A Study to Assess the Safety, Tolerability and Glucose-Lowering Efficacy of MK-0893 in Participants With Type 2 Diabetes Mellitus (MK-0893-005)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT02004886

First received: December 3, 2013
Last updated: March 31, 2015
Last verified: March 2015
History of Changes

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Purpose

This study will assess the safety, tolerability and glucose-lowering efficacy of MK-0893 in participants with type 2 diabetes mellitus. The primary hypothesis is that MK-0893 will reduce 24-hour weighted mean glucose (WMG) significantly more than placebo.

Condition	Intervention	Phase
Type 2 Diabetes Mellitus	Drug: MK-0893 Drug: Metformin Drug: Placebo	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Multi-Center, Double-Blind, Double-Dummy, Placebo-Controlled, Parallel Panel Study to Assess the Safety, Tolerability and Glucose-Lowering Efficacy of MK-0893 in Patients With Type 2 Diabetes Mellitus

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Metformin Metformin hydrochloride

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Change From Baseline in 24-hour Weighted Mean Glucose (WMG) at Week 4 [Time Frame: Baseline and Week 4]
  [Designated as safety issue: No]

  Blood samples were collected 30 minutes prior to all meals, and 15, 30, 60, 90, 120, 180 minutes post-meal, then and at midnight, 3 AM, and the next morning at 6:30 AM and 7:30 AM. A 24-hour weighted mean glucose (WMG) was determined by averaging multiple plasma glucose measurements over a 24-hour period.

- Number of Participants Experiencing an Adverse Event (AE) [Time Frame: Up to 42 days] [Designated as safety issue: Yes]

  An adverse event (AE) is any unfavorable and unintended change in the structure, function or chemistry of the body temporally associated with study drug administration whether or not considered related to the use of the product.

- Number of Participants Discontinuing Study Treatment Due to an AE [Time Frame: Up to 28 days] [Designated as safety issue: Yes]

  An AE is any unfavorable and unintended change in the structure, function or chemistry of the body temporally associated with study drug administration whether or not considered related to the use of the product.

Secondary Outcome Measures:

- Change From Baseline in Fasting Plasma Glucose (FPG) [Time Frame: Baseline and Week 4] [Designated as safety issue: No]

  Plasma Glucose levels were measured at Baseline and at Week 4. The change from baseline was defined as the Week 4 value minus the Baseline value.

- Change From Baseline in Fructosamine at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]

  Fructosamine levels in the blood were measured at Baseline and at Week 4. The change from baseline was defined as the Week 4 value minus the Baseline value.

- Change From Baseline in Fasting C-peptide at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]

  Fasting C-peptide levels in the blood were measured at Baseline and at Week 4. The change from baseline was defined as the Week 4 value minus the Baseline value.

- Change From Baseline in Fasting Insulin at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]

  Fasting insulin levels in the blood were measured at Baseline and at Week 4. The change from baseline was defined as the Week 4 value minus the Baseline value.

- Change From Baseline in 2-hour Post-prandial Glucose Excursion at Week 4 [Time Frame: Baseline and Week 4]
  [Designated as safety issue: No]

  2-hour post-prandial glucose excursion is the change in glucose concentration in the blood 2 hours after a meal. Change from baseline in 2-hour post-prandial glucose excursion at Week 4 is defined as Week 4 minus baseline.

- Change From Baseline in 3-hour Area Under the Plasma Concentration Versus Time Curve (AUC) for Glucose at Week 4
  [Time Frame: Baseline and Week 4] [Designated as safety issue: No]

  Blood samples collected for glucose 30 minutes prior to the breakfast meal and 15, 30, 60, 90, 120, 180 minutes post-meal. AUC is a measure of the amount of drug in the blood over time. 3-hour AUC for Glucose was measured at Baseline and at Week 4. The change from baseline was defined as the Week 4 value minus the Baseline value.

- Change From Baseline in 3-hour AUC for C-peptide at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]

  Blood samples were collected for C-peptide 30 minutes prior to the breakfast meal and 15, 30, 60, 90, 120, 180 minutes post-meal. AUC is a measure of the amount of drug in the blood over time. 3-hour AUC for C-peptide was measured at Baseline and at Week 4. The change from baseline was defined as the Week 4 value minus the Baseline value.

- Change From Baseline in 3-hour Insulin Total AUC at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]

  Blood samples were collected for insulin 30 minutes prior to the breakfast meal and 15, 30, 60, 90, 120, 180 minutes post-meal. AUC is a measure of the amount of drug in the blood over time. 3-hour Insulin Total AUC was measured at Baseline and at Week 4. The change from baseline was defined as the Week 4 value minus the Baseline value.

Enrollment: 74
Study Start Date: August 2006
Study Completion Date: February 2007
Primary Completion Date: February 2007 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: MK-0893 (40 mg) MK-0893 40-mg q.d. (quaque die, once daily) group will receive MK-0893 40-mg tablets (after loading dose with 160 mg) and matching placebo to metformin and matching placebo to MK-0893.	Drug: MK-0893 10 mg and 100 mg tablets Drug: Placebo Placebo tablets matching MK-0893 Drug: Placebo Placebo tablets matching metformin
Experimental: MK-0893 (120 mg) MK-0893 at 120 mg q.d. group will receive MK-0893 120 mg q.d. tablets (after loading dose of 500 mg on Day 1) and matching placebo tablets to metformin and matching placebo to MK-0893	Drug: MK-0893 10 mg and 100 mg tablets Drug: Placebo Placebo tablets matching MK-0893 Drug: Placebo Placebo tablets matching metformin
Active Comparator: Metformin (2000 mg) Metformin taken orally, 500 mg tablets, Day 1 to Day 6: 500 mg b.i.d. (bis in die, twice daily), Day 7 to Day 13: 1000 mg in the morning and 500 mg in the evening, and Day 14 to Day 28: 1000 mg. b.i.d. and matching placebo to MK-0893.	Drug: Metformin 500 mg metformin tablets Other Names: • Glucophage • Glucophage XR • Glumetza • Fortamet • Riomet Drug: Placebo Placebo tablets matching MK-0893
Placebo Comparator: Placebo Placebo tablets matching the MK-0893 and placebo tablets matching metformin.	Drug: Placebo Placebo tablets matching MK-0893 Drug: Placebo Placebo tablets matching metformin

Eligibility

Ages Eligible for Study: 21 Years to 65 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Type 2 diabetes
- Not currently on antihyperglycemic agent (AHA) or AHA monotherapy (not to include treatment with insulin or thiazolidinediones [i.e., peroxisome proliferator activated receptor-gamma, PPARγ agents])
- male or a female of non-childbearing potential. Women must be postmenopausal or premenopausal and documented surgically sterilized
- A body mass index (BMI) that is > 20 and ≤ 40 kg/m2

Exclusion Criteria:

- History of type 1 diabetes or assessed by the investigator as possibly having type 1 diabetes
- History of ketoacidosis; clinically unstable or rapidly progressive diabetic retinopathy, nephropathy, neuropathy
- Treatment for diabetes within 3 months of study participation with combination anti-hyperglycemic therapy, insulin or thiazolidinediones (e.g., rosiglitazone or pioglitazone)
- oral corticosteroid medications within 2 weeks prior to study participation, or requires digoxin, warfarin, warfarin-like anticoagulants, theophylline, anti-dysrhythmic or anti-seizure medications, immunosuppressants, or anti-neoplastic agents, or herbal remedies
- History of acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV)
- History of gastrointestinal problems or disorders or extensive bowel or gastric surgery
- History of significant or unstable cardiovascular disease
- History of neoplastic disease
- History of hepatic disease
- History of seizures, epilepsy or other neurologic disease
- History of myelodysplastic or pre-leukemic disorders or other severe hematological disorder

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT02004886 History of Changes
Other Study ID Numbers: 0893-005
Study First Received: December 3, 2013
Results First Received: January 31, 2014
Last Updated: March 31, 2015
Health Authority: United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:

Diabetes Mellitus	Therapeutic Uses
Diabetes Mellitus, Type 2	Pharmacologic Actions
Glucose Metabolism Disorders	Molecular Mechanisms of Pharmacological Action
Metabolic Diseases	Physiological Effects of Drugs
Endocrine System Diseases	Metformin

Additional relevant MeSH terms:

Diabetes Mellitus	Metformin
Diabetes Mellitus, Type 2	Molecular Mechanisms of Pharmacological Action
Endocrine System Diseases	Hypoglycemic Agents

Glucose Metabolism Disorders
Metabolic Diseases

Pharmacologic Actions
Physiological Effects of Drugs

ClinicalTrials.gov processed this record on April 14, 2016

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A Study to Assess the Safety, Tolerability and Glucose-Lowering Efficacy of MK-0893 in Participants With Type 2 Diabetes Mellitus (MK-0893-005)

