Name of Sponsor:	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., NJ, USA
German Competent Authority:	Bundesamt für Arzneimittel und Medizinprodukte BfArM – Vorlagenummer: 4035105
Sponsor's Protocol Code Number:	0431-082
EudraCT Number:	2008-006719-20

Protocol Title:

TECOS: A Randomized, Placebo Controlled Clinical Trial to Evaluate Cardiovascular Outcomes after Treatment with Sitagliptin in Patients with Type 2 Diabetes Mellitus and Inadequate Glycemic Control

Protocol-Amendment(s):	# 1 dated 13-Sep-2010 # 2 dated 03-Apr-2012 # 3 dated 05-Sep-2013 # 4 dated 12-Feb-2014

Name of Finished Product:	JANUVIA®
Name of Active Substance:	Sitagliptin
Date of Marketing Authorization:	21-March-2007
Marketing Authorization Number(s):	EU/1/07/383/001-024

Name of Finished Product:	JANUMET®
Name of Active Substance:	Sitagliptin-Metformin
Date of Marketing Authorization:	16-July-2008
Marketing Authorization Number(s):	EU/1/08/455/001-022

2 SYNOPSIS

SPONSOR:	**Merck Sharp & Dohme Corp., a Subsidiary of Merck & Co., Inc.**	
COMPOUND NAME:	**MK-0431**	
INDICATION:	Type 2 diabetes mellitus	
PROTOCOL TITLE:	TECOS: A Randomized, Placebo Controlled Clinical Trial to Evaluate Cardiovascular Outcomes after Treatment with Sitagliptin in Patients with Type 2 Diabetes Mellitus and Inadequate Glycemic Control	
TRIAL IDENTIFIERS:	Protocol Number:	P082
	Clinical Phase:	III
	US IND Number:	65495
TRIAL CENTERS:	This trial was conducted at 674 sites in 38 countries: 118 in the United States, 23 in Argentina, 24 in Australia, 8 in Belgium, 15 in Brazil, 16 in Bulgaria, 12 in Chile, 9 in China, 12 in Colombia, 25 in the Czech Republic, 26 in Canada, 9 in Estonia, 6 in Finland, 7 in France, 30 in Germany, 10 in Hong Kong, 12 in Hungary, 17 in Israel, 15 in Italy, 22 in India, 15 in the Republic of Korea, 11 in Latvia, 12 in Lithuania, 11 in Malaysia, 17 in the Netherlands, 6 in Norway, 9 in New Zealand, 24 in Poland, 14 in Romania, 26 in the Russian Federation, 3 in Singapore, 7 in Slovakia, 21 in South Africa, 13 in Spain, 9 in Sweden, 13 in Taiwan, 10 in Turkey, and 37 in the United Kingdom. The list of investigators and other important trial participants, and investigator qualifications are in [16.1.4].	
DESIGN:	This was a multinational, placebo-controlled, double-blind, randomized, parallel-group pragmatic clinical trial. Eligible patients had T2DM with an HbA1c of ≥6.5% (48 mmol/mol) and ≤8.0% (64 mmol/mol) on stable doses of either monotherapy or dual combination therapy with metformin, pioglitazone, or a sulfonylurea, or, after a protocol amendment [16.1.1.2], on stable doses of insulin (i.e., ±20% of the scheduled total daily insulin dose) either alone or in combination with metformin, for at least 3 months (i.e., no adjustments to oral antihyperglycemic therapy in the past 3 months). In addition, patients were at least 50 years of age with preexisting documented vascular disease in the coronary, cerebral, or peripheral arteries. A total of 14,735 patients were randomly allocated to treatment with either sitagliptin once daily or placebo in a 1:1 ratio; of these, 14,671 were included in the intent to treat (ITT) population. For patients with estimated glomerular filtration rate (eGFR) ≥50 mL/min/1.73 m^2, the starting dose of sitagliptin or placebo was 100 mg q.d.; for	

<table>
<tr><td></td><td colspan="2">patients with eGFR 30 to <50 mL/min/1.73 m^2, the starting dose of sitagliptin or matching placebo was 50 mg q.d.
If not stopped early as a result of interim analyses, the study was planned to continue until 1300 patients with a confirmed cardiovascular (CV) event in the primary composite endpoint occurred and at least 36 months had elapsed from the time that at least 2000 patients on metformin monotherapy at baseline had been randomized to blinded study drug. The study was monitored by an independent Data and Safety Monitoring Board (DSMB). The DSMB charter and DSMB statistical analysis plan are provided in [16.1.1.7], and [16.1.9.4] , respectively.
An independent Clinical Events Classification Committee (CECC) reviewed and adjudicated each suspected clinical endpoint event and were blinded to treatment.
It was anticipated that patients would see their usual care physicians at least twice per year, since they were all high-risk (due to the combination of vascular disease and diabetes requiring drug therapy). The study follow-up was a blend of study visits and phone calls during the double-blind placebo-controlled treatment period, which was anticipated to provide approximately 4-5 years of patient follow-up. For the duration of the study, the CECC adjudication forms and supporting documents pertaining to events were collated by patient number and kept in a locked, confidential archive at DCRI. The CECC document packets for each event were forwarded to the Sponsor after database lock. A description of the organization and membership of the CECC is found in the CECC charter, provided in [16.1.1.8].
For additional information about trial design, see the Protocol in [16.1.1]. Sample case report forms are in [16.1.2]. Randomization schema by center is in [16.1.7].</td></tr>
<tr><td></td><td>Planned duration of main phase:

Planned duration of run-in phase:

Planned duration of extension phase:</td><td>Event-driven trial (1300 PP events in the primary composite endpoint)
Approximately 4 – 5 years
Not applicable

Not applicable</td></tr>
<tr><td>Objectives</td><td colspan="2">The primary objective was to compare the impact of including sitagliptin as part of usual care vs. usual care without sitagliptin (or other dipeptidyl peptidase-4 inhibitors [DPP-4 inhibitors] or glucagon-like peptide-1 [GLP-1] analogues) on CV outcomes as measured by the time to first event in the primary CV composite</td></tr>
</table>

	endpoint of CV-related death, nonfatal myocardial infarction (MI), nonfatal stroke, or unstable angina requiring hospitalization. Secondary objectives compared sitagliptin as part of usual care vs. usual care without sitagliptin on the following: (1) The time to first event in a secondary composite CV endpoint of CV-related death, nonfatal MI, and nonfatal stroke; (2) The time to first event for each of the following individual CV endpoints: confirmed CV-related death, MI (fatal + nonfatal), stroke (fatal + nonfatal), and unstable angina requiring hospitalization; (3) All-cause mortality; (4) Hospital admissions for congestive heart failure (CHF); (5) Change from baseline in HbA1c over time; (6) Change in renal function (based on estimated glomerular filtration rate [eGFR] using the Modification of Diet in Renal Disease [MDRD] method); (7) In patients not receiving insulin at baseline, time to initiation of chronic insulin therapy. Chronic insulin therapy is defined as a continuous period of insulin use of more than 3 months; (8) In patients not receiving insulin at baseline, time to addition of first cointerventional agent (i.e., next oral antihyperglycemic agent (AHA) or chronic insulin, where chronic insulin therapy is defined as a continuous period of insulin use of more than 3 months); (9) Medical resource utilization during the trial (e.g., hospitalizations and outpatient physician visits).

Hypotheses	**Hypothesis a**: Sitagliptin, when used as part of usual care, is noninferior to usual care without sitagliptin with regard to the risk of developing a confirmed event in the primary CV composite endpoint. **Hypothesis b**: If hypothesis a is satisfied: Sitagliptin, when used as part of usual care, is superior to usual care without sitagliptin with regard to the risk of developing a confirmed event in the primary CV composite endpoint A sequential analysis strategy for the primary endpoint of MACE plus and the key secondary endpoint of MACE was included in the Statistical Analysis Plan (Section 5.3, Statistical Analysis Plan (SAP), Version 3.0, 10 September 2014). Each sequential step was tested at a 1-sided significance level of 0.025. If the success criterion for a given hypothesis test was not met, no following hypotheses were to be formally tested. • Non-inferiority of sitagliptin vs. placebo for the primary endpoint MACE plus in the Per Protocol (PP) population. • Non-inferiority of sitagliptin vs. placebo for the secondary endpoint MACE in the PP population. • Superiority of sitagliptin vs. placebo for the primary endpoint MACE plus in the ITT population. • Superiority of sitagliptin vs. placebo for the secondary endpoint MACE in the ITT population.	
Treatments groups	Treatment 1	Sitagliptin tablet taken orally once daily in the morning 7,266
	Treatment 2	Matching placebo tablet taken orally once daily in the morning 7,274
	Total APaT population	14,540
Starting dose – based on eGFR value provided to IVRS[a, b]	eGFR ≥50 mL/min/1.73 m^2	Sitagliptin or placebo 100 mg q.d. Sitagliptin – 6,575 Placebo – 6,602 All patients – 13,177
	eGFR = 30 to <50 mL/min/1.73 m^2	Sitagliptin or placebo 50 mg q.d. Sitagliptin – 691 Placebo – 671 All patients – 1,362

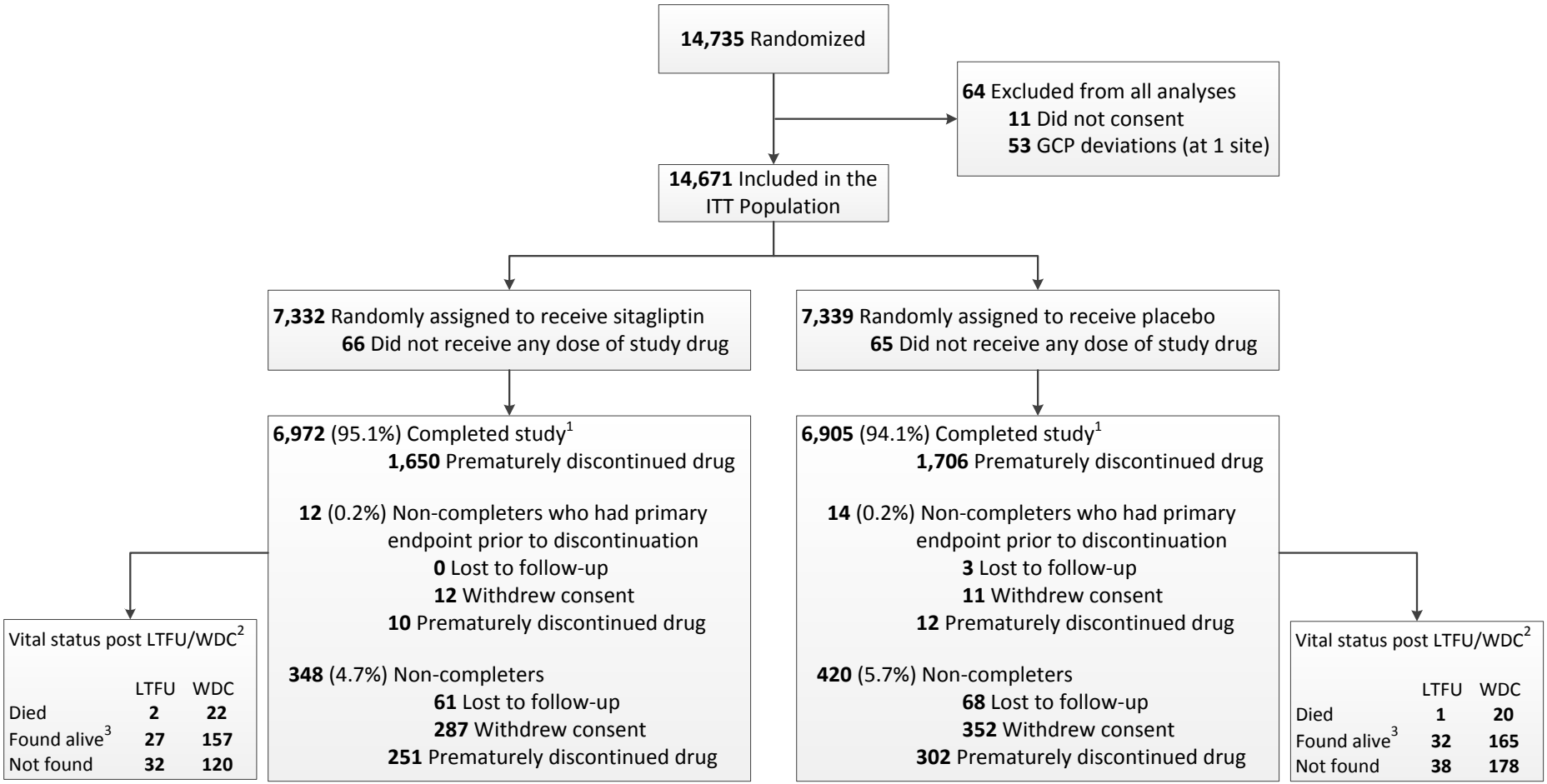
[a] There were two different sources of eGFR data: initial study drug dosage and subsequent dose adjustments were based on eGFR values that the site provided to the IVRS, and the site also entered eGFR data in the eCRF. There were 3 patients, for whom the eCRF data show eGFR <30 mL/min/1.73m^2 (actual values were 29, 29, and23 mL/min/1.73m^2): 1patient in the sitagliptin group, and 2 patients in the placebo group. However, for these 3 patients, the site in fact entered an eGFR of "≥30–<50 mL/min/1.73m^2" in IVRS, and hence the 3 patients are among those assigned to a study drug dose of 50 mg. As subsequent eGFR data reported to the IVRS, 1 of the 3 patients was subsequently changed to a study drug dose of 25 mg. [b] One patient in the placebo group was missing the initial eGFR value reported to the IVRS and so had no dose assigned. This patient was also missing the baseline eGFR in the eCRF.	
DOSAGE/ FORMULATION NUMBERS	The bulk product descriptions and manufacturing lot numbers of sitagliptin and placebo that were shipped to study sites are listed in [16.1.6].
Bottle defect in some clinical supplies (not distributed to patients):	A physical defect was observed in one lot of 120cc high-density polyethylene (HDPE) bottles (LOT WL00036788) used for packaging some clinical supplies that were used in this study. An inspection/replacement plan was implemented to identify potentially affected bottles and removed them from the clinical supply chain. Of the 59,400 bottles potentially affected, 59,390 bottles were inspected and 262 bottles were found to have holes as defects. Not all bottles potentially affected were inspected because some bottles were returned prior to the defect being identified. Stability assessments did not identify any potential impact to drug potency, dissolution, disintegration or degradate levels which were likely to cause patients to have experienced differences in the effects of the study drug or to impact the measured outcomes of the study due to the bottle defect. Affected supplies were not distributed to patients in this study. The study blinding was not broken during implementation of the plan and no patients were excluded from analysis due to the bottle defect.

Endpoints and definitions	Primary endpoint	Time to first MACE plus	Time from randomization to first confirmed event in the primary composite CV endpoint of MACE plus (CV-related death, nonfatal MI, nonfatal stroke, or unstable angina requiring hospitalization)
	Key secondary endpoint	Time to first MACE	Time from randomization to first confirmed event in the composite CV endpoint of MACE

			(CV-related death, nonfatal MI, or nonfatal stroke)
	Secondary endpoints	Time to first confirmed event for individual CV endpoints	Time from randomization to each of the components of the primary composite endpoint (CV-related death, MI [fatal + nonfatal], stroke [fatal +nonfatal], and unstable angina requiring hospitalization)
		Time to all-cause mortality	Time from randomization to death due to any cause
		Time to congestive heart failure (CHF)	Time from randomization to hospital admission for confirmed CHF
		Change from baseline over time	Urinary albumin to creatinine ratio eGFR (MDRD) HbA1c (% and mmol/mol)
		Time to initiation of chronic insulin therapy	Time from randomization to the start of the first instance of chronic insulin therapy, defined as continuous use longer than three months in patients not receiving insulin at baseline
		Time to initiation of first cointerventional agent	Time from randomization to the start of the first instance of initiation of a cointerventional agent, i.e. next oral AHA or chronic insulin therapy in patients not receiving insulin at baseline

		Hospitalizations	Count of hospitalizations for any reason
Database lock	31-MAR-2015	Trial status	16-DEC-2008 (first patient first visit) to 30-MAR-2015 (last patient last visit)
ANALYSIS:	The Statistical Analysis Plan is provided in [16.1.9.1]. Additional analyses and changes to the proposed analyses and data handling specification in the SAP are described in a supplemental SAP [16.1.9.3]		
Analysis description	For all time-to-event analyses (defined as [first event date – randomization date] +1 in patients with events and as [appropriate censoring date based on analytic population – randomization date] +1 in patients without events), the treatment groups were analyzed using a Cox proportional hazards model that included treatment as an explanatory factor and region as a stratification factor unless specified otherwise. The Efron method was used for handling ties. P-value and confidence intervals for the HR were based on the Wald statistic.		

RESULTS	
Study Patients	A total of 14,735 patients underwent randomization from December 2008 through July 2012. Of these patients, 14,671 were included in the ITT population, with 7,332 assigned to receive sitagliptin and 7,339 assigned to receive placebo. The study was closed in March 2015, after the requisite minimum of 1300 patients were confirmed to have had a primary composite outcome. Median follow-up was 3.0 years (interquartile range, 2.3 to 3.8; maximum, 5.7). Overall, 95.1% of patients in the sitagliptin group and 94.1% of those in the placebo group completed the study, with 26.1% and 27.5% of all study patients, respectively, discontinuing study medication prematurely. The sitagliptin and placebo groups were well balanced with respect to demographic characteristics and the use of antihyperglycemic agents and secondary cardiovascular prevention medications. At baseline, mean (SD) HbA1c was 7.2% (0.5%), and patients had been living with diabetes for a mean of 11.6 years (8.1) (ITT population). Disposition of patients is summarized in the CONSORT diagram:



1: Patients who completed study alive, or died and were not at a final status of lost to follow-up (LTFU) or withdrew consent (WDC) prior to death are counted as completers.
2: Vital status summary is among all non-completers regardless of primary endpoint status prior to LTFU/WDC.
3: Found alive after LTFU/WDC on or after 05 May 2014.

RESULTS

Primary and Secondary Outcomes Analyses

Per Protