ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 08/07/2012

ClinicalTrials.gov ID: NCT01128153

Study Identification

Unique Protocol ID:	D1680L00006
Brief Title:	Saxagliptin Triple Oral Therapy
Official Title:	A 24-week, Multicentre, Randomised, Double-Blind, Placebo-Controlled Phase IIIb Study to Evaluate Efficacy and Safety of Saxagliptin in Combination With Metformin and Sulfonylurea in Subjects With Type 2 Diabetes Who Have Inadequate Glycaemic Control With Combination of Metformin and Sulfonylurea
Secondary IDs:	CV181-117

Study Status

Record Verification:	August 2012
Overall Status:	Completed
Study Start:	June 2010
Primary Completion:	June 2011 [Actual]
Study Completion:	June 2011 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	Bristol-Myers Squibb

Oversight

FDA Regulated?:	Yes

Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 10/H0402/29 Board Name: NHS National Research Ethics ServiceLeicestershire, Northamptonshire & Rutland Research Ethics Committee 2 Board Affiliation: National Health Service Phone: +44 (0) 115 883 9428 Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Australia: Therapeutic Goods Administration Australia: Human Research Ethics Committee United Kingdom: National Health Service United Kingdom: Medicines and Healthcare Products Regulatory Agency India: Drugs Controller General of India India: Institutional Review Board Korea: Food and Drug Administration Thailand: Ethical Committee Thailand: Ministry of Public Health

Study Description

Brief Summary:	The purpose of this study is to determine whether the addition of saxagliptin to a patient's combination treatment of metformin and sulfonylurea for a 24 week period will provide better control of the patient's type 2 diabetes and will be well tolerated.
Detailed Description:	A 24-week, Multicentre, Randomised, Double-Blind, Placebo-Controlled Phase IIIb Study to Evaluate Efficacy and Safety of Saxagliptin in Combination with Metformin and Sulfonylurea in Subjects with Type 2 Diabetes who have Inadequate Glycaemic Control with Combination of Metformin and Sulfonylurea

Conditions

Conditions:	Type 2 Diabetes
Keywords:	Type 2 Diabetes Inadequate Glycaemic Control Saxagliptin Metformin Sulfonylurea Triple Oral Therapy

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	257 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Saxagliptin 5 mg once daily	Drug: Saxagliptin 5 mg tablet once daily for 24 weeks to be taken orally Other Names: • Onglyza
Placebo Comparator: Placebo once daily	Drug: Placebo tablet once daily for 24 weeks to be taken orally

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria: • Written Informed Consent

- Males or females with type 2 diabetes with inadequate glycaemic control (HbA1c > or = 7% and < or = 10%) despite being on combination of metformin and sulfonylurea for at least 8 weeks prior to Visit 1
- BMI < or = 40 kg/m2

Exclusion Criteria:

- Symptoms of poorly controlled diabetes including but not limited to marked polyuria and marked polydipsia with > 10% weight loss in 3 months prior to entry, or other signs and symptoms
- History of diabetic ketoacidosis or hyperosmolar non-ketotic coma
- Current or prior use within 3 months of Visit 1 of insulin, DDP4 inhibitor, GLP-1 analogues, and/or other oral anti-diabetic agents (other than metformin or sulfonylurea)
- Treatment with CYP3A4 inducers and/or potent CYP3A4/5 inhibitor
- Estimated CrCl < 60 ml/min at Visit 2
- CHF (NYHA class III or IV) and/or LVEF <40%
- Active liver disease and/or significant abnormal liver function defined as AST and/or ALT > 3 x ULN and/or bilirubin > 2.0 mg/dL at Visit 2.
- Creatine kinase > or = 10 x ULN at Visit 2

Contacts/Locations

Study Officials: Jayanti Visvanthan, MD
Study Chair
AstraZeneca

Simon Fisher, MD
Study Chair
AstraZeneca

Vinod Mattoo, MD
Study Chair
Bristol-Myers Squibb

Robert Moses, MBBS
Study Principal Investigator
Sydney Diabetes Centre

Locations: Australia, New South Wales
Research Site
Broadmeadow, New South Wales, Australia

Australia
Research Site
Camperdown, Australia

Australia, South Australia

Research Site
Daw Park, South Australia, Australia

Research Site
Elizabeth Vale, South Australia, Australia

Australia
Research Site
Herston, Australia

Australia, Victoria
Research Site
Melbourne, Victoria, Australia

Australia, New South Wales
Research Site
Wollongong, New South Wales, Australia

Canada, Prince Edward Island
Research Site
Charlottetown, Prince Edward Island, Canada

Research Site
Kensington, Prince Edward Island, Canada

Canada, Ontario
Research Site
Newmarket, Ontario, Canada

Canada, Newfoundland and Labrador
Research Site
St. John's, Newfoundland and Labrador, Canada

Canada, Nova Scotia
Research Site
Sydney Mines, Nova Scotia, Canada

Canada, Ontario
Research Site
Thornhill, Ontario, Canada

Research Site
Toronto, Ontario, Canada

United Kingdom
Research Site

Ashford, United Kingdom

Research Site
Belfast, United Kingdom

Research Site
Blackpool, United Kingdom

Research Site
Chesterfield, United Kingdom

Research Site
Coventry, United Kingdom

Research Site
ELY, Cambridgeshire, United Kingdom

Research Site
Glasgow, United Kingdom

Research Site
Peterborough, United Kingdom

Research Site
Reading, Berks, United Kingdom

Research Site
Wellingborough, United Kingdom

Research Site
Westbury, Wiltshire, United Kingdom

Research Site
Whitstable, Kent, United Kingdom

India
Research Site
Bangalore, Karnataka, India

Research Site
Coimbatore, Tamil Nadu, India

Research Site
Indore, Madhya Pradesh, India

Research Site

Karnal, Haryana, India

Research Site
Pune, Maharashtra, India

Korea, Republic of
Research Site
Daegu, Korea, Republic of

Research Site
Goyang, Kyounggi-do, Korea, Republic of

Research Site
Seoul, Korea, Republic of

Research Site
Wonju, Kangwon-do, Korea, Republic of

Thailand
Research Site
Bangkok, Thailand

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Participants were recruited to the study from 35 centres in 6 countries (Australia, United Kingdom, Canada, Korea, India and Thailand). Participants were recruited between June 2010 and December 2010.
Pre-Assignment Details	Participants were screened over 2 week period. 383 participants enrolled; 126 excluded (11 declined, 114 did not meet eligibility criteria, 1 lost to follow up).

Reporting Groups

	Description
SAXAGLIPTIN	Saxagliptin 5 mg tablet once daily for 24 weeks to be taken orally
PLACEBO	Placebo tablet once daily for 24 weeks to be taken orally

Overall Study

	SAXAGLIPTIN	PLACEBO
Started	129 [1]	128 [1]
Full Analysis Set	127 [2]	128 [2]
Completed	113 [3]	113 [3]
Not Completed	16	15
Adverse Event	1	3
Condition under investigation worsened	8	7
Withdrawal by Subject	2	3
Incorrect enrolment to study	2	1
Protocol Violation	2	0
Developed discontinuation criteria	1	1

[1] Randomised
[2] Received at least 1 dose of investigational product during 24 week blinded period
[3] Completed 24 weeks

Baseline Characteristics

Reporting Groups

	Description
SAXAGLIPTIN	Saxagliptin 5 mg tablet once daily for 24 weeks to be taken orally
PLACEBO	Placebo tablet once daily for 24 weeks to be taken orally

Baseline Measures

	SAXAGLIPTIN	PLACEBO	Total
Number of Participants	129	128	257

	SAXAGLIPTIN	PLACEBO	Total
Age, Continuous [units: years] Mean (Standard Deviation)	57.2 (9.55)	56.8 (11.49)	57.0 (10.54)
Gender, Male/Female [units: Participants]			
Female	49	54	103
Male	80	74	154
Race/Ethnicity, Customized [units: Participants]			
White	59	57	116
Asian	70	71	141
Region of Enrollment [units: Participants]			
Australia	25	25	50
Canada	10	10	20
India	35	34	69
Korea, Republic of	25	24	49
Thailand	8	10	18
United Kingdom	26	25	51
BMI [units: kg/m2] Mean (Standard Deviation)	29.4 (5.26)	29.1 (4.93)	29.2 (5.09)
HbA1c [units: %] Mean (Standard Deviation)	8.38 (0.856)	8.19 (0.832)	8.28 (0.848)
2-hour Postprandial Glucose [units: mg/dL] Mean (Standard Deviation)	269.18 (76.814)	265.6 (69.713)	267.39 (73.220)
2-hour Postprandial glucose [units: mmol/L] Mean (Standard Deviation)	14.94 (4.263)	14.74 (3.869)	14.84 (4.064)
Fasting Plasma Glucose [units: mg/dL] Mean (Standard Deviation)	162.24 (47.322)	155.45 (38.37)	158.84 (43.125)

	SAXAGLIPTIN	PLACEBO	Total
Fasting Plasma Glucose [units: mmol/L] Mean (Standard Deviation)	9.00 (2.626)	8.63 (2.130)	8.82 (2.393)

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change in HbA1c From Baseline to Week 24, Last Observation Carried Forward (LOCF)
Measure Description	Adjusted Mean Change in HbA1c from baseline to Week 24 using analysis of covariance model
Time Frame	From Baseline to Week 24 weeks
Safety Issue?	No
Anticipated Reporting Date	June 2012

Analysis Population Description

Full Analysis Set which included all participants randomised to the study who received at least 1 dose of investigational product and who had a non-missing baseline value and at least 1 post-baseline measure. The full analysis set follows intention-to-treat principle.

Reporting Groups

	Description
Arm 1 - SAXAGLIPTIN	Saxagliptin 5 mg tablet once daily for 24 weeks to be taken orally
Arm 2 - PLACEBO	Placebo tablet once daily for 24 weeks to be taken orally

Measured Values

	Arm 1 - SAXAGLIPTIN	Arm 2 - PLACEBO
Number of Participants Analyzed	127	127
Change in HbA1c From Baseline to Week 24, Last Observation Carried Forward (LOCF) [units: percent] Mean (95% Confidence Interval)	-0.74 (-0.89 to -0.60)	-0.08 (-0.23 to 0.07)

Statistical Analysis 1 for Change in HbA1c From Baseline to Week 24, Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Arm 1 - SAXAGLIPTIN, Arm 2 - PLACEBO
	Comments	[Not specified]

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.66
	Confidence Interval	(2-Sided) 95% -0.86 to -0.47
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.099
	Estimation Comments	Adjusted mean treatment difference from the ANCOVA model (Saxagliptin – Placebo)

2. Secondary Outcome Measure:

Measure Title	Change in 2-hour Postprandial Glucose (PPG) From Baseline to Week 24, Last Observation Carried Forward (LOCF) Measured as [mg/dL]
Measure Description	Adjusted Mean Change in 2-hour PPG from baseline to Week 24 using analysis of covariance model
Time Frame	From Baseline to Week 24
Safety Issue?	No
Anticipated Reporting Date	June 2012

Analysis Population Description

Full Analysis Set which included all participants randomised to the study who received at least 1 dose of investigational product and who had a non-missing baseline value and at least 1 post-baseline measure. The full analysis set follows intention-to-treat principle.

Reporting Groups

	Description
Arm 1 - SAXAGLIPTIN	Saxagliptin 5 mg tablet once daily for 24 weeks to be taken orally
Arm 2 - PLACEBO	Placebo tablet once daily for 24 weeks to be taken orally

Measured Values

	Arm 1 - SAXAGLIPTIN	Arm 2 - PLACEBO
Number of Participants Analyzed	115	113
Change in 2-hour Postprandial Glucose (PPG) From Baseline to Week 24, Last Observation Carried Forward (LOCF) Measured as [mg/dL] [units: mg/dL] Mean (95% Confidence Interval)	-11.66 (-23.38 to 0.07)	5.08 (-6.45 to 16.60)

Statistical Analysis 1 for Change in 2-hour Postprandial Glucose (PPG) From Baseline to Week 24, Last Observation Carried Forward (LOCF) Measured as [mg/dL]

Statistical Analysis Overview	Comparison Groups	Arm 1 - SAXAGLIPTIN, Arm 2 - PLACEBO
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0301
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-16.74
	Confidence Interval	(2-Sided) 95% -31.85 to -1.62
	Parameter Dispersion	Type: Standard Error of the mean Value: 7.667
	Estimation Comments	Adjusted mean treatment difference from the ANCOVA model (Saxagliptin – Placebo)

3. Secondary Outcome Measure:

Measure Title	Change in 2-hour Postprandial Glucose (PPG) From Baseline to Week 24, Last Observation Carried Forward (LOCF) Measured as [mmol/L]

Measure Description	Adjusted Mean Change in 2-hour PPG from baseline to Week 24 using analysis of covariance model
Time Frame	From Baseline to Week 24
Safety Issue?	No
Anticipated Reporting Date	June 2012

Analysis Population Description

Full Analysis Set which included all participants randomised to the study who received at least 1 dose of investigational product and who had a non-missing baseline value and at least 1 post-baseline measure. The full analysis set follows intention-to-treat principle.

Reporting Groups

	Description
Arm 1 - SAXAGLIPTIN	Saxagliptin 5 mg tablet once daily for 24 weeks to be taken orally
Arm 2 - PLACEBO	Placebo tablet once daily for 24 weeks to be taken orally

Measured Values

	Arm 1 - SAXAGLIPTIN	Arm 2 - PLACEBO
Number of Participants Analyzed	115	113
Change in 2-hour Postprandial Glucose (PPG) From Baseline to Week 24, Last Observation Carried Forward (LOCF) Measured as [mmol/L] [units: mmol/L] Mean (95% Confidence Interval)	-0.65 (-1.30 to 0.00)	0.28 (-0.36 to 0.92)

Statistical Analysis 1 for Change in 2-hour Postprandial Glucose (PPG) From Baseline to Week 24, Last Observation Carried Forward (LOCF) Measured as [mmol/L]

Statistical Analysis Overview	Comparison Groups	Arm 1 - SAXAGLIPTIN, Arm 2 - PLACEBO
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0301
	Comments	[Not specified]
	Method	ANCOVA

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.93
	Confidence Interval	(2-Sided) 95% -1.77 to -0.09
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.426
	Estimation Comments	Adjusted mean treatment difference from the ANCOVA model (Saxagliptin – Placebo)

4. Secondary Outcome Measure:

Measure Title	Change in Fasting Plasma Glucose (FPG) From Baseline to Week 24, Last Observation Carried Forward (LOCF) Measured as [mg/dL]
Measure Description	Adjusted Mean Change in fasting plasma glucose from baseline to Week 24 using analysis of covariance
Time Frame	From Baseline to Week 24
Safety Issue?	No
Anticipated Reporting Date	June 2012

Analysis Population Description

Full Analysis Set which included all participants randomised to the study who received at least 1 dose of investigational product and who had a non-missing baseline value and at least 1 post-baseline measure. The full analysis set follows intention-to-treat principle.

Reporting Groups

	Description
Arm 1 - SAXAGLIPTIN	Saxagliptin 5 mg tablet once daily for 24 weeks to be taken orally
Arm 2 - PLACEBO	Placebo tablet once daily for 24 weeks to be taken orally

Measured Values

	Arm 1 - SAXAGLIPTIN	Arm 2 - PLACEBO
Number of Participants Analyzed	121	123
Change in Fasting Plasma Glucose (FPG) From Baseline to Week 24, Last Observation Carried Forward (LOCF) Measured as [mg/dL] [units: mg/dL] Mean (95% Confidence Interval)	-5.28 (-12.67 to 2.11)	2.62 (-4.47 to 9.71)

Statistical Analysis 1 for Change in Fasting Plasma Glucose (FPG) From Baseline to Week 24, Last Observation Carried Forward (LOCF) Measured as [mg/dL]

Statistical Analysis Overview	Comparison Groups	Arm 1 - SAXAGLIPTIN, Arm 2 - PLACEBO
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0868
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-7.90
	Confidence Interval	(2-Sided) 95% -16.96 to 1.15
	Parameter Dispersion	Type: Standard Error of the mean Value: 4.595
	Estimation Comments	Adjusted mean treatment difference from the ANCOVA model (Saxagliptin – Placebo)

5. Secondary Outcome Measure:

Measure Title	Change in Fasting Plasma Glucose (FPG) From Baseline to Week 24, Last Observation Carried Forward (LOCF) Measured as [mmol/L]
Measure Description	Adjusted Mean Change in FPG from baseline to Week 24 using analysis of covariance model
Time Frame	From Baseline to Week 24
Safety Issue?	No
Anticipated Reporting Date	June 2012

Analysis Population Description

Full Analysis Set which included all participants randomised to the study who received at least 1 dose of investigational product and who had a non-missing baseline value and at least 1 post-baseline measure. The full analysis set follows intention-to-treat principle.

Reporting Groups

	Description
Arm 1 - SAXAGLIPTIN	Saxagliptin 5 mg tablet once daily for 24 weeks to be taken orally
Arm 2 - PLACEBO	Placebo tablet once daily for 24 weeks to be taken orally

Measured Values

	Arm 1 - SAXAGLIPTIN	Arm 2 - PLACEBO
Number of Participants Analyzed	121	123
Change in Fasting Plasma Glucose (FPG) From Baseline to Week 24, Last Observation Carried Forward (LOCF) Measured as [mmol/L] [units: mmol/L] Mean (95% Confidence Interval)	-0.29 (-0.70 to 0.12)	0.15 (-0.25 to 0.54)

Statistical Analysis 1 for Change in Fasting Plasma Glucose (FPG) From Baseline to Week 24, Last Observation Carried Forward (LOCF) Measured as [mmol/L]

Statistical Analysis Overview	Comparison Groups	Arm 1 - SAXAGLIPTIN, Arm 2 - PLACEBO
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0868
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.44
	Confidence Interval	(2-Sided) 95% -0.94 to 0.06
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.255
	Estimation Comments	Adjusted mean treatment difference from the ANCOVA model (Saxagliptin – Placebo)

6. Secondary Outcome Measure:

Measure Title	Proportion of Participants Achieving a Therapeutic Response: HbA1c Less Than 7% at Week 24, Last Observation Carried Forward (LOCF)
Measure Description	Number of participants achieving a glycaemic response defined as HbA1c less than 7% at Week 24
Time Frame	From Baseline to Week 24
Safety Issue?	No
Anticipated Reporting Date	June 2012

Analysis Population Description

Full Analysis Set which included all participants randomised to the study who received at least 1 dose of investigational product and who had a non-missing baseline value and at least 1 post-baseline measure. The full analysis set follows intention-to-treat principle.

Reporting Groups

	Description
Arm 1 - SAXAGLIPTIN	Saxagliptin 5 mg tablet once daily for 24 weeks to be taken orally
Arm 2 - PLACEBO	Placebo tablet once daily for 24 weeks to be taken orally

Measured Values

	Arm 1 - SAXAGLIPTIN	Arm 2 - PLACEBO
Number of Participants Analyzed	127	127
Proportion of Participants Achieving a Therapeutic Response: HbA1c Less Than 7% at Week 24, Last Observation Carried Forward (LOCF) [units: Participants]	39	12

Statistical Analysis 1 for Proportion of Participants Achieving a Therapeutic Response: HbA1c Less Than 7% at Week 24, Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Arm 1 - SAXAGLIPTIN, Arm 2 - PLACEBO
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	9.006
	Confidence Interval	(2-Sided) 95% 3.852 to 21.05
	Estimation Comments	Estimated Odds Ratio from the logistic regression model (Saxa/Placebo)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
SAXAGLIPTIN	Saxagliptin 5 mg tablet once daily for 24 weeks to be taken orally
PLACEBO	Placebo tablet once daily for 24 weeks to be taken orally

Serious Adverse Events

	SAXAGLIPTIN	PLACEBO
	Affected/At Risk (%)	Affected/At Risk (%)
Total	3/129 (2.33%)	7/128 (5.47%)
Hepatobiliary disorders		
Hepatitis [A] †	1/129 (0.78%)	0/128 (0%)
Infections and infestations		
Influenza [A] †	0/129 (0%)	1/128 (0.78%)
Lower Respiratory Tract Infection [A] †	1/129 (0.78%)	0/128 (0%)

	SAXAGLIPTIN	PLACEBO
	Affected/At Risk (%)	Affected/At Risk (%)
Osteomyelitis [A] †	0/129 (0%)	1/128 (0.78%)
Injury, poisoning and procedural complications		
Cartilage Injury [A] †	0/129 (0%)	1/128 (0.78%)
Musculoskeletal and connective tissue disorders		
Arthritis [A] †	0/129 (0%)	1/128 (0.78%)
Musculoskeletal Stiffness [A] †	0/129 (0%)	1/128 (0.78%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Laryngeal Cancer [A] †	1/129 (0.78%)	0/128 (0%)
Squamous Cell Carcinoma [A] †	0/129 (0%)	1/128 (0.78%)
Renal and urinary disorders		
Renal Colic [A] †	0/129 (0%)	1/128 (0.78%)
Respiratory, thoracic and mediastinal disorders		
Asthma [A] †	0/129 (0%)	1/128 (0.78%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 14.0

Other Adverse Events

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

	SAXAGLIPTIN	PLACEBO
	Affected/At Risk (%)	Affected/At Risk (%)
Total	53/129 (41.09%)	65/128 (50.78%)
Blood and lymphatic system disorders		
Anaemia [A] †	1/129 (0.78%)	5/128 (3.91%)
Gastrointestinal disorders		
Constipation [A] †	1/129 (0.78%)	3/128 (2.34%)

	SAXAGLIPTIN	PLACEBO
	Affected/At Risk (%)	Affected/At Risk (%)
Diarrhoea [A] †	7/129 (5.43%)	5/128 (3.91%)
Flatulence [A] †	4/129 (3.1%)	0/128 (0%)
Gastritis [A] †	3/129 (2.33%)	3/128 (2.34%)
Nausea [A] †	2/129 (1.55%)	4/128 (3.12%)
Infections and infestations		
Nasopharyngitis [A] †	8/129 (6.2%)	12/128 (9.38%)
Oral Candidiasis [A] †	0/129 (0%)	3/128 (2.34%)
Pharyngitis [A] †	0/129 (0%)	3/128 (2.34%)
Upper Respiratory Tract Infection [A] †	6/129 (4.65%)	6/128 (4.69%)
Urinary Tract Infection [A] †	4/129 (3.1%)	8/128 (6.25%)
Metabolism and nutrition disorders		
Dyslipidaemia [A] †	5/129 (3.88%)	7/128 (5.47%)
Hyperglycaemia [A] †	4/129 (3.1%)	4/128 (3.12%)
Musculoskeletal and connective tissue disorders		
Arthralgia [A] †	2/129 (1.55%)	3/128 (2.34%)
Back Pain [A] †	1/129 (0.78%)	4/128 (3.12%)
Pain In Extremity [A] †	2/129 (1.55%)	4/128 (3.12%)
Nervous system disorders		
Dizziness [A] †	3/129 (2.33%)	2/128 (1.56%)
Headache [A] †	4/129 (3.1%)	3/128 (2.34%)
Neuropathy Peripheral [A] †	3/129 (2.33%)	0/128 (0%)
Psychiatric disorders		
Insomnia [A] †	0/129 (0%)	3/128 (2.34%)

	SAXAGLIPTIN	PLACEBO
	Affected/At Risk (%)	Affected/At Risk (%)
Respiratory, thoracic and mediastinal disorders		
Cough [A] †	4/129 (3.1%)	1/128 (0.78%)
Skin and subcutaneous tissue disorders		
Rash [A] †	2/129 (1.55%)	3/128 (2.34%)
Vascular disorders		
Hypertension [A] †	7/129 (5.43%)	2/128 (1.56%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 14.0

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.

At least 60 days prior to submission of any material for publication or presentation, PI shall provide Sponsor with such material for review. If requested in writing by Sponsor, PI shall withhold material from submission for publication or presentation for an additional 90 days from the date of Sponsor's request.

Results Point of Contact:

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