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First received: December 3, 2013
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History of Changes

Results First Received: January 31, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Type 2 Diabetes Mellitus
Interventions:	Drug: MK-0893 Drug: Metformin Drug: Placebo

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
A total of 13 clinical sites were used in this study in the following countries: Austria, Germany, New Zealand, Russia, and the United States of America.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
MK-0893 (40 mg)	MK-0893 40-mg, once daily
MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo

Participant Flow: Overall Study

	MK-0893 (40 mg)	MK-0893 (120 mg)	Metformin (2000 mg)	Placebo
STARTED	**19**	**18**	**18**	**19**
COMPLETED	**18**	**17**	**18**	**19**
NOT COMPLETED	**1**	**1**	**0**	**0**
Adverse Event	**0**	**1**	**0**	**0**
Unable to attend future visits	**1**	**0**	**0**	**0**

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
MK-0893 (40 mg)	MK-0893 40-mg, once daily
MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo
Total	Total of all reporting groups

Baseline Measures

	MK-0893 (40 mg)	MK-0893 (120 mg)	Metformin (2000 mg)	Placebo	Total
Number of Participants [units: participants]	**19**	**18**	**18**	**19**	**74**
Age [units: Years] Mean (Standard Deviation)	**54.5 (7.1)**	**55.8 (6.8)**	**54.7 (8.7)**	**51.5 (9.3)**	**54.1 (8.0)**

Gender [units: Participants]					
Female	**8**	**9**	**12**	**7**	**36**
Male	**11**	**9**	**6**	**12**	**38**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in 24-hour Weighted Mean Glucose (WMG) at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Primary
Measure Title	Change From Baseline in 24-hour Weighted Mean Glucose (WMG) at Week 4
Measure Description	Blood samples were collected 30 minutes prior to all meals, and 15, 30, 60, 90, 120, 180 minutes post-meal, then and at midnight, 3 AM, and the next morning at 6:30 AM and 7:30 AM. A 24-hour weighted mean glucose (WMG) was determined by averaging multiple plasma glucose measurements over a 24-hour period.
Time Frame	Baseline and Week 4
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.
Completers Population was used for all efficacy analyses, and required that a participant took at least one dose of study therapy, had a baseline measurement, and had a post-randomization measurement in the treatment period at Week 4.

Reporting Groups

	Description
MK-0893 (40 mg)	MK-0893 40-mg, once daily
MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo

Measured Values

	MK-0893 (40 mg)	**MK-0893 (120 mg)**	**Metformin (2000 mg)**	**Placebo**
Number of Participants Analyzed [units: participants]	**18**	**17**	**18**	**19**
Change From Baseline in 24-hour Weighted Mean Glucose (WMG) at Week 4 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-37.9 (-47.1 to -28.8)**	**-65.7 (-74.8 to -56.5)**	**-38.1 (-47.0 to -29.2)**	**-12.0 (-20.7 to -3.4)**

Statistical Analysis 1 for Change From Baseline in 24-hour Weighted Mean Glucose (WMG) at Week 4

Groups [1]	MK-0893 (40 mg) vs. Placebo

Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-25.9
95% Confidence Interval	-38.4 to -13.3

[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:
	Terms for treatment, prior AHA therapy status, and baseline 24-hour WMG value as a covariate.
[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 From Baseline in 24-hour Weighted Mean Glucose (WMG) at Week 4

Groups [1]	MK-0893 (120 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	<0.001
Median Difference (Final Values) [4]	-53.6
95% Confidence Interval	-66.1 to -41.1

[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:
	Terms for treatment, prior AHA therapy status, and baseline 24-hour WMG value as a covariate.
[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 3 for Change From Baseline in 24-hour Weighted Mean Glucose (WMG) at Week 4

Groups [1]	Metformin (2000 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-26.0
95% Confidence Interval	-38.4 to -13.6

[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:
	Terms for treatment, prior AHA therapy status, and baseline 24-hour WMG value as a covariate.
[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: Number of Participants Experiencing an Adverse Event (AE) [Time Frame: Up to 42 days]

Measure Type	Primary
Measure Title	Number of Participants Experiencing an Adverse Event (AE)
Measure Description	An adverse event (AE) is any unfavorable and unintended change in the structure, function or chemistry of the body temporally associated with study drug administration whether or not considered related to the use of the product.
Time Frame	Up to 42 days
Safety Issue	Yes

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.
Safety Population included all randomized participants who initiated study therapy.

