Protocol Registration Receipt
07/31/2014

Grantor: CDER IND/IDE Number: 65177 Serial Number:

A Study to Determine the Safety and Efficacy of Albiglutide Administered in Combination With Insulin Glargine

This study has been completed.

Sponsor:	GlaxoSmithKline
Collaborators:	
Information provided by (Responsible Party):	GlaxoSmithKline
ClinicalTrials.gov Identifier:	NCT00976391

Purpose

This study will examine the safety and efficacy of albiglutide in combination with insulin glargine as compared with the combination of insulin glargine and preprandial lispro insulin in subjects with type 2 diabetes.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Biological/Vaccine: albiglutide + insulin glargine	Phase 3

Condition	Intervention	Phase
	Drug: insulin glargine + preprandial lispro insulin	

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Open Label, Randomized, Safety/Efficacy Study
Official Title: A Randomized, Open-Label, Active-Controlled, Parallel-Group, Multicenter Study to Determine the Safety and Efficacy of Albiglutide Administered in Combination With Insulin Glargine as Compared With the Combination of Insulin Glargine and Preprandial Lispro Insulin 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 26 [Time Frame: Baseline and Week 26] [Designated as safety issue: No]
  HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. The 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 26 minus the value at BL. The analysis was performed using an Analysis of Covariance (ANCOVA) model with treatment group, region, history of prior myocardial infarction (yes versus no), and age category (<65 years versus ≥65 years) as factors and Baseline HbA1c as a continuous covariate.The last observation carried forward (LOCF) method was used to impute missing 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.

Secondary Outcome Measures:

- Change From Baseline in HbA1c at Weeks 36, 48 and 52 [Time Frame: Baseline and Weeks 36, 48 and 52] [Designated as safety issue: No]
  HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. Baseline is defined as the last available assessment on or prior to the first dose of study drug. 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.
- Change From Baseline in Fasting Plasma Glucose (FPG) at Week 26 [Time Frame: Baseline and Week 26] [Designated as safety issue: No]
  The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. The Baseline FPG value is 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 FPG + Baseline HbA1c category + region
- Change From Baseline in Fasting Plasma Glucose (FPG) at Weeks 36, 48 and 52 [Time Frame: Baseline and Weeks 36, 48 and 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. Change from Baseline was calculated as the post-Baseline FPG minus the Baseline FPG. This analysis used observed FPG values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.

- Number of Participants Who Achieved HbA1c Response Level of <6.5% and <7.0% at Week 26 [Time Frame: Week 26] [Designated as safety issue: No]
  The number of participants who acheieved the HbA1c treatment goal (i.e., HbA1c response levels of <6.5% and <7.0% at Week 26) were assessed.
- Time to Hyperglycemia Rescue [Time Frame: From the start of study medication until the end of the treatment (up to Week 52)] [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: HbA1c >9.0% and <0.5% decrease from Baseline between >=Week 4 and <Week 8; HbA1c >9.0% and <0.5% decrease from Baseline between >=Week 8 and <Week 12; HbA1c >8.5% and >=4 weeks since uptitration between >=Week 12 and <Week 16; HbA1c >8.0% and >=4 weeks since uptitration; HbA1c >7.5% and >=4 weeks between >Week 26 and >=Week 48 since uptitration. Participants could have been rescued at any time after Week 4. Time to hyperglycemia rescue is the time between the date of first dose and the date of hyperglycemia rescue plus 1 day, or the time between the date of first dose and the date of last visit during active treatment period plus 1 day for participants not requiring rescue. This time is divided by 7 to express the result in weeks.
- Change From Baseline in Body Weight at Week 26 [Time Frame: Baseline and Week 26] [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 + Baseline HbA1c category + prior myocardial infarction history + age category + region + current oral antidiabetic therapy.
- Change From Baseline in Body Weight at Weeks 36, 48 and 52 [Time Frame: Baseline and Weeks 36, 48 and 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. This analysis used observed body weight values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.

Enrollment: 586
Study Start Date: September 2009
Study Completion Date: October 2011
Primary Completion Date: October 2011

Arms	Assigned Interventions
Active Comparator: albiglutide + insulin glargine albiglutide in combination with insulin glargine	Biological/Vaccine: albiglutide + insulin glargine albiglutide in combination with insulin glargine

Arms	Assigned Interventions
Active Comparator: insulin glargine + preprandial lispro insulin insulin glargine in combination with preprandial lispro insulin	Drug: insulin glargine + preprandial lispro insulin insulin glargine in combination with preprandial lispro insulin

This randomized, open-label, active-controlled, parallel-group, multicenter study evaluates the safety and efficacy of a weekly subcutaneously injected dose of albiglutide in combination with insulin glargine as compared with the combination of insulin glargine and preprandial lispro insulin in subjects with type 2 diabetes. Subjects with a historical diagnosis of type 2 diabetes who are inadequately controlled despite the use of insulin glargine or other intermediate- or long-acting insulins for >/= 6 months but < 5 years, with or without oral antidiabetic medications, who are unable to achieve a glycosylated hemoglobin value of < 7% will be recruited into the study. Subjects must also be willing and capable of pursuing an intensive regimen of both basal and preprandial insulin.

Eligibility

Ages Eligible for Study: 18 Years to 75 Years
Genders Eligible for Study: Both

Inclusion Criteria:

