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ID: SYR-322_303 Efficacy and Safety of Alogliptin Compared to Glipizide in Elderly Diabetics NCT00707993

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Participant Flow

Recruitment Details	Participants enrolled at 110 investigative sites in Hungary, India, Israel, Mexico, Peru, Poland, Romania, Russia, South Africa, the Ukraine and the United States from 25 June 2008 to 30 August 2010.
Pre-Assignment Details	Participants with a historical diagnosis of type 2 diabetes mellitus were enrolled in one of two, once-daily (QD) treatment groups.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**	Total (Not public)
Arm/Group Description	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.	
Period Title: Overall Study			
Started	222	219	441
Completed	133	125	258
Not Completed	89	94	183
Reason Not Completed			
Adverse Event	16	20	36
Protocol Violation	4	7	11
Lost to Follow-up	0	4	4
Withdrawal by Subject	12	16	28
Hyperglycemic Rescue	55	47	102
Other	2	0	2
NOTE : "Other" is not sufficiently descriptive for "Other" Reason Not Completed. Please provide a more descriptive label.			
(Not Public)	Not Completed = 89 Total from all reasons = 89	Not Completed = 94 Total from all reasons = 94	

Baseline Characteristics

Arm/Group Title	Alogliptin 25 mg QD	Glipizide 5 mg QD	Total
Arm/Group Description	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.	
Overall Number of Baseline Participants	222	219	**441**
Baseline Analysis Population Description [Not specified]			
Age, Continuous Mean (Standard Deviation) Units: years	70.1 (4.42)	69.8 (4.07)	69.9 (4.24)
Age, Customized Measure Type: Number Units: participants			
<75 years	186	193	379
≥75 years	36	26	62
Gender, Male/Female Measure Type: Number Units: participants			
Female	120	123	243
Male	102	96	198
Ethnicity (NIH/OMB) Measure Type: Number Units: participants			
Hispanic or Latino	79	70	149
Not Hispanic or Latino	143	149	292
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Measure Type: Number Units: participants			
American Indian or Alaska Native	12	13	25
Asian	19	26	45
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	16	20	36
White	169	154	323
More than one race	6	6	12
Unknown or Not Reported	0	0	0
Weight Mean (Standard Deviation) Units: kg	78.60 (14.842)	78.81 (15.239)	78.70 (15.024)
Body Mass Index (BMI) Mean (Standard Deviation) Units: kg/m2	29.58 (4.348)	30.02 (4.459)	29.79 (4.404)
Diabetes duration Mean (Standard Deviation) Units: years	6.25 (6.285)	5.94 (6.276)	6.10 (6.275)
Glomerular Filtration Rate (GFR) [1]			

Mean (Standard Deviation) **Units: mL/min/1.73 m2**	73.62 (14.762)	72.89 (15.524)	73.26 (15.133)

[1] Using the Modification of Diet in Renal Disease method.

Smoking history **Measure Type: Number** **Units: participants**			
Never smoked	160	168	328
Current smoker	16	11	27
Ex-smoker	46	40	86

Outcome Measures

1. Primary Outcome

Title: Change From Baseline in Glycosylated Hemoglobin at Week 52.

Description: The change in the percentage of glycosylated hemoglobin (the concentration of glucose bound to hemoglobin as a percent of the absolute maximum that can be bound) collected at week 52 or final visit and glycosylated hemoglobin collected at baseline.

Time Frame: Baseline and Week 52.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Randomized participants who received at least 1 dose of study drug, had measurements at Baseline and at the visit, and who met pre-specified criteria (no major protocol violations) for inclusion in the Per Protocol Set. Missing data were imputed using last observation carried forward (LOCF).

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**
Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	180	162
Least Squares Mean (Standard Error) **Units: percentage of Glycosylated Hemoglobin**	-0.14 (0.063)	-0.09 (0.067)

Statistical Analysis 1 1 Note

Statistical Analysis Overview	**Comparison Groups**	Alogliptin 25 mg QD, Glipizide 5 mg QD
	Comments	Primary null hypothesis: the average Week 52 HbA1c change from Baseline for alogliptin is inferior to that for glipizide (1-sided 97.5% CI

		[alpha=0.025] compared to non-inferiority margin of 0.4%). If the primary null hypothesis was rejected (non-inferiority demonstrated), an additional comparison for statistical superiority of alogliptin was performed. The CI was re-evaluated; statistical superiority declared if the upper limit was < 0%.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	NOTE : A Method for the statistical test has been specified, but a P-Value has not been entered.
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Treatment, randomization schedule, and geographic region as class effects; baseline value for the endpoint as a continuous covariate.
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-0.05
	Confidence Interval	(1-Sided) 97.5% 0.13
	Estimation Comments	[Not specified]

2. Secondary Outcome

Title: Change From Baseline in Glycosylated Hemoglobin

Description: The change in the value of glycosylated hemoglobin (the concentration of glucose bound to hemoglobin as a percent of the absolute maximum that can be bound) collected at each week indicated including final visit relative to baseline.

Time Frame: Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 26, Week 34 and Week 42.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Randomized participants who received at least 1 dose of study drug, had measurements at Baseline and at the visit, and who met pre-specified criteria (no major protocol violations) for inclusion in the Per Protocol Set. Missing data were imputed using last observation carried forward (LOCF).

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**
Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	180	162
Least Squares Mean (Standard Error) Units: percentage of Glycosylated Hemoglobin		
Week 4 (n=175; n=148)	-0.14 (0.047)	-0.11 (0.051)
Week 8 (n=180; n=161)	-0.27 (0.051)	-0.23 (0.054)
Week 12 (n=180; n=162)	-0.34 (0.053)	-0.25 (0.055)
Week 16 (n=180; n=162)	-0.31 (0.050)	-0.32 (0.052)
Week 20 (n=180; n=162)	-0.31 (0.051)	-0.27 (0.054)
Week 26 (n=180; n=162)	-0.28 (0.052)	-0.25 (0.055)
Week 34 (n=180; n=162)	-0.21 (0.056)	-0.21 (0.059)
Week 42 (n=180; n=162)	-0.17 (0.062)	-0.17 (0.065)

3. Secondary Outcome

Title: Incidence of Hypoglycemia

Description: Percentage of participants with at least one hypoglycemic episode during 52 week study.

Time Frame: On occurrence (up to 52 weeks).

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Percentages based on the number of Safety Set participants in each treatment group.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**
Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Measure Type: Number Units: percentage of participants	5.4	26.0

4. Secondary Outcome

Title: Incidence of Marked Hyperglycemia (Fasting Plasma Glucose ≥200 mg Per dL).

Description: The number of participants with a fasting plasma glucose value ≥ to 200 mg per dL during the 52 week study.

Time Frame: On Occurrence (up to 52 weeks).

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set).

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**
Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Measure Type: Number Units: participants		
Baseline to <Week 4	30	17
Week 4 to <Week 8	11	5
Week 8 to <Week 12	12	8

Week 12 to <Week 16	11	8
Week 16 to <Week 20	5	4
Week 20 to <Week 26	2	3
Week 26 to <Week 34	3	8
Week 34 to <Week 42	2	4
Week 42 to Week 52	9	6
Overall	50	37

5. Secondary Outcome

Title: Incidence of Hyperglycemic Rescue

Description: The number of participants requiring rescue for failing to achieve pre-specified glycemic targets during the 52 week study.

Time Frame: On Occurrence (up to 52 weeks).

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set). Participants who discontinued prior to Week 2 were excluded from analysis.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**

Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Measure Type: Number Units: participants		
Week 2 to <Week 4	1	0
Week 4 to <Week 8	2	1
Week 8 to <Week 12	1	0
Week 12 to <Week 16	14	14
Week 16 to <Week 20	6	9
Week 20 to <Week 26	5	8
Week 26 to <Week 34	10	2
Week 34 to <Week 42	6	7
Week 42 to Week 52	10	6
Overall	50	37

6. Secondary Outcome

Title: Change From Baseline in Fasting Plasma Glucose

Description: The change in the value of fasting plasma glucose collected at each week indicated including final visit relative to baseline.

Time Frame: Baseline, Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 26, Week 34, Week 42 and Week 52.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set) with last observation carried forward.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**
Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Least Squares Mean (Standard Error) Units: mg/dL		
Week 2 (n=196; n=199)	-3.8 (1.93)	-5.0 (1.91)
Week 4 (n=217; n=213)	-7.7 (1.93)	-7.6 (1.95)
Week 8 (n=217; n=214)	-8.9 (1.76)	-8.7 (1.77)
Week 12 (n=217; n=214)	-10.2 (1.84)	-9.9 (1.86)
Week 16 (n=217; n=214)	-7.9 (1.85)	-11.4 (1.86)
Week 20 (n=217; n=214)	-9.8 (1.78)	-8.7 (1.79)
Week 26 (n=217; n=214)	-7.9 (1.97)	-6.2 (1.99)
Week 34 (n=217; n=214)	-5.4 (1.98)	-5.7 (1.99)
Week 42 (n=217; n=214)	-3.6 (2.13)	-7.4 (2.14)
Week 52 (n=217; n=214)	-2.4 (2.24)	-4.2 (2.26)

7. Secondary Outcome

Title:	Change From Baseline in 2-hour Postprandial Glucose
Description:	The change in postprandial (after eating a meal) glucose levels at week 52 relative to baseline. Standard 2-hour postprandial glucose (PPG) tests performed following an overnight fast and evaluated right before and after a 120-minute (2-hour) timeframe relative to ingestion of a standard oral glucose drink.
Time Frame:	Baseline and Week 52.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set).

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**
Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Least Squares Mean (Standard Error) Units: mg/dL		
Week 52 PPG level (n=109; n=93)	-5.80 (5.530)	6.30 (5.989)
Week 52 PPG excursion (n=109; n=93)	1.82 (4.434)	7.17 (4.804)

8. Secondary Outcome

Title: Change From Baseline in Fasting Proinsulin

Description: The change between the value of fasting proinsulin collected at each week indicated including final visit relative to baseline.

Time Frame: Baseline, Week 12, Week 26, Week 42 and Week 52.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set) with last observation carried forward.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**
Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.

Number of Participants Analyzed	222	219
Least Squares Mean (Standard Error) Units: pmol/L		
Week 12 (n=207; n=186)	-6.0 (0.99)	1.0 (1.05)
Week 26 (n=211; n=194)	-4.6 (1.49)	3.0 (1.56)
Week 42 (n=211; n=194)	-4.6 (1.48)	3.1 (1.54)
Week 52 (n=211; n=194)	-4.9 (1.42)	3.0 (1.48)

9. Secondary Outcome

Title: Change From Baseline in Insulin

Description: The change between the value of insulin collected at each week indicated including final visit relative to baseline.

Time Frame: Baseline, Week 12, Week 26, Week 42 and Week 52.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set) with last observation carried forward.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**
Arm/Group Description:	Alogliptin 25 mg, tablets, orally,	Alogliptin placebo-matching

	once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Least Squares Mean (Standard Error) Units: mcIU/mL		
Week 12 (n=207; n=188)	-2.36 (0.673)	0.84 (0.707)
Week 26 (n=210; n=194)	-0.41 (1.548)	3.03 (1.611)
Week 42 (n=210; n=194)	-0.58 (1.254)	1.53 (1.305)
Week 52 (n=210; n=194)	-1.72 (1.731)	3.15 (1.801)

10. Secondary Outcome

Title: Change From Baseline in Proinsulin/Insulin Ratio

Description: The change between the ratio value of proinsulin and insulin collected at each week indicated including final visit relative to baseline.

Time Frame: Baseline, Week 12, Week 26, Week 42 and Week 52.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set) with last observation carried forward.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**
Arm/Group Description:	Alogliptin 25 mg, tablets, orally,	Alogliptin placebo-matching

	once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Least Squares Mean (Standard Error) Units: ratio		
Week 12 (n=206; n=185)	-0.288 (0.1035)	0.053 (0.1092)
Week 26 (n=210; n=193)	-0.253 (0.4333)	0.562 (0.4520)
Week 42 (n=210; n=193)	-0.289 (0.1500)	0.183 (0.1565)
Week 52 (n=210; n=193)	-0.155 (0.0899)	-0.057 (0.0938)

11. Secondary Outcome

Title: Homeostasis Model Assessment of Beta Cell Function

Description: The change between homeostasis model assessment of beta cell function collected at each week indicated including final visit relative to baseline. Homeostasis model assessment of beta cell function measures beta cell function, calculated by a constant (20) times insulin, divided by fasting plasma glucose minus a constant (3.5).

Time Frame: Baseline, Week 12, Week 26, Week 42 and Week 52.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set) with last observation carried forward.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**
Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Least Squares Mean (Standard Error) Units: percent score of beta cell function		
Week 12 (n=203; n=184)	-6.104 (8.3062)	30.081 (8.7264)
Week 26 (n=207; n=193)	-0.136 (9.7088)	31.669 (10.0562)
Week 42 (n=207; n=193)	-5.571 (7.1395)	16.004 (7.3950)
Week 52 (n=207; n=193)	-9.755 (13.8868)	35.281 (14.3836)

12. Secondary Outcome

Title: Change From Baseline in Body Weight

Description: The change in body weight measured at each week indicated including final visit from baseline.

Time Frame: Baseline, Week 8, Week 12, Week 26, Week 42 and Week 52.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set) with last observation carried forward.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**
Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Least Squares Mean (Standard Error) Units: kg		
Week 8 (n=213; n=200)	-0.42 (0.118)	0.55 (0.122)
Week 12 (n=215; n=203)	-0.52 (0.142)	0.42 (0.146)
Week 26 (n=215; n=204)	-0.68 (0.188)	0.66 (0.193)
Week 42 (n=215; n=204)	-0.72 (0.211)	0.57 (0.216)
Week 52 (n=215; n=204)	-0.62 (0.227)	0.60 (0.233)

13. Secondary Outcome

Title: Change From Baseline in Serum Lipids (Total Cholesterol)

Description: The change in total cholesterol measured at each week indicated including final visit from baseline.

Time Frame: Baseline, Week 8, Week 12, Week 26, Week 42 and Week 52.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set) with last observation carried forward.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**

Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Least Squares Mean (Standard Error) Units: mg/dL		
Week 8 (n=208; n=195)	-5.6 (2.01)	-1.6 (2.08)
Week 12 (n=213; n=201)	-4.2 (2.06)	-0.7 (2.12)
Week 26 (n=213; n=201)	1.6 (2.03)	0.1 (2.09)
Week 42 (n=213; n=201)	0.2 (2.07)	0.1 (2.13)
Week 52 (n=213; n=201)	-0.8 (2.28)	-0.5 (2.35)

14. Secondary Outcome

Title:	Change From Baseline in Serum Lipids (High-Density Lipoprotein Cholesterol)
Description:	The change in high-density lipoprotein cholesterol measured at each week indicated including final visit from baseline.
Time Frame:	Baseline, Week 8, Week 12, Week 26, Week 42 and Week 52.
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set) with last observation carried forward.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**

Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Least Squares Mean (Standard Error) Units: mg/dL		
Week 8 (n=206; n=193)	-0.1 (0.59)	1.2 (0.61)
Week 12 (n=212; n=201)	0.4 (0.47)	0.5 (0.48)
Week 26 (n=212; n=201)	1.7 (0.50)	0.2 (0.52)
Week 42 (n=212; n=201)	1.4 (0.59)	0.1 (0.61)
Week 52 (n=212; n=201)	0.8 (0.50)	0.3 (0.51)

15. Secondary Outcome

Title: Change From Baseline in Serum Lipids (Low-Density Lipoprotein Cholesterol)

Description: The change in low-density lipoprotein cholesterol measured at each week indicated including final visit from baseline.

Time Frame: Baseline, Week 8, Week 12, Week 26, Week 42 and Week 52.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set) with last observation carried forward.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**

Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Least Squares Mean (Standard Error) Units: mg/dL		
Week 8 (n=200; n=185)	-3.2 (1.70)	-2.8 (1.76)
Week 12 (n=208; n=195)	-2.0 (1.75)	-2.4 (1.81)
Week 26 (n=208; n=196)	3.1 (1.67)	-1.1 (1.72)
Week 42 (n=208; n=197)	1.2 (1.79)	-0.8 (1.84)
Week 52 (n=209; n=197)	0.9 (1.83)	-1.4 (1.88)

16. Secondary Outcome

Title: Change From Baseline in Serum Lipids (Triglycerides)

Description: The change in triglycerides measured at each week indicated including final visit from baseline.

Time Frame: Baseline, Week 8, Week 12, Week 26, Week 42 and Week 52.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set) with last observation carried forward.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**

Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Least Squares Mean (Standard Error) Units: mg/dL		
Week 8 (n=208; n=195)	-12.8 (5.04)	2.7 (5.20)
Week 12 (n=213; n=201)	-15.5 (5.72)	7.5 (5.89)
Week 26 (n=213; n=201)	-16.3 (4.74)	3.9 (4.88)
Week 42 (n=213; n=201)	-12.6 (5.01)	5.5 (5.16)
Week 52 (n=213; n=201)	-13.2 (5.27)	1.9 (5.42)

17. Secondary Outcome

Title: Change From Baseline in High Sensitivity C-reactive Protein

Description: The change between the high sensitivity C-reactive protein value collected at each week indicated including final visit from baseline.

Time Frame: Baseline, Week 12, Week 26, Week 42 and Week 52.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set) with last observation carried forward.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**

Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Least Squares Mean (Standard Error) Units: mg/L		
Week 12 (n=209; n=192)	0.45 (0.699)	0.10 (0.730)
Week 26 (n=212; n=198)	-0.02 (0.682)	0.47 (0.706)
Week 42 (n=212; n=198)	0.33 (0.736)	0.53 (0.762)
Week 52 (n=212; n=198)	0.01 (0.656)	0.21 (0.679)

18. Secondary Outcome

Title: Incidence of Subjects Achieving Glycosylated Hemoglobin <=7%

Description: The percentage of participants with a value for the percentage of glycosylated hemoglobin (HbA1c; the percentage of hemoglobin that is bound to glucose) less than or equal to 6.5 and 7.0% during the 52 week study.

Time Frame: Baseline and Week 52.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set) with last observation carried forward.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**

Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.
Number of Participants Analyzed	222	219
Measure Type: Number Units: percentage of participants		
HbA1c ≤6.5%	22.3	18.2
HbA1c ≤7.0%	48.8	45.3

19. Secondary Outcome

Title: Incidence of Glycosylated Hemoglobin Decrease From Baseline.

Description: The percentage of participants with a decrease from baseline in the percentage of glycosylated hemoglobin (the percentage of hemoglobin that is bound to glucose) greater than or equal to 0.5, 1.0, 1.5 and 2.0% during the 52 week study.

Time Frame: Baseline and Week 52.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

All randomized participants who had at least 1 dose of study medication (full analysis set) with last observation carried forward.

Arm/Group Title	**Alogliptin 25 mg QD**	**Glipizide 5 mg QD**
Arm/Group Description:	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.

Number of Participants Analyzed	222	219
Measure Type: Number Units: percentage of participants		
Decrease from Baseline in HbA1c ≥0.5%	32.1	29.0
Decrease from Baseline in HbA1c ≥1.0%	12.6	10.3
Decrease from Baseline in HbA1c ≥1.5%	5.1	2.3
Decrease from Baseline in HbA1c ≥2.0%	2.8	1.4

Adverse Events

Time Frame	Treatment-emergent adverse events are adverse events that started after the first dose of double-blind study drug and no more than 14 days after the last dose of double-blind study drug.
Additional Description	At each visit the investigator was to document any occurrence of adverse events and abnormal laboratory findings. Any event spontaneously reported by the participant or observed by the investigator was recorded, irrespective of the relation to study treatment.
Source Vocabulary Name	MedDRA 13.0
Assessment Type	Systematic Assessment

Arm/Group Title	Alogliptin 25 mg QD	Glipizide 5 mg QD
Arm/Group Description	Alogliptin 25 mg, tablets, orally, once daily and glipizide placebo matching tablets, orally, once daily for up to 52 weeks.	Alogliptin placebo-matching tablets, orally, once daily and glipizide 5 mg to 10 mg, tablets, orally, once daily up to 52 weeks.

Serious Adverse Events

	Alogliptin 25 mg QD Affected / at Risk (%)	**Glipizide 5 mg QD** Affected / at Risk (%)
Total	16/222 (7.21%)	13/219 (5.94%)
Cardiac disorders		
Angina pectoris † A	1/222 (0.45%)	0/219 (0%)
Cardiac failure † A	1/222 (0.45%)	0/219 (0%)
Cardiac failure congestive † A	1/222 (0.45%)	1/219 (0.46%)
Coronary artery disease † A	1/222 (0.45%)	0/219 (0%)
Ischaemic cardiomyopathy † A	0/222 (0%)	1/219 (0.46%)
Left ventricular failure † A	1/222 (0.45%)	0/219 (0%)
Myocardial infarction † A	0/222 (0%)	1/219 (0.46%)
Ear and labyrinth disorders		
Sudden hearing loss † A	1/222 (0.45%)	0/219 (0%)
Hepatobiliary disorders		
Bile duct stone † A	1/222 (0.45%)	0/219 (0%)
Cholecystitis acute † A	1/222 (0.45%)	1/219 (0.46%)
Cholelithiasis † A	0/222 (0%)	2/219 (0.91%)
Infections and infestations		
Diverticulitis † A	1/222 (0.45%)	0/219 (0%)
Pyelonephritis acute † A	0/222 (0%)	1/219 (0.46%)
Respiratory tract infection viral † A	0/222 (0%)	1/219 (0.46%)
Urosepsis † A	0/222 (0%)	1/219 (0.46%)
Injury, poisoning and procedural complications		
Fall † A	2/222 (0.9%)	0/219 (0%)
Graft thrombosis † A	0/222 (0%)	1/219 (0.46%)
Multiple fractures † A	1/222 (0.45%)	0/219 (0%)
Postoperative fever † A	1/222 (0.45%)	0/219 (0%)
Seroma † A	1/222 (0.45%)	0/219 (0%)
Stress fracture † A	0/222 (0%)	1/219 (0.46%)
Upper limb fracture † A	1/222 (0.45%)	0/219 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast cancer † A	1/222 (0.45%)	0/219 (0%)
Cervix carcinoma † A	1/222 (0.45%)	0/219 (0%)
Nervous system disorders		
Cerebrovascular accident † A	0/222 (0%)	1/219 (0.46%)
Dizziness † A	0/222 (0%)	1/219 (0.46%)
Transient ischaemic attack † A	1/222 (0.45%)	0/219 (0%)
Renal and urinary disorders		
Calculus ureteric † A	1/222 (0.45%)	0/219 (0%)
Renal failure acute † A	0/222 (0%)	1/219 (0.46%)

Reproductive system and breast disorders		
Benign prostatic hyperplasia † A	1/222 (0.45%)	0/219 (0%)
Respiratory, thoracic and mediastinal disorders		
Pulmonary hypertension † A	1/222 (0.45%)	0/219 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 13.0

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	3%	
	Alogliptin 25 mg QD Affected / at Risk (%)	**Glipizide 5 mg QD** Affected / at Risk (%)
Total	103/222 (46.4%)	105/219 (47.95%)
Gastrointestinal disorders		
Diarrhoea † A	9/222 (4.05%)	14/219 (6.39%)
Dyspepsia † A	7/222 (3.15%)	1/219 (0.46%)
Nausea † A	7/222 (3.15%)	8/219 (3.65%)
General disorders		
Pyrexia † A	2/222 (0.9%)	7/219 (3.2%)
Infections and infestations		
Bronchitis † A	6/222 (2.7%)	9/219 (4.11%)
Nasopharyngitis † A	13/222 (5.86%)	10/219 (4.57%)
Pharyngitis † A	5/222 (2.25%)	7/219 (3.2%)
Upper respiratory tract infection † A	12/222 (5.41%)	5/219 (2.28%)
Urinary tract infection † A	26/222 (11.71%)	23/219 (10.5%)
Investigations		
C-reactive protein increased † A	9/222 (4.05%)	3/219 (1.37%)
Metabolism and nutrition disorders		
Dyslipidaemia † A	5/222 (2.25%)	10/219 (4.57%)
Hypoglycaemia † A	0/222 (0%)	8/219 (3.65%)
Musculoskeletal and connective tissue disorders		
Arthralgia † A	10/222 (4.5%)	12/219 (5.48%)
Back pain † A	9/222 (4.05%)	11/219 (5.02%)
Osteoarthritis † A	3/222 (1.35%)	8/219 (3.65%)
Pain in extremity † A	6/222 (2.7%)	7/219 (3.2%)
Nervous system disorders		
Dizziness † A	13/222 (5.86%)	18/219 (8.22%)
Headache † A	16/222 (7.21%)	15/219 (6.85%)
Vascular disorders		
Hypertension † A	12/222 (5.41%)	10/219 (4.57%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 13.0

Limitations and Caveats

[Not Specified]

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.

No publication related to study results will be published prior to publication of a multi-center report submitted for publication within 18 months after conclusion or termination of a study at all study sites. Results publications will be submitted to sponsor for review 60 days in advance of publication. Sponsor can require removal of confidential information unrelated to study results. Sponsor can embargo a proposed publication for another 60 days to preserve intellectual property.

Results Point of Contact

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