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Trial record **1 of 1** for: 28431754DIA3002
Previous Study | Return to List | Next Study

The CANTATA-MSU Trial (CANagliflozin Treatment And Trial Analysis - Metformin and SUlphonylurea)

This study has been completed.

Sponsor:
Janssen Research & Development, LLC

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

ClinicalTrials.gov Identifier:
NCT01106625

First received: April 1, 2010
Last updated: June 12, 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 10, 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: Canagliflozin Drug: Placebo Drug: Metformin Drug: Sulphonylruea

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 sulphonylurea therapy. The study was conducted between 07 April 2010 and 17 April 2012 and recruited patients from 85 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
A total of 469 patients were randomly allocated to the 3 treatment arms in the study. All 469 patients received at least 1 dose of study drug and were included in the modified intent-to-treat analysis set (used for the week 26 efficacy analyses). All 469 patients were included in the week 26 and week 52 safety analysis sets.

Reporting Groups

	Description
Placebo	Each patient received matching placebo once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.

Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.

Participant Flow for 2 periods

Period 1: Core Period: Baseline to Week 26

	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg
STARTED	156	157	156
COMPLETED	123	129	129
NOT COMPLETED	33	28	27
Adverse Event	6	8	8
Lost to Follow-up	5	0	4
Physician Decision	1	0	0
Protocol Violation	2	1	3
Withdrawal by Subject	6	9	7
Unable to take rescue therapy	4	1	0
Creatinine, or eGFR withdrawal criteria	0	1	1
Noncompliance with study drug	1	1	0
Not specified	8	7	4

Period 2: Extension Period: Week 26 to Week 52

	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg
STARTED	119 [1]	127 [2]	128 [3]
COMPLETED	90	109	111
NOT COMPLETED	29	18	17
Adverse Event	2	2	3
Lost to Follow-up	1	3	2
Physician Decision	2	0	1
Protocol Violation	0	1	0
Withdrawal by Subject	4	1	1
Unable to take rescue therapy	14	5	4
Creatinine or eGFR withdrawal criteria	1	1	2
Not specified	5	5	4

[1] 4 pts discontinued last day of core: physician decision (1), noncompliance (1), not specified (2).
[2] 2 pts discontinued last day of core: adverse event (1), not specified (1).
[3] 1 pt discontinued last day of core: withdrawal by subject (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	Each patient received matching placebo once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Total	Total of all reporting groups

Baseline Measures

	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg	Total
Number of Participants [units: participants]	**156**	**157**	**156**	**469**
Age [units: participants]				
<=18 years	**0**	**0**	**0**	**0**
Between 18 and 65 years	**130**	**121**	**134**	**385**
>=65 years	**26**	**36**	**22**	**84**
Age [units: years] Mean (Standard Deviation)	**56.7 (8.36)**	**57.3 (10.47)**	**56 (8.95)**	**56.7 (9.3)**
Gender [units: participants]				
Female	**80**	**81**	**69**	**230**
Male	**76**	**76**	**87**	**239**
Region of Enrollment [units: participants]				
AUSTRALIA	**3**	**6**	**4**	**13**
BELGIUM	**3**	**1**	**6**	**10**
FRANCE	**4**	**7**	**9**	**20**
GUATEMALA	**15**	**12**	**16**	**43**
HUNGARY	**11**	**14**	**11**	**36**
ISRAEL	**1**	**6**	**8**	**15**
MEXICO	**11**	**11**	**11**	**33**
RUSSIAN FEDERATION	**14**	**13**	**8**	**35**
SPAIN	**5**	**7**	**8**	**20**
UNITED KINGDOM	**8**	**6**	**5**	**19**
UNITED STATES	**81**	**74**	**70**	**225**

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	Each patient received matching placebo once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**150**	**155**	**152**
Change in HbA1c From Baseline to Week 26 [units: Percent] Least Squares Mean (Standard Error)	**-0.13 (0.075)**	**-0.85 (0.075)**	**-1.06 (0.076)**

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

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-0.71
Standard Error of the mean	(0.097)
95% Confidence Interval	-0.904 to -0.524

[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 vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-0.92
Standard Error of the mean	(0.097)
95% Confidence Interval	-1.114 to -0.732

[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	Each patient received matching placebo once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with protocol-specified doses of metformin and

	sulphonylurea.

Measured Values

	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg
Number of Participants Analyzed [units: participants]	**150**	**155**	**152**
Percentage of Patients With HbA1c <7% at Week 26 [units: Percentage of patients]	**18**	**43.2**	**56.6**

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

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	4.42
95% Confidence Interval	2.48 to 7.87

[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 vs. Canagliflozin 300 mg
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	8.80
95% Confidence Interval	4.86 to 15.95

[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	Each patient received matching placebo once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**150**	**155**	**152**
Change in Fasting Plasma Glucose (FPG) From Baseline to Week 26 [units: mg/dL] Least Squares Mean (Standard Error)	**4.11 (3.629)**	**-18.2 (3.629)**	**-30.5 (3.650)**

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

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-22.3
Standard Error of the mean	(4.627)
95% Confidence Interval	-31.53 to -13.16

[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 vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-34.6
Standard Error of the mean	(4.692)
95% Confidence Interval	-43.86 to -25.42

[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: 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	Each patient received matching placebo once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.

Measured Values

	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg
Number of Participants Analyzed [units: participants]	**150**	**156**	**154**
Percent Change in Body Weight From Baseline to Week 26 [units: Percent change] Least Squares Mean (Standard Error)	**-0.7 (0.3)**	**-2.1 (0.3)**	**-2.6 (0.3)**

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

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-1.4
Standard Error of the mean	(0.4)
95% Confidence Interval	-2.1 to -0.7

[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 vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-2.0
Standard Error of the mean	(0.4)
95% Confidence Interval	-2.7 to -1.3

[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: 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	Each patient received matching placebo once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**150**	**156**	**154**
Change in Systolic Blood Pressure (SBP) From Baseline to Week 26 [units: mmHg] Least Squares Mean (Standard Error)	**-2.65 (0.982)**	**-4.89 (0.976)**	**-4.27 (0.980)**

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

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	0.077
Least-Squares Mean Difference [4]	-2.24

Standard Error of the mean	(1.262)
95% Confidence Interval	-4.719 to 0.241

[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 vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	0.201
Least-Squares Mean Difference [4]	-1.62
Standard Error of the mean	(1.266)
95% Confidence Interval	-4.111 to 0.866

[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: 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	Each patient received matching placebo once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**134**	**145**	**142**
Percent Change in Triglycerides From Baseline to Week 26 [units: Percent change] Least Squares Mean (Standard Error)	**11.6 (4.2)**	**5.4 (4.2)**	**8.5 (4.2)**

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

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	0.256
Least-Squares Mean Difference [4]	-6.2
Standard Error of the mean	(5.4)
95% Confidence Interval	-16.9 to 4.5

[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 Triglycerides From Baseline to Week 26

Groups [1]	Placebo vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	0.571
Least-Squares Mean Difference [4]	-3.1

Standard Error of the mean	(5.5)
95% Confidence Interval	-13.8 to 7.6

[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 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	Each patient received matching placebo once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 100 mg	Each patient received 100 mg of canagliflozin once daily for for 52 weeks with protocol-specified doses of metformin and sulphonylurea.
Canagliflozin 300 mg	Each patient received 300 mg of canagliflozin once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**135**	**145**	**141**
Percent Change in High-density Lipoprotein Cholesterol (HDL-C) From Baseline to Week 26 [units: Percent change]	**3.2 (1.3)**	**5.7 (1.3)**	**6.5 (1.3)**

Least Squares Mean (Standard Error)			

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

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	0.153
Least-Squares Mean Difference [4]	2.5
Standard Error of the mean	(1.7)
95% Confidence Interval	-0.9 to 5.9

[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 High-density Lipoprotein Cholesterol (HDL-C) From Baseline to Week 26

Groups [1]	Placebo vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	0.056
Least-Squares Mean Difference [4]	3.4
Standard Error of the mean	(1.8)
95% Confidence Interval	-0.1 to 6.8

[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.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were reported for the duration of the study; each patient participated in the study for approximately 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.

Reporting Groups

	Description
Placebo: Baseline to Week 26	Each patient received matching placebo once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea. 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 protocol-specified doses of metformin and sulphonylurea. 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 protocol-specified doses of metformin and sulphonylurea. Data are presented for Baseline to Week 26.
Placebo: Baseline to Week 52	Each patient received matching placebo once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea. 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 protocol-specified doses of metformin and sulphonylurea. 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 protocol-specified doses of metformin and sulphonylurea. Data are presented for Baseline to Week 52.

Serious Adverse Events

	Placebo: Baseline to Week 26	Canagliflozin 100 mg: Baseline to Week 26	Canagliflozin 300 mg: Baseline to Week 26	Placebo: 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	**9/156 (5.77%)**	**5/157 (3.18%)**	**6/156 (3.85%)**	**13/156 (8.33%)**	**7/157 (4.46%)**	**8/156 (5.13%)**
Cardiac disorders						
Angina pectoris * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**
Atrial fibrillation * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**1/157 (0.64%)**	**0/156 (0.00%)**	**0/156 (0.00%)**	**1/157 (0.64%)**	**0/156 (0.00%)**
Coronary artery stenosis * 1 [3]						
# participants affected / at risk	**1/156 (0.64%)**	**1/157 (0.64%)**	**0/156 (0.00%)**	**1/156 (0.64%)**	**1/157 (0.64%)**	**0/156 (0.00%)**
Myocardial infarction * 1 [3]						
# participants affected / at risk	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**
Gastrointestinal disorders						
Abdominal pain * 1 [3]						
# participants affected / at risk	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**
Mechanical ileus * 1 [3]						
# participants affected / at risk	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**

General disorders						
Chest pain * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**0/156 (0.00%)**	**0/157 (0.00%)**	**1/156 (0.64%)**
Ulcer haemorrhage * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**1/156 (0.64%)**	**0/156 (0.00%)**	**0/157 (0.00%)**	**1/156 (0.64%)**
Hepatobiliary disorders						
Biliary dyskinesia * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**1/156 (0.64%)**	**0/156 (0.00%)**	**0/157 (0.00%)**	**1/156 (0.64%)**
Cholecystitis * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**1/156 (0.64%)**	**0/156 (0.00%)**	**0/157 (0.00%)**	**1/156 (0.64%)**
Cholecystitis chronic * 1 [3]						
# participants affected / at risk	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**
Infections and infestations						
Diverticulitis * 1 [3]						
# participants affected / at risk	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**
Gangrene * 1 [3]						
# participants affected / at risk	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**
Lobar pneumonia * 1 [3]						
# participants affected / at risk	**1/156 (0.64%)**	**0/157 (0.00%)**	**1/156 (0.64%)**	**1/156 (0.64%)**	**0/157 (0.00%)**	**1/156 (0.64%)**
Pneumonia * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**1/157 (0.64%)**	**0/156 (0.00%)**	**0/156 (0.00%)**	**1/157 (0.64%)**	**0/156 (0.00%)**
Scrotal gangrene * 1 [3]						
# participants affected / at risk	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**
Urinary tract infection * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**1/156 (0.64%)**	**0/156 (0.00%)**	**0/157 (0.00%)**	**1/156 (0.64%)**
Urosepsis * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**1/157 (0.64%)**	**0/156 (0.00%)**	**0/156 (0.00%)**	**1/157 (0.64%)**	**0/156 (0.00%)**
Injury, poisoning and procedural complications						
Ankle fracture * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**
Road traffic accident * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**
Wound complication * 1 [3]						

# participants affected / at risk	0/156 (0.00%)	0/157 (0.00%)	1/156 (0.64%)	0/156 (0.00%)	0/157 (0.00%)	1/156 (0.64%)
Metabolism and nutrition disorders						
Diabetic ketoacidosis * 1 [3]						
# participants affected / at risk	0/156 (0.00%)	0/157 (0.00%)	0/156 (0.00%)	0/156 (0.00%)	1/157 (0.64%)	0/156 (0.00%)
Musculoskeletal and connective tissue disorders						
Arthralgia * 1 [3]						
# participants affected / at risk	0/156 (0.00%)	1/157 (0.64%)	0/156 (0.00%)	0/156 (0.00%)	1/157 (0.64%)	0/156 (0.00%)
Musculoskeletal chest pain * 1 [3]						
# participants affected / at risk	0/156 (0.00%)	0/157 (0.00%)	1/156 (0.64%)	0/156 (0.00%)	0/157 (0.00%)	1/156 (0.64%)
Spinal osteoarthritis * 1 [3]						
# participants affected / at risk	1/156 (0.64%)	0/157 (0.00%)	0/156 (0.00%)	1/156 (0.64%)	0/157 (0.00%)	0/156 (0.00%)
Back pain * 1 [3]						
# participants affected / at risk	1/156 (0.64%)	0/157 (0.00%)	0/156 (0.00%)	1/156 (0.64%)	0/157 (0.00%)	0/156 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Colon cancer * 1 [3]						
# participants affected / at risk	1/156 (0.64%)	0/157 (0.00%)	0/156 (0.00%)	1/156 (0.64%)	0/157 (0.00%)	0/156 (0.00%)
Nervous system disorders						
Cerebrovascular accident * 1 [3]						
# participants affected / at risk	0/156 (0.00%)	1/157 (0.64%)	0/156 (0.00%)	0/156 (0.00%)	1/157 (0.64%)	0/156 (0.00%)
Renal and urinary disorders						
Nephrolithiasis * 1 [3]						
# participants affected / at risk	0/156 (0.00%)	0/157 (0.00%)	0/156 (0.00%)	0/156 (0.00%)	0/157 (0.00%)	1/156 (0.64%)
Urinary incontinence * 1 [3]						
# participants affected / at risk	0/156 (0.00%)	0/157 (0.00%)	0/156 (0.00%)	1/156 (0.64%)	0/157 (0.00%)	0/156 (0.00%)
Calculus ureteric * 1 [3]						
# participants affected / at risk	0/156 (0.00%)	1/157 (0.64%)	0/156 (0.00%)	0/156 (0.00%)	1/157 (0.64%)	0/156 (0.00%)
Hydronephrosis * 1 [3]						
# participants affected / at risk	0/156 (0.00%)	1/157 (0.64%)	0/156 (0.00%)	0/156 (0.00%)	1/157 (0.64%)	0/156 (0.00%)
Reproductive system and breast disorders						
Uterine enlargement * 1 [3]						

# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**1/156 (0.64%)**	**0/157 (0.00%)**	**0/156 (0.00%)**
Uterine prolapse * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**0/156 (0.00%)**	**1/157 (0.64%)**	**0/156 (0.00%)**
Skin and subcutaneous tissue disorders						
Skin ulcer * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**1/156 (0.64%)**	**0/156 (0.00%)**	**0/157 (0.00%)**	**1/156 (0.64%)**
Vascular disorders						
Deep vein thrombosis * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**1/156 (0.64%)**	**0/156 (0.00%)**	**0/157 (0.00%)**	**1/156 (0.64%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MEDDRA 14.0/15.0
[3] Source vocabulary is MEDDRA 14.0 for Week 26 and MEDDRA 15.0 for Week 52.

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were reported for the duration of the study; each patient participated in the study for approximately 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.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo: Baseline to Week 26	Each patient received matching placebo once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea. 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 protocol-specified doses of metformin and sulphonylurea. 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 protocol-specified doses of metformin and sulphonylurea. Data are presented for Baseline to Week 26.
Placebo: Baseline to Week 52	Each patient received matching placebo once daily for 52 weeks with protocol-specified doses of metformin and sulphonylurea. 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 protocol-specified doses of metformin and sulphonylurea. 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 protocol-specified doses of metformin and sulphonylurea. Data are presented for Baseline to Week 52.

Other Adverse Events

	Placebo: Baseline to Week 26	**Canagliflozin 100 mg: Baseline to Week 26**	**Canagliflozin 300 mg: Baseline to Week 26**	**Placebo: 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	**31/156 (19.87%)**	**42/157 (26.75%)**	**38/156 (24.36%)**	**52/156 (33.33%)**	**63/157 (40.13%)**	**54/156 (34.62%)**
Gastrointestinal disorders						
Diarrhoea * 1 [3]						
# participants affected / at risk	**5/156 (3.21%)**	**5/157 (3.18%)**	**10/156 (6.41%)**	**5/156 (3.21%)**	**8/157 (5.10%)**	**11/156 (7.05%)**
Infections and infestations						
Influenza * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**8/156 (5.13%)**	**4/157 (2.55%)**	**8/156 (5.13%)**
Sinusitis * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**3/156 (1.92%)**	**8/157 (5.10%)**	**3/156 (1.92%)**
Nasopharyngitis * 1 [3]						
# participants affected / at risk	**4/156 (2.56%)**	**6/157 (3.82%)**	**8/156 (5.13%)**	**10/156 (6.41%)**	**9/157 (5.73%)**	**9/156 (5.77%)**
Upper respiratory tract infection * 1 [3]						
# participants affected / at risk	**10/156 (6.41%)**	**17/157 (10.83%)**	**6/156 (3.85%)**	**13/156 (8.33%)**	**21/157 (13.38%)**	**9/156 (5.77%)**
Urinary tract infection * 1 [3]						
# participants affected / at risk	**8/156 (5.13%)**	**9/157 (5.73%)**	**7/156 (4.49%)**	**12/156 (7.69%)**	**12/157 (7.64%)**	**9/156 (5.77%)**
Vulvovaginal mycotic infection * 1 [3]						
# participants affected / at risk	**2/156 (1.28%)**	**8/157 (5.10%)**	**8/156 (5.13%)**	**2/156 (1.28%)**	**9/157 (5.73%)**	**8/156 (5.13%)**
Metabolism and nutrition disorders						
Hypoglycaemia * 1 [3]						
# participants affected / at risk	**6/156 (3.85%)**	**11/157 (7.01%)**	**9/156 (5.77%)**	**9/156 (5.77%)**	**13/157 (8.28%)**	**11/156 (7.05%)**
Musculoskeletal and connective tissue disorders						
Arthralgia * 1 [3]						
# participants						

affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**8/156 (5.13%)**	**8/157 (5.10%)**	**8/156 (5.13%)**
Nervous system disorders						
Headache * 1 [3]						
# participants affected / at risk	**0/156 (0.00%)**	**0/157 (0.00%)**	**0/156 (0.00%)**	**5/156 (3.21%)**	**11/157 (7.01%)**	**2/156 (1.28%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MEDDRA 14.0/15.0
[3] Source vocabulary is MEDDRA 14.0 for Week 26 and MEDDRA 15.0 for Week 52.

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:

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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:	NCT01106625 History of Changes
Other Study ID Numbers:	CR017005 **28431754DIA3002** (Other Identifier: Janssen Research & Development, LLC)
Study First Received:	April 1, 2010
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Last Updated:	June 12, 2013
Health Authority:	United States: Food and Drug Administration Hungary: National Institute for Quality and Organizational Development in Healthcare and Medicines

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