- Subjects with type 2 diabetes, currently treated with insulin glargine or other intermediate- or long-acting insulin, with or without oral antidiabetic medications, but experiencing inadequate glycemic control and willing and capable of participating in a regimen of intensive insulin administration. A subject who has been on an intermediate- or long acting insulin for >/=6 months but <5 years, and, in spite of dosage adjustments based on home blood glucose monitoring, is unable to achieve a HbA1c of <7%.
- BMI >/= 20kg/m2 and </=45 kg/m2
- Fasting C-peptide >/=0.8 ng/mL (>/= 0.26 nmol/L)
- HbA1c between 7.0% and 10.5%, inclusive
- Use of oral or systemically injected glucocorticoids is generally not allowed within 3 months before randomization; inhaled, intra articular, and topical corticosteroids are allowed
- Hemoglobin </=11 g/dL for male subjects and >/=10 g/dL for female subjects
- Creatinine clearance >60 mL/min (calculated using the Cockcroft Gault formula)
- Thyroid stimulating hormone level is normal or clinically euthyroid as demonstrated by further thyroid tests (e.g., T4, T3, thyroid-binding globulin)
- Female subjects of childbearing potential (i.e., not surgically sterile and/or not postmenopausal) must be practicing adequate contraception. Adequate contraception must be practiced for the duration of participation in the study including the 8 week Posttreatment Follow-up Period
- Able and willing to monitor his or her own blood glucose concentrations with a home glucose monitor as per the protocol recommendations of self

administration
- No major illness or debility that in the investigator’s opinion prohibits the subject from actively participating in their diabetes management and completing the study
- Able and willing to provide written informed consent

Exclusion Criteria:

- History of cancer, other than squamous cell or basal cell carcinoma of the skin, that has not been in full remission for at least 3 years before Screening.
- History of treated diabetic gastroparesis
- Current ongoing symptomatic biliary disease or history of pancreatitis
- 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
- Recent clinically significant cardiovascular and/or cerebrovascular disease including but not limited to the following:
    - Previous history of stroke or transient ischemic attack within 1 month before Screening.
    - Acute coronary syndrome, which includes the following:
    - Documented MI within the 2 months before Screening and during the period up until receiving the first dose of study medication
    - Any cardiac surgery including percutaneous transluminal coronary angioplasty, coronary stent placement, or coronary artery bypass graft surgery within the 2 months before Screening and during the period up until receiving the first dose of study medication
    - Unstable angina not responsive to nitroglycerin within the 2 months before Screening and during the period up until receiving the first dose of study medication
    - Unstable cardiac rhythm, however, as an example, controlled atrial fibrillation is allowed
    - Current or history of heart failure (New York Heart Association class I to IV).
    - Resting systolic pressure is >160 mm Hg and/or diastolic pressure >100 mm Hg.
    - QTc interval (Fridericia) >470 ms confirmed by a central reader at Screening
- History of stroke or other central nervous system disorder that would negatively impact the subject’s ability to participate in a program of intensive insulin management (eg, physically or mentally incapable of performing home blood glucose monitoring or administering and/or adjusting insulin dosage)
- Hemoglobinopathy that may affect determination of HbA1c
- History of human immunodeficiency virus infection
- History of total bilirubin >1.5 × ULN unless the subject has a previously known history of Gilbert’s syndrome and a fractionated bilirubin that shows conjugated bilirubin <35% of total bilirubin
- ALT or aspartate aminotransferase (AST) >2.5 ×ULN
- Fasting triglyceride level >850 mg/dL at Screening or Week -1 (Visit 5).
- Acute symptomatic (within 3 months before Screening) infection with hepatitis B or hepatitis C; however, subjects with past or chronic hepatitis B or hepatitis C are allowed provided the requirements for ALT, AST, and total bilirubin are met
- History of a psychiatric disorder that will affect the subject’s ability to participate in the study

- History of alcohol or substance abuse within 1 year before Screening
- Positive urine drug screen at Screening, unless the subject is taking a medically approved medication for which a positive drug screen simply verifies the use of this medication
- Hypoglycemia unawareness which has impaired cognitive function and required outside assistance
- Female subject is pregnant (confirmed by laboratory testing), lactating, or <6 weeks postpartum
- Known allergy to any GLP 1 analogue, insulin, other study medications' excipients, excipients of albiglutide, or Baker's yeast
- Receipt of any investigational drug within the 30 days, or 5 half lives whichever is longer, before Screening or a history of receipt of an investigational antidiabetic drug within the 3 months before randomization, or receipt of albiglutide in previous studies
- Current use of any GLP 1 analogue
- History of type 1 diabetes mellitus, diabetic complications (e.g., active proliferative retinopathy or severe diabetic neuropathy) that in the opinion of the investigator would preclude effective participation in the study, or a history of ketoacidosis or hyperosmolar coma
- Contraindications (as per the prescribing information) for the use of either background or potential randomized study medications (e.g., insulin glargine or lispro insulin)
- History or family history of medullary carcinoma
- History or family history of multiple endocrine neoplasia type 2

Contacts and Locations

Locations

United States, Alabama

GSK Investigational Site

Birmingham, Alabama, United States, 35205

GSK Investigational Site

Dothan, Alabama, United States, 36301

United States, Arizona

GSK Investigational Site

Gilbert, Arizona, United States, 85295

GSK Investigational Site

Phoenix, Arizona, United States, 85028

GSK Investigational Site

Phoenix, Arizona, United States, 85050

United States, Arkansas

GSK Investigational Site

Jonesboro, Arkansas, United States, 72401

GSK Investigational Site

Searcy, Arkansas, United States, 72143

United States, California

GSK Investigational Site

Chino, California, United States, 91710

GSK Investigational Site

Commerce, California, United States, 90040

GSK Investigational Site

Fresno, California, United States, 93720

GSK Investigational Site

Fullerton, California, United States, 92835

GSK Investigational Site

Huntington Beach, California, United States, 92646

GSK Investigational Site

La Jolla, California, United States, 92037

GSK Investigational Site

LaJolla, California, United States, 92037

GSK Investigational Site

Long Beach, California, United States, 90806

GSK Investigational Site

Los Alamitos, California, United States, 90720

GSK Investigational Site

Los Angeles, California, United States, 90073

GSK Investigational Site

Mission Viejo, California, United States, 92691

GSK Investigational Site

Sacramento, California, United States, 95821

GSK Investigational Site

San Diego, California, United States, 92128

GSK Investigational Site

San Diego, California, United States, 92117

GSK Investigational Site

San Diego, California, United States, 92117

GSK Investigational Site

San Diego, California, United States, 92161

GSK Investigational Site

Satna Monica, California, United States, 90404

GSK Investigational Site

Spring Valley, California, United States, 91978

GSK Investigational Site

Tustin, California, United States, 92780

GSK Investigational Site

Walnut Creek, California, United States, 94598

GSK Investigational Site

West Hills, California, United States, 91307

United States, Colorado

GSK Investigational Site

Denver, Colorado, United States, 80220

United States, Connecticut

GSK Investigational Site

New Britain, Connecticut, United States, 06050

GSK Investigational Site

Trumbull, Connecticut, United States, 06611

GSK Investigational Site

Waterbury, Connecticut, United States, 06708

United States, Florida

GSK Investigational Site

Boynton Beach, Florida, United States, 33437

GSK Investigational Site

Clearwater, Florida, United States, 33756

GSK Investigational Site

Cutler Bay, Florida, United States, 33189

GSK Investigational Site

Hallandale Beach, Florida, United States, 33009

GSK Investigational Site

Jacksonville, Florida, United States, 32205

GSK Investigational Site

Lauderdale Lakes, Florida, United States, 33319

GSK Investigational Site

Miami, Florida, United States, 33156

GSK Investigational Site

Orlando, Florida, United States, 32822

GSK Investigational Site

Plantation, Florida, United States, 33317

GSK Investigational Site

West Palm Beach, Florida, United States, 33401

United States, Georgia

GSK Investigational Site

Atlanta, Georgia, United States, 30338

GSK Investigational Site

Atlanta, Georgia, United States, 30308

GSK Investigational Site

Blue Ridge, Georgia, United States, 30513

GSK Investigational Site

Columbus, Georgia, United States, 31904

GSK Investigational Site

Savannah, Georgia, United States, 31419

GSK Investigational Site

Snellville, Georgia, United States, 30078

United States, Hawaii

GSK Investigational Site

Honolulu, Hawaii, United States, 96813

GSK Investigational Site

Honolulu, Hawaii, United States, 96814

United States, Idaho

GSK Investigational Site

Idaho Falls, Idaho, United States, 83404

United States, Illinois

GSK Investigational Site

La Grange, Illinois, United States, 60525

United States, Indiana

GSK Investigational Site

Avon, Indiana, United States, 46123

GSK Investigational Site

Evansville, Indiana, United States, 47714

GSK Investigational Site

Lafayette, Indiana, United States, 47904

United States, Iowa

GSK Investigational Site

Council Bluffs, Iowa, United States, 51501

GSK Investigational Site

Des Moines, Iowa, United States, 50314

GSK Investigational Site

Iowa City, Iowa, United States, 52243

United States, Kansas

GSK Investigational Site

Newton, Kansas, United States, 67114

GSK Investigational Site

Topeka, Kansas, United States, 66606

United States, Kentucky

GSK Investigational Site

Lexington, Kentucky, United States, 40504

GSK Investigational Site

Lexington, Kentucky, United States, 40503

United States, Louisiana

GSK Investigational Site

Shreveport, Louisiana, United States, 71101

United States, Maryland

GSK Investigational Site

Hyattsville, Maryland, United States, 20782

United States, Massachusetts

GSK Investigational Site

Haverhill, Massachusetts, United States, 01830

United States, Michigan

GSK Investigational Site

Ann Arbor, Michigan, United States, 48106

GSK Investigational Site

Benzonia, Michigan, United States, 49616

GSK Investigational Site

Bloomfield Hills, Michigan, United States, 48302

GSK Investigational Site

Dearborn, Michigan, United States, 48124

GSK Investigational Site

Kalamazoo, Michigan, United States, 49048

GSK Investigational Site

Kalamazoo, Michigan, United States, 49009

United States, Mississippi

GSK Investigational Site

Picayune, Mississippi, United States, 39466

United States, Missouri

GSK Investigational Site

Chesterfield, Missouri, United States, 63017

GSK Investigational Site

Jefferson City, Missouri, United States, 65109

GSK Investigational Site

Kansas City, Missouri, United States

GSK Investigational Site

Springfield, Missouri, United States, 65807

GSK Investigational Site

St. Louis, Missouri, United States, 63141

GSK Investigational Site

St. Louis, Missouri, United States, 63110

United States, Montana

GSK Investigational Site

Great Falls, Montana, United States, 59405

United States, Nebraska

GSK Investigational Site

Omaha, Nebraska, United States, 68131

GSK Investigational Site

Omaha, Nebraska, United States, 68124

United States, New Jersey

GSK Investigational Site

Haddon Heights, New Jersey, United States, 08035

United States, New York

GSK Investigational Site

New York, New York, United States, 10025

GSK Investigational Site

North Massapequa, New York, United States, 11758

United States, North Carolina

GSK Investigational Site

Asheville, North Carolina, United States, 28803

GSK Investigational Site

Asheville, North Carolina, United States, 28803

GSK Investigational Site

Burlington, North Carolina, United States, 27215

GSK Investigational Site

Durham, North Carolina, United States, 27710

GSK Investigational Site

Hickory, North Carolina, United States, 28601

GSK Investigational Site

Morehead City, North Carolina, United States, 28557

GSK Investigational Site

Tabor City, North Carolina, United States, 28463

United States, Ohio

GSK Investigational Site

Akron, Ohio, United States, 44320

GSK Investigational Site

Canal Fulton, Ohio, United States, 44614

GSK Investigational Site

Cincinnati, Ohio, United States, 45245

GSK Investigational Site

Cleveland, Ohio, United States, 44122

GSK Investigational Site

Columbus, Ohio, United States, 43213

GSK Investigational Site

Dayton, Ohio, United States, 45439

United States, Oklahoma

GSK Investigational Site

Oklahoma City, Oklahoma, United States, 73104

GSK Investigational Site

Oklahoma City, Oklahoma, United States, 73103

GSK Investigational Site

Tulsa, Oklahoma, United States, 74136

GSK Investigational Site

Tulsa, Oklahoma, United States, 74104

United States, Pennsylvania

GSK Investigational Site

Bensalem, Pennsylvania, United States, 19020

GSK Investigational Site

Carlisle, Pennsylvania, United States, 17013

GSK Investigational Site

Tipton, Pennsylvania, United States, 16684

GSK Investigational Site

Uniontown, Pennsylvania, United States, 15401

United States, South Carolina

GSK Investigational Site

Greenville, South Carolina, United States, 29615

GSK Investigational Site

Greenville, South Carolina, United States, 29601

GSK Investigational Site

Murrells Inlet, South Carolina, United States, 29576

United States, Tennessee

GSK Investigational Site

Clarksville, Tennessee, United States, 37043

GSK Investigational Site

Johnson City, Tennessee, United States, 37604

GSK Investigational Site

McKenzie, Tennessee, United States, 38201

GSK Investigational Site

Memphis, Tennessee, United States, 38125

GSK Investigational Site

Tullahoma, Tennessee, United States, 37398

United States, Texas

GSK Investigational Site

Arlington, Texas, United States, 76012

GSK Investigational Site

Bedford, Texas, United States, 76201

GSK Investigational Site

Corpus Christi, Texas, United States, 78404

GSK Investigational Site

Dallas, Texas, United States, 75230

GSK Investigational Site

Dallas, Texas, United States, 75246

GSK Investigational Site

Dallas, Texas, United States, 75230

GSK Investigational Site

Dallas, Texas, United States, 75224

GSK Investigational Site

Dallas, Texas, United States, 75251

GSK Investigational Site

El Paso, Texas, United States, 79925

GSK Investigational Site

Houston, Texas, United States, 77058

GSK Investigational Site

Houston, Texas, United States, 77030

GSK Investigational Site

Houston, Texas, United States, 77074

GSK Investigational Site

Houston, Texas, United States, 77024

GSK Investigational Site

Houston, Texas, United States, 77074

GSK Investigational Site

Katy, Texas, United States, 77450

GSK Investigational Site

Lake Jackson, Texas, United States, 77566

GSK Investigational Site

Midland, Texas, United States, 79707

GSK Investigational Site

North Richland Hills, Texas, United States, 76180

GSK Investigational Site

San Antonio, Texas, United States, 78215

GSK Investigational Site

San Antonio, Texas, United States, 78218

GSK Investigational Site

Schertz, Texas, United States, 78154

GSK Investigational Site

Sugar Land, Texas, United States, 77478

GSK Investigational Site

Temple, Texas, United States, 76508

United States, Utah

GSK Investigational Site

Bountiful, Utah, United States, 84010

GSK Investigational Site

Salt Lake City, Utah, United States, 84124

GSK Investigational Site

Salt Lake City, Utah, United States, 84102

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

Richmond, Virginia, United States, 23294

United States, Washington

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

Brazil

GSK Investigational Site

Brasília, Brazil, 71625-009

GSK Investigational Site

Mogi das Cruzes, Brazil, 08780 - 090

GSK Investigational Site

Porto Alegre, Rio Grande Do Sul, Brazil, 90035-170

France

GSK Investigational Site

Armentières, France, 59280

GSK Investigational Site

Venissieux, France, 69200

Germany

GSK Investigational Site

Berlin, Berlin, Germany, 10115

GSK Investigational Site

Witten, Nordrhein-Westfalen, Germany, 58455

GSK Investigational Site

Mainz, Rheinland-Pfalz, Germany, 55116

GSK Investigational Site

Dresden, Sachsen, Germany, 01307

Hong Kong

GSK Investigational Site

Shatin, Hong Kong

India

GSK Investigational Site
Bangalore, India, 560043
GSK Investigational Site
Bangalore, India, 560 054
GSK Investigational Site
Bangalore, India, 560052
GSK Investigational Site
Chennai, India, 600020
GSK Investigational Site
Manipal, India, 576104

Korea, Republic of

GSK Investigational Site
Goyang-si, Korea, Republic of, 411706
GSK Investigational Site
Koyang-shi, Korea, Republic of, 411710
GSK Investigational Site
Seongnam-si, Korea, Republic of, 463712
GSK Investigational Site
Seongnam-si,, Korea, Republic of, 463-707
GSK Investigational Site
Seoul, Korea, Republic of, 135-720
GSK Investigational Site
Seoul, Korea, Republic of, 139-872
GSK Investigational Site
Seoul, Korea, Republic of, 137-701
GSK Investigational Site
Suwon, Kyonggi-do, Korea, Republic of, 443-721

Mexico

GSK Investigational Site
Mexico City, Mexico, 03300
GSK Investigational Site
Pachuca, Hidalgo, Mexico, 42086
GSK Investigational Site
Puebla, Puebla, Mexico, 72190

Peru

GSK Investigational Site

Trujillo, Peru

GSK Investigational Site

Ica, Ica, Peru, 11

GSK Investigational Site

Huacho, Lima, Peru

GSK Investigational Site

Lima, Lima, Peru, 01

GSK Investigational Site

Piura, Piura, Peru

Philippines

GSK Investigational Site

Marikina City, Philippines, 1810

GSK Investigational Site

Pasay, Philippines, 1300

GSK Investigational Site

Pasig, Philippines, 1600

GSK Investigational Site

Quezon City, Philippines, 1102

GSK Investigational Site

San Juan, Philippines, 1500

GSK Investigational Site

Tagbilaran City, Philippines, 6300

GSK Investigational Site

Taytay Rizal, Philippines, 1920

South Africa

GSK Investigational Site

Bellville, South Africa, 7530

GSK Investigational Site

Cape Town, South Africa, 7530

GSK Investigational Site

Kempton Park, South Africa, 1619

GSK Investigational Site

Parow, South Africa, 7505

GSK Investigational Site

Somerset West, South Africa, 7130

GSK Investigational Site

Port Elizabeth, Eastern Cape, South Africa, 6014

GSK Investigational Site

Boksburg North, Gauteng, South Africa, 1459

GSK Investigational Site

Johannesburg, Gauteng, South Africa, 01820

GSK Investigational Site

Johannesburg, Gauteng, South Africa, 2013

GSK Investigational Site

Johannesburg, Gauteng, South Africa, 2193

GSK Investigational Site

Lenasia, Gauteng, South Africa, 1827

GSK Investigational Site

Pretoria, Gauteng, South Africa, 00083

GSK Investigational Site

Durban, KwaZulu- Natal, South Africa, 4068

GSK Investigational Site

Durban, KwaZulu- Natal, South Africa, 4000

Spain

GSK Investigational Site

Alzira, Spain, 46600

GSK Investigational Site

Barcelona, Spain, 08022

GSK Investigational Site

Madrid, Spain, 28034

GSK Investigational Site

Palma de Mallorca, Spain, 07010

GSK Investigational Site

Sabadell, Spain, 08208

GSK Investigational Site

Sevilla, Spain, 41003

Taiwan

GSK Investigational Site

Taichung, Taiwan, 404

GSK Investigational Site
Tainan, Taiwan, 71044
GSK Investigational Site
Taipei, Taiwan, 11490
GSK Investigational Site
Taipei, Taiwan, 100
GSK Investigational Site
Taipei County, Taiwan, 23137

