MRS. Only those participants available at the specified time points were analyzed.

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 30 mg
Number of Participants Analyzed	5	6
Change From Baseline in Cardiac Energetics (PCr/ATP) Measured by 31P Magnetic Resonance Spectroscopy (MRS) [units: ratio] Least Squares Mean (95% Confidence Interval)	0.33 (-0.29 to 0.94)	0.11 (-0.45 to 0.67)

10. Secondary Outcome Measure:

Measure Title	Change From Baseline in Cardiac and Liver Fat by Proton Spectroscopy (1H MRS)
Measure Description	Change in Baseline in cardiac and liver fat by proton spectroscopy was planned at Baseline and Week 13. The protocol allowed for sites to perform all or only efficacy assessments, depending on site designation, capability and feasibility. No sites that enrolled participants into this study were able to perform this outcome measure.
Time Frame	Baseline and Week 13

Safety Issue?	No

Analysis Population Description

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	0	0	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

11. Secondary Outcome Measure:

Measure Title	Change From Baseline in Exercise Capacity Assessed by 6-minute Walk Test
Measure Description	The six minute walk test was performed at Baseline and Week 13. All

	participantss were given standardized instructions and the distance walked was measured. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
Time Frame	Baseline and Week 13
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	28	12	13	27
Change From Baseline in Exercise	1.03 (0.98 to	1.10 (0.96 to	1.14 (1.00 to	1.05 (1.00 to

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Capacity Assessed by 6-minute Walk Test [units: Meters] Geometric Mean (95% Confidence Interval)	1.07)	1.25)	1.30)	1.10)

12. Secondary Outcome Measure:

Measure Title	Change From Baseline in Serum N-terminal Fragment Brain Natriuretic Peptide (NT-BNP) Level
Measure Description	Baseline is defined as the last available assessment on or prior to the first dose of study medication. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
Time Frame	Change from Baseline at Week 13
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously

	Description
	into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	28	12	12	25
Change From Baseline in Serum N-terminal Fragment Brain Natriuretic Peptide (NT-BNP) Level [units: Nanogram per liter] Geometric Mean (Standard Error)	0.90 (10.43)	0.90 (34.20)	0.70 (31.50)	0.90 (25.73)

13. Secondary Outcome Measure:

Measure Title	Change From Baseline in Plasma Levels of Glucose, and Free Fatty Acids (FFA)
Measure Description	Blood samples for biomarker analysis of fasting levels of glucose and FFA were collected at Weeks 1, 7 and 13; glucose was also collected at Weeks 2, 4, 6, 8, 10, and 12. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
Time Frame	Baseline and Week 13
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	30	12	13	27
Change From Baseline in Plasma Levels of Glucose, and Free Fatty Acids (FFA) [units: Millimole per liter (mmol/L)] Geometric Mean (Standard Error)				
FFA (n=24, 10, 12, 22)	0.81 (0.03)	0.90 (0.05)	0.74 (0.04)	0.87 (0.05)
Glucose (n=29, 12, 13, 27)	1.01 (0.14)	0.91 (0.27)	1.00 (0.16)	1.00 (0.17)

14. Secondary Outcome Measure:

Measure Title	Change From Baseline in Plasma Levels of Insulin
Measure Description	Blood samples for biomarker analysis of fasting levels of insulin were collected at Weeks 1, 7 and 13. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
Time Frame	Baseline and Week 13
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	28	12	13	26
Change From Baseline in Plasma Levels of Insulin [units: picomole per liter (pmol/L)] Geometric Mean (Standard Error)	0.9 (18.08)	0.7 (30.49)	1.0 (15.41)	1.2 (15.56)

15. Secondary Outcome Measure:

Measure Title	Change From Baseline in Quality of Life as Assessed by the Minnesota Living With Heart Failure Questionnaire
Measure Description	Minnesota living with heart failure questionnaire (MLHFQ) is a validated instrument to measure participant-reported quality of life at Baseline and Week 13. For each of 21 items, participants rated the effects of heart failure and its treatment on physical, socioeconomic and psychological aspects of their life. To measure the effects of symptoms, functional limitations, psychological distress on an individual's quality of life, the MLHF questionnaire asks each participant to indicate their response using a 6-point scale (ranging from 0 to 5, 0=no, 1=very little, and 5=very much). The min and max scores can range from 0 to 105. The likert scale measures the effect of heart failure and treatments for heart failure on an individual's ability to live as they want. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
Time Frame	Baseline and Week 13
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	29	12	13	27
Change From Baseline in Quality of Life as Assessed by the Minnesota Living With Heart Failure Questionnaire [units: Scores on a scale] Geometric Mean (95% Confidence Interval)	0.8 (0.6 to 1.0)	0.7 (0.4 to 1.2)	0.7 (0.5 to 1.0)	0.7 (0.5 to 0.9)

16. Secondary Outcome Measure:

Measure Title	Number of Participants With Any Adverse Events (AEs) and Serious Adverse Events (SAEs)

Measure Description	An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. An SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or is a congenital anomaly/birth defect. Please refer to the AE/SAE section for further details.
Time Frame	Baseline and Week 13
Safety Issue?	No

Analysis Population Description

All Subject Population: all randomized participants who received >= 1 dose of study medication. Only those participants available at the specified time points were analyzed.

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously

	Description
	into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	30	12	13	27
Number of Participants With Any Adverse Events (AEs) and Serious Adverse Events (SAEs) [units: Participants]				
Any AE	25	12	12	20
Any SAEs	4	2	2	0

17. Secondary Outcome Measure:

Measure Title	Number of Participants With Adverse Events by the Indicated Severity
Measure Description	An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. An SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or is a congenital anomaly/birth defect. Severity categories: Mild: an event that was easily tolerated by the

	participant, causing minimal discomfort and not interfering with everyday activities;Moderate: an event that was sufficiently discomforting to interfere with normal everyday activities; Severe: an event that prevents normal everyday activities.
Time Frame	Baseline and Week 13
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Measured Values

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants Analyzed	30	12	13	27

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Number of Participants With Adverse Events by the Indicated Severity [units: Participants]				
Mild	10	6	4	12
Moderate	13	4	6	6
Severe	2	2	2	2

Reported Adverse Events

Reporting Groups

	Description
Placebo	Participants received albiglutide matching placebo weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 3.75 mg	Participants received albiglutide 3.75 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 15 mg	Participants received albiglutide 15 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.
Albiglutide 30 mg	Participants received albiglutide 30 mg weekly injected subcutaneously into the abdomen using a fixed-dose, prefilled, single-use injector pen.

Time Frame

Serious adverse events (SAEs) and non-serious AEs collected from the start of study medication and within 30 days after the end

of study medication (Week 13) are reported.

Additional Description

AEs and non-serious AEs are reported for members of the All subjects Population, comprised of all participants randomized to treatment, who have taken at least one dose of study medication.

Serious Adverse Events

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Total # participants affected/at risk	4/30 (13.33%)	2/12 (16.67%)	2/13 (15.38%)	0/27 (0%)
Cardiac disorders				
Atrial Fibrillation †[A]				
# participants affected/at risk	1/30 (3.33%)	0/12 (0%)	0/13 (0%)	0/27 (0%)
# events				
Cardiac Failure Congestive †[A]				
# participants affected/at risk	1/30 (3.33%)	0/12 (0%)	0/13 (0%)	0/27 (0%)
# events				
Ventricular Tachycardia †[A]				
# participants affected/at risk	1/30 (3.33%)	0/12 (0%)	0/13 (0%)	0/27 (0%)
# events				
Gastrointestinal disorders				

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Small Intestinal Obstruction † [A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
General disorders				
Device Malfunction † [A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Infections and infestations				
Urinary Tract Infection † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Injury, poisoning and procedural complications				
Procedural Vomiting † [A]				
# participants affected/at risk	1/30 (3.33%)	0/12 (0%)	0/13 (0%)	0/27 (0%)
# events				
Metabolism and nutrition				

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
disorders				
Dehydration † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Vascular disorders				
Hypotension † [A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	1/13 (7.69%)	0/27 (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: 5%

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Total # participants affected/at risk	22/30 (73.33%)	11/12 (91.67%)	11/13 (84.62%)	19/27 (70.37%)
Blood and lymphatic system disorders				
Anaemia † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
# events				
Eosinophilia † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Thrombocytopenia † [A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Cardiac disorders				
Angina pectoris † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	2/13 (15.38%)	0/27 (0%)
# events				
Atrial fibrillation † [A]				
# participants affected/at risk	0/30 (0%)	2/12 (16.67%)	0/13 (0%)	0/27 (0%)
# events				
Cardiac failure † [A]				
# participants affected/at risk	2/30 (6.67%)	2/12 (16.67%)	2/13 (15.38%)	0/27 (0%)
# events				

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Palpitations † [A]				
# participants affected/at risk	1/30 (3.33%)	1/12 (8.33%)	0/13 (0%)	1/27 (3.7%)
# events				
Ventricular extrasystoles † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Ventricular tachycardia † [A]				
# participants affected/at risk	1/30 (3.33%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Eye disorders				
Dry eye † [A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Vision blurred † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Gastrointestinal disorders				

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Abdominal discomfort †[A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	0/13 (0%)	2/27 (7.41%)
# events				
Abdominal pain †[A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	1/27 (3.7%)
# events				
Abdominal pain upper †[A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Constipation †[A]				
# participants affected/at risk	1/30 (3.33%)	0/12 (0%)	1/13 (7.69%)	2/27 (7.41%)
# events				
Diarrhoea †[A]				
# participants affected/at risk	5/30 (16.67%)	2/12 (16.67%)	3/13 (23.08%)	4/27 (14.81%)
# events				
Nausea †[A]				
# participants affected/at risk	3/30 (10%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
# events				
Vomiting † [A]				
# participants affected/at risk	3/30 (10%)	0/12 (0%)	1/13 (7.69%)	2/27 (7.41%)
# events				
General disorders				
Fatigue † [A]				
# participants affected/at risk	1/30 (3.33%)	2/12 (16.67%)	0/13 (0%)	2/27 (7.41%)
# events				
Implant site pain † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Injection site haematoma † [A]				
# participants affected/at risk	1/30 (3.33%)	2/12 (16.67%)	2/13 (15.38%)	0/27 (0%)
# events				
Injection site pain † [A]				
# participants affected/at risk	2/30 (6.67%)	0/12 (0%)	0/13 (0%)	0/27 (0%)
# events				

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Injection site pruritus † [A]				
# participants affected/at risk	1/30 (3.33%)	1/12 (8.33%)	0/13 (0%)	1/27 (3.7%)
# events				
Immune system disorders				
Seasonal allergy † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Infections and infestations				
Ear infection † [A]				
# participants affected/at risk	0/30 (0%)	2/12 (16.67%)	0/13 (0%)	0/27 (0%)
# events				
Eye infection † [A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Nasopharyngitis † [A]				
# participants affected/at risk	3/30 (10%)	1/12 (8.33%)	0/13 (0%)	1/27 (3.7%)

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
# events				
Respiratory tract infection † [A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Subcutaneous abscess † [A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Upper respiratory tract infection † [A]				
# participants affected/at risk	4/30 (13.33%)	2/12 (16.67%)	1/13 (7.69%)	2/27 (7.41%)
# events				
Urinary tract infection † [A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Vulvovaginal mycotic infection † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Injury, poisoning and procedural complications				
Contusion † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	0/13 (0%)	3/27 (11.11%)
# events				
Excoriation † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Investigations				
Blood creatinine increased † [A]				
# participants affected/at risk	1/30 (3.33%)	0/12 (0%)	0/13 (0%)	3/27 (11.11%)
# events				
Blood urea increased † [A]				
# participants affected/at risk	1/30 (3.33%)	1/12 (8.33%)	0/13 (0%)	2/27 (7.41%)
# events				
Brain natriuretic peptide increased † [A]				
# participants affected/at	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
risk				
# events				
International normalised ratio increased † [A]				
# participants affected/at risk	1/30 (3.33%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Lipase increased † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	0/13 (0%)	3/27 (11.11%)
# events				
Metabolism and nutrition disorders				
Gout † [A]				
# participants affected/at risk	1/30 (3.33%)	1/12 (8.33%)	1/13 (7.69%)	0/27 (0%)
# events				
Impaired fasting glucose † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	2/27 (7.41%)
# events				
Increased appetite † [A]				
# participants affected/at	2/30 (6.67%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
risk				
# events				
Musculoskeletal and connective tissue disorders				
Arthralgia †[A]				
# participants affected/at risk	0/30 (0%)	2/12 (16.67%)	0/13 (0%)	2/27 (7.41%)
# events				
Back pain †[A]				
# participants affected/at risk	1/30 (3.33%)	1/12 (8.33%)	2/13 (15.38%)	0/27 (0%)
# events				
Muscle spasms †[A]				
# participants affected/at risk	1/30 (3.33%)	0/12 (0%)	1/13 (7.69%)	1/27 (3.7%)
# events				
Musculoskeletal chest pain †[A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Musculoskeletal discomfort				

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
† [A]				
# participants affected/at risk	2/30 (6.67%)	0/12 (0%)	0/13 (0%)	0/27 (0%)
# events				
Musculoskeletal pain † [A]				
# participants affected/at risk	2/30 (6.67%)	0/12 (0%)	1/13 (7.69%)	1/27 (3.7%)
# events				
Osteopenia † [A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Nervous system disorders				
Dizziness † [A]				
# participants affected/at risk	2/30 (6.67%)	2/12 (16.67%)	1/13 (7.69%)	2/27 (7.41%)
# events				
Headache † [A]				
# participants affected/at risk	2/30 (6.67%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Paraesthesia † [A]				

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Presyncope †[A]				
# participants affected/at risk	2/30 (6.67%)	0/12 (0%)	0/13 (0%)	0/27 (0%)
# events				
Transient ischaemic attack †[A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Psychiatric disorders				
Anxiety †[A]				
# participants affected/at risk	1/30 (3.33%)	1/12 (8.33%)	1/13 (7.69%)	0/27 (0%)
# events				
Insomnia †[A]				
# participants affected/at risk	2/30 (6.67%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Renal and urinary disorders				

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
Renal failure acute †[A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	1/13 (7.69%)	0/27 (0%)
# events				
Reproductive system and breast disorders				
Breast tenderness †[A]				
# participants affected/at risk	1/30 (3.33%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Respiratory, thoracic and mediastinal disorders				
Dyspnoea †[A]				
# participants affected/at risk	2/30 (6.67%)	0/12 (0%)	2/13 (15.38%)	1/27 (3.7%)
# events				
Dyspnoea paroxysmal nocturnal †[A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Epistaxis †[A]				
# participants affected/at	0/30 (0%)	0/12 (0%)	0/13 (0%)	2/27 (7.41%)

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
risk				
# events				
Hypoventilation † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Oropharyngeal pain † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	0/13 (0%)	2/27 (7.41%)
# events				
Rales † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Rhinitis allergic † [A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Sinus congestion † [A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Wheezing † [A]				

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Skin and subcutaneous tissue disorders				
Acne †[A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Acne cystic †[A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Actinic keratosis †[A]				
# participants affected/at risk	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)
# events				
Hyperhidrosis †[A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Pruritus †[A]				
# participants affected/at	0/30 (0%)	0/12 (0%)	1/13 (7.69%)	0/27 (0%)

	Placebo	Albiglutide 3.75 mg	Albiglutide 15 mg	Albiglutide 30 mg
risk				
# events				
Rash papular † [A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Seborrhoeic dermatitis † [A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Vascular disorders				
Hot flush † [A]				
# participants affected/at risk	0/30 (0%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				
Hypotension † [A]				
# participants affected/at risk	2/30 (6.67%)	1/12 (8.33%)	0/13 (0%)	0/27 (0%)
# events				

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

More Information

Certain Agreements:

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

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

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

Limitations and Caveats:

Results Point of Contact:

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