Reporting Groups

	Description
MK-0893 (40 mg)	MK-0893 40-mg, once daily
MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo

Measured Values

	MK-0893 (40 mg)	**MK-0893 (120 mg)**	**Metformin (2000 mg)**	**Placebo**
Number of Participants Analyzed [units: participants]	**19**	**18**	**18**	**19**
Number of Participants Experiencing an Adverse Event (AE) [units: Number of Participants]	**3**	**7**	**9**	**8**

No statistical analysis provided for Number of Participants Experiencing an Adverse Event (AE)

3. Primary: Number of Participants Discontinuing Study Treatment Due to an AE [Time Frame: Up to 28 days]

Measure Type	Primary
Measure Title	Number of Participants Discontinuing Study Treatment Due to an AE
Measure Description	An AE is any unfavorable and unintended change in the structure, function or chemistry of the body temporally associated with study drug administration whether or not considered related to the use of the product.
Time Frame	Up to 28 days
Safety Issue	Yes

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.
Safety Population included all randomized participants who initiated study therapy.

Reporting Groups

	Description
MK-0893 (40 mg)	MK-0893 40-mg, once daily
MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo

Measured Values

	MK-0893 (40 mg)	**MK-0893 (120 mg)**	**Metformin (2000 mg)**	**Placebo**
Number of Participants Analyzed [units: participants]	**19**	**18**	**18**	**19**
Number of Participants Discontinuing Study Treatment Due to an AE [units: Number of Participants]	**0**	**1**	**0**	**0**

No statistical analysis provided for Number of Participants Discontinuing Study Treatment Due to an AE

4. Secondary: Change From Baseline in Fasting Plasma Glucose (FPG) [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG)
Measure Description	Plasma Glucose levels were measured at Baseline and at Week 4. The change from baseline was defined as the Week 4 value minus the Baseline value.
Time Frame	Baseline and Week 4
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.
Completers Population was used for all efficacy analyses, and required that a participant took at least one dose of study therapy, had a baseline measurement, and had a post-randomization measurement in the treatment period at Week 4.

Reporting Groups

	Description
MK-0893 (40 mg)	MK-0893 40-mg, once daily
MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo

Measured Values

	MK-0893 (40 mg)	**MK-0893 (120 mg)**	**Metformin (2000 mg)**	**Placebo**
Number of Participants Analyzed [units: participants]	**18**	**17**	**18**	**19**
Change From Baseline in Fasting Plasma Glucose (FPG) [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-32.5 (-45.1 to -19.8)**	**-57.7 (-70.3 to -45.1)**	**-22.8 (-35.0 to -10.5)**	**-14.1 (-26.1 to -2.2)**

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

Groups [1]	MK-0893 (40 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.04
Mean Difference (Final Values) [4]	-18.3
95% Confidence Interval	-35.7 to -0.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Relevant baseline efficacy measurements were the covariates.
[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 From Baseline in Fasting Plasma Glucose (FPG)

Groups [1]	MK-0893 (120 mg) vs. Placebo

Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-43.6
95% Confidence Interval	-60.9 to -26.3

[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:
	Relevant baseline efficacy measurements were the covariates.
[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 3 for Change From Baseline in Fasting Plasma Glucose (FPG)

Groups [1]	Metformin (2000 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.320
Mean Difference (Final Values) [4]	-8.6
95% Confidence Interval	-25.7 to 8.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Relevant baseline efficacy measurements were the covariates.
[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 From Baseline in Fructosamine at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Change From Baseline in Fructosamine at Week 4
Measure Description	Fructosamine levels in the blood were measured at Baseline and at Week 4. The change from baseline was defined as the Week 4 value minus the Baseline value.
Time Frame	Baseline and Week 4

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.
Completers Population was used for all efficacy analyses, and required that a participant took at least one dose of study therapy, had a baseline measurement, and had a post-randomization measurement in the treatment period at Week 4.

Reporting Groups

	Description
MK-0893 (40 mg)	MK-0893 40-mg, once daily
MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo

Measured Values

	MK-0893 (40 mg)	**MK-0893 (120 mg)**	**Metformin (2000 mg)**	**Placebo**
Number of Participants Analyzed [units: participants]	**18**	**17**	**18**	**19**
Change From Baseline in Fructosamine at Week 4 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**NA** [1]	**NA** [1]	**NA** [1]	**NA** [1]

[1] Data for this outcome measure were not collected or analyzed.