United Kingdom

GSK Investigational Site
Hull, United Kingdom, HU3 2RW
GSK Investigational Site
London, United Kingdom, SE 1 9RT
GSK Investigational Site
Plymouth, United Kingdom, PL6 8BX
GSK Investigational Site
Liverpool, Merseyside, United Kingdom, L7 8XP

Investigators

Study Director:	GSK Clinical Trials	GlaxoSmithKline

More Information

Responsible Party:	GlaxoSmithKline
Study ID Numbers:	108486
Health Authority:	United States: Food and Drug Administration

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Study Results

Participant Flow

Pre-Assignment Details

Participants (par.) who met eligibility criteria and completed a 4-8 week Run-in/Stabilization Period were then randomized to a

52-week Treatment Period, followed by 8 weeks of post-treatment follow-up. A total of 920 par. were screened; 586 par. were randomized, and 566 par. received >=1 treatment dose.

Reporting Groups

	Description
Albiglutide 30 mg With Insulin Glargine	Participants received albiglutide 30 milligrams (mg) as a subcutaneous injection weekly (with uptitration to 50 mg weekly if needed) via a fully disposable pen injector system combined with insulin glargine (with uptitration if needed) as prescribed by their physician. Participants did not receive investigational product during the Follow-up Period.
Preprandial Lispro Insulin With Insulin Glargine	Participants received a combination of insulin glargine (with uptitration if needed) and preprandial lispro insulin (with uptitration as appropriate) as prescribed by their physician.Participants did not receive investigational product during the Follow-up Period.

Treatment Period (52 Weeks)

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Started	285	281
Completed	243	242
Not Completed	42	39
Adverse Event	16	2
Protocol Violation	1	1
Noncompliance	4	4
Lost to Follow-up	10	8
Withdrawal by Subject	9	19

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Physician Decision	1	1
Termination of Study/Site by GSK	0	4
Pregnancy	1	0

Follow-up Period (8 Weeks)

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Started	285	281
Completed	256	247
Not Completed	29	34
Adverse Event	3	1
Noncompliance	2	2
Lost to Follow-up	14	12
Did not Entered Follow-up	6	8
Withdrawal by Subject	4	7
Termination of Study/Site by GSK	0	4

Baseline Characteristics

Reporting Groups

	Description
Albiglutide 30 mg With Insulin Glargine	Participants received albiglutide 30 mg as a subcutaneous injection weekly (with uptitration to 50 mg weekly if needed) via a fully disposable pen injector system combined with insulin glargine (with uptitration if needed) as prescribed by their physician. Participants did not receive investigational product during the Follow-up Period.
Preprandial Lispro Insulin With Insulin Glargine	Participants received a combination of insulin glargine (with uptitration if needed) and preprandial lispro insulin (with uptitration as appropriate) as prescribed by their physician.Participants did not receive investigational product during the Follow-up Period.

Baseline Measures

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine	Total
Number of Participants	285	281	566
Age, Continuous [units: Years] Mean (Standard Deviation)	54.8 (9.10)	56.3 (8.87)	55.6 (9.01)
Gender, Male/Female [units: Participants]			
Female	153	145	298
Male	132	136	268
Race/Ethnicity, Customized [1] [units: Participants]			
African American/African Heritage	39	34	73

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine	Total
American Indian or Alaskan Native	29	20	49
Asian - Central/South Asian Heritage	17	17	34
Asian - East Asian Heritage	15	17	32
Asian - South East Asian Heritage	16	16	32
Native Hawaiian or Other Pacific Islander	1	3	4
White - Arabic/North African Heritage	2	3	5
White - White/Caucasian/European Heritage	174	171	345
Other-Black	1	0	1
Other-Native American	0	1	1

[1] A participant may have been counted in more than 1 category.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at Week 26

Measure Description	HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. The 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 26 minus the value at BL. The analysis was performed using an Analysis of Covariance (ANCOVA) model with treatment group, region, history of prior myocardial infarction (yes versus no), and age category (<65 years versus ≥65 years) as factors and Baseline HbA1c as a continuous covariate.The last observation carried forward (LOCF) method was used to impute missing 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.
Time Frame	Baseline and Week 26
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 26.

Reporting Groups

	Description
Albiglutide 30 mg With Insulin Glargine	Participants received albiglutide 30 mg as a subcutaneous injection weekly (with uptitration to 50 mg weekly if needed) via a fully disposable pen injector system combined with insulin glargine (with uptitration if needed) as prescribed by their physician. Participants did not receive investigational product during the Follow-up Period.
Preprandial Lispro Insulin With Insulin Glargine	Participants received a combination of insulin glargine (with uptitration if needed) and preprandial lispro insulin (with uptitration as appropriate)

	Description
	as prescribed by their physician.Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Number of Participants Analyzed	279	278
Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at Week 26 [units: Percentage of HbA1c in the blood] Least Squares Mean (Standard Error)	-0.82 (0.058)	-0.66 (0.058)

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

Groups	Albiglutide 30 mg With Insulin Glargine, Preprandial Lispro Insulin With Insulin Glargine
Non-Inferiority/Equivalence Test	Yes
Method	t-test, 1 sided
P-Value	<0.0001
Mean Difference (Net)	-0.16
95% Confidence Interval	-0.32 to 0.00

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

[Not specified.]

P-value from a one-sided t-test to test whether the difference of least square means (albiglutide – preprandial lispro insulin) is less

than or equal to the pre-specified non-inferiority margin of 0.4%

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

[Not specified.]

