Protocol Registration Receipt
05/22/2014

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

A Study to Determine the Safety and Efficacy of Albiglutide in Patients With Type 2 Diabetes

This study has been completed.

Sponsor:	GlaxoSmithKline
Collaborators:	
Information provided by (Responsible Party):	GlaxoSmithKline
ClinicalTrials.gov Identifier:	NCT00838916

Purpose

A study to determine the safety and efficacy of albiglutide in subjects with type 2 diabetes.

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

Study Type: Interventional

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

Official Title: A Randomized, Open-label, Parallel-group, Multicenter Study to Determine the Efficacy and Long-term Safety of Albiglutide Compared With 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 52 [Time Frame: Baseline and Week 52] [Designated as safety issue: No]
  HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. The BL HbA1c value is defined as the last non-missing value before the start of treatment. Change from BL was calculated as the value at Week 52 minus the value at BL. Based on analysis of covariance (ANCOVA): change = treatment + BL HbA1c + prior myocardial infarction history + age category + region + current antidiabetic therapy. Difference of least squares means (albiglutide - insulin glargine) is from the ANCOVA model. The last observation carried forward (LOCF) method was used to impute missing post-Baseline 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 Week 156 [Time Frame: Baseline and Week 156] [Designated as safety issue: No]
  HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. Baseline HbA1c value is defined as the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. This analysis used observed HbA1c values, excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.
- Change From Baseline in Fasting Plasma Glucose (FPG) at Week 52 [Time Frame: Baseline and Week 52] [Designated as safety issue: No]
  The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. The Baseline FPG value is the last non-missing value before the start of treatment. The LOCF method was used to impute missing post-Baseline FPG values. FPG values obtained after hyperglycemia rescue were treated as missing and replaced with pre-rescue values. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Based on ANCOVA: change = treatment + Baseline FPG + Baseline HbA1c category + prior myocardial infarction history + age category + region + current antidiabetic therapy.
- Change From Baseline in Fasting Plasma Glucose (FPG) at Week 156 [Time Frame: Baseline and Week 156] [Designated as safety issue: No]
  The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. The Baseline FPG value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
- Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 52 [Time Frame: Week 52] [Designated as safety issue: No]
  The number of participants who achieved the HbA1c treatment goal (i.e., HbA1c response levels of <6.5%, <7%, and <7.5% at Week 52) were assessed.
- Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 156 [Time Frame: Week 156] [Designated as safety issue: No]

The number of participants who achieved the HbA1c treatment goal (i.e., HbA1c response levels of <6.5%, <7%, and <7.5% at Week 156) were assessed.

- Time to Hyperglycemia Rescue [Time Frame: From the start of study medication until the end of the treatment (up to Week 156)] [Designated as safety issue: No]

  Participants who experienced persistent hyperglycemia (high blood glucose) could have qualified for hyperglycemia rescue. The conditions for hyperglycemia rescue were as follows: FPG >=280 milligrams/deciliter (mg/dL) between >=Week 2 and <Week 4; FPG >=250 mg/dL between >=Week 4 and <Week 12; HbA1c >=8.5% and a <=0.5% reduction from Baseline between >=Week 12 and <Week 24; HbA1c >=8.5% between >=Week 24 and <Week 48; HbA1c >=8.0% between >= Week 48 and <Week 156. Participants could have been rescued at any time on or after Week 2. Time to hyperglycemia rescue is defined as the time between the date of the first dose of study medication and the date of hyperglycemia rescue plus 1 day, or the time between the date of the first dose of study medication and the date of the last visit during the active treatment period plus 1 day for participants not requiring rescue. This time was divided by 7 to express the result in weeks.
- Change From Baseline in Body Weight at Week 52 [Time Frame: Baseline and Week 52] [Designated as safety issue: No]

  The Baseline value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight. The LOCF method was used to impute missing post-Baseline weight values. Weight values obtained after hyperglycemia rescue were treated as missing and replaced with prerescue values. Based on ANCOVA: change = treatment + Baseline weight + Baseline HbA1c category + prior myocardial infarction history + age category + region + current antidiabetic therapy.
- Change From Baseline in Body Weight at Week 156 [Time Frame: Baseline and Week 156] [Designated as safety issue: No]

  The Baseline value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight.
- Change From Baseline in Glucose Profile Measured by 24-hour Area Under Curve (AUC) at Week 52 [Time Frame: Baseline and Week 52] [Designated as safety issue: No]

  A 24-hour glucose profile was collected at Baseline and Week 52 at a subset of sites in a subset of participants per treatment group using the continuous glucose monitoring device. Glucose measurements were obtained at 5 minute increments in the 24-hour period. The area under the curve (AUC) was determined using the trapezoidal method on the measurements obtained during the first 24 hours of continuous monitoring. This analysis used observed values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed. The Baseline value is the last non-missing value before the start of treatment.
- Albiglutide Plasma Concentrations at Week 8 and Week 24 [Time Frame: Weeks 8 and 24] [Designated as safety issue: No]

  Albiglutide plasma concentration data was analyzed at Week 8 pre-dose, Week 8 post-dose, Week 24 pre-dose and Week 24 post-dose. All participants receiving albiglutide were initiated on a 30 mg weekly dosing regimen; however, beginning at Week 4, uptitration of albiglutide was allowed based on glycemic response. As such, albiglutide plasma concentrations achieved at each sampling time represent a mixed population of participants receiving either 30 mg or 50 mg weekly for various durations.

Enrollment: 779
Study Start Date: February 2009
Study Completion Date: May 2013

Primary Completion Date: January 2012

Arms	Assigned Interventions
Experimental: albiglutide weekly injection albiglutide weekly subcutaneous injection	Biological/Vaccine: albiglutide albiglutide weekly injection
Active Comparator: insulin glargine insulin glargine daily injection	Drug: insulin glargine insulin glargine

Eligibility

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

Inclusion Criteria:

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

Exclusion Criteria:

- females who are pregnant, lactating or within <6 weeks post-partum
- current symptomatic heart failure (NYHA Class III-IV)

Contacts and Locations

Locations

United States, Alabama

GSK Investigational Site
Alabaster, Alabama, United States, 35007
GSK Investigational Site
Birmingham, Alabama, United States, 35205
GSK Investigational Site

Birmingham, Alabama, United States, 35235

GSK Investigational Site

Dothan, Alabama, United States, 36301

GSK Investigational Site

Hueytown, Alabama, United States, 35023

GSK Investigational Site

Mobile, Alabama, United States, 36617

GSK Investigational Site

Tuscaloosa, Alabama, United States, 35406

United States, Arizona

GSK Investigational Site

Chandler, Arizona, United States, 85224

GSK Investigational Site

Gilbert, Arizona, United States, 85295

GSK Investigational Site

Green Valley, Arizona, United States, 85614

GSK Investigational Site

Phoenix, Arizona, United States, 85032

GSK Investigational Site

Phoenix, Arizona, United States, 85051

GSK Investigational Site

Phoenix, Arizona, United States, 85032

GSK Investigational Site

Tucson, Arizona, United States, 85712

GSK Investigational Site

Tucson, Arizona, United States, 85745

United States, Arkansas

GSK Investigational Site

Bull Shoals, Arkansas, United States, 72619

GSK Investigational Site

Harrisburg, Arkansas, United States, 72432

GSK Investigational Site

Hot Springs, Arkansas, United States, 71913

GSK Investigational Site

Jonesboro, Arkansas, United States, 72401

GSK Investigational Site

Jonesboro, Arkansas, United States, 72401

GSK Investigational Site

Little Rock, Arkansas, United States, 72205

GSK Investigational Site

Searcy, Arkansas, United States, 72143

United States, California

GSK Investigational Site

Buena Park, California, United States, 90620

GSK Investigational Site

Buena Park, California, United States, 90620

GSK Investigational Site

Cathedral City, California, United States, 92234

GSK Investigational Site

Chino, California, United States, 91710

GSK Investigational Site

Chula Vista, California, United States, 91911

GSK Investigational Site

Commerce, California, United States, 90040

GSK Investigational Site

Escondido, California, United States, 92026

GSK Investigational Site

Foothill Ranch, California, United States, 92610

GSK Investigational Site

Fountain Valley, California, United States, 92708

GSK Investigational Site

Fresno, California, United States, 93720

GSK Investigational Site

Fullerton, California, United States, 92835

GSK Investigational Site

Huntington Beach, California, United States, 92648

GSK Investigational Site

Huntington Beach, California, United States, 92646

GSK Investigational Site

Irvine, California, United States, 92618

GSK Investigational Site
La Jolla, California, United States, 92037
GSK Investigational Site
LaJolla, California, United States, 92037
GSK Investigational Site
Lakewood, California, United States, 90712
GSK Investigational Site
Loma Linda, California, United States, 92354
GSK Investigational Site
Long Beach, California, United States, 90806
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, 90025
GSK Investigational Site
Los Angeles, California, United States, 90017
GSK Investigational Site
Los Angeles, California, United States, 90022
GSK Investigational Site
Mission Viejo, California, United States, 92691
GSK Investigational Site
Northridge, California, United States, 91325
GSK Investigational Site
Palm Desert, California, United States, 92260
GSK Investigational Site
Pasadena, California, United States, 91105
GSK Investigational Site
Riverside, California, United States, 92506
GSK Investigational Site
Sacramento, California, United States, 95821
GSK Investigational Site
Sacramento, California, United States, 95825
GSK Investigational Site

Sacramento, California, United States, 95825

GSK Investigational Site

San Diego, California, United States, 92117

GSK Investigational Site

San Diego, California, United States, 92120

GSK Investigational Site

San Diego, California, United States, 92120

GSK Investigational Site

San Diego, California, United States, 92117

GSK Investigational Site

San Diego, California, United States, 92128

GSK Investigational Site

Satna Monica, California, United States, 90404

GSK Investigational Site

Spring Valley, California, United States, 91978

GSK Investigational Site

Tarzana, California, United States, 91356

GSK Investigational Site

Tustin, California, United States, 92780

GSK Investigational Site

Victorville, California, United States, 92395

GSK Investigational Site

Vista, California, United States, 92083

GSK Investigational Site

West Hills, California, United States, 91307

United States, Colorado

GSK Investigational Site

Denver, Colorado, United States, 80209

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, Delaware

GSK Investigational Site

Middletown, Delaware, United States, 19709

United States, Florida

GSK Investigational Site

Boynton Beach, Florida, United States, 33426

GSK Investigational Site

Boynton Beach, Florida, United States, 33437

GSK Investigational Site

Clearwater, Florida, United States, 33765

GSK Investigational Site

Clearwater, Florida, United States, 33756

GSK Investigational Site

Cocoa, Florida, United States, 32927

GSK Investigational Site

Cutler Bay, Florida, United States, 33189

GSK Investigational Site

Deerfield Beach, Florida, United States, 33442

GSK Investigational Site

Delray Beach, Florida, United States, 33445

GSK Investigational Site

Edgewater, Florida, United States, 32132

GSK Investigational Site

Fort Lauderdale, Florida, United States, 33316

GSK Investigational Site

Gainesville, Florida, United States, 32605

GSK Investigational Site

Hallandale Beach, Florida, United States, 33009

GSK Investigational Site

Hialeah, Florida, United States, 33012

GSK Investigational Site

Hialeah, Florida, United States, 33013

GSK Investigational Site

Hollywood, Florida, United States, 33023

GSK Investigational Site

Jacksonville, Florida, United States, 32205
GSK Investigational Site
Lauderdale Lakes, Florida, United States, 33319
GSK Investigational Site
Marianna, Florida, United States, 32446
GSK Investigational Site
Miami, Florida, United States, 33156
GSK Investigational Site
Miami, Florida, United States, 33135
GSK Investigational Site
North Miami, Florida, United States, 33161
GSK Investigational Site
Ocala, Florida, United States, 34471
GSK Investigational Site
Orlando, Florida, United States, 32822
GSK Investigational Site
Ormond Beach, Florida, United States, 32174
GSK Investigational Site
Oviedo, Florida, United States, 32765
GSK Investigational Site
Panama City, Florida, United States, 32401
GSK Investigational Site
Pembroke Pines, Florida, United States, 33026
GSK Investigational Site
Plantation, Florida, United States, 33317
GSK Investigational Site
Ponte Verda, Florida, United States, 32081
GSK Investigational Site
St. Cloud, Florida, United States, 34769
GSK Investigational Site
St. Petersburg, Florida, United States, 33709
GSK Investigational Site
Tampa, Florida, United States, 33603
GSK Investigational Site
West Palm Beach, Florida, United States, 33401