No statistical analysis provided for Change From Baseline in Fructosamine at Week 4

6. Secondary: Change From Baseline in Fasting C-peptide at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Change From Baseline in Fasting C-peptide at Week 4
Measure Description	Fasting C-peptide levels in the blood were measured at Baseline and at Week 4. The change from baseline was defined as the Week 4 value minus the Baseline value.
Time Frame	Baseline and Week 4
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.
Completers Population was used for all efficacy analyses, and required that a participant took at least one dose of study therapy, had a baseline measurement, and had a post-randomization measurement in the treatment period at Week 4.

Reporting Groups

	Description
MK-0893 (40 mg)	MK-0893 40-mg, once daily
MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo

Measured Values

	MK-0893 (40 mg)	MK-0893 (120 mg)	Metformin (2000 mg)	Placebo
Number of Participants Analyzed [units: participants]	**18**	**17**	**18**	**19**
Change From Baseline in Fasting C-peptide at Week 4 [units: ng/mL] Least Squares Mean (95% Confidence Interval)	**0.1 (-0.5 to 0.7)**	**-0.3 (-0.8 to 0.3)**	**-0.1 (-0.6 to 0.5)**	**-0.0 (-0.6 to 0.5)**

Statistical Analysis 1 for Change From Baseline in Fasting C-peptide at Week 4

Groups [1]	MK-0893 (40 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.751
Mean Difference (Final Values) [4]	0.1
95% Confidence Interval	-0.7 to 0.9

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

Statistical Analysis 2 for Change From Baseline in Fasting C-peptide at Week 4

Groups [1]	MK-0893 (120 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.581
Mean Difference (Final Values) [4]	-0.2
95% Confidence Interval	-1.0 to 0.6

[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 3 for Change From Baseline in Fasting C-peptide at Week 4

Groups [1]	Metformin (2000 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.918
Mean Difference (Final Values) [4]	-0.0
95% Confidence Interval	-0.8 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.

7. Secondary: Change From Baseline in Fasting Insulin at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Change From Baseline in Fasting Insulin at Week 4
Measure Description	Fasting insulin levels in the blood were measured at Baseline and at Week 4. The change from baseline was defined as the Week 4 value minus the Baseline value.
Time Frame	Baseline and Week 4
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.
Completers Population was used for all efficacy analyses, and required that a participant took at least one dose of study therapy, had a baseline

measurement, and had a post-randomization measurement in the treatment period at Week 4.

Reporting Groups

	Description
MK-0893 (40 mg)	MK-0893 40-mg, once daily
MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo

Measured Values

	MK-0893 (40 mg)	MK-0893 (120 mg)	Metformin (2000 mg)	Placebo
Number of Participants Analyzed [units: participants]	**18**	**17**	**18**	**19**
Change From Baseline in Fasting Insulin at Week 4 [units: µIU/mL] Least Squares Mean (95% Confidence Interval)	**NA** [1]	**NA** [1]	**NA** [1]	**NA** [1]

[1] Data for this outcome measure were not collected or analyzed.

No statistical analysis provided for Change From Baseline in Fasting Insulin at Week 4

8. Secondary: Change From Baseline in 2-hour Post-prandial Glucose Excursion at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Change From Baseline in 2-hour Post-prandial Glucose Excursion at Week 4
Measure Description	2-hour post-prandial glucose excursion is the change in glucose concentration in the blood 2 hours after a meal. Change from baseline in 2-hour post-prandial glucose excursion at Week 4 is defined as Week 4 minus baseline.
Time Frame	Baseline and Week 4
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.
Completers Population was used for all efficacy analyses, and required that a participant took at least one dose of study therapy, had a baseline measurement, and had a post-randomization measurement in the treatment period at Week 4.

Reporting Groups

	Description
MK-0893 (40 mg)	MK-0893 40-mg, once daily
MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo

Measured Values

	MK-0893 (40 mg)	MK-0893 (120 mg)	Metformin (2000 mg)	Placebo
Number of Participants Analyzed [units: participants]	**18**	**17**	**18**	**19**
Change From Baseline in 2-hour Post-prandial Glucose Excursion at Week 4 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-10.5 (-20.2 to -0.8)**	**-15.3 (-25.1 to -5.5)**	**-29.0 (-38.4 to -19.5)**	**-2.8 (-12.2 to 6.5)**

Statistical Analysis 1 for Change From Baseline in 2-hour Post-prandial Glucose Excursion at Week 4

Groups [1]	MK-0893 (40 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.253
Mean Difference (Final Values) [4]	-7.7
95% Confidence Interval	-21.1 to 5.6

[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 Change From Baseline in 2-hour Post-prandial Glucose Excursion at Week 4

Groups [1]	MK-0893 (120 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.070
Mean Difference (Final Values) [4]	-12.5
95% Confidence Interval	-26.0 to 1.0

[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 3 for Change From Baseline in 2-hour Post-prandial Glucose Excursion at Week 4

Groups [1]	Metformin (2000 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-26.1
95% Confidence Interval	-39.5 to -12.8

[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: Change From Baseline in 3-hour Area Under the Plasma Concentration Versus Time Curve (AUC) for Glucose at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Change From Baseline in 3-hour Area Under the Plasma Concentration Versus Time Curve (AUC) for Glucose at Week 4
Measure Description	Blood samples collected for glucose 30 minutes prior to the breakfast meal and 15, 30, 60, 90, 120, 180 minutes post-meal. AUC is a measure of the amount of drug in the blood over time. 3-hour AUC for Glucose was measured at Baseline and at Week 4. The change from baseline was defined as the Week 4 value minus the Baseline value.
Time Frame	Baseline and Week 4
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.
Completers Population was used for all efficacy analyses, and required that a participant took at least one dose of study therapy, had a baseline measurement, and had a post-randomization measurement in the treatment period at Week 4.

Reporting Groups

	Description
MK-0893 (40 mg)	MK-0893 40-mg, once daily

MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo

Measured Values

	MK-0893 (40 mg)	MK-0893 (120 mg)	Metformin (2000 mg)	Placebo
Number of Participants Analyzed [units: participants]	**18**	**17**	**18**	**19**
Change From Baseline in 3-hour Area Under the Plasma Concentration Versus Time Curve (AUC) for Glucose at Week 4 [units: mg hr/dL] Least Squares Mean (95% Confidence Interval)	**-128.8 (-169.5 to -88.2)**	**-230.2 (-270.5 to -189.9)**	**-136.7 (-175.7 to -97.6)**	**-39.0 (-77.3 to -0.8)**

Statistical Analysis 1 for Change From Baseline in 3-hour Area Under the Plasma Concentration Versus Time Curve (AUC) for Glucose at Week 4

Groups [1]	MK-0893 (40 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.002
Mean Difference (Final Values) [4]	-89.9
95% Confidence Interval	-145.6 to -34.0

[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:
	Relevant baseline efficacy measurements were the covariates.
[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 From Baseline in 3-hour Area Under the Plasma Concentration Versus Time Curve (AUC) for Glucose at Week 4

Groups [1]	MK-0893 (120 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-191.1
95% Confidence Interval	-246.4 to -135.9

[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:
	Relevant baseline efficacy measurements were the covariates.
[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 3 for Change From Baseline in 3-hour Area Under the Plasma Concentration Versus Time Curve (AUC) for Glucose at Week 4

Groups [1]	Metformin (2000 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.001
Mean Difference (Final Values) [4]	-97.7
95% Confidence Interval	-152.4 to -42.9

[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:
	Relevant baseline efficacy measurements were the covariates.
[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: Change From Baseline in 3-hour AUC for C-peptide at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Change From Baseline in 3-hour AUC for C-peptide at Week 4
Measure Description	Blood samples were collected for C-peptide 30 minutes prior to the breakfast meal and 15, 30, 60, 90, 120, 180 minutes post-meal. AUC is a measure of the amount of drug in the blood over time. 3-hour AUC for C-peptide was measured at Baseline and at Week 4. The change from baseline was defined as the Week 4 value minus the Baseline value.
Time Frame	Baseline and Week 4
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.
Completers Population was used for all efficacy analyses, and required that a participant took at least one dose of study therapy, had a baseline measurement, and had a post-randomization measurement in the treatment period at Week 4.

Reporting Groups

	Description
MK-0893 (40 mg)	MK-0893 40-mg, once daily
MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo

Measured Values

	MK-0893 (40 mg)	MK-0893 (120 mg)	Metformin (2000 mg)	Placebo
Number of Participants Analyzed [units: participants]	**18**	**16**	**18**	**18**
Change From Baseline in 3-hour AUC for C-peptide at Week 4 [units: ng hr/mL] Least Squares Mean (95% Confidence Interval)	**1.0 (-0.9 to 2.9)**	**-0.5 (-2.5 to 1.4)**	**-0.2 (-2.1 to 1.6)**	**-0.1 (-1.9 to 1.8)**

Statistical Analysis 1 for Change From Baseline in 3-hour AUC for C-peptide at Week 4

Groups [1]	MK-0893 (40 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.408
Mean Difference (Final Values) [4]	1.1
95% Confidence Interval	-1.5 to 3.7

[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 Change From Baseline in 3-hour AUC for C-peptide at Week 4

Groups [1]	MK-0893 (120 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.741
Mean Difference (Final Values) [4]	-0.4

95% Confidence Interval	-3.1 to 2.2

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

Statistical Analysis 3 for Change From Baseline in 3-hour AUC for C-peptide at Week 4

Groups [1]	Metformin (2000 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.906
Mean Difference (Final Values) [4]	-0.2
95% Confidence Interval	-2.8 to 2.5

[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.

11. Secondary: Change From Baseline in 3-hour Insulin Total AUC at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Change From Baseline in 3-hour Insulin Total AUC at Week 4
Measure Description	Blood samples were collected for insulin 30 minutes prior to the breakfast meal and 15, 30, 60, 90, 120, 180 minutes post-meal. AUC is a measure of the amount of drug in the blood over time. 3-hour Insulin Total AUC was measured at Baseline and at Week 4. The change from baseline was defined as the Week 4 value minus the Baseline value.
Time Frame	Baseline and Week 4
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.
Completers Population was used for all efficacy analyses, and required that a participant took at least one dose of study therapy, had a baseline measurement, and had a post-randomization measurement in the treatment period at Week 4.

Reporting Groups

	Description
MK-0893 (40 mg)	MK-0893 40-mg, once daily
MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo

Measured Values

	MK-0893 (40 mg)	**MK-0893 (120 mg)**	**Metformin (2000 mg)**	**Placebo**
Number of Participants Analyzed [units: participants]	**17**	**15**	**18**	**19**
Change From Baseline in 3-hour Insulin Total AUC at Week 4 [units: µIU hr/mL] Least Squares Mean (95% Confidence Interval)	**5.3 (-15.5 to 26.1)**	**6.1 (-15.3 to 27.6)**	**1.2 (-18.4 to 20.7)**	**7.8 (-11.2 to 26.8)**

Statistical Analysis 1 for Change From Baseline in 3-hour Insulin Total AUC at Week 4

Groups [1]	MK-0893 (40 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.857
Mean Difference (Final Values) [4]	-2.5
95% Confidence Interval	-30.4 to 25.3

[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.

Statistical Analysis 2 for Change From Baseline in 3-hour Insulin Total AUC at Week 4

Groups [1]	MK-0893 (120 mg) vs. Placebo
Method [2]	ANCOVA

P Value [3]	0.906
Mean Difference (Final Values) [4]	-1.7
95% Confidence Interval	-30.3 to 26.9

[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 3 for Change From Baseline in 3-hour Insulin Total AUC at Week 4

Groups [1]	Metformin (2000 mg) vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.630
Mean Difference (Final Values) [4]	-6.6
95% Confidence Interval	-34.0 to 20.8

[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	Up to 42 days
Additional Description	Safety Population included all randomized participants who initiated study therapy. Adverse events were collected up to 14 days after last dose of study drug.

Reporting Groups

	Description
MK-0893 (40 mg)	MK-0893 40-mg, once daily
MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo

Serious Adverse Events

	MK-0893 (40 mg)	MK-0893 (120 mg)	Metformin (2000 mg)	Placebo
Total, serious adverse events				
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**0/18 (0.00%)**	**0/19 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 42 days
Additional Description	Safety Population included all randomized participants who initiated study therapy. Adverse events were collected up to 14 days after last dose of study drug.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
MK-0893 (40 mg)	MK-0893 40-mg, once daily
MK-0893 (120 mg)	MK-0893, 120 mg, once daily
Metformin (2000 mg)	Metformin, oral, 1000 mg, twice daily
Placebo	Placebo

Other Adverse Events

	MK-0893 (40 mg)	MK-0893 (120 mg)	Metformin (2000 mg)	Placebo
Total, other (not including serious) adverse events				
# participants affected / at risk	**3/19 (15.79%)**	**7/18 (38.89%)**	**9/18 (50.00%)**	**8/19 (42.11%)**
Ear and labyrinth disorders				
External Ear Pain † 1				
# participants affected / at risk	**1/19 (5.26%)**	**0/18 (0.00%)**	**0/18 (0.00%)**	**0/19 (0.00%)**