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

[Not specified.]

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in HbA1c at Weeks 36, 48 and 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. Baseline is defined as the last available assessment on or prior to the first dose of study drug. 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 36, 48 and 52
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). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the ITT Population.

Reporting Groups

	Description
Albiglutide 30 mg With Insulin Glargine	Participants received albiglutide 30 mg as a subcutaneous injection weekly (with uptitration to 50 mg weekly if needed) via a fully disposable pen injector system combined with insulin glargine (with

	Description
	uptitration if needed) as prescribed by their physician. Participants did not receive investigational product during the Follow-up Period.
Preprandial Lispro Insulin With Insulin Glargine	Participants received a combination of insulin glargine (with uptitration if needed) and preprandial lispro insulin (with uptitration as appropriate) as prescribed by their physician.Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Number of Participants Analyzed	250	254
Change From Baseline in HbA1c at Weeks 36, 48 and 52 [units: Percentage of HbA1c in the blood] Mean (Standard Deviation)		
Week 36, n=173, 182	-1.04 (0.990)	-0.88 (0.924)
Week 48, n=140, 153	-0.97 (1.070)	-0.81 (0.961)
Week 52, n=121, 141	-1.01 (1.024)	-0.84 (0.925)

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG) at Week 26
Measure Description	The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. The Baseline FPG value is 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 FPG + Baseline HbA1c category + region
Time Frame	Baseline and Week 26
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 26.

Reporting Groups

	Description
Albiglutide 30 mg With Insulin Glargine	Participants received albiglutide 30 mg as a subcutaneous injection weekly (with uptitration to 50 mg weekly if needed) via a fully disposable pen injector system combined with insulin glargine (with uptitration if needed) as prescribed by their physician. Participants did not receive investigational product during the Follow-up Period.
Preprandial Lispro Insulin With Insulin Glargine	Participants received a combination of insulin glargine (with uptitration if needed) and preprandial lispro insulin (with uptitration as appropriate) as prescribed by their physician.Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Number of Participants Analyzed	282	279
Change From Baseline in Fasting Plasma Glucose (FPG) at Week 26 [units: Millimoles per liter (mmol/L)] Least Squares Mean (Standard Error)	-0.99 (0.164)	-0.71 (0.164)

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG) at Weeks 36, 48 and 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. Change from Baseline was calculated as the post-Baseline FPG minus the Baseline FPG. This analysis used observed FPG values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.
Time Frame	Baseline and Weeks 36, 48 and 52
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 title).

Reporting Groups

	Description
Albiglutide 30 mg With Insulin Glargine	Participants received albiglutide 30 mg as a subcutaneous injection weekly (with uptitration to 50 mg weekly if needed) via a fully disposable pen injector system combined with insulin glargine (with uptitration if needed) as prescribed by their physician. Participants did not receive investigational product during the Follow-up Period.
Preprandial Lispro Insulin With Insulin Glargine	Participants received a combination of insulin glargine (with uptitration if needed) and preprandial lispro insulin (with uptitration as appropriate) as prescribed by their physician.Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Number of Participants Analyzed	171	182
Change From Baseline in Fasting Plasma Glucose (FPG) at Weeks 36, 48 and 52 [units: Millimoles per liter (mmol/L)] Mean (Standard Deviation)		
Week 36, n=171, 182	-1.41 (2.905)	-0.91 (3.039)
Week 48, n=131, 151	-1.13 (3.078)	-1.07 (2.965)
Week 52, n=121, 139	-1.36 (3.054)	-0.97 (3.305)

5. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved HbA1c Response

	Level of <6.5% and <7.0% at Week 26
Measure Description	The number of participants who acheieved the HbA1c treatment goal (i.e., HbA1c response levels of <6.5% and <7.0% at Week 26) were assessed.
Time Frame	Week 26
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Albiglutide 30 mg With Insulin Glargine	Participants received albiglutide 30 mg as a subcutaneous injection weekly (with uptitration to 50 mg weekly if needed) via a fully disposable pen injector system combined with insulin glargine (with uptitration if needed) as prescribed by their physician. Participants did not receive investigational product during the Follow-up Period.
Preprandial Lispro Insulin With Insulin Glargine	Participants received a combination of insulin glargine (with uptitration if needed) and preprandial lispro insulin (with uptitration as appropriate) as prescribed by their physician.Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Number of Participants Analyzed	279	278
Number of Participants Who Achieved		

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
HbA1c Response Level of <6.5% and <7.0% at Week 26 [units: Participants]		
HbA1c <6.5 %	31	23
HbA1c <7.0 %	83	70

6. 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: HbA1c >9.0% and <0.5% decrease from Baseline between >=Week 4 and <Week 8; HbA1c >9.0% and <0.5% decrease from Baseline between >=Week 8 and <Week 12; HbA1c >8.5% and >=4 weeks since uptitration between >=Week 12 and <Week 16; HbA1c >8.0% and >=4 weeks since uptitration; HbA1c >7.5% and >=4 weeks between >Week 26 and >=Week 48 since uptitration. Participants could have been rescued at any time after Week 4. Time to hyperglycemia rescue is the time between the date of first dose and the date of hyperglycemia rescue plus 1 day, or the time between the date of first dose and the date of last visit during active treatment period plus 1 day for participants not requiring rescue. This time is divided by 7 to express the result in weeks.
Time Frame	From the start of study medication until the end of the treatment (up to Week 52)

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
Albiglutide 30 mg With Insulin Glargine	Participants received albiglutide 30 mg as a subcutaneous injection weekly (with uptitration to 50 mg weekly if needed) via a fully disposable pen injector system combined with insulin glargine (with uptitration if needed) as prescribed by their physician. Participants did not receive investigational product during the Follow-up Period.
Preprandial Lispro Insulin With Insulin Glargine	Participants received a combination of insulin glargine (with uptitration if needed) and preprandial lispro insulin (with uptitration as appropriate) as prescribed by their physician.Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Number of Participants Analyzed	282	281
Time to Hyperglycemia Rescue [units: Weeks] Median (95% Confidence Interval)	NA (NA to NA) [1]	NA (NA to NA) [2]

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

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

interval.

7. Secondary Outcome Measure:

Measure Title	Change From Baseline in Body Weight at Week 26
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 + Baseline HbA1c category + prior myocardial infarction history + age category + region + current oral antidiabetic therapy.
Time Frame	Baseline and Week 26
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 26.

Reporting Groups

	Description
Albiglutide 30 mg With Insulin Glargine	Participants received albiglutide 30 mg as a subcutaneous injection weekly (with uptitration to 50 mg weekly if needed) via a fully disposable pen injector system combined with insulin glargine (with uptitration if needed) as prescribed by their physician. Participants did not receive investigational product during the Follow-up Period.
Preprandial Lispro Insulin With Insulin Glargine	Participants received a combination of insulin glargine (with uptitration if needed) and preprandial lispro insulin (with uptitration as appropriate) as prescribed by their physician.Participants did not receive

	Description
	investigational product during the Follow-up Period.

Measured Values

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Number of Participants Analyzed	282	280
Change From Baseline in Body Weight at Week 26 [units: Kilograms] Least Squares Mean (Standard Error)	-0.73 (0.194)	0.81 (0.195)

8. Secondary Outcome Measure:

Measure Title	Change From Baseline in Body Weight at Weeks 36, 48 and 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. This analysis used observed body weight values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.
Time Frame	Baseline and Weeks 36, 48 and 52
Safety Issue?	No

Analysis Population Description

ITT Population with observed values. Only those participants who were available at the indicated time points were analyzed (represented by n=X, X in the category title).

Reporting Groups

	Description
Albiglutide 30 mg With Insulin Glargine	Participants received albiglutide 30 mg as a subcutaneous injection weekly (with uptitration to 50 mg weekly if needed) via a fully disposable pen injector system combined with insulin glargine (with uptitration if needed) as prescribed by their physician. Participants did not receive investigational product during the Follow-up Period.
Preprandial Lispro Insulin With Insulin Glargine	Participants received a combination of insulin glargine (with uptitration if needed) and preprandial lispro insulin (with uptitration as appropriate) as prescribed by their physician.Participants did not receive investigational product during the Follow-up Period.

Measured Values

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Number of Participants Analyzed	172	182
Change From Baseline in Body Weight at Weeks 36, 48 and 52 [units: Kilograms] Mean (Standard Deviation)		
Week 36, n=172, 182	-0.42 (3.656)	1.31 (4.005)
Week 48, n=142, 153	-0.60 (3.928)	1.56 (3.846)
Week 52, n=122, 141	-0.70 (4.023)	1.44 (4.053)

Reported Adverse Events

Reporting Groups

	Description
Albiglutide 30 mg With Insulin Glargine	Participants received albiglutide 30 mg as a subcutaneous injection weekly (with uptitration to 50 mg weekly if needed) via a fully disposable pen injector system combined with insulin glargine (with uptitration if needed) as prescribed by their physician. Participants did not receive investigational product during the Follow-up Period.
Preprandial Lispro Insulin With Insulin Glargine	Participants received a combination of insulin glargine (with uptitration if needed) and preprandial lispro insulin (with uptitration as appropriate) as prescribed by their physician.Participants did not receive investigational product during the Follow-up Period.

Time Frame

On-treatment serious adverse events (SAEs) and non-serious adverse events (AEs), defined as those events occurring while participants were on treatment up until 56 days after the last dose (up to Week 60), are reported.

Additional Description

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

Serious Adverse Events

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Total # participants affected/at risk	38/285 (13.33%)	29/281 (10.32%)
Cardiac disorders		
Acute myocardial infarction †[A]		

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
# participants affected/at risk	2/285 (0.7%)	1/281 (0.36%)
# events		
Angina unstable † [A]		
# participants affected/at risk	1/285 (0.35%)	2/281 (0.71%)
# events		
Atrial fibrillation † [A]		
# participants affected/at risk	2/285 (0.7%)	0/281 (0%)
# events		
Coronary artery disease † [A]		
# participants affected/at risk	0/285 (0%)	4/281 (1.42%)
# events		
Myocardial infarction † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Ventricular fibrillation † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
# events		
Ventricular tachycardia † [A]		
# participants affected/at risk	1/285 (0.35%)	1/281 (0.36%)
# events		
Ear and labyrinth disorders		
Vertigo † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Eye disorders		
Angle closure glaucoma † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Diabetic retinopathy † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Gastrointestinal		

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
disorders		
Enterocele † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Gastritis † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Hiatus hernia † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Large intestine Perforation † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
General disorders		
Chest pain † [A]		
# participants affected/at	1/285 (0.35%)	2/281 (0.71%)

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
risk		
# events		
Electrocution † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Non-cardiac chest pain † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Hepatobiliary disorders		
Cholecystitis Chronic † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Infections and infestations		
Abscess limb † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Appendicitis † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Bacterial sepsis † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Cellulitis † [A]		
# participants affected/at risk	1/285 (0.35%)	2/281 (0.71%)
# events		
Gastroenteritis † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Gastroenteritis viral † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Infection † [A]		

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Lobar pneumonia †[A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Sepsis †[A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Sinusitis †[A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Tracheobronchitis †[A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Tuberculosis †[A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
# events		
Injury, poisoning and procedural complications		
Facial bones fracture † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Fibula fracture † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Head injury † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Incisional hernia † [A]		
# participants affected/at risk	1/285 (0.35%)	2/281 (0.71%)
# events		
Ligament rupture † [A]		
# participants affected/at	1/285 (0.35%)	0/281 (0%)

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
risk		
# events		
Limb injury † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Muscle rupture † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Road traffic accident † [A]		
# participants affected/at risk	2/285 (0.7%)	0/281 (0%)
# events		
Spinal compression fracture † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Tendon rupture † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
# events		
Metabolism and nutrition disorders		
Hypokalaemia † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Musculoskeletal and connective tissue disorders		
Arthralgia † [A]		
# participants affected/at risk	0/285 (0%)	0/281 (0%)
# events		
Back pain † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Pain in extremity † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
# events		
Trigger finger † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Acute myeloid leukaemia † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Colon cancer † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Ovarian germ cell teratoma benign † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
# events		
Phaeochromocytoma † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Pituitary tumour benign † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Tongue neoplasm malignant stage unspecified † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Psychiatric disorders		
Completed suicide † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Renal and urinary disorders		