GSK Investigational Site

West Palm Beach, Florida, United States, 33401

United States, Georgia

GSK Investigational Site

Atlanta, Georgia, United States, 30309

GSK Investigational Site

Atlanta, Georgia, United States, 30308

GSK Investigational Site

Atlanta, Georgia, United States, 30338

GSK Investigational Site

Atlanta, Georgia, United States, 30342

GSK Investigational Site

Atlanta, Georgia, United States, 30312

GSK Investigational Site

Atlanta, Georgia, United States, 30342

GSK Investigational Site

Atlanta, Georgia, United States, 30328

GSK Investigational Site

Blue Ridge, Georgia, United States, 30513

GSK Investigational Site

Columbus, Georgia, United States, 31904

GSK Investigational Site

Columbus, Georgia, United States, 31904

GSK Investigational Site

Decatur, Georgia, United States, 30032

GSK Investigational Site

Decatur, Georgia, United States, 30032

GSK Investigational Site

Savannah, Georgia, United States, 31406

GSK Investigational Site

Savannah, Georgia, United States, 31419

GSK Investigational Site

Snellville, Georgia, United States, 30078

GSK Investigational Site

Stone Mountain, Georgia, United States, 30088

United States, Hawaii

GSK Investigational Site

Honolulu, Hawaii, United States, 96813

GSK Investigational Site

Honolulu, Hawaii, United States, 96814

GSK Investigational Site

Honolulu, Hawaii, United States, 96813

United States, Idaho

GSK Investigational Site

Boise, Idaho, United States, 83702

GSK Investigational Site

Idaho Falls, Idaho, United States, 83404

United States, Illinois

GSK Investigational Site

Aurora, Illinois, United States, 60504

GSK Investigational Site

Chicago, Illinois, United States, 60607

GSK Investigational Site

Evergreen Park, Illinois, United States, 60805

GSK Investigational Site

Gurnee, Illinois, United States, 60031

GSK Investigational Site

La Grange, Illinois, United States, 60525

GSK Investigational Site

Naperville, Illinois, United States, 60564

GSK Investigational Site

Peoria, Illinois, United States, 61602

United States, Indiana

GSK Investigational Site

Avon, Indiana, United States, 46123

GSK Investigational Site

Evansville, Indiana, United States, 47714

GSK Investigational Site

Fishers, Indiana, United States, 46037

GSK Investigational Site

Indianapolis, Indiana, United States, 46254

GSK Investigational Site

La Porte, Indiana, United States, 46350

GSK Investigational Site

Lafayette, Indiana, United States, 47904

GSK Investigational Site

South Bend, Indiana, United States, 46614

United States, Iowa

GSK Investigational Site

Council Bluffs, Iowa, United States, 51501

GSK Investigational Site

Des Moines, Iowa, United States, 50314

GSK Investigational Site

Dubuque, Iowa, United States, 52001

GSK Investigational Site

Iowa City, Iowa, United States, 52243

GSK Investigational Site

Waterloo, Iowa, United States, 50701

United States, Kansas

GSK Investigational Site

Arkansas City, Kansas, United States, 67005

GSK Investigational Site

Mission, Kansas, United States, 66202

GSK Investigational Site

Newton, Kansas, United States, 67114

GSK Investigational Site

Overland Park, Kansas, United States, 66211

GSK Investigational Site

Topeka, Kansas, United States, 66606

GSK Investigational Site

Wichita, Kansas, United States, 67211

United States, Kentucky

GSK Investigational Site

Fort Mitchell, Kentucky, United States, 41017

GSK Investigational Site

Lexington, Kentucky, United States, 40504

GSK Investigational Site

Lexington, Kentucky, United States, 40504

GSK Investigational Site

Lexington, Kentucky, United States, 40503

GSK Investigational Site

Louisville, Kentucky, United States, 40202

GSK Investigational Site

Madisonville, Kentucky, United States, 42431

GSK Investigational Site

Paducah, Kentucky, United States, 42003

United States, Louisiana

GSK Investigational Site

Covington, Louisiana, United States, 70433

GSK Investigational Site

Lake Charles, Louisiana, United States, 70601

GSK Investigational Site

Shreveport, Louisiana, United States, 71115

GSK Investigational Site

Shreveport, Louisiana, United States, 71101

United States, Maryland

GSK Investigational Site

Baltimore, Maryland, United States, 21237

GSK Investigational Site

Hyattsville, Maryland, United States, 20782

GSK Investigational Site

Oxon Hill, Maryland, United States, 20745

United States, Massachusetts

GSK Investigational Site

Haverhill, Massachusetts, United States, 01830

United States, Michigan

GSK Investigational Site

Bay City, Michigan, United States, 48706

GSK Investigational Site

Benzonia, Michigan, United States, 49616

GSK Investigational Site

Bloomfield Hills, Michigan, United States, 48302

GSK Investigational Site

Cadillac, Michigan, United States, 49601

GSK Investigational Site

Dearborn, Michigan, United States, 48124

GSK Investigational Site

Interlochen, Michigan, United States, 49643

GSK Investigational Site

Kalamazoo, Michigan, United States, 49009

GSK Investigational Site

Kalamazoo, Michigan, United States, 49048

GSK Investigational Site

St Clair Shores, Michigan, United States, 48081

United States, Minnesota

GSK Investigational Site

Brooklyn Center, Minnesota, United States, 55430

United States, Mississippi

GSK Investigational Site

Gulfport, Mississippi, United States, 39501

GSK Investigational Site

Picayune, Mississippi, United States, 39466

GSK Investigational Site

Rolling Fork, Mississippi, United States, 39159

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

Kansas City, Missouri, United States, 64106

GSK Investigational Site

St. Louis, Missouri, United States, 63117

GSK Investigational Site

St. Louis, Missouri, United States, 63108

GSK Investigational Site

West Plains, Missouri, United States, 65775

United States, Montana

GSK Investigational Site

Butte, Montana, United States, 59701

GSK Investigational Site

Great Falls, Montana, United States, 59405

United States, Nebraska

GSK Investigational Site

Broken Bow, Nebraska, United States, 68822

GSK Investigational Site

Lincoln, Nebraska, United States, 68516

GSK Investigational Site

Omaha, Nebraska, United States, 68124

GSK Investigational Site

Omaha, Nebraska, United States, 68131

GSK Investigational Site

Omaha, Nebraska, United States, 68134

United States, Nevada

GSK Investigational Site

Las Vegas, Nevada, United States, 89106

GSK Investigational Site

Las Vegas, Nevada, United States, 89130

GSK Investigational Site

Las Vegas, Nevada, United States, 89103

GSK Investigational Site

Las Vegas, Nevada, United States, 89128

GSK Investigational Site

Las Vegas, Nevada, United States, 89102

United States, New Jersey

GSK Investigational Site

Berlin, New Jersey, United States, 08009

GSK Investigational Site

Elizabeth, New Jersey, United States, 07202

GSK Investigational Site

Haddon Heights, New Jersey, United States, 08035

GSK Investigational Site

Hainesport, New Jersey, United States, 08036

GSK Investigational Site

New Brunswick, New Jersey, United States, 08903

GSK Investigational Site

Stratford, New Jersey, United States, 08084

United States, New Mexico

GSK Investigational Site

Albuquerque, New Mexico, United States, 87106

United States, New York

GSK Investigational Site

New York, New York, United States, 10022

GSK Investigational Site

North Massapequa, New York, United States, 11758

GSK Investigational Site

Syracuse, New York, United States, 13210

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

Calabash, North Carolina, United States, 28467

GSK Investigational Site

Fayetteville, North Carolina, United States, 28304

GSK Investigational Site

Greensboro, North Carolina, United States, 27405

GSK Investigational Site

Hickory, North Carolina, United States, 28601

GSK Investigational Site

Lenoir, North Carolina, United States, 28645

GSK Investigational Site

Mint HIll, North Carolina, United States, 28227

GSK Investigational Site

Morehead City, North Carolina, United States, 28557

GSK Investigational Site

Shelby, North Carolina, United States, 28150

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

Cincinnati, Ohio, United States, 45227

GSK Investigational Site

Cleveland, Ohio, United States, 44122

GSK Investigational Site

Columbus, Ohio, United States, 43213

GSK Investigational Site

Columbus, Ohio, United States, 43212

GSK Investigational Site

Dayton, Ohio, United States, 45439

GSK Investigational Site

Dayton, Ohio, United States, 45432

GSK Investigational Site

Kettering, Ohio, United States, 45429

GSK Investigational Site

Mason, Ohio, United States, 45040

GSK Investigational Site

Maumee, Ohio, United States, 43537-9402

GSK Investigational Site

Thornville, Ohio, United States, 43076

GSK Investigational Site

Zanesville, Ohio, United States, 43701

United States, Oklahoma

GSK Investigational Site

Oklahoma City, Oklahoma, United States, 73116

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

GSK Investigational Site

Tulsa, Oklahoma, United States, 74104

United States, Oregon

GSK Investigational Site

Ashland, Oregon, United States, 97520

United States, Pennsylvania

GSK Investigational Site

Bensalem, Pennsylvania, United States, 19020

GSK Investigational Site

Carlisle, Pennsylvania, United States, 17013

GSK Investigational Site

Downington, Pennsylvania, United States, 19335

GSK Investigational Site

Harrisburg, Pennsylvania, United States, 17112

GSK Investigational Site

Landsdale, Pennsylvania, United States, 19446

GSK Investigational Site

Pittsburgh, Pennsylvania, United States, 15243

GSK Investigational Site

Tipton, Pennsylvania, United States, 16684

GSK Investigational Site

Uniontown, Pennsylvania, United States, 15401

GSK Investigational Site

Uniontown, Pennsylvania, United States, 15401

United States, Rhode Island

GSK Investigational Site

East Providence, Rhode Island, United States, 02914

United States, South Carolina

GSK Investigational Site

Columbia, South Carolina, United States, 29201

GSK Investigational Site

Greenville, South Carolina, United States, 29601

GSK Investigational Site

Greenville, South Carolina, United States, 29615

GSK Investigational Site

Greer, South Carolina, United States, 29651

GSK Investigational Site

Manning, South Carolina, United States, 29102

GSK Investigational Site

Murrells Inlet, South Carolina, United States, 29576

GSK Investigational Site

North Myrtle Beach, South Carolina, United States, 29582

GSK Investigational Site

Orangeburg, South Carolina, United States, 29115

GSK Investigational Site

Simpsonville, South Carolina, United States, 29681

GSK Investigational Site

Taylors, South Carolina, United States, 29687

GSK Investigational Site

Taylors, South Carolina, United States, 29687

United States, Tennessee

GSK Investigational Site
Bristol, Tennessee, United States, 37620
GSK Investigational Site
Chattanooga, Tennessee, United States, 37421
GSK Investigational Site
Clarksville, Tennessee, United States, 37043
GSK Investigational Site
Columbia, Tennessee, United States, 38401
GSK Investigational Site
Fayetteville, Tennessee, United States, 37334
GSK Investigational Site
Johnson City, Tennessee, United States, 37604
GSK Investigational Site
McKenzie, Tennessee, United States, 38201
GSK Investigational Site
Nashville, Tennessee, United States, 37203
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
Cleburne, Texas, United States, 76033
GSK Investigational Site
Corpus Christi, Texas, United States, 78414
GSK Investigational Site
Corpus Christi, Texas, United States, 78404
GSK Investigational Site
Dallas, Texas, United States, 75235
GSK Investigational Site
Dallas, Texas, United States, 75235
GSK Investigational Site
Dallas, Texas, United States, 75230

GSK Investigational Site
Dallas, Texas, United States, 75251
GSK Investigational Site
Dallas, Texas, United States, 75230
GSK Investigational Site
Dallas, Texas, United States, 75246
GSK Investigational Site
Dallas, Texas, United States, 75224
GSK Investigational Site
Deer Park, Texas, United States, 77536
GSK Investigational Site
El Paso, Texas, United States, 79925
GSK Investigational Site
Fort Worth, Texas, United States, 76135
GSK Investigational Site
Fort Worth, Texas, United States, 76104
GSK Investigational Site
Fort Worth, Texas, United States, 76104
GSK Investigational Site
Houston, Texas, United States, 77070
GSK Investigational Site
Houston, Texas, United States, 77036
GSK Investigational Site
Houston, Texas, United States, 77034
GSK Investigational Site
Houston, Texas, United States, 77058
GSK Investigational Site
Houston, Texas, United States, 77024
GSK Investigational Site
Houston, Texas, United States, 77027
GSK Investigational Site
Houston, Texas, United States, 77074
GSK Investigational Site
Houston, Texas, United States, 77030
GSK Investigational Site

Houston, Texas, United States, 77024

GSK Investigational Site

Houston, Texas, United States, 77094

GSK Investigational Site

Houston, Texas, United States, 77036

GSK Investigational Site

Houston, Texas, United States, 77074

GSK Investigational Site

Houston, Texas, United States, 77055

GSK Investigational Site

Hurst, Texas, United States, 76054

GSK Investigational Site

Hurst, Texas, United States, 76054

GSK Investigational Site

Katy, Texas, United States, 77450

GSK Investigational Site

Lake Jackson, Texas, United States, 77566

GSK Investigational Site

Lewisville, Texas, United States, 75067

GSK Investigational Site

Midland, Texas, United States, 79705

GSK Investigational Site

North Richland Hills, Texas, United States, 76180

GSK Investigational Site

Odessa, Texas, United States, 79761

GSK Investigational Site

San Antonio, Texas, United States, 78205

GSK Investigational Site

San Antonio, Texas, United States, 78224

GSK Investigational Site

San Antonio, Texas, United States, 78217

GSK Investigational Site

San Antonio, Texas, United States, 78229

GSK Investigational Site

San Antonio, Texas, United States, 78229

GSK Investigational Site

San Antonio, Texas, United States, 78218

GSK Investigational Site

San Antonio, Texas, United States, 78258

GSK Investigational Site

San Antonio, Texas, United States, 78215

GSK Investigational Site

San Antonio, Texas, United States, 78229

GSK Investigational Site

Schertz, Texas, United States, 78154

GSK Investigational Site

Sugar Land, Texas, United States, 77479

GSK Investigational Site

Sugarland, Texas, United States, 77479

United States, Utah

GSK Investigational Site

Bountiful, Utah, United States, 84010

GSK Investigational Site

Murray, Utah, United States, 84123

GSK Investigational Site

Orem, Utah, United States, 84058

GSK Investigational Site

Salt Lake City, Utah, United States, 84120

GSK Investigational Site

West Jordan, Utah, United States, 84088

GSK Investigational Site

West Valley City, Utah, United States, 84120

United States, Vermont

GSK Investigational Site

South Burlington, Vermont, United States, 05403

United States, Virginia

GSK Investigational Site

Burke, Virginia, United States, 22015

GSK Investigational Site

Hampton, Virginia, United States, 23666

GSK Investigational Site

Manassas, Virginia, United States, 20110

GSK Investigational Site

Richmond, Virginia, United States, 23294

GSK Investigational Site

Suffolk, Virginia, United States, 23434

GSK Investigational Site

Weber City, Virginia, United States, 24290

United States, Washington

GSK Investigational Site

Renton, Washington, United States, 98057

GSK Investigational Site

Richland, Washington, United States, 99352

GSK Investigational Site

Selah, Washington, United States, 98942

GSK Investigational Site

Spokane, Washington, United States, 99216

GSK Investigational Site

Spokane, Washington, United States, 99208

GSK Investigational Site

Tacoma, Washington, United States, 98405

United States, West Virginia

GSK Investigational Site

Lewisburg, West Virginia, United States, 24901

United States, Wisconsin

GSK Investigational Site

Milwaukee, Wisconsin, United States, 53226

Russian Federation

GSK Investigational Site

Arkhangelsk, Russian Federation, 163045

GSK Investigational Site

Irkutsk, Russian Federation, 664003

GSK Investigational Site

Nizhniy Novgorod, Russian Federation, 603126

GSK Investigational Site

Saratov, Russian Federation, 410030

GSK Investigational Site

Smolensk, Russian Federation, 214019

GSK Investigational Site

Yaroslavl, Russian Federation, 150062

South Africa

GSK Investigational Site

Cape Town, 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

Port Elizabeth, Eastern Cape, South Africa, 6014

GSK Investigational Site

Johannesburg, Gauteng, South Africa, 01820

GSK Investigational Site

Johannesburg, Gauteng, South Africa, 2013

GSK Investigational Site

Lenasia, Gauteng, South Africa, 1827

GSK Investigational Site

Parktown, Gauteng, South Africa, 2193

GSK Investigational Site

Pretoria, Gauteng, South Africa, 00083

GSK Investigational Site

Phoenix, KwaZulu- Natal, South Africa, 4068

GSK Investigational Site

Somerset West, Western Province, South Africa, 7129

United Kingdom

GSK Investigational Site

Liverpool, United Kingdom, L9 7AL

GSK Investigational Site
London, United Kingdom, SE1 9NH
GSK Investigational Site
Blackpool, Lancashire, United Kingdom, FY4 3AD
GSK Investigational Site
Sunbury-on-Thames, Middlesex, United Kingdom, TW16 6RH
GSK Investigational Site
Port Glasgow, Renfrewshire, United Kingdom, PA14 6HW
GSK Investigational Site
Coventry, West Midlands, United Kingdom, CV2 2DX

Investigators

Study Director:	GSK Clinical Trials	GlaxoSmithKline

More Information

Responsible Party:	GlaxoSmithKline
Study ID Numbers:	112754
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 week Run-in/Stabilization Period were then randomized to a 156-week Treatment Period, followed by 8 weeks of post-treatment follow-up. A total of 1060 par. were screened; 779 par. were randomized, and 745 par. received >=1 treatment dose.

Reporting Groups

	Description
Albiglutide 30 mg + Metformin	Participants received albiglutide 30 milligrams (mg) weekly (with

	Description
+/- Sulfonylurea	up-titration to 50 mg weekly if required) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.
Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Participants received 10 units of insulin glargine daily (with dose adjusted weekly depending on the need for additional glycemic control) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.

Treatment Period (156 Weeks)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Started	504	241
Completed	308	164
Not Completed	196	77
Adverse Event	50	11
Protocol Violation	12	3
Noncompliance	21	14
Severe or Repeated Hypoglycaemia	1	0
Lost to Follow-up	19	18

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Withdrawal by Subject	81	29
Physician Decision	6	1
Termination of Study/Site by GSK	1	0
Missing	3	1
Pregnancy	2	0

Follow-up Period (8 Weeks)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Started	504 [1]	241 [2]
Completed	408	190
Not Completed	96	51
Adverse Event	10	5
Noncompliance	6	5
Lost to Follow-up	38	22
Did not Enter Follow-up Period	7	7
Withdrawn from Follow-up	26	12

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Participation		
Physician Decision	2	0
Termination of Study/Site by GSK	2	0
Withdrawal by Subject	2	0
Missing	3	0

[1] Participants withdrawing from the Treatment Period entered the Follow-up Period.

[2] Participants withdrawing from the Treatment Period entered the Follow-up Period.

Baseline Characteristics

Reporting Groups

	Description
Albiglutide 30 mg + Metformin +/- Sulfonylurea	Participants received albiglutide 30 milligrams (mg) weekly (with up-titration to 50 mg weekly if required) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.
Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Participants received 10 units of insulin glargine daily (with dose adjusted weekly depending on the need for additional glycemic control) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week

	Description
	post-treatment Follow-up Period.

Baseline Measures

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Total
Number of Participants	504	241	745
Age, Continuous [units: Years] Mean (Standard Deviation)	55.8 (9.33)	54.7 (9.75)	55.5 (9.48)
Gender, Male/Female [units: Participants]			
Female	218	109	327
Male	286	132	418
Race/Ethnicity, Customized [units: Participants]			
African American/African Heritage	130	64	194
American Indian or Alaskan Native	3	1	4
Asian - Central/South Asian Heritage	7	5	12
Asian - East Asian Heritage	2	1	3
Asian - Japanese Heritage	0	1	1

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Total
Asian - South East Asian Heritage	16	8	24
Native Hawaiian or Other Pacific Islander	1	0	1
White - Arabic/North African Heritage	7	2	9
White - White/Caucasian/European Heritage	342	158	500
Other - Central American Indian	1	0	1
Other - Hispanic	0	1	1
Other - Mexican	1	0	1

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at Week 52
Measure Description	HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. The BL HbA1c value is defined as the last non-missing value before the start of treatment. Change from BL was calculated as the value at

	Week 52 minus the value at BL. Based on analysis of covariance (ANCOVA): change = treatment + BL HbA1c + prior myocardial infarction history + age category + region + current antidiabetic therapy. Difference of least squares means (albiglutide – insulin glargine) is from the ANCOVA model. The last observation carried forward (LOCF) method was used to impute missing post-Baseline 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 52
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Albiglutide 30 mg + Metformin +/- Sulfonylurea	Participants received albiglutide 30 milligrams (mg) weekly (with up-titration to 50 mg weekly if required) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.
Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Participants received 10 units of insulin glargine daily (with dose adjusted weekly depending on the need for additional glycemic control) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.

Measured Values

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Number of Participants Analyzed	493	238
Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at Week 52 [units: Percentage of HbA1c in the blood] Least Squares Mean (Standard Error)	-0.67 (0.044)	-0.79 (0.064)

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

Groups	Albiglutide 30 mg + Metformin +/- Sulfonylurea, Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Method	ANCOVA
Mean Difference (Net)	0.11
95% Confidence Interval	-0.04 to 0.27

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

[Not specified.]

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

[Not specified.]

Statistical Analysis 2 for Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at Week 52

Groups	Albiglutide 30 mg + Metformin +/- Sulfonylurea, Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Non-Inferiority/Equivalence Test	Yes
Method	t-test, 1 sided

P-Value	0.0086

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

[Not specified.]

To test whether the difference of least square means (albiglutide - insulin glargine) is equal to the pre-specified non-inferiority margin of 0.3%

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

p-value is for non-inferiority testing of albiglutide versus insulin glargine

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

[Not specified.]

Statistical Analysis 3 for Change From Baseline (BL) in Glycosylated Hemoglobin (HbA1c) at Week 52

Groups	Albiglutide 30 mg + Metformin +/- Sulfonylurea, Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Method	t-test, 2 sided
P-Value	0.1463

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:

p-value is for superiority testing of albiglutide versus insulin glargine

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

The p-value is from a two-sided t-test to test whether the difference of least square means (albiglutide – insulin glargine) is equal to zero.

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in HbA1c at Week 156
Measure Description	HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over a 2- to 3-month period. Baseline HbA1c value is defined as the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. This analysis used observed HbA1c values, excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.
Time Frame	Baseline and Week 156
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Albiglutide 30 mg + Metformin +/- Sulfonylurea	Participants received albiglutide 30 milligrams (mg) weekly (with up-titration to 50 mg weekly if required) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.
Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Participants received 10 units of insulin glargine daily (with dose adjusted weekly depending on the need for additional glycemic control) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.

Measured Values

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Number of Participants Analyzed	123	88
Change From Baseline in HbA1c at Week 156 [units: Percentage of HbA1c in the blood] Mean (Standard Deviation)	-0.83 (0.980)	-1.00 (0.922)

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG) at Week 52
Measure Description	The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. The Baseline FPG value is the last non-missing value before the start of treatment. The LOCF method was used to impute missing post-Baseline FPG values. FPG values obtained after hyperglycemia rescue were treated as missing and replaced with pre-rescue values. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Based on ANCOVA: change = treatment + Baseline FPG + Baseline HbA1c category + prior myocardial infarction history + age category + region + current antidiabetic therapy.
Time Frame	Baseline and Week 52
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population with LOCF. Only those participants with a value at Baseline and at the specified visit were analyzed. Values were carried

forward for participants who were rescued or discontinued from active treatment before Week 52.

Reporting Groups

	Description
Albiglutide 30 mg + Metformin +/- Sulfonylurea	Participants received albiglutide 30 milligrams (mg) weekly (with up-titration to 50 mg weekly if required) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.
Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Participants received 10 units of insulin glargine daily (with dose adjusted weekly depending on the need for additional glycemic control) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.

Measured Values

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Number of Participants Analyzed	494	238
Change From Baseline in Fasting Plasma Glucose (FPG) at Week 52 [units: Millimoles per liter (mmol/L)] Least Squares Mean (Standard Error)	-0.87 (0.127)	-2.06 (0.184)

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG)

	at Week 156
Measure Description	The FPG test measures blood sugar levels after the participant has not eaten (fasted) for 12 to 14 hours. The Baseline FPG value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline value minus the Baseline value.
Time Frame	Baseline and Week 156
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Albiglutide 30 mg + Metformin +/- Sulfonylurea	Participants received albiglutide 30 milligrams (mg) weekly (with up-titration to 50 mg weekly if required) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.
Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Participants received 10 units of insulin glargine daily (with dose adjusted weekly depending on the need for additional glycemic control) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.

Measured Values

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Number of Participants Analyzed	119	86
Change From Baseline in Fasting Plasma Glucose (FPG) at Week 156 [units: Millimoles per liter (mmol/L)] Mean (Standard Deviation)	-0.83 (2.803)	-2.19 (3.420)

5. Secondary Outcome Measure:

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

Analysis Population Description

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

Reporting Groups

	Description
Albiglutide 30 mg + Metformin +/- Sulfonylurea	Participants received albiglutide 30 milligrams (mg) weekly (with up-titration to 50 mg weekly if required) as a subcutaneous injection via

	Description
	a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.
Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Participants received 10 units of insulin glargine daily (with dose adjusted weekly depending on the need for additional glycemic control) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.

Measured Values

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Number of Participants Analyzed	493	238
Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 52 [units: Participants]		
HbA1c <6.5%	54	25
HbA1c <7%	156	78
HbA1c <7.5%	268	135

6. Secondary Outcome Measure:

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

Analysis Population Description

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

Reporting Groups

	Description
Albiglutide 30 mg + Metformin +/- Sulfonylurea	Participants received albiglutide 30 milligrams (mg) weekly (with up-titration to 50 mg weekly if required) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.
Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Participants received 10 units of insulin glargine daily (with dose adjusted weekly depending on the need for additional glycemic control) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.

Measured Values

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Number of Participants Analyzed	123	88
Number of Participants Who Achieved Clinically Meaningful HbA1c Response Levels of <6.5%, <7%, and <7.5% at Week 156 [units: Participants]		
HbA1c <6.5%	33	18
HbA1c <7%	59	46
HbA1c <7.5%	85	71

7. Secondary Outcome Measure:

Measure Title	Time to Hyperglycemia Rescue
Measure Description	Participants who experienced persistent hyperglycemia (high blood glucose) could have qualified for hyperglycemia rescue. The conditions for hyperglycemia rescue were as follows: FPG >=280 milligrams/deciliter (mg/dL) between >=Week 2 and <Week 4; FPG >=250 mg/dL between >=Week 4 and <Week 12; HbA1c >=8.5% and a <=0.5% reduction from Baseline between >=Week 12 and <Week 24; HbA1c >=8.5% between >=Week 24 and <Week 48; HbA1c >=8.0% between >= Week 48 and <Week 156. Participants could have been rescued at any time on or after Week 2. Time to hyperglycemia rescue is defined as the time between the date of the first dose of study medication and the date of hyperglycemia rescue plus 1 day, or the time between the date of the first dose of study medication and the date of the last visit during the active treatment period plus 1 day for

	participants not requiring rescue. This time was divided by 7 to express the result in weeks.
Time Frame	From the start of study medication until the end of the treatment (up to Week 156)
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Albiglutide 30 mg + Metformin +/- Sulfonylurea	Participants received albiglutide 30 milligrams (mg) weekly (with up-titration to 50 mg weekly if required) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.
Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Participants received 10 units of insulin glargine daily (with dose adjusted weekly depending on the need for additional glycemic control) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.

Measured Values

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Number of Participants Analyzed	496	239

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Time to Hyperglycemia Rescue [units: Weeks] Median (95% Confidence Interval)	107.57 (96.43 to 143.43)	NA (NA to NA) [1]

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

8. Secondary Outcome Measure:

Measure Title	Change From Baseline in Body Weight at Week 52
Measure Description	The Baseline value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline weight minus the Baseline weight. The LOCF method was used to impute missing post-Baseline weight values. Weight values obtained after hyperglycemia rescue were treated as missing and replaced with prerescue values. Based on ANCOVA: change = treatment + Baseline weight + Baseline HbA1c category + prior myocardial infarction history + age category + region + current antidiabetic therapy.
Time Frame	Baseline and Week 52
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Albiglutide 30 mg + Metformin +/- Sulfonylurea	Participants received albiglutide 30 milligrams (mg) weekly (with up-titration to 50 mg weekly if required) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.
Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Participants received 10 units of insulin glargine daily (with dose adjusted weekly depending on the need for additional glycemic control) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.

Measured Values

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Number of Participants Analyzed	495	238
Change From Baseline in Body Weight at Week 52 [units: Kilograms] Least Squares Mean (Standard Error)	-1.05 (0.171)	1.56 (0.247)

9. Secondary Outcome Measure:

Measure Title	Change From Baseline in Body Weight at Week 156
Measure Description	The Baseline value is the last non-missing value before the start of treatment. Change from Baseline was calculated as the post-Baseline

	weight minus the Baseline weight.
Time Frame	Baseline and Week 156
Safety Issue?	No

Analysis Population Description

ITT Population with observed values. Only those participants who were available at the indicated time points were analyzed. This analysis used observed body weight values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed.

Reporting Groups

	Description
Albiglutide 30 mg + Metformin +/- Sulfonylurea	Participants received albiglutide 30 milligrams (mg) weekly (with up-titration to 50 mg weekly if required) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.
Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Participants received 10 units of insulin glargine daily (with dose adjusted weekly depending on the need for additional glycemic control) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.

Measured Values

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Number of Participants Analyzed	122	89

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Change From Baseline in Body Weight at Week 156 [units: Kilograms] Mean (Standard Deviation)	-3.47 (6.300)	0.90 (4.890)

10. Secondary Outcome Measure:

Measure Title	Change From Baseline in Glucose Profile Measured by 24-hour Area Under Curve (AUC) at Week 52
Measure Description	A 24-hour glucose profile was collected at Baseline and Week 52 at a subset of sites in a subset of participants per treatment group using the continuous glucose monitoring device. Glucose measurements were obtained at 5 minute increments in the 24-hour period. The area under the curve (AUC) was determined using the trapezoidal method on the measurements obtained during the first 24 hours of continuous monitoring. This analysis used observed values excluding those obtained after hyperglycemia rescue; no missing data imputation was performed. The Baseline value is the last non-missing value before the start of treatment.
Time Frame	Baseline and Week 52
Safety Issue?	No

Analysis Population Description

Glucose Profile Substudy Population: all participants who participated in the 24-hour glucose profile substudy . Only those participants with a value at Baseline and Week 52 were analyzed.

Reporting Groups

	Description
Albiglutide 30 mg + Metformin +/- Sulfonylurea	Participants received albiglutide 30 milligrams (mg) weekly (with up-titration to 50 mg weekly if required) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.
Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Participants received 10 units of insulin glargine daily (with dose adjusted weekly depending on the need for additional glycemic control) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.

Measured Values

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Number of Participants Analyzed	13	9
Change From Baseline in Glucose Profile Measured by 24-hour Area Under Curve (AUC) at Week 52 [units: Millimoles per hour per liter (mmol.h/L)] Mean (Standard Deviation)	0.457 (2.9898)	-1.657 (1.9453)

11. Secondary Outcome Measure:

Measure Title	Albiglutide Plasma Concentrations at Week 8 and Week 24

Measure Description	Albiglutide plasma concentration data was analyzed at Week 8 pre-dose, Week 8 post-dose, Week 24 pre-dose and Week 24 post-dose. All participants receiving albiglutide were initiated on a 30 mg weekly dosing regimen; however, beginning at Week 4, uptitration of albiglutide was allowed based on glycemic response. As such, albiglutide plasma concentrations achieved at each sampling time represent a mixed population of participants receiving either 30 mg or 50 mg weekly for various durations.
Time Frame	Weeks 8 and 24
Safety Issue?	No

Analysis Population Description

ITT population. Only those participants with a PK sample available for analysis at the indicated time points were analyzed.

Reporting Groups

	Description
Albiglutide 30 mg + Metformin +/- Sulfonylurea	Participants received albiglutide 30 milligrams (mg) weekly (with up-titration to 50 mg weekly if required) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.

Measured Values

	Albiglutide 30 mg + Metformin +/- Sulfonylurea
Number of Participants Analyzed	459
Albiglutide Plasma Concentrations at Week 8 and Week 24 [units: nanograms/milliliter (ng/mL)]	

	Albiglutide 30 mg + Metformin +/- Sulfonylurea
Mean (Standard Deviation)	
Week 8, Pre-dose, n=408	1642.83 (892.570)
Week 8, Post-dose, n=398	1911.35 (966.180)
Week 24, Pre-dose, n=416	2159.30 (1211.714)
Week 24, Post-dose, n=401	2748.15 (1503.945)

Reported Adverse Events

Reporting Groups

	Description
Albiglutide 30 mg + Metformin +/- Sulfonylurea	Participants received albiglutide 30 milligrams (mg) weekly (with up-titration to 50 mg weekly if required) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.
Insulin Glargine 10 Units + Metformin +/- Sulfonylurea	Participants received 10 units of insulin glargine daily (with dose adjusted weekly depending on the need for additional glycemic control) as a subcutaneous injection via a fully disposable pen injector system plus metformin >=1500 mg daily plus or minus sulfonylurea from Baseline to Week 156. All participants returned for the 8-week post-treatment Follow-up Period.

Time Frame

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

Additional Description

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

Serious Adverse Events

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Total # participants affected/at risk	92/504 (18.25%)	46/241 (19.09%)
Blood and lymphatic system disorders		
Anaemia † [A]		
# participants affected/at risk	3/504 (0.6%)	0/241 (0%)
# events		
Idiopathic thrombocytopenic purpura † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Iron deficiency anaemia † [A]		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Cardiac disorders		
Acute coronary syndrome † [A]		
# participants affected/at risk	1/504 (0.2%)	1/241 (0.41%)
# events		
Acute myocardial infarction † [A]		
# participants affected/at risk	3/504 (0.6%)	2/241 (0.83%)
# events		
Angina pectoris † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Angina unstable † [A]		
# participants affected/at risk	2/504 (0.4%)	3/241 (1.24%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# events		
Arteriosclerosis coronary artery † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Atrial fibrillation † [A]		
# participants affected/at risk	3/504 (0.6%)	0/241 (0%)
# events		
Atrial flutter † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Bradycardia † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Cardiac failure congestive † [A]		
# participants affected/at	2/504 (0.4%)	2/241 (0.83%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
risk		
# events		
Cardiomyopathy † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Conduction disorder † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Coronary artery disease † [A]		
# participants affected/at risk	5/504 (0.99%)	2/241 (0.83%)
# events		
Coronary artery insufficiency † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Myocardial infarction † [A]		
# participants affected/at	3/504 (0.6%)	0/241 (0%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
risk		
# events		
Sinus bradycardia † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Ventricular tachycardia † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Eye disorders		
Cataract † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Retinal detachment † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Gastrointestinal		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
disorders		
Abdominal hernia †[A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Abdominal pain upper †[A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Ascites †[A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Diarrhoea †[A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Gastrointestinal haemorrhage †[A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# events		
Gastrooesophageal reflux disease †[A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Haemorrhoids †[A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Lower gastrointestinal haemorrhage †[A]		
# participants affected/at risk	2/504 (0.4%)	0/241 (0%)
# events		
Pancreatitis †[A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Peptic ulcer †[A]		
# participants affected/at	0/504 (0%)	1/241 (0.41%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
risk		
# events		
Umbilical hernia †[A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
General disorders		
Chest pain †[A]		
# participants affected/at risk	5/504 (0.99%)	4/241 (1.66%)
# events		
Death †[A]		
# participants affected/at risk	2/504 (0.4%)	1/241 (0.41%)
# events		
Device leakage †[A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Generalised oedema †[A]		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Non-cardiac chest pain †[A]		
# participants affected/at risk	4/504 (0.79%)	0/241 (0%)
# events		
Sudden cardiac death †[A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Hepatobiliary disorders		
Cholecystitis Acute †[A]		
# participants affected/at risk	0/504 (0%)	3/241 (1.24%)
# events		
Cholelithiasis †[A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Hepatitis †[A]		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Immune system disorders		
Anaphylactic reaction † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Infections and infestations		
Appendicitis † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Arthritis bacterial † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Bacterial pyelonephritis † [A]		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Bronchitis †[A]		
# participants affected/at risk	3/504 (0.6%)	0/241 (0%)
# events		
Bronchopneumonia †[A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Cellulitis †[A]		
# participants affected/at risk	1/504 (0.2%)	2/241 (0.83%)
# events		
Diverticulitis †[A]		
# participants affected/at risk	0/504 (0%)	2/241 (0.83%)
# events		
Epiglottitis †[A]		
# participants affected/at	1/504 (0.2%)	0/241 (0%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
risk		
# events		
Eye abscess † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Gangrene † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Gastroenteritis † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Hepatitis B † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Lobar pneumonia † [A]		
# participants affected/at risk	2/504 (0.4%)	0/241 (0%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# events		
Localised infection † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Osteomyelitis † [A]		
# participants affected/at risk	3/504 (0.6%)	0/241 (0%)
# events		
Perirectal abscess † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Pneumonia † [A]		
# participants affected/at risk	4/504 (0.79%)	0/241 (0%)
# events		
Pyelonephritis † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Staphylococcal infection † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Tracheobronchitis † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Urinary tract infection † [A]		
# participants affected/at risk	0/504 (0%)	2/241 (0.83%)
# events		
Injury, poisoning and procedural complications		
Arterial injury † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Femur fracture † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# events		
Gastroenteritis radiation † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Heat stroke † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Hip fracture † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Meniscus lesion † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Road traffic accident † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Seroma † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Skeletal injury † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Toxicity to various agents † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Wound dehiscence † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Metabolism and nutrition disorders		
Hypoglycaemia † [A]		
# participants affected/at	1/504 (0.2%)	2/241 (0.83%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
risk		
# events		
Musculoskeletal and connective tissue disorders		
Arthritis † [A]		
# participants affected/at risk	0/504 (0%)	2/241 (0.83%)
# events		
Bursitis † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Cervical spinal stenosis † [A]		
# participants affected/at risk	1/504 (0.2%)	1/241 (0.41%)
# events		
Intervertebral disc protrusion † [A]		
# participants affected/at risk	2/504 (0.4%)	0/241 (0%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# events		
Neuropathic arthropathy † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Osteoarthritis † [A]		
# participants affected/at risk	2/504 (0.4%)	3/241 (1.24%)
# events		
Pathological fracture † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Periarthritis † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Rotator cuff syndrome † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Spondylolisthesis † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Acute myeloid leukaemia † [A]		
# participants affected/at risk	2/504 (0.4%)	0/241 (0%)
# events		
Breast cancer † [A]		
# participants affected/at risk	1/504 (0.2%)	1/241 (0.41%)
# events		
Endometrial cancer † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Lung adenocarcinoma metastatic † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Lung neoplasm † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Lung neoplasm malignant † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Lung squamous cell carcinoma stage unspecified † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Meningioma † [A]		
# participants affected/at	1/504 (0.2%)	0/241 (0%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
risk		
# events		
Myelodysplastic syndrome † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Oesophageal carcinoma † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Prostate cancer † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Sarcoma † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Nervous system disorders		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Cerebrovascular accident † [A]		
# participants affected/at risk	2/504 (0.4%)	0/241 (0%)
# events		
Migraine † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Neuropathy peripheral † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Syncope † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Transient ischaemic attack † [A]		
# participants affected/at risk	2/504 (0.4%)	0/241 (0%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# events		
Psychiatric disorders		
Confusional state †[A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Depression †[A]		
# participants affected/at risk	2/504 (0.4%)	0/241 (0%)
# events		
Schizophrenia †[A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Renal and urinary disorders		
Calculus ureteric †[A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Calculus urinary † [A]		
# participants affected/at risk	2/504 (0.4%)	0/241 (0%)
# events		
Hydronephrosis † [A]		
# participants affected/at risk	2/504 (0.4%)	0/241 (0%)
# events		
Nephrolithiasis † [A]		
# participants affected/at risk	1/504 (0.2%)	1/241 (0.41%)
# events		
Renal failure acute † [A]		
# participants affected/at risk	1/504 (0.2%)	1/241 (0.41%)
# events		
Reproductive system and breast disorders		
Dysfunctional uterine bleeding † [A]		
# participants affected/at	0/504 (0%)	1/241 (0.41%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
risk		
# events		
Menorrhagia † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Respiratory, thoracic and mediastinal disorders		
Acute respiratory failure † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Asthma † [A]		
# participants affected/at risk	2/504 (0.4%)	0/241 (0%)
# events		
Bronchospasm † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Chronic obstructive pulmonary disease †[A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Dyspnoea †[A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Pneumothorax †[A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Pulmonary embolism †[A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Pulmonary hypertension †[A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Skin and subcutaneous tissue disorders		
Diabetic foot † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Vascular disorders		
Deep vein thrombosis † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Diabetic vascular disorder † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Haematoma † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Haemorrhage † [A]		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Hypertension † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Hypotension † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		
Peripheral ischaemia † [A]		
# participants affected/at risk	1/504 (0.2%)	0/241 (0%)
# events		
Peripheral vascular disorder † [A]		
# participants affected/at risk	0/504 (0%)	1/241 (0.41%)
# events		

† Indicates events were collected by systematic assessment.

Other Adverse Events

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

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Total # participants affected/at risk	429/504 (85.12%)	199/241 (82.57%)
Blood and lymphatic system disorders		
Anaemia † [A]		
# participants affected/at risk	14/504 (2.78%)	12/241 (4.98%)
# events		
Cardiac disorders		
Palpitations † [A]		
# participants affected/at risk	3/504 (0.6%)	5/241 (2.07%)
# events		
Ear and labyrinth disorders		
Vertigo † [A]		
# participants affected/at risk	11/504 (2.18%)	6/241 (2.49%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# events		
Eye disorders		
Cataract † [A]		
# participants affected/at risk	28/504 (5.56%)	13/241 (5.39%)
# events		
Diabetic retinopathy † [A]		
# participants affected/at risk	18/504 (3.57%)	10/241 (4.15%)
# events		
Gastrointestinal disorders		
Abdominal pain † [A]		
# participants affected/at risk	14/504 (2.78%)	8/241 (3.32%)
# events		
Constipation † [A]		
# participants affected/at risk	29/504 (5.75%)	4/241 (1.66%)
# events		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Diarrhoea †[A]		
# participants affected/at risk	55/504 (10.91%)	19/241 (7.88%)
# events		
Dyspepsia †[A]		
# participants affected/at risk	21/504 (4.17%)	7/241 (2.9%)
# events		
Gastrooesophageal reflux disease †[A]		
# participants affected/at risk	15/504 (2.98%)	6/241 (2.49%)
# events		
Nausea †[A]		
# participants affected/at risk	67/504 (13.29%)	18/241 (7.47%)
# events		
Toothache †[A]		
# participants affected/at risk	5/504 (0.99%)	5/241 (2.07%)
# events		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Vomiting † [A]		
# participants affected/at risk	27/504 (5.36%)	13/241 (5.39%)
# events		
General disorders		
Chest pain † [A]		
# participants affected/at risk	5/504 (0.99%)	8/241 (3.32%)
# events		
Fatigue † [A]		
# participants affected/at risk	21/504 (4.17%)	3/241 (1.24%)
# events		
Injection site erythema † [A]		
# participants affected/at risk	14/504 (2.78%)	0/241 (0%)
# events		
Injection site haematoma † [A]		
# participants affected/at risk	24/504 (4.76%)	20/241 (8.3%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# events		
Injection site reaction †[A]		
# participants affected/at risk	50/504 (9.92%)	8/241 (3.32%)
# events		
Oedema peripheral †[A]		
# participants affected/at risk	30/504 (5.95%)	15/241 (6.22%)
# events		
Pain †[A]		
# participants affected/at risk	4/504 (0.79%)	6/241 (2.49%)
# events		
Pyrexia †[A]		
# participants affected/at risk	5/504 (0.99%)	7/241 (2.9%)
# events		
Immune system disorders		
Seasonal allergy †[A]		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# participants affected/at risk	11/504 (2.18%)	6/241 (2.49%)
# events		
Infections and infestations		
Bronchitis †[A]		
# participants affected/at risk	44/504 (8.73%)	27/241 (11.2%)
# events		
Cellulitis †[A]		
# participants affected/at risk	15/504 (2.98%)	7/241 (2.9%)
# events		
Cystitis †[A]		
# participants affected/at risk	5/504 (0.99%)	5/241 (2.07%)
# events		
Gastroenteritis †[A]		
# participants affected/at risk	19/504 (3.77%)	6/241 (2.49%)
# events		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Influenza † [A]		
# participants affected/at risk	38/504 (7.54%)	22/241 (9.13%)
# events		
Nasopharyngitis † [A]		
# participants affected/at risk	55/504 (10.91%)	24/241 (9.96%)
# events		
Onychomycosis † [A]		
# participants affected/at risk	12/504 (2.38%)	2/241 (0.83%)
# events		
Pharyngitis † [A]		
# participants affected/at risk	10/504 (1.98%)	6/241 (2.49%)
# events		
Pneumonia † [A]		
# participants affected/at risk	12/504 (2.38%)	5/241 (2.07%)
# events		
Sinusitis † [A]		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# participants affected/at risk	50/504 (9.92%)	23/241 (9.54%)
# events		
Tinea pedis † [A]		
# participants affected/at risk	11/504 (2.18%)	1/241 (0.41%)
# events		
Tooth abscess † [A]		
# participants affected/at risk	11/504 (2.18%)	4/241 (1.66%)
# events		
Upper respiratory tract infection † [A]		
# participants affected/at risk	83/504 (16.47%)	37/241 (15.35%)
# events		
Urinary tract infection † [A]		
# participants affected/at risk	47/504 (9.33%)	21/241 (8.71%)
# events		
Injury, poisoning and		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
procedural complications		
Contusion †[A]		
# participants affected/at risk	7/504 (1.39%)	9/241 (3.73%)
# events		
Ligament sprain †[A]		
# participants affected/at risk	10/504 (1.98%)	5/241 (2.07%)
# events		
Muscle strain †[A]		
# participants affected/at risk	10/504 (1.98%)	8/241 (3.32%)
# events		
Investigations		
Weight increased †[A]		
# participants affected/at risk	6/504 (1.19%)	5/241 (2.07%)
# events		
Metabolism and nutrition disorders		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Decreased appetite †[A]		
# participants affected/at risk	14/504 (2.78%)	4/241 (1.66%)
# events		
Dyslipidaemia †[A]		
# participants affected/at risk	12/504 (2.38%)	7/241 (2.9%)
# events		
Hypoglycaemia †[A]		
# participants affected/at risk	187/504 (37.1%)	117/241 (48.55%)
# events		
Musculoskeletal and connective tissue disorders		
Arthralgia †[A]		
# participants affected/at risk	50/504 (9.92%)	17/241 (7.05%)
# events		
Arthritis †[A]		
# participants affected/at	11/504	2/241 (0.83%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
risk	(2.18%)	
# events		
Back pain †[A]		
# participants affected/at risk	37/504 (7.34%)	20/241 (8.3%)
# events		
Muscle spasms †[A]		
# participants affected/at risk	19/504 (3.77%)	6/241 (2.49%)
# events		
Musculoskeletal pain †[A]		
# participants affected/at risk	17/504 (3.37%)	19/241 (7.88%)
# events		
Myalgia †[A]		
# participants affected/at risk	9/504 (1.79%)	6/241 (2.49%)
# events		
Osteoarthritis †[A]		
# participants affected/at risk	21/504 (4.17%)	9/241 (3.73%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# events		
Pain in extremity †[A]		
# participants affected/at risk	25/504 (4.96%)	17/241 (7.05%)
# events		
Rotator cuff syndrome †[A]		
# participants affected/at risk	4/504 (0.79%)	6/241 (2.49%)
# events		
Spinal osteoarthritis †[A]		
# participants affected/at risk	3/504 (0.6%)	5/241 (2.07%)
# events		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma †[A]		
# participants affected/at risk	3/504 (0.6%)	5/241 (2.07%)
# events		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Nervous system disorders		
Carpal tunnel syndrome † [A]		
# participants affected/at risk	4/504 (0.79%)	6/241 (2.49%)
# events		
Diabetic neuropathy † [A]		
# participants affected/at risk	26/504 (5.16%)	15/241 (6.22%)
# events		
Dizziness † [A]		
# participants affected/at risk	30/504 (5.95%)	8/241 (3.32%)
# events		
Headache † [A]		
# participants affected/at risk	46/504 (9.13%)	20/241 (8.3%)
# events		
Psychiatric disorders		
Anxiety † [A]		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# participants affected/at risk	22/504 (4.37%)	13/241 (5.39%)
# events		
Depression †[A]		
# participants affected/at risk	14/504 (2.78%)	7/241 (2.9%)
# events		
Insomnia †[A]		
# participants affected/at risk	13/504 (2.58%)	13/241 (5.39%)
# events		
Respiratory, thoracic and mediastinal disorders		
Asthma †[A]		
# participants affected/at risk	12/504 (2.38%)	5/241 (2.07%)
# events		
Cough †[A]		
# participants affected/at risk	39/504 (7.74%)	29/241 (12.03%)
# events		

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
Dyspnoea † [A]		
# participants affected/at risk	7/504 (1.39%)	10/241 (4.15%)
# events		
Nasal congestion † [A]		
# participants affected/at risk	11/504 (2.18%)	1/241 (0.41%)
# events		
Oropharyngeal pain † [A]		
# participants affected/at risk	16/504 (3.17%)	7/241 (2.9%)
# events		
Sinus congestion † [A]		
# participants affected/at risk	9/504 (1.79%)	7/241 (2.9%)
# events		
Skin and subcutaneous tissue disorders		
Dermatitis contact † [A]		
# participants affected/at risk	9/504 (1.79%)	5/241 (2.07%)

	Albiglutide 30 mg + Metformin +/- Sulfonylurea	Insulin Glargine 10 Units + Metformin +/- Sulfonylurea
# events		
Hyperkeratosis † [A]		
# participants affected/at risk	5/504 (0.99%)	5/241 (2.07%)
# events		
Rash † [A]		
# participants affected/at risk	15/504 (2.98%)	10/241 (4.15%)
# events		
Vascular disorders		
Hypertension † [A]		
# participants affected/at risk	67/504 (13.29%)	29/241 (12.03%)
# events		

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

More Information

Certain Agreements:

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

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

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

Limitations and Caveats:

Results Point of Contact:

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