Eye disorders				
Eye Irritation † 1				
# participants affected / at risk	**0/19 (0.00%)**	**1/18 (5.56%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
Vision Blurred † 1				
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**0/18 (0.00%)**	**1/19 (5.26%)**
Gastrointestinal disorders				
Abdominal Pain † 1				
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**1/18 (5.56%)**	**0/19 (0.00%)**
Abdominal Pain Lower † 1				
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**0/18 (0.00%)**	**1/19 (5.26%)**
Diarrhoea † 1				
# participants affected / at risk	**0/19 (0.00%)**	**2/18 (11.11%)**	**3/18 (16.67%)**	**0/19 (0.00%)**
Dry Mouth † 1				
# participants affected / at risk	**0/19 (0.00%)**	**1/18 (5.56%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
Flatulence † 1				
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**1/18 (5.56%)**	**2/19 (10.53%)**
Gingival Pain † 1				
# participants affected / at risk	**1/19 (5.26%)**	**0/18 (0.00%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
Nausea † 1				
# participants affected / at risk	**1/19 (5.26%)**	**0/18 (0.00%)**	**1/18 (5.56%)**	**1/19 (5.26%)**
Stomach Discomfort † 1				
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**0/18 (0.00%)**	**2/19 (10.53%)**
Vomiting † 1				
# participants affected / at risk	**1/19 (5.26%)**	**0/18 (0.00%)**	**1/18 (5.56%)**	**0/19 (0.00%)**
General disorders				
Asthenia † 1				
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**1/18 (5.56%)**	**0/19 (0.00%)**
Chest Discomfort † 1				
# participants affected / at risk	**0/19 (0.00%)**	**1/18 (5.56%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
Fatigue † 1				
# participants affected / at risk	**0/19 (0.00%)**	**1/18 (5.56%)**	**0/18 (0.00%)**	**1/19 (5.26%)**
Feeling Abnormal † 1				
# participants affected / at risk	**0/19 (0.00%)**	**1/18 (5.56%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
Nodule † 1				
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**1/18 (5.56%)**	**0/19 (0.00%)**
Pyrexia † 1				
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**1/18 (5.56%)**	**0/19 (0.00%)**
Thirst † 1				
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**0/18 (0.00%)**	**1/19 (5.26%)**
Infections and infestations				
Herpes Simplex † 1				

# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
Influenza † 1				
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/18 (0.00%)	0/19 (0.00%)
Nasopharyngitis † 1				
# participants affected / at risk	0/19 (0.00%)	2/18 (11.11%)	0/18 (0.00%)	2/19 (10.53%)
Otitis Media † 1				
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/18 (0.00%)	0/19 (0.00%)
Sinusitis † 1				
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
Viral Infection † 1				
# participants affected / at risk	1/19 (5.26%)	1/18 (5.56%)	0/18 (0.00%)	1/19 (5.26%)
Investigations				
Blood Glucose Increased † 1				
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
Metabolism and nutrition disorders				
Dyslipidaemia † 1				
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
Fluid Retention † 1				
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/18 (0.00%)	0/19 (0.00%)
Musculoskeletal and connective tissue disorders				
Arthritis † 1				
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/18 (0.00%)	0/19 (0.00%)
Back Pain † 1				
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
Nervous system disorders				
Dizziness † 1				
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	2/18 (11.11%)	1/19 (5.26%)
Headache † 1				
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	2/18 (11.11%)	0/19 (0.00%)
Renal and urinary disorders				
Dysuria † 1				
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
Reproductive system and breast disorders				
Testicular Pain † 1				
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
Respiratory, thoracic and mediastinal disorders				
Bronchospasm † 1				
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/18 (0.00%)	0/19 (0.00%)
Cough † 1				
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/18 (0.00%)	0/19 (0.00%)
Dyspnoea † 1				

# participants affected / at risk	**0/19 (0.00%)**	**1/18 (5.56%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
Pharyngolaryngeal Pain † 1				
# participants affected / at risk	**1/19 (5.26%)**	**1/18 (5.56%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
Rales † 1				
# participants affected / at risk	**0/19 (0.00%)**	**1/18 (5.56%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
Skin and subcutaneous tissue disorders				
Rash Erythematous † 1				
# participants affected / at risk	**0/19 (0.00%)**	**1/18 (5.56%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
Vascular disorders				
Hypertension † 1				
# participants affected / at risk	**0/19 (0.00%)**	**1/18 (5.56%)**	**0/18 (0.00%)**	**0/19 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 9.1

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: The sponsor must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372
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Responsible Party:	Merck Sharp & Dohme Corp.
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