Trial record **1 of 1** for: 28431754DIA3012
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The CANTATA-MP Trial (CANagliflozin Treatment and Trial Analysis - Metformin and Pioglitazone)

This study has been completed.

Sponsor:
Janssen Research & Development, LLC

Information provided by (Responsible Party):
Janssen Research & Development, LLC

ClinicalTrials.gov Identifier:
NCT01106690

First received: April 1, 2010
Last updated: June 26, 2013
Last verified: June 2013
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: April 2, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
Condition:	Diabetes Mellitus, Type 2
Interventions:	Drug: Placebo Drug: Canagliflozin Drug: Sitagliptin Drug: Metformin Drug: Pioglitazone

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
This study evaluated the efficacy and safety of canagliflozin in patients with type 2 diabetes mellitus with inadequate control despite treatment with metformin and pioglitazone. The study was conducted between 13 April 2010 and 20 November 2011 and recruited patients from 74 study centers in 11 countries worldwide.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
344 patients were randomly allocated to the 3 treatment arms. 342 patients received at least 1 dose of study drug and were included in the modified intent-to-treat (mITT) analysis set (used for the Week 26 efficacy analysis) and safety analysis set (used for the Week 26 and Week 52 safety analyses).

Reporting Groups

	Description
Placebo/Sitagliptin	Each patient received matching placebo once daily for 26 weeks with stable doses of metformin and pioglitazone. At Week 26, patients were switched from placebo to 100 mg of sitagliptin once daily with stable doses of metformin and pioglitazone until Week 52.

Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.

Participant Flow for 2 periods

Period 1: Core Period: Baseline to Week 26

	Placebo/Sitagliptin	Canagliflozin 100 mg	Canagliflozin 300 mg
STARTED	**115**	**113**	**114**
COMPLETED	**91**	**104**	**101**
NOT COMPLETED	**24**	**9**	**13**
Adverse Event	**6**	**1**	**4**
Lost to Follow-up	**1**	**1**	**2**
Protocol Violation	**1**	**0**	**0**
Withdrawal by Subject	**4**	**1**	**0**
Creatinine or eGFR withdrawal criteria	**0**	**3**	**1**
Noncompliance with study drug	**0**	**1**	**0**
Unable to take rescue therapy	**1**	**0**	**0**
Lack of efficacy on rescue therapy	**1**	**0**	**0**
Not specified	**10**	**2**	**6**

Period 2: Extension Period: Week 26 to Week 52

	Placebo/Sitagliptin	Canagliflozin 100 mg	Canagliflozin 300 mg
STARTED	**90** [1]	**103** [1]	**96** [2]
COMPLETED	**78**	**96**	**89**
NOT COMPLETED	**12**	**7**	**7**
Adverse Event	**1**	**1**	**0**
Withdrawal by Subject	**1**	**0**	**0**
Physician Decision	**0**	**2**	**2**
Noncompliance with study drug	**0**	**0**	**1**
Unable to take rescue therapy	**1**	**1**	**0**
Not specified	**8**	**3**	**4**
Lost to Follow-up	**1**	**0**	**0**

[1] 1 pt completed core but did not enter ext: physician decision(1).
[2] 5 pts completed core but did not exter ext: lost to f/u(1), not spec(2), AE(1), eGFR criteria(1).

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Placebo/Sitagliptin	Each patient received matching placebo once daily for 26 weeks with stable doses of metformin and pioglitazone. At Week 26, patients were switched from placebo to 100 mg of sitagliptin once daily with stable doses of metformin and pioglitazone until Week 52.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.
Total	Total of all reporting groups

Baseline Measures

	Placebo/Sitagliptin	Canagliflozin 100 mg	Canagliflozin 300 mg	Total
Number of Participants [units: participants]	**115**	**113**	**114**	**342**
Age [units: participants]				
<=18 years	**0**	**0**	**0**	**0**
Between 18 and 65 years	**83**	**83**	**83**	**249**
>=65 years	**32**	**30**	**31**	**93**
Age [units: years] Mean (Standard Deviation)	**58.3 (9.56)**	**56.7 (10.36)**	**57 (10.19)**	**57.4 (10.03)**
Gender [units: participants]				
Female	**39**	**36**	**51**	**126**
Male	**76**	**77**	**63**	**216**
Region of Enrollment [units: participants]				
CANADA	**24**	**22**	**21**	**67**
FINLAND	**7**	**3**	**3**	**13**
FRANCE	**1**	**0**	**1**	**2**
GERMANY	**7**	**5**	**7**	**19**
GREECE	**0**	**0**	**1**	**1**
INDIA	**10**	**10**	**5**	**25**
MEXICO	**7**	**3**	**11**	**21**
SPAIN	**8**	**5**	**2**	**15**
THAILAND	**5**	**8**	**4**	**17**
UNITED KINGDOM	**3**	**2**	**3**	**8**
UNITED STATES	**43**	**55**	**56**	**154**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in HbA1c From Baseline to Week 26 [Time Frame: Day 1 (Baseline) and Week 26]

Measure Type	Primary
Measure Title	Change in HbA1c From Baseline to Week 26
Measure Description	The table below shows the least-squares (LS) mean change in HbA1c from Baseline to Week 26 for each treatment group. The statistical analyses show the treatment differences (ie, each canagliflozin group minus placebo) in the LS mean change.
Time Frame	Day 1 (Baseline) and Week 26
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis used mITT analysis set (all randomized patients who received at least 1 dose of study drug). Last-observation-carried-forward method used for missing Week 26 values. Measurements taken pre-rescue used as last observation in patients receiving glycemic rescue therapy. Table includes only patients with both baseline and post baseline values.

Reporting Groups

	Description
Placebo/Sitagliptin	Each patient received matching placebo once daily for 26 weeks with stable doses of metformin and pioglitazone. At Week 26, patients were switched from placebo to 100 mg of sitagliptin once daily with stable doses of metformin and pioglitazone until Week 52.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.

Measured Values

	Placebo/Sitagliptin	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**114**	**113**	**112**
Change in HbA1c From Baseline to Week 26 [units: Percent] Least Squares Mean (Standard Error)	**-0.26 (0.069)**	**-0.89 (0.069)**	**-1.03 (0.070)**

Statistical Analysis 1 for Change in HbA1c From Baseline to Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-0.62
Standard Error of the mean	(0.095)
95% Confidence Interval	-0.811 to -0.437

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Change in HbA1c From Baseline to Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-0.76
Standard Error of the mean	(0.096)
95% Confidence Interval	-0.951 to -0.575

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Percentage of Patients With HbA1c <7% at Week 26 [Time Frame: Week 26]

Measure Type	Secondary
Measure Title	Percentage of Patients With HbA1c <7% at Week 26
Measure Description	The table below shows the percentage of patients with HbA1c<7% at Week 26 in each treatment group. The statistical analyses show the treatment differences (ie, each canagliflozin group minus placebo) in the percentage.
Time Frame	Week 26
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis used mITT analysis set (all randomized patients who received at least 1 dose of study drug). Last-observation-carried-forward method used for missing Week 26 values. Measurements taken pre-rescue used as last observation in patients receiving glycemic rescue therapy. Table includes only patients with both baseline and post baseline values.

Reporting Groups

	Description
Placebo/Sitagliptin	Each patient received matching placebo once daily for 26 weeks with stable doses of metformin and pioglitazone. At Week 26, patients were switched from placebo to 100 mg of sitagliptin once daily with stable doses of metformin and pioglitazone until Week 52.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.

Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.

Measured Values

	Placebo/Sitagliptin	Canagliflozin 100 mg	Canagliflozin 300 mg
Number of Participants Analyzed [units: participants]	**114**	**113**	**112**
Percentage of Patients With HbA1c <7% at Week 26 [units: Percentage of patients]	**32.5**	**46.9**	**64.3**

Statistical Analysis 1 for Percentage of Patients With HbA1c <7% at Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 100 mg
Method [2]	Regression, Logistic
P Value [3]	0.007
Odds Ratio (OR) [4]	2.40
95% Confidence Interval	1.26 to 4.57

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percentage of Patients With HbA1c <7% at Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 300 mg
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	5.38
95% Confidence Interval	2.73 to 10.60

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

3. Secondary: Change in Fasting Plasma Glucose (FPG) From Baseline to Week 26 [Time Frame: Day 1 (Baseline) and Week 26]

Measure Type	Secondary
Measure Title	Change in Fasting Plasma Glucose (FPG) From Baseline to Week 26
Measure Description	The table below shows the least-squares (LS) mean change in FPG from Baseline to Week 26 for each treatment group. The statistical analyses show the treatment differences (ie, each canagliflozin group minus placebo) in the LS mean change.
Time Frame	Day 1 (Baseline) and Week 26
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis used mITT analysis set (all randomized patients who received at least 1 dose of study drug). Last-observation-carried-forward method used for missing Week 26 values. Measurements taken pre-rescue used as last observation in patients receiving glycemic rescue therapy. Table includes only patients with both baseline and post baseline values.

Reporting Groups

	Description
Placebo/Sitagliptin	Each patient received matching placebo once daily for 26 weeks with stable doses of metformin and pioglitazone. At Week 26, patients were switched from placebo to 100 mg of sitagliptin once daily with stable doses of metformin and pioglitazone until Week 52.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.

Measured Values

	Placebo/Sitagliptin	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**114**	**113**	**112**
Change in Fasting Plasma Glucose (FPG) From Baseline to Week 26 [units: mg/dL] Least Squares Mean (Standard Error)	**2.54 (2.785)**	**-26.8 (2.796)**	**-33.2 (2.817)**

Statistical Analysis 1 for Change in Fasting Plasma Glucose (FPG) From Baseline to Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-29.4
Standard Error of the mean	(3.857)
95% Confidence Interval	-36.96 to -21.78

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

	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Change in Fasting Plasma Glucose (FPG) From Baseline to Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-35.7
Standard Error of the mean	(3.861)
95% Confidence Interval	-43.30 to -28.11

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

4. Secondary: Change in Homeostasis Model Assessment (HOMA2-%B) From Baseline to Week 26 [Time Frame: Day 1 (Baseline) and Week 26]

Measure Type	Secondary
Measure Title	Change in Homeostasis Model Assessment (HOMA2-%B) From Baseline to Week 26
Measure Description	HOMA2-%B is a measure of beta cell function (the cells in the pancreas that produce and store insulin). The table below shows the least-squares (LS) mean change in HOMA2-%B from Baseline to Week 26 for each treatment group. The statistical analyses show the treatment differences (ie, each canagliflozin group minus placebo) in the LS mean change.
Time Frame	Day 1 (Baseline) and Week 26
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis used mITT analysis set (all randomized patients who received at least 1 dose of study drug). Last-observation-carried-forward method used for missing Week 26 values. Measurements taken pre-rescue used as last observation in patients receiving glycemic rescue

therapy. Table includes only patients with both baseline and post baseline values.

Reporting Groups

	Description
Placebo/Sitagliptin	Each patient received matching placebo once daily for 26 weeks with stable doses of metformin and pioglitazone. At Week 26, patients were switched from placebo to 100 mg of sitagliptin once daily with stable doses of metformin and pioglitazone until Week 52.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.

Measured Values

	Placebo/Sitagliptin	Canagliflozin 100 mg	Canagliflozin 300 mg
Number of Participants Analyzed [units: participants]	**100**	**103**	**105**
Change in Homeostasis Model Assessment (HOMA2-%B) From Baseline to Week 26 [units: HOMA2-%B] Least Squares Mean (Standard Error)	**0.91 (1.833)**	**15.19 (1.809)**	**18.14 (1.790)**

Statistical Analysis 1 for Change in Homeostasis Model Assessment (HOMA2-%B) From Baseline to Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	14.28
Standard Error of the mean	(2.521)
95% Confidence Interval	9.315 to 19.236

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Change in Homeostasis Model Assessment (HOMA2-%B) From Baseline to Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	<0.001

Least-Squares Mean Difference [4]	17.23
Standard Error of the mean	(2.509)
95% Confidence Interval	12.293 to 22.166

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

5. Secondary: Percent Change in Body Weight From Baseline to Week 26 [Time Frame: Day 1 (Baseline) and Week 26]

Measure Type	Secondary
Measure Title	Percent Change in Body Weight From Baseline to Week 26
Measure Description	The table below shows the least-squares (LS) mean percent change in body weight from Baseline to Week 26 for each treatment group. The statistical analyses show the treatment differences (ie, each canagliflozin group minus placebo) in the LS mean percent change.
Time Frame	Day 1 (Baseline) and Week 26
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis used mITT analysis set (all randomized patients who received at least 1 dose of study drug). Last-observation-carried-forward method used for missing Week 26 values. Measurements taken pre-rescue used as last observation in patients receiving glycemic rescue therapy. Table includes only patients with both baseline and post baseline values.

Reporting Groups

	Description
Placebo/Sitagliptin	Each patient received matching placebo once daily for 26 weeks with stable doses of metformin and pioglitazone. At Week 26, patients were switched from placebo to 100 mg of sitagliptin once daily with stable doses of metformin and pioglitazone until Week 52.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.

Measured Values

	Placebo/Sitagliptin	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**114**	**113**	**112**
Percent Change in Body Weight From Baseline to Week 26 [units: Percent change]	**-0.1 (0.3)**	**-2.8 (0.3)**	**-3.8 (0.3)**

Least Squares Mean (Standard Error)			

Statistical Analysis 1 for Percent Change in Body Weight From Baseline to Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-2.7
Standard Error of the mean	(0.4)
95% Confidence Interval	-3.6 to -1.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change in Body Weight From Baseline to Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-3.7
Standard Error of the mean	(0.4)
95% Confidence Interval	-4.6 to -2.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

6. Secondary: Change in Systolic Blood Pressure (SBP) From Baseline to Week 26 [Time Frame: Day 1 (Baseline) and Week 26]

Measure Type	Secondary

Measure Title	Change in Systolic Blood Pressure (SBP) From Baseline to Week 26
Measure Description	The table below shows the least-squares (LS) mean change in SBP from Baseline to Week 26 for each treatment group. The statistical analyses show the treatment differences (ie, each canagliflozin group minus placebo) in the LS mean change.
Time Frame	Day 1 (Baseline) and Week 26
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis used mITT analysis set (all randomized patients who received at least 1 dose of study drug). Last-observation-carried-forward method used for missing Week 26 values. Measurements taken pre-rescue used as last observation in patients receiving glycemic rescue therapy. Table includes only patients with both baseline and post baseline values.

Reporting Groups

	Description
Placebo/Sitagliptin	Each patient received matching placebo once daily for 26 weeks with stable doses of metformin and pioglitazone. At Week 26, patients were switched from placebo to 100 mg of sitagliptin once daily with stable doses of metformin and pioglitazone until Week 52.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.

Measured Values

	Placebo/Sitagliptin	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**114**	**113**	**112**
Change in Systolic Blood Pressure (SBP) From Baseline to Week 26 [units: mmHg] Least Squares Mean (Standard Error)	**-1.24 (1.033)**	**-5.30 (1.036)**	**-4.70 (1.044)**

Statistical Analysis 1 for Change in Systolic Blood Pressure (SBP) From Baseline to Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	0.005
Least-Squares Mean Difference [4]	-4.07
Standard Error of the mean	(1.430)
95% Confidence Interval	-6.879 to -1.251

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Change in Systolic Blood Pressure (SBP) From Baseline to Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	0.016
Least-Squares Mean Difference [4]	-3.46
Standard Error of the mean	(1.433)
95% Confidence Interval	-6.281 to -0.643

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

7. Secondary: Percent Change in Triglycerides From Baseline to Week 26 [Time Frame: Day 1 (Baseline) and Week 26]

Measure Type	Secondary
Measure Title	Percent Change in Triglycerides From Baseline to Week 26
Measure Description	The table below shows the least-squares (LS) mean percent change in triglycerides from Baseline to Week 26 for each treatment group. The statistical analyses show the treatment differences (ie, each canagliflozin group minus placebo) in the LS mean percent change.
Time Frame	Day 1 (Baseline) and Week 26
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis used mITT analysis set (all randomized patients who received at least 1 dose of study drug). Last-observation-carried-forward method used for missing Week 26 values. Measurements taken pre-rescue used as last observation in patients receiving glycemic rescue therapy. Table includes only patients with both baseline and post baseline values.

Reporting Groups

	Description
Placebo/Sitagliptin	Each patient received matching placebo once daily for 26 weeks with stable doses of metformin and pioglitazone. At Week 26, patients were switched from placebo to 100 mg of sitagliptin once daily with stable doses of metformin and pioglitazone until Week 52.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and

	pioglitazone.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.

Measured Values

	Placebo/Sitagliptin	Canagliflozin 100 mg	Canagliflozin 300 mg
Number of Participants Analyzed [units: participants]	**105**	**108**	**109**
Percent Change in Triglycerides From Baseline to Week 26 [units: Percent change] Least Squares Mean (Standard Error)	**15.2 (4.1)**	**3.2 (4.1)**	**-1.7 (4.1)**

Statistical Analysis 1 for Percent Change in Triglycerides From Baseline to Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	0.034
Least-Squares Mean Difference [4]	-12.1
Standard Error of the mean	(5.7)
95% Confidence Interval	-12.1 to -0.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change in Triglycerides From Baseline to Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	0.003
Least-Squares Mean Difference [4]	-16.9
Standard Error of the mean	(5.7)
95% Confidence Interval	-28.1 to -5.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	No text entered.
[4]	Other relevant estimation information:
	No text entered.

8. Secondary: Percent Change in High-density Lipoprotein Cholesterol (HDL-C) From Baseline to Week 26 [Time Frame: Day 1 (Baseline) and Week 26]

Measure Type	Secondary
Measure Title	Percent Change in High-density Lipoprotein Cholesterol (HDL-C) From Baseline to Week 26
Measure Description	The table below shows the least-squares (LS) mean percent change in HDL-C from Baseline to Week 26 for each treatment group. The statistical analyses show the treatment differences (ie, each canagliflozin group minus placebo) in the LS mean percent change.
Time Frame	Day 1 (Baseline) and Week 26
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis used mITT analysis set (all randomized patients who received at least 1 dose of study drug). Last-observation-carried-forward method used for missing Week 26 values. Measurements taken pre-rescue used as last observation in patients receiving glycemic rescue therapy. Table includes only patients with both baseline and post baseline values.

Reporting Groups

	Description
Placebo/Sitagliptin	Each patient received matching placebo once daily for 26 weeks with stable doses of metformin and pioglitazone. At Week 26, patients were switched from placebo to 100 mg of sitagliptin once daily with stable doses of metformin and pioglitazone until Week 52.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone.

Measured Values

	Placebo/Sitagliptin	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**105**	**107**	**109**
Percent Change in High-density Lipoprotein Cholesterol (HDL-C) From Baseline to Week 26 [units: Percent change] Least Squares Mean (Standard Error)	**2.4 (1.4)**	**7.2 (1.3)**	**8.9 (1.3)**

Statistical Analysis 1 for Percent Change in High-density Lipoprotein Cholesterol (HDL-C) From Baseline to Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	0.010

Least-Squares Mean Difference [4]	4.8
Standard Error of the mean	(1.9)
95% Confidence Interval	1.2 to 8.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change in High-density Lipoprotein Cholesterol (HDL-C) From Baseline to Week 26

Groups [1]	Placebo/Sitagliptin vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	6.5
Standard Error of the mean	(1.9)
95% Confidence Interval	2.8 to 10.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse event data were collected for the duration of study (52 weeks).
Additional Description	The total number of adverse events listed in the "Other (non-Serious) Adverse Events" table are based upon a cut-off of greater than or equal to 5 percent of patients experiencing the adverse event in any treatment arm either during the 26-week period or entire 52-week period.

Reporting Groups

	Description
Placebo/Sitagliptin: Baseline to Week 26	Each patient received matching placebo once daily for 26 weeks with stable doses of metformin

	and pioglitazone. At Week 26, patients were switched from placebo to 100 mg of sitagliptin once daily with stable doses of metformin and pioglitazone until Week 52. Data are presented for Baseline to Week 26.
Canagliflozin 100 mg: Baseline to Week 26	Each patient received 100 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone. Data are presented for Baseline to Week 26.
Canagliflozin 300 mg: Baseline to Week 26	Each patient received 300 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone. Data are presented for Baseline to Week 26.
Placebo/Sitagliptin: Baseline to Week 52	Each patient received matching placebo once daily for 26 weeks with stable doses of metformin and pioglitazone. At Week 26, patients were switched from placebo to 100 mg of sitagliptin once daily with stable doses of metformin and pioglitazone until Week 52. Data are presented for Baseline to Week 52.
Canagliflozin 100 mg: Baseline to Week 52	Each patient received 100 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone. Data are presented for Baseline to Week 52.
Canagliflozin 300 mg: Baseline to Week 52	Each patient received 300 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone. Data are presented for Baseline to Week 52.

Serious Adverse Events

	Placebo/Sitagliptin: Baseline to Week 26	Canagliflozin 100 mg: Baseline to Week 26	Canagliflozin 300 mg: Baseline to Week 26	Placebo/Sitagliptin: Baseline to Week 52	Canagliflozin 100 mg: Baseline to Week 52	Canagliflozin 300 mg: Baseline to Week 52
Total, serious adverse events						
# participants affected / at risk	**5/115 (4.35%)**	**3/113 (2.65%)**	**4/114 (3.51%)**	**6/115 (5.22%)**	**8/113 (7.08%)**	**7/114 (6.14%)**
Cardiac disorders						
Acute coronary syndrome * 1 [3]						
# participants affected / at risk	**1/115 (0.87%)**	**0/113 (0.00%)**	**0/114 (0.00%)**	**1/115 (0.87%)**	**0/113 (0.00%)**	**0/114 (0.00%)**
Gastrointestinal disorders						
Dyspepsia * 1 [3]						
# participants affected / at risk	**1/115 (0.87%)**	**0/113 (0.00%)**	**0/114 (0.00%)**	**1/115 (0.87%)**	**0/113 (0.00%)**	**0/114 (0.00%)**
General disorders						
Chest pain * 1 [3]						
# participants affected / at risk	**0/115 (0.00%)**	**1/113 (0.88%)**	**0/114 (0.00%)**	**0/115 (0.00%)**	**1/113 (0.88%)**	**0/114 (0.00%)**
Hepatobiliary disorders						
Cholecystitis acute * 1 [3]						
# participants affected / at risk	**0/115 (0.00%)**	**1/113 (0.88%)**	**0/114 (0.00%)**	**0/115 (0.00%)**	**1/113 (0.88%)**	**0/114 (0.00%)**
Infections and infestations						
Anal abscess * 1 [3]						
# participants affected / at risk	**0/115 (0.00%)**	**1/113 (0.88%)**	**0/114 (0.00%)**	**0/115 (0.00%)**	**1/113 (0.88%)**	**0/114 (0.00%)**
Escherichia bacteraemia * 1 [3]						
# participants					**0/113 (0.00%)**	**0/114 (0.00%)**

affected / at risk	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)	1/115 (0.87%)		
Gastrointestinal infection * 1 [3]						
# participants affected / at risk	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)
Osteomyelitis * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	1/114 (0.88%)	0/115 (0.00%)	0/113 (0.00%)	1/114 (0.88%)
Sepsis syndrome * 1 [3]						
# participants affected / at risk	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)
Bacterial Sepsis * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	0/114 (0.00%)	0/115 (0.00%)	1/113 (0.88%)	0/114 (0.00%)
Bronchopneumonia * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	0/114 (0.00%)	0/115 (0.00%)	1/113 (0.88%)	0/114 (0.00%)
Cellulitis * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	0/114 (0.00%)	0/115 (0.00%)	0/113 (0.00%)	1/114 (0.88%)
Injury, poisoning and procedural complications						
Concussion * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	1/114 (0.88%)	0/115 (0.00%)	0/113 (0.00%)	1/114 (0.88%)
Laceration * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	1/114 (0.88%)	0/115 (0.00%)	0/113 (0.00%)	1/114 (0.88%)
Periprosthetic fracture * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	1/113 (0.88%)	0/114 (0.00%)	0/115 (0.00%)	1/113 (0.88%)	0/114 (0.00%)
Subdural haematoma * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	1/114 (0.88%)	0/115 (0.00%)	0/113 (0.00%)	1/114 (0.88%)
Tibia fracture * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	0/114 (0.00%)	0/115 (0.00%)	0/113 (0.00%)	1/114 (0.88%)
Investigations						
Arteriogram coronary * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	0/114 (0.00%)	0/115 (0.00%)	1/113 (0.88%)	0/114 (0.00%)
Musculoskeletal and connective tissue disorders						
Spinal column stenosis * 1 [3]						
# participants					0/113 (0.00%)	0/114 (0.00%)

affected / at risk	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)	1/115 (0.87%)		
Dupuytren's contracture * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	0/114 (0.00%)	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)
Osteoarthritis * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	0/114 (0.00%)	0/115 (0.00%)	1/113 (0.88%)	0/114 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Breast cancer * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	1/114 (0.88%)	0/115 (0.00%)	0/113 (0.00%)	1/114 (0.88%)
Nervous system disorders						
Cerebrovascular accident * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	0/114 (0.00%)	0/115 (0.00%)	0/113 (0.00%)	1/114 (0.88%)
Dizziness postural * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	0/114 (0.00%)	0/115 (0.00%)	1/113 (0.88%)	0/114 (0.00%)
Reproductive system and breast disorders						
Pelvic prolapse * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	0/113 (0.00%)	0/114 (0.00%)	0/115 (0.00%)	1/113 (0.88%)	0/114 (0.00%)
Respiratory, thoracic and mediastinal disorders						
Chronic obstructive pulmonary disease * 1 [3]						
# participants affected / at risk	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)
Dyspnoea * 1 [3]						
# participants affected / at risk	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)
Hypercapnia * 1 [4]						
# participants affected / at risk	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)
Restrictive pulmonary disease * 1 [3]						
# participants affected / at risk	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)
Vascular disorders						
Hypotension * 1 [3]						
# participants affected / at risk	1/115 (0.87%)	0/113 (0.00%)	0/114 (0.00%)	1/115 (0.87%)	1/113 (0.88%)	0/114 (0.00%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MEDDRA 14.1 / 15.0
[3] MEDDRA 14.1 used for Week 26/MEDDRA 15.0 for Week 52
[4] MEDDRA 14.1 used for Week 26/MEDDRA 15.0 for Week 52.

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse event data were collected for the duration of study (52 weeks).
Additional Description	The total number of adverse events listed in the "Other (non-Serious) Adverse Events" table are based upon a cut-off of greater than or equal to 5 percent of patients experiencing the adverse event in any treatment arm either during the 26-week period or entire 52-week period.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo/Sitagliptin: Baseline to Week 26	Each patient received matching placebo once daily for 26 weeks with stable doses of metformin and pioglitazone. At Week 26, patients were switched from placebo to 100 mg of sitagliptin once daily with stable doses of metformin and pioglitazone until Week 52. Data are presented for Baseline to Week 26.
Canagliflozin 100 mg: Baseline to Week 26	Each patient received 100 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone. Data are presented for Baseline to Week 26.
Canagliflozin 300 mg: Baseline to Week 26	Each patient received 300 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone. Data are presented for Baseline to Week 26.
Placebo/Sitagliptin: Baseline to Week 52	Each patient received matching placebo once daily for 26 weeks with stable doses of metformin and pioglitazone. At Week 26, patients were switched from placebo to 100 mg of sitagliptin once daily with stable doses of metformin and pioglitazone until Week 52. Data are presented for Baseline to Week 52.
Canagliflozin 100 mg: Baseline to Week 52	Each patient received 100 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone. Data are presented for Baseline to Week 52.
Canagliflozin 300 mg: Baseline to Week 52	Each patient received 300 mg of canagliflozin once daily for 52 weeks with stable doses of metformin and pioglitazone. Data are presented for Baseline to Week 52.

Other Adverse Events

	Placebo/Sitagliptin: Baseline to Week 26	**Canagliflozin 100 mg: Baseline to Week 26**	**Canagliflozin 300 mg: Baseline to Week 26**	**Placebo/Sitagliptin: Baseline to Week 52**	**Canagliflozin 100 mg: Baseline to Week 52**	**Canagliflozin 300 mg: Baseline to Week 52**
Total, other (not including serious) adverse events						
# participants affected / at risk	**31/115 (26.96%)**	**35/113 (30.97%)**	**40/114 (35.09%)**	**49/115 (42.61%)**	**48/113 (42.48%)**	**57/114 (50.00%)**
Gastrointestinal disorders						
Diarrhoea * 1 [3]						
# participants affected / at risk	**6/115 (5.22%)**	**4/113 (3.54%)**	**4/114 (3.51%)**	**7/115 (6.09%)**	**7/113 (6.19%)**	**6/114 (5.26%)**
General disorders						
Oedema peripheral * 1 [4]						
# participants						

affected / at risk	2/115 (1.74%)	2/113 (1.77%)	4/114 (3.51%)	4/115 (3.48%)	2/113 (1.77%)	6/114 (5.26%)
Infections and infestations						
Nasopharyngitis * 1 [3]						
# participants affected / at risk	6/115 (5.22%)	6/113 (5.31%)	11/114 (9.65%)	13/115 (11.30%)	11/113 (9.73%)	15/114 (13.16%)
Upper respiratory tract infection * 1 [3]						
# participants affected / at risk	7/115 (6.09%)	9/113 (7.96%)	5/114 (4.39%)	9/115 (7.83%)	14/113 (12.39%)	8/114 (7.02%)
Urinary tract infection * 1 [3]						
# participants affected / at risk	6/115 (5.22%)	4/113 (3.54%)	4/114 (3.51%)	9/115 (7.83%)	5/113 (4.42%)	9/114 (7.89%)
Vulvovaginal mycotic infection * 1 [3]						
# participants affected / at risk	0/115 (0.00%)	3/113 (2.65%)	6/114 (5.26%)	1/115 (0.87%)	3/113 (2.65%)	6/114 (5.26%)
Metabolism and nutrition disorders						
Hypoglycaemia * 1 [5]						
# participants affected / at risk	2/115 (1.74%)	1/113 (0.88%)	6/114 (5.26%)	3/115 (2.61%)	3/113 (2.65%)	5/114 (4.39%)
Musculoskeletal and connective tissue disorders						
Arthralgia * 1 [3]						
# participants affected / at risk	2/115 (1.74%)	1/113 (0.88%)	6/114 (5.26%)	3/115 (2.61%)	3/113 (2.65%)	9/114 (7.89%)
Back pain * 1 [3]						
# participants affected / at risk	3/115 (2.61%)	8/113 (7.08%)	5/114 (4.39%)	4/115 (3.48%)	10/113 (8.85%)	7/114 (6.14%)
Muscle spasms * 1 [4]						
# participants affected / at risk	3/115 (2.61%)	1/113 (0.88%)	3/114 (2.63%)	6/115 (5.22%)	2/113 (1.77%)	4/114 (3.51%)
Nervous system disorders						
Headache * 1 [4]						
# participants affected / at risk	4/115 (3.48%)	3/113 (2.65%)	5/114 (4.39%)	5/115 (4.35%)	3/113 (2.65%)	6/114 (5.26%)

Renal and urinary disorders						
Pollakiuria * 1 [3]						
# participants affected / at risk	**1/115 (0.87%)**	**5/113 (4.42%)**	**7/114 (6.14%)**	**1/115 (0.87%)**	**6/113 (5.31%)**	**8/114 (7.02%)**
Respiratory, thoracic and mediastinal disorders						
Cough * 1 [3]						
# participants affected / at risk	**6/115 (5.22%)**	**3/113 (2.65%)**	**1/114 (0.88%)**	**7/115 (6.09%)**	**5/113 (4.42%)**	**2/114 (1.75%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MEDDRA 14.1 / 15.0
[3] MEDDRA 14.1 used for Week 26/MEDDRA 15.0 for Week 52
[4] MEDDRA 14.1 used for Week 26/MEDDRA 15.0 for Week 52.
[5] MEDDRA 14.1 used for Week 26/MEDDRA 15.0 for Week 52. In the Week 26 study report, 2 patients had hypoglycaemia recorded in error by the investigator, which were corrected in the Week 52 study report.

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: A copy of the manuscript must be provided to the sponsor for review at least 60 days before submission for publication or presentation. If requested in writing, such publication will be withheld for up to an additional 60 days.

Results Point of Contact:

Name/Title: Vice President, Franchise Medical Leader, Cardiovascular & Metabolism Franchise
Organization: Janssen Research & Development, LLC
phone: 1-800-526-7736

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Watts NB, Bilezikian JP, Usiskin K, Edwards R, Desai M, Law G, Meininger G. Effects of Canagliflozin on Fracture Risk in Patients With Type 2 Diabetes Mellitus. J Clin Endocrinol Metab. 2016 Jan;101(1):157-66. doi: 10.1210/jc.2015-3167. Epub 2015 Nov 18.

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Responsible Party:	Janssen Research & Development, LLC
ClinicalTrials.gov Identifier:	NCT01106690 History of Changes
Other Study ID Numbers:	CR017032 **28431754DIA3012** (Other Identifier: Janssen Research & Development, LLC)
Study First Received:	April 1, 2010
Results First Received:	April 2, 2013
Last Updated:	June 26, 2013
Health Authority:	United States: Food and Drug Administration Great Britain: Medicines and Healthcare Products Regulatory Agency

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