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Renal failure † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Reproductive system and breast disorders		
Benign prostatic hyperplasia † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Cervical cyst † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Respiratory, thoracic and mediastinal disorders		
Asthma † [A]		
# participants affected/at risk	2/285 (0.7%)	0/281 (0%)
# events		

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Skin and subcutaneous tissue disorders		
Angioedema † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Vascular disorders		
Arteriosclerosis † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (0%)
# events		
Haemorrhage † [A]		
# participants affected/at risk	0/285 (0%)	1/281 (0.36%)
# events		
Malignant hypertension † [A]		
# participants affected/at risk	1/285 (0.35%)	0/281 (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%

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Total # participants affected/at risk	188/285 (65.96%)	178/281 (63.35%)
Eye disorders		
Cataract †[A]		
# participants affected/at risk	11/285 (3.86%)	9/281 (3.2%)
# events		
Diabetic Retinopathy †[A]		
# participants affected/at risk	18/285 (6.32%)	23/281 (8.19%)
# events		
Macular Oedema †[A]		
# participants affected/at risk	7/285 (2.46%)	4/281 (1.42%)
# events		
Gastrointestinal disorders		
Abdominal Pain †[A]		
# participants affected/at risk	7/285 (2.46%)	1/281 (0.36%)

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
# events		
Constipation † [A]		
# participants affected/at risk	12/285 (4.21%)	6/281 (2.14%)
# events		
Diarrhoea † [A]		
# participants affected/at risk	41/285 (14.39%)	16/281 (5.69%)
# events		
Dyspepsia † [A]		
# participants affected/at risk	12/285 (4.21%)	1/281 (0.36%)
# events		
Gastritis † [A]		
# participants affected/at risk	9/285 (3.16%)	5/281 (1.78%)
# events		
Gastroesophageal Reflux Disease † [A]		
# participants affected/at risk	10/285 (3.51%)	4/281 (1.42%)
# events		

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Nausea †[A]		
# participants affected/at risk	37/285 (12.98%)	6/281 (2.14%)
# events		
Vomiting †[A]		
# participants affected/at risk	20/285 (7.02%)	4/281 (1.42%)
# events		
General disorders		
Fatigue †[A]		
# participants affected/at risk	7/285 (2.46%)	3/281 (1.07%)
# events		
Injection Site Haematoma †[A]		
# participants affected/at risk	6/285 (2.11%)	5/281 (1.78%)
# events		
Injection Site Reaction †[A]		
# participants affected/at risk	12/285 (4.21%)	2/281 (0.71%)
# events		

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Oedema Peripheral † [A]		
# participants affected/at risk	11/285 (3.86%)	24/281 (8.54%)
# events		
Infections and infestations		
Bronchitis † [A]		
# participants affected/at risk	13/285 (4.56%)	17/281 (6.05%)
# events		
Gastroenteritis † [A]		
# participants affected/at risk	7/285 (2.46%)	10/281 (3.56%)
# events		
Gastroenteritis Viral † [A]		
# participants affected/at risk	6/285 (2.11%)	8/281 (2.85%)
# events		
Influenza † [A]		
# participants affected/at risk	8/285 (2.81%)	11/281 (3.91%)

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
# events		
Nasopharyngitis † [A]		
# participants affected/at risk	30/285 (10.53%)	29/281 (10.32%)
# events		
Sinusitis † [A]		
# participants affected/at risk	14/285 (4.91%)	9/281 (3.2%)
# events		
Upper Repiratory Tract Infection † [A]		
# participants affected/at risk	27/285 (9.47%)	20/281 (7.12%)
# events		
Urinary Tract Infection † [A]		
# participants affected/at risk	29/285 (10.18%)	27/281 (9.61%)
# events		
Injury, poisoning and procedural complications		
Contusion † [A]		

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
# participants affected/at risk	6/285 (2.11%)	9/281 (3.2%)
# events		
Metabolism and nutrition disorders		
Dyslipidaemia †[A]		
# participants affected/at risk	6/285 (2.11%)	8/281 (2.85%)
# events		
Musculoskeletal and connective tissue disorders		
Arthralgia †[A]		
# participants affected/at risk	6/285 (2.11%)	12/281 (4.27%)
# events		
Back Pain †[A]		
# participants affected/at risk	13/285 (4.56%)	20/281 (7.12%)
# events		
Muscle Spasms †[A]		

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
# participants affected/at risk	6/285 (2.11%)	5/281 (1.78%)
# events		
Musculoskeletal Pain † [A]		
# participants affected/at risk	13/285 (4.56%)	4/281 (1.42%)
# events		
Osteoarthritis † [A]		
# participants affected/at risk	8/285 (2.81%)	7/281 (2.49%)
# events		
Pain in Extremity † [A]		
# participants affected/at risk	12/285 (4.21%)	13/281 (4.63%)
# events		
Nervous system disorders		
Diabetic Neuropathy † [A]		
# participants affected/at risk	3/285 (1.05%)	8/281 (2.85%)
# events		

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Headache †[A]		
# participants affected/at risk	21/285 (7.37%)	12/281 (4.27%)
# events		
Psychiatric disorders		
Depression †[A]		
# participants affected/at risk	5/285 (1.75%)	8/281 (2.85%)
# events		
Respiratory, thoracic and mediastinal disorders		
Cough †[A]		
# participants affected/at risk	7/285 (2.46%)	7/281 (2.49%)
# events		
Skin and subcutaneous tissue disorders		
Ecchymosis †[A]		
# participants affected/at risk	4/285 (1.4%)	8/281 (2.85%)
# events		

	Albiglutide 30 mg With Insulin Glargine	Preprandial Lispro Insulin With Insulin Glargine
Vascular disorders		
Hypertension † [A]		
# participants affected/at risk	16/285 (5.61%)	17/281 (6.05%)
# 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: