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Trial record **1 of 1** for: 28431754DIA3005
Previous Study | Return to List | Next Study

The CANTATA-M (CANagliflozin Treatment and Trial Analysis - Monotherapy) Trial

This study has been completed.

Sponsor:
Janssen Research & Development, LLC

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

ClinicalTrials.gov Identifier:
NCT01081834

First received: March 4, 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 15, 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: Sitagliptin

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 inadequately controlled with diet and exercise. The study was conducted between 08 February 2010 and 18 August 2011 and recruited patients from 90 study centers in 17 countries worldwide.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
678 patients were enrolled into the study; 587 patients in the main study and 91 patients in the high glycemic substudy. 584 patients in the main study and all 91 patients in the high glycemic substudy received at least one dose of study drug and were included in the modified intent-to-treat (mITT) analyses sets and the safety analyses sets.

Reporting Groups

	Description
Main Study: Placebo/Sitagliptin	In the Main Study, each patient received matching placebo once daily for 26 weeks and were then switched from placebo to 100 mg of sitagliptin once daily until Week 52.
Main Study: Canagliflozin 100 mg	In the Main Study, each patient received 100 mg of canagliflozin once daily for 52 weeks.
Main Study: Canagliflozin 300 mg	In the Main Study, each patient received 300 mg of canagliflozin once daily for 52 weeks.
High Glycemic Substudy: Canagliflozin 100 mg	In the High Glycemic Substudy, each patient received 100 mg of canagliflozin once daily for 26 weeks only. No patients received treatment during the period Week 26 to Week 52.
High Glycemic Substudy: Canagliflozin 300 mg	In the High Glycemic Substudy, each patient received 300 mg of canagliflozin once daily for 26 weeks only. No patients received treatment during the period Week 26 to Week 52.

Participant Flow for 2 periods

Period 1: Core Period: Baseline to Week 26

	Main Study: Placebo/Sitagliptin	Main Study: Canagliflozin 100 mg	Main Study: Canagliflozin 300 mg	High Glycemic Substudy: Canagliflozin 100 mg	High Glycemic Substudy: Canagliflozin 300 mg
STARTED	192	195	197	47	44
COMPLETED	160	172	175	40	40
NOT COMPLETED	32	23	22	7	4
Pregnancy	1	0	0	0	0
Adverse Event	2	5	3	1	1
Death	1	0	0	0	0
Lost to Follow-up	2	2	5	0	0
Protocol Violation	0	4	0	0	2
Withdrawal by Subject	15	3	9	3	1
Noncompliance with study drug	3	4	2	2	0
Unable to take rescue therapy	1	0	0	0	0
Not specified	4	4	3	1	0
Lack of efficacy on rescue therapy	3	1	0	0	0

Period 2: Extension Period: Week 26 to Week 52

	Main Study: Placebo/Sitagliptin	Main Study: Canagliflozin 100 mg	Main Study: Canagliflozin 300 mg	High Glycemic Substudy: Canagliflozin 100 mg	High Glycemic Substudy: Canagliflozin 300 mg
STARTED	155 [1]	170 [2]	170 [3]	0 [4]	0 [4]
COMPLETED	135	152	165	0	0
NOT COMPLETED	20	18	5	0	0
Adverse Event	1	0	0	0	0
Death	1	0	0	0	0
Lost to Follow-up	4	4	0	0	0
Protocol Violation	0	1	0	0	0
Withdrawal by Subject	1	2	0	0	0
Unable to take rescue therapy	1	0	1	0	0
Creatinine or eGFR withdrawal criteria	1	4	0	0	0
Not specified	4	5	4	0	0
Lack of efficacy on rescue therapy	7	1	0	0	0
Physician Decision	0	1	0	0	0

[1] 5 pts discontinued on last day of core: lack of efficacy on rescue (2), not specified (NS) (3).
[2] 2 pts discontinued on last day of core: adverse event (AE) (1), protocol violation (PV) (1).
[3] 5 pts discontinued last day of core: AE (1), lost f/u (1), PV (1), NS (1), physician decision (1).
[4] The treatment duration for the High Glycemic Substudy was 26 weeks only.

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
Main Study: Placebo/Sitagliptin	In the Main Study, each patient received matching placebo once daily for 26 weeks and were then switched from placebo to 100 mg of sitagliptin once daily until Week 52.
Main Study: Canagliflozin 100 mg	In the Main Study, each patient received 100 mg of canagliflozin once daily for 52 weeks.
Main Study: Canagliflozin 300 mg	In the Main Study, each patient received 300 mg of canagliflozin once daily for 52 weeks.
High Glycemic Substudy: Canagliflozin 100 mg	In the High Glycemic Substudy, each patient received 100 mg of canagliflozin once daily for 26 weeks.
High Glycemic Substudy: Canagliflozin 300 mg	In the High Glycemic Substudy, each patient received 300 mg of canagliflozin once daily for 26 weeks.
Total	Total of all reporting groups

Baseline Measures

	Main Study: Placebo/Sitagliptin	Main Study: Canagliflozin 100 mg	Main Study: Canagliflozin 300 mg	High Glycemic Substudy: Canagliflozin 100 mg	High Glycemic Substudy: Canagliflozin 300 mg	Total
Number of Participants [units: participants]	**192**	**195**	**197**	**47**	**44**	**675**
Age [units: participants]						
<=18 years	**0**	**0**	**0**	**0**	**0**	**0**
Between 18 and 65 years	**150**	**156**	**160**	**42**	**41**	**549**
>=65 years	**42**	**39**	**37**	**5**	**3**	**126**
Age [units: years] Mean (Standard Deviation)	**55.7 (10.88)**	**55.1 (10.83)**	**55.3 (10.17)**	**49.7 (11.12)**	**48.8 (10.92)**	**54.5 (10.85)**
Gender [units: participants]						
Female	**104**	**114**	**108**	**24**	**25**	**375**
Male	**88**	**81**	**89**	**23**	**19**	**300**
Region of Enrollment [units: participants]						
AUSTRIA	**1**	**2**	**1**	**0**	**0**	**4**
COLOMBIA	**8**	**8**	**6**	**3**	**0**	**25**
ESTONIA	**6**	**5**	**5**	**0**	**0**	**16**
GUATEMALA	**10**	**10**	**13**	**9**	**10**	**52**
ICELAND	**4**	**4**	**8**	**2**	**2**	**20**
INDIA	**8**	**11**	**8**	**5**	**2**	**34**
LITHUANIA	**17**	**10**	**12**	**2**	**1**	**42**
MALAYSIA	**6**	**2**	**7**	**1**	**0**	**16**
MEXICO	**19**	**23**	**19**	**2**	**2**	**65**
PHILIPPINES	**3**	**4**	**6**	**4**	**4**	**21**
POLAND	**1**	**4**	**3**	**0**	**0**	**8**
ROMANIA	**20**	**16**	**18**	**2**	**4**	**60**

SOUTH AFRICA	**9**	**6**	**11**	**1**	**2**	**29**
SOUTH KOREA	**10**	**8**	**7**	**1**	**1**	**27**
SPAIN	**3**	**2**	**3**	**0**	**0**	**8**
SWEDEN	**11**	**18**	**18**	**0**	**1**	**48**
UNITED STATES	**56**	**62**	**52**	**15**	**15**	**200**

Outcome Measures

Hide All Outcome Measures

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

Measure Type	Primary
Measure Title	Change in HbA1c From Baseline to Week 26 (Main Study)
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	In the Main Study, each patient recieved matching placebo once daily for 26 weeks and were then switched from placebo to 100 mg of sitagliptin once daily until Week 52.
Canagliflozin 100 mg	In the Main Study, each patient received 100 mg of canagliflozin once daily for 52 weeks.
Canagliflozin 300 mg	In the Main Study, each pateint received 300 mg of canagliflozin once daily for 52 weeks.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**189**	**191**	**194**
Change in HbA1c From Baseline to Week 26 (Main Study) [units: Percent] Least Squares Mean (Standard Error)	**0.14 (0.065)**	**-0.77 (0.065)**	**-1.03 (0.064)**

Statistical Analysis 1 for Change in HbA1c From Baseline to Week 26 (Main Study)

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-0.91
Standard Error of the mean	(0.091)
95% Confidence Interval	-1.088 to -0.729

[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 (Main Study)

Groups [1]	Placebo vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-1.16
Standard Error of the mean	(0.091)
95% Confidence Interval	-1.342 to -0.985

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

Measure Type	Primary
Measure Title	Change in HbA1c From Baseline to Week 26 (High Glycemic Substudy)
Measure Description	The table below shows the least-squares (LS) mean change in HbA1c from Baseline to Week 26 for each treatment group in patients randomized to the High Glycemic Substudy.
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	In the High Glycemic Substudy, no patients received placebo.
Canagliflozin 100 mg	In the High Glycemic Substudy, each patient received 100 mg of canagliflozin once daily for 26 weeks.
Canagliflozin 300 mg	In the High Glycemic Substudy, each pateint received 300 mg of canagliflozin once daily for 26 weeks.

Measured Values

	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg
Number of Participants Analyzed [units: participants]	**0**	**46**	**43**
Change in HbA1c From Baseline to Week 26 (High Glycemic Substudy) [units: Percent] Least Squares Mean (Standard Error)		**-2.13 (0.220)**	**-2.56 (0.227)**

No statistical analysis provided for Change in HbA1c From Baseline to Week 26 (High Glycemic Substudy)

3. Secondary: Percentage of Patients With HbA1c <7% at Week 26 (Main Study) [Time Frame: Week 26]

Measure Type	Secondary
Measure Title	Percentage of Patients With HbA1c <7% at Week 26 (Main Study)
Measure Description	The table below shows the percentage of patients with HbA1c <7% at Week 26. 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	In the Main Study, each patient recieved matching placebo once daily for 26 weeks and were then switched from placebo to 100 mg of sitagliptin once daily until Week 52.
Canagliflozin 100 mg	In the Main Study, each patient received 100 mg of canagliflozin once daily for 52 weeks.
Canagliflozin 300 mg	In the Main Study, each pateint received 300 mg of canagliflozin once daily for 52 weeks.

Measured Values

	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg
Number of Participants Analyzed [units: participants]	**189**	**191**	**194**
Percentage of Patients With HbA1c <7% at Week 26 (Main Study) [units: Percentage of patients]	**20.6**	**44.5**	**62.4**

Statistical Analysis 1 for Percentage of Patients With HbA1c <7% at Week 26 (Main Study)

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	5.34
95% Confidence Interval	3.10 to 9.23

[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 (Main Study)

Groups [1]	Placebo vs. Canagliflozin 300 mg
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	14.61
95% Confidence Interval	8.14 to 26.25

[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 Fasting Plasma Glucose (FPG) From Baseline to Week 26 (Main Study) [Time Frame: Day 1 (Baseline) and Week 26]

Measure Type	Secondary
Measure Title	Change in Fasting Plasma Glucose (FPG) From Baseline to Week 26 (Main Study)
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	In the Main Study, each patient received matching placebo once daily for 26 weeks and were then switched from placebo to 100 mg of sitagliptin once daily until Week 52.
Canagliflozin 100 mg	In the Main Study, each patient received 100 mg of canagliflozin once daily for 52 weeks.
Canagliflozin 300 mg	In the Main Study, each pateint received 300 mg of canagliflozin once daily for 52 weeks.

Measured Values

	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg
Number of Participants Analyzed			

[units: participants]	**184**	**188**	**192**
Change in Fasting Plasma Glucose (FPG) From Baseline to Week 26 (Main Study) [units: mg/dL] Least Squares Mean (Standard Error)	**8.33 (2.448)**	**-27.2 (2.412)**	**-35.0 (2.391)**

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

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-35.5
Standard Error of the mean	(3.420)
95% Confidence Interval	-42.22 to -28.78

[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 (Main Study)

Groups [1]	Placebo vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-43.4
Standard Error of the mean	(3.402)
95% Confidence Interval	-50.06 to -36.69

[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 2-hour Post-prandial Glucose From Baseline to Week 26 (Main Study) [Time Frame: Day 1 (Baseline) and Week 26]

Measure Type	Secondary
Measure Title	Change in 2-hour Post-prandial Glucose From Baseline to Week 26 (Main Study)

Measure Description	The table below shows the least-squares (LS) mean change in 2-hour post-prandial glucose 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	In the Main Study, each patient received matching placebo once daily for 26 weeks and were then switched from placebo to 100 mg of sitagliptin once daily until Week 52.
Canagliflozin 100 mg	In the Main Study, each patient received 100 mg of canagliflozin once daily for 52 weeks.
Canagliflozin 300 mg	In the Main Study, each pateint received 300 mg of canagliflozin once daily for 52 weeks.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**126**	**154**	**157**
Change in 2-hour Post-prandial Glucose From Baseline to Week 26 (Main Study) [units: mg/dL] Least Squares Mean (Standard Error)	**5.19 (4.204)**	**-42.9 (3.763)**	**-58.8 (3.741)**

Statistical Analysis 1 for Change in 2-hour Post-prandial Glucose From Baseline to Week 26 (Main Study)

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-49.1
Standard Error of the mean	(5.629)
95% Confidence Interval	-59.12 to -36.99

[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 2-hour Post-prandial Glucose From Baseline to Week 26 (Main Study)

Groups [1]	Placebo vs. Canagliflozin 300 mg
Method [2]	ANCOVA

P Value [3]	<0.001
Least-Squares Mean Difference [4]	-64.0
Standard Error of the mean	(5.616)
95% Confidence Interval	-75.02 to -52.94

[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 Body Weight From Baseline to Week 26 (Main Study) [Time Frame: Day 1 (Baseline) and Week 26]

Measure Type	Secondary
Measure Title	Percent Change in Body Weight From Baseline to Week 26 (Main Study)
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	In the Main Study, each patient received matching placebo once daily for 26 weeks and were then switched from placebo to 100 mg of sitagliptin once daily until Week 52.
Canagliflozin 100 mg	In the Main Study, each patient received 100 mg of canagliflozin once daily for 52 weeks.
Canagliflozin 300 mg	In the Main Study, each pateint received 300 mg of canagliflozin once daily for 52 weeks.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**190**	**192**	**194**
Percent Change in Body Weight From Baseline to Week 26 (Main Study) [units: Percent change] Least Squares Mean (Standard Error)	**-0.6 (0.2)**	**-2.8 (0.2)**	**-3.9 (0.2)**

Statistical Analysis 1 for Percent Change in Body Weight From Baseline to Week 26 (Main Study)

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	ANCOVA

P Value [3]	<0.001
Least-Squares Mean Difference [4]	-2.2
Standard Error of the mean	(0.3)
95% Confidence Interval	-2.9 to -1.6

[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.

Statistical Analysis 2 for Percent Change in Body Weight From Baseline to Week 26 (Main Study)

Groups [1]	Placebo vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-3.3
Standard Error of the mean	(0.3)
95% Confidence Interval	-4.0 to -2.6

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

Measure Type	Secondary
Measure Title	Change in Systolic Blood Pressure (SBP) From Baseline to Week 26 (Main Study)
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	In the Main Study, each patient received matching placebo once daily for 26 weeks and were then switched from placebo to 100 mg of sitagliptin once daily until Week 52.
Canagliflozin 100 mg	In the Main Study, each patient received 100 mg of canagliflozin once daily for 52 weeks.
Canagliflozin 300 mg	In the Main Study, each pateint received 300 mg of canagliflozin once daily for 52 weeks.

Measured Values

	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg
Number of Participants Analyzed [units: participants]	**190**	**192**	**195**
Change in Systolic Blood Pressure (SBP) From Baseline to Week 26 (Main Study) [units: mmHg] Least Squares Mean (Standard Error)	**0.38 (0.780)**	**-3.34 (0.775)**	**-5.04 (0.769)**

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

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-3.71
Standard Error of the mean	(1.093)
95% Confidence Interval	-5.860 to -1.568

[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 (Main Study)

Groups [1]	Placebo vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	-5.42
Standard Error of the mean	(1.088)
95% Confidence Interval	-7.556 to -3.280

[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 Triglycerides From Baseline to Week 26 (Main Study) [Time Frame: Day 1 (Baseline) and Week 26]

Measure Type	Secondary
Measure Title	Percent Change in Triglycerides From Baseline to Week 26 (Main Study)
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	In the Main study, each patient received matching placebo once daily for 26 weeks and were then switched from placebo to 100 mg of sitagliptin once daily until Week 52.
Canagliflozin 100 mg	In the Main Study, each patient received 100 mg of canagliflozin once daily for 52 weeks.
Canagliflozin 300 mg	In the Main Study, each pateint received 300 mg of canagliflozin once daily for 52 weeks.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**171**	**183**	**183**
Percent Change in Triglycerides From Baseline to Week 26 (Main Study) [units: Percent change] Least Squares Mean (Standard Error)	**7.8 (3.5)**	**2.5 (3.3)**	**-2.4 (3.3)**

Statistical Analysis 1 for Percent Change in Triglycerides From Baseline to Week 26 (Main Study)

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	0.267
Least-Squares Mean Difference [4]	-5.3
Standard Error of the mean	(4.8)
95% Confidence Interval	-14.8 to 4.1

[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 (Main Study)

Groups [1]	Placebo vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	0.034
Least-Squares Mean Difference [4]	-10.2
Standard Error of the mean	(4.8)
95% Confidence Interval	-19.6 to -0.8

[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.

9. Secondary: Percent Change in High-density Lipoprotein Cholesterol (HDL-C) From Baseline to Week 26 (Main Study) [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 (Main Study)
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	In the Main Study, each patient received matching placebo once daily for 26 weeks and were then switched from placebo to 100 mg of sitagliptin once daily until Week 52.
Canagliflozin 100 mg	In the Main Study, each patient received 100 mg of canagliflozin once daily for 52 weeks.
Canagliflozin 300 mg	In the Main Study, each pateint received 300 mg of canagliflozin once daily for 52 weeks.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**

Number of Participants Analyzed [units: participants]	**170**	**182**	**183**
Percent Change in High-density Lipoprotein Cholesterol (HDL-C) From Baseline to Week 26 (Main Study) [units: Percent change] Least Squares Mean (Standard Error)	**4.4 (1.4)**	**11.2 (1.4)**	**10.5 (1.4)**

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

Groups [1]	Placebo vs. Canagliflozin 100 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Least-Squares Mean Difference [4]	6.7
Standard Error of the mean	(1.9)
95% Confidence Interval	2.9 to 10.6

[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.

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

Groups [1]	Placebo vs. Canagliflozin 300 mg
Method [2]	ANCOVA
P Value [3]	0.002
Least-Squares Mean Difference [4]	6.0
Standard Error of the mean	(1.9)
95% Confidence Interval	2.2 to 9.9

[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.

10. Secondary: Percentage of Patients With HbA1c <7% at Week 26 (High Glycemic Substudy) [Time Frame: Week 26]

Measure Type	Secondary
Measure Title	Percentage of Patients With HbA1c <7% at Week 26 (High Glycemic Substudy)

Measure Description	The table below shows the percentage of patients with HbA1c <7% at Week 26 for each treatment group in patients randomized to the High Glycemic Substudy.
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	In the High Glycemic Substudy, no patients received placebo.
Canagliflozin 100 mg	In the High Glycemic Substudy, each patient received 100 mg of canagliflozin once daily for 26 weeks.
Canagliflozin 300 mg	In the High Glycemic Substudy, each pateint received 300 mg of canagliflozin once daily for 26 weeks.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**0**	**46**	**43**
Percentage of Patients With HbA1c <7% at Week 26 (High Glycemic Substudy) [units: Percentage of patients]		**17.4**	**11.6**

No statistical analysis provided for Percentage of Patients With HbA1c <7% at Week 26 (High Glycemic Substudy)

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

Measure Type	Secondary
Measure Title	Change in Fasting Plasma Glucose (FPG) From Baseline to Week 26 (High Glycemic Substudy)
Measure Description	The table below shows the least-squares (LS) mean change in FPG from Baseline to Week 26 for each treatment group in patients randomized to the High Glycemic Substudy.
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	In the High Glycemic Substudy, no patients received placebo.
Canagliflozin 100 mg	In the High Glycemic Substudy, each patient received 100 mg of canagliflozin once daily for 26 weeks.
Canagliflozin 300 mg	In the High Glycemic Substudy, each pateint received 300 mg of canagliflozin once daily for 26 weeks.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed			

[units: participants]	**0**	**45**	**43**
Change in Fasting Plasma Glucose (FPG) From Baseline to Week 26 (High Glycemic Substudy) [units: mg/dL] Least Squares Mean (Standard Error)		**-81.7 (6.459)**	**-86.3 (6.553)**

No statistical analysis provided for Change in Fasting Plasma Glucose (FPG) From Baseline to Week 26 (High Glycemic Substudy)

12. Secondary: Change in 2-hour Post-prandial Glucose From Baseline to Week 26 (High Glycemic Substudy) [Time Frame: Day 1 (Baseline) and Week 26]

Measure Type	Secondary
Measure Title	Change in 2-hour Post-prandial Glucose From Baseline to Week 26 (High Glycemic Substudy)
Measure Description	The table below shows the least-squares (LS) mean change in 2-hour post-prandial glucose from Baseline to Week 26 for each treatment group in patients randomized to the High Glycemic Substudy.
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	In the High Glycemic Substudy, no patients received placebo.
Canagliflozin 100 mg	In the High Glycemic Substudy, each patient received 100 mg of canagliflozin once daily for 26 weeks.
Canagliflozin 300 mg	In the High Glycemic Substudy, each pateint received 300 mg of canagliflozin once daily for 26 weeks.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**0**	**30**	**34**
Change in 2-hour Post-prandial Glucose From Baseline to Week 26 (High Glycemic Substudy) [units: mg/dL] Least Squares Mean (Standard Error)		**-118 (10.179)**	**-126 (9.437)**

No statistical analysis provided for Change in 2-hour Post-prandial Glucose From Baseline to Week 26 (High Glycemic Substudy)

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

Measure Type	Secondary
Measure Title	Percent Change in Body Weight From Baseline to Week 26 (High Glycemic Substudy)
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 in patients randomized to the High Glycemic Substudy.
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	In the High Glycemic Substudy, no patients received placebo.
Canagliflozin 100 mg	In the High Glycemic Substudy, each patient received 100 mg of canagliflozin once daily for 26 weeks.
Canagliflozin 300 mg	In the High Glycemic Substudy, each pateint received 300 mg of canagliflozin once daily for 26 weeks.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**0**	**46**	**43**
Percent Change in Body Weight From Baseline to Week 26 (High Glycemic Substudy) [units: Percent change] Least Squares Mean (Standard Error)		**-3.0 (0.6)**	**-3.8 (0.6)**

No statistical analysis provided for Percent Change in Body Weight From Baseline to Week 26 (High Glycemic Substudy)

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

Measure Type	Secondary
Measure Title	Change in Systolic Blood Pressure (SBP) From Baseline to Week 26 (High Glycemic Substudy)
Measure Description	The table below shows the least-squares (LS) mean change in SBP from Baseline to Week 26 for each treatment group in patients randomized to the High Glycemic Substudy.
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	In the High Glycemic Substudy, no patients received placebo.
Canagliflozin 100 mg	In the High Glycemic Substudy, each patient received 100 mg of canagliflozin once daily for 26 weeks.
Canagliflozin 300 mg	In the High Glycemic Substudy, each pateint received 300 mg of canagliflozin once daily for 26 weeks.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**0**	**46**	**43**
Change in Systolic Blood Pressure (SBP) From Baseline to Week 26 (High Glycemic Substudy) [units: mmHg]		**-4.47 (1.754)**	**-4.97 (1.800)**

Least Squares Mean (Standard Error)			

No statistical analysis provided for Change in Systolic Blood Pressure (SBP) From Baseline to Week 26 (High Glycemic Substudy)

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

Measure Type	Secondary
Measure Title	Percent Change in Triglycerides From Baseline to Week 26 (High Glycemic Substudy)
Measure Description	The table below shows the least-squares mean percent change in triglycerides from Baseline to Week 26 for each treatment group in patients randomized to the High Glycemic Substudy.
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	In the High Glycemic Substudy, no patients received placebo.
Canagliflozin 100 mg	In the High Glycemic Substudy, each patient received 100 mg of canagliflozin once daily for 26 weeks.
Canagliflozin 300 mg	In the High Glycemic Substudy, each pateint received 300 mg of canagliflozin once daily for 26 weeks.

Measured Values

	Placebo	**Canagliflozin 100 mg**	**Canagliflozin 300 mg**
Number of Participants Analyzed [units: participants]	**0**	**44**	**43**
Percent Change in Triglycerides From Baseline to Week 26 (High Glycemic Substudy) [units: Percent change] Least Squares Mean (Standard Error)		**-0.6 (7.4)**	**-12.7 (7.5)**

No statistical analysis provided for Percent Change in Triglycerides From Baseline to Week 26 (High Glycemic Substudy)

16. Secondary: Percent Change in High-density Lipoprotein Cholesterol (HDL-C) From Baseline to Week 26 (High Glycemic Substudy) [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 (High Glycemic Substudy)
Measure Description	The table below shows the least-squares mean percent change in HDL-C from Baseline to Week 26 for each treatment group in patients randomized to the High Glycemic Substudy.
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	In the High Glycemic Substudy, no patients received placebo.
Canagliflozin 100 mg	In the High Glycemic Substudy, each patient received 100 mg of canagliflozin once daily for 26 weeks.
Canagliflozin 300 mg	In the High Glycemic substudy, each pateint received 300 mg of canagliflozin once daily for 26 weeks.

Measured Values

	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg
Number of Participants Analyzed [units: participants]	**0**	**44**	**43**
Percent Change in High-density Lipoprotein Cholesterol (HDL-C) From Baseline to Week 26 (High Glycemic Substudy) [units: Percent change] Least Squares Mean (Standard Error)		**2.4 (2.9)**	**10.8 (2.9)**

No statistical analysis provided for Percent Change in High-density Lipoprotein Cholesterol (HDL-C) From Baseline to Week 26 (High Glycemic Substudy)

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
Main Study (Baseline to Week 26): Placebo	Each patient received matching placebo once daily for 26 weeks and were then switched from placebo to 100 mg of sitagliptin once daily until Week 52. Data are presented for Baseline to Week 26.
Main Study (Baseline to Week 26): Cana 100 mg	Each patient received 100 mg of canagliflozin (Cana) once daily for 52 weeks. Data are presented for Baseline to Week 26.
Main Study (Baseline to Week 26): Cana 300 mg	Each patient received 300 mg of canagliflozin (Cana) once daily for 52 weeks. Data are presented for Baseline to Week 26.
Main Study (Baseline to Week 52): Placebo/Sitagliptin	Each patient received matching placebo once daily for 26 weeks and were then switched from placebo to 100 mg of sitagliptin once daily until Week 52. Data are presented for Baseline to Week 52.
Main Study (Baseline to Week 52): Cana 100 mg	Each patient received 100 mg of canagliflozin (Cana) once daily for 52 weeks. Data are presented for Baseline to Week 52.
Main Study (Baseline to Week 52): Cana 300 mg	Each patient received 300 mg of canagliflozin (Cana) once daily for 52 weeks. Data are presented for Baseline to Week 52.
High Glycemic Substudy (Baseline to Week 26): Cana 100 mg	Each patient received 100 mg of canagliflozin (Cana) once daily for 26 weeks. Data are only available for Baseline to Week 26.
High Glycemic Substudy (Baseline to Week 26): Cana 300 mg	Each patient received 300 mg of canagliflozin (Cana) once daily for 26 weeks. Data are only available for Baseline to Week 26.

Serious Adverse Events

	Main Study (Baseline to Week 26): Placebo	Main Study (Baseline to Week 26): Cana 100 mg	Main Study (Baseline to Week 26): Cana 300 mg	Main Study (Baseline to Week 52): Placebo/Sitagliptin	Main Study (Baseline to Week 52): Cana 100 mg	Main Study (Baseline to Week 52): Cana 300 mg	High Glycemic Substudy (Baseline to Week 26): Cana 100	High Glycemic Substudy (Baseline to Week 26): Cana 300

							mg	mg
Total, serious adverse events								
# participants affected / at risk	**4/192 (2.08%)**	**8/195 (4.10%)**	**2/197 (1.02%)**	**11/192 (5.73%)**	**11/195 (5.64%)**	**5/197 (2.54%)**	**0/47 (0.00%)**	**1/44 (2.27%)**
Cardiac disorders								
Coronary artery disease * 1								
# participants affected / at risk	**0/192 (0.00%)**	**1/195 (0.51%)**	**0/197 (0.00%)**	**0/192 (0.00%)**	**1/195 (0.51%)**	**0/197 (0.00%)**	**0/47 (0.00%)**	**0/44 (0.00%)**
Myocardial infarction * 1								
# participants affected / at risk	**0/192 (0.00%)**	**0/195 (0.00%)**	**0/197 (0.00%)**	**0/192 (0.00%)**	**1/195 (0.51%)**	**0/197 (0.00%)**	**0/47 (0.00%)**	**0/44 (0.00%)**
Pericardial effusion * 1								
# participants affected / at risk	**0/192 (0.00%)**	**0/195 (0.00%)**	**0/197 (0.00%)**	**1/192 (0.52%)**	**0/195 (0.00%)**	**0/197 (0.00%)**	**0/47 (0.00%)**	**0/44 (0.00%)**
Gastrointestinal disorders								
Abdominal pain * 1								
# participants affected / at risk	**0/192 (0.00%)**	**1/195 (0.51%)**	**0/197 (0.00%)**	**0/192 (0.00%)**	**1/195 (0.51%)**	**0/197 (0.00%)**	**0/47 (0.00%)**	**0/44 (0.00%)**
Intestinal obstruction * 1								
# participants affected / at risk	**1/192 (0.52%)**	**0/195 (0.00%)**	**0/197 (0.00%)**	**1/192 (0.52%)**	**0/195 (0.00%)**	**0/197 (0.00%)**	**0/47 (0.00%)**	**0/44 (0.00%)**
Nausea * 1								
# participants affected / at risk	**0/192 (0.00%)**	**1/195 (0.51%)**	**0/197 (0.00%)**	**0/192 (0.00%)**	**1/195 (0.51%)**	**0/197 (0.00%)**	**0/47 (0.00%)**	**0/44 (0.00%)**
Vomiting * 1								
# participants affected / at risk	**0/192 (0.00%)**	**1/195 (0.51%)**	**0/197 (0.00%)**	**0/192 (0.00%)**	**1/195 (0.51%)**	**0/197 (0.00%)**	**0/47 (0.00%)**	**0/44 (0.00%)**
Abdominal hernia * 1								
# participants affected / at risk	**0/192 (0.00%)**	**0/195 (0.00%)**	**0/197 (0.00%)**	**1/192 (0.52%)**	**0/195 (0.00%)**	**0/197 (0.00%)**	**0/47 (0.00%)**	**0/44 (0.00%)**
Inguinal hernia * 1								
# participants affected / at risk	**0/192 (0.00%)**	**0/195 (0.00%)**	**0/197 (0.00%)**	**0/192 (0.00%)**	**0/195 (0.00%)**	**1/197 (0.51%)**	**0/47 (0.00%)**	**0/44 (0.00%)**
Umbilical hernia * 1								

# participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	0/197 (0.00%)	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Hepatobiliary disorders								
Ischaemic hepatitis * 1								
# participants affected / at risk	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Liver disorder * 1								
# participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	0/197 (0.00%)	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Infections and infestations								
Abscess limb * 1								
# participants affected / at risk	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Bacterial prostatitis * 1								
# participants affected / at risk	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Cellulitis * 1								
# participants affected / at risk	1/192 (0.52%)	1/195 (0.51%)	0/197 (0.00%)	1/192 (0.52%)	1/195 (0.51%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Diverticulitis * 1								
# participants affected / at risk	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Pneumonia * 1								
# participants affected / at risk	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Septic shock * 1								
# participants affected / at risk	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Appendicitis * 1								
# participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	0/197 (0.00%)	0/192 (0.00%)	0/195 (0.00%)	1/197 (0.51%)	0/47 (0.00%)	0/44 (0.00%)
Gastrointestinal infection * 1								
# participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	0/197 (0.00%)	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)

Pulmonary tuberculosis [*1]								
# participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	0/197 (0.00%)	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Viral pericarditis [*1]								
# participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	0/197 (0.00%)	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Injury, poisoning and procedural complications								
Ankle fracture [*1]								
# participants affected / at risk	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Brain herniation [*1]								
# participants affected / at risk	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Wound [*1]								
# participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	1/197 (0.51%)	0/192 (0.00%)	0/195 (0.00%)	1/197 (0.51%)	0/47 (0.00%)	0/44 (0.00%)
Skeletal injury [*1]								
# participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	0/197 (0.00%)	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Spinal column injury [*1]								
# participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	0/197 (0.00%)	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Investigations								
Hepatic enzyme increased [*1]								
# participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	0/197 (0.00%)	0/192 (0.00%)	0/195 (0.00%)	0/197 (0.00%)	0/47 (0.00%)	1/44 (2.27%)
Musculoskeletal and connective tissue disorders								
Osteoarthritis [*1]								
# participants affected / at risk	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and								

polyps)								
Prostate cancer [*1]								
# participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	0/197 (0.00%)	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Nervous system disorders								
Haemorrhage intracranial [*1]								
# participants affected / at risk	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Peripheral sensory neuropathy [*1]								
# participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	0/197 (0.00%)	1/192 (0.52%)	0/195 (0.00%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Renal and urinary disorders								
Renal colic [*1]								
# participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	1/197 (0.51%)	0/192 (0.00%)	0/195 (0.00%)	1/197 (0.51%)	0/47 (0.00%)	0/44 (0.00%)
Renal failure acute [*1]								
# participants affected / at risk	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Respiratory, thoracic and mediastinal disorders								
Pulmonary embolism [*1]								
# participants affected / at risk	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Asthma [*1]								
# participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	0/197 (0.00%)	0/192 (0.00%)	0/195 (0.00%)	1/197 (0.51%)	0/47 (0.00%)	0/44 (0.00%)
Skin and subcutaneous tissue disorders								
Urticaria [*1]								
# participants affected / at risk	0/192 (0.00%)	2/195 (1.03%)	0/197 (0.00%)	0/192 (0.00%)	2/195 (1.03%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)
Vascular disorders								
Deep vein thrombosis [*1]								
#								

participants affected / at risk	0/192 (0.00%)	0/195 (0.00%)	1/197 (0.51%)	0/192 (0.00%)	0/195 (0.00%)	1/197 (0.51%)	0/47 (0.00%)	0/44 (0.00%)
Thrombosis * 1								
# participants affected / at risk	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/192 (0.00%)	1/195 (0.51%)	0/197 (0.00%)	0/47 (0.00%)	0/44 (0.00%)

* Events were collected by non-systematic assessment

1 Term from vocabulary, MEDDRA 14.0

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
Main Study (Baseline to Week 26): Placebo	Each patient received matching placebo once daily for 26 weeks and were then switched from placebo to 100 mg of sitagliptin once daily until Week 52. Data are presented for Baseline to Week 26.
Main Study (Baseline to Week 26): Cana 100 mg	Each patient received 100 mg of canagliflozin (Cana) once daily for 52 weeks. Data are presented for Baseline to Week 26.
Main Study (Baseline to Week 26): Cana 300 mg	Each patient received 300 mg of canagliflozin (Cana) once daily for 52 weeks. Data are presented for Baseline to Week 26.
Main Study (Baseline to Week 52): Placebo/Sitagliptin	Each patient received matching placebo once daily for 26 weeks and were then switched from placebo to 100 mg of sitagliptin once daily until Week 52. Data are presented for Baseline to Week 52.
Main Study (Baseline to Week 52): Cana 100 mg	Each patient received 100 mg of canagliflozin (Cana) once daily for 52 weeks. Data are presented for Baseline to Week 52.
Main Study (Baseline to Week 52): Cana 300 mg	Each patient received 300 mg of canagliflozin (Cana) once daily for 52 weeks. Data are presented for Baseline to Week 52.
High Glycemic Substudy (Baseline to Week 26): Cana 100 mg	Each patient received 100 mg of canagliflozin (Cana) once daily for 26 weeks. Data are only available for Baseline to Week 26.
High Glycemic Substudy (Baseline to Week 26): Cana 300 mg	Each patient received 300 mg of canagliflozin (Cana) once daily for 26 weeks. Data are only available for Baseline to Week 26.

Other Adverse Events

	Main Study (Baseline to Week 26): Placebo	Main Study (Baseline to Week 26): Cana 100 mg	Main Study (Baseline to Week 26): Cana 300 mg	Main Study (Baseline to Week 52): Placebo/Sitagliptin	Main Study (Baseline to Week 52): Cana 100 mg	Main Study (Baseline to Week 52): Cana 300 mg	High Glycemic Substudy (Baseline to Week 26): Cana 100 mg	High Glycem Substu (Baseline Week 2 Cana 300
Total, other (not including serious) adverse events								
# participants affected / at risk	38/192 (19.79%)	39/195 (20.00%)	51/197 (25.89%)	63/192 (32.81%)	54/195 (27.69%)	69/197 (35.03%)	6/47 (12.77%)	6/44 (13.6
Infections and infestations								

Nasopharyngitis [*1]								
# participants affected / at risk	**10/192 (5.21%)**	**10/195 (5.13%)**	**16/197 (8.12%)**	**15/192 (7.81%)**	**14/195 (7.18%)**	**20/197 (10.15%)**	**2/47 (4.26%)**	**3/44 (6.8**
Upper respiratory tract infection [*1]								
# participants affected / at risk	**11/192 (5.73%)**	**7/195 (3.59%)**	**9/197 (4.57%)**	**18/192 (9.38%)**	**8/195 (4.10%)**	**14/197 (7.11%)**	**0/47 (0.00%)**	**0/44 (0.0**
Urinary tract infection [*1]								
# participants affected / at risk	**8/192 (4.17%)**	**14/195 (7.18%)**	**9/197 (4.57%)**	**11/192 (5.73%)**	**16/195 (8.21%)**	**12/197 (6.09%)**	**3/47 (6.38%)**	**2/44 (4.5**
Influenza [*1]								
# participants affected / at risk	**0/192 (0.00%)**	**0/195 (0.00%)**	**0/197 (0.00%)**	**7/192 (3.65%)**	**12/195 (6.15%)**	**8/197 (4.06%)**	**0/47 (0.00%)**	**0/44 (0.0**
Musculoskeletal and connective tissue disorders								
Back pain [*1]								
# participants affected / at risk	**6/192 (3.13%)**	**5/195 (2.56%)**	**12/197 (6.09%)**	**9/192 (4.69%)**	**5/195 (2.56%)**	**15/197 (7.61%)**	**0/47 (0.00%)**	**0/44 (0.0**
Pain in extremity [*1]								
# participants affected / at risk	**0/192 (0.00%)**	**0/195 (0.00%)**	**0/197 (0.00%)**	**0/192 (0.00%)**	**0/195 (0.00%)**	**0/197 (0.00%)**	**1/47 (2.13%)**	**3/44 (6.8**
Arthralgia [*1]								
# participants affected / at risk	**0/192 (0.00%)**	**0/195 (0.00%)**	**0/197 (0.00%)**	**13/192 (6.77%)**	**10/195 (5.13%)**	**3/197 (1.52%)**	**0/47 (0.00%)**	**0/44 (0.0**
Nervous system disorders								
Headache [*1]								
# participants affected / at risk	**7/192 (3.65%)**	**14/195 (7.18%)**	**12/197 (6.09%)**	**12/192 (6.25%)**	**19/195 (9.74%)**	**17/197 (8.63%)**	**0/47 (0.00%)**	**0/44 (0.0**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MEDDRA 14.0

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.

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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: NCT01081834 History of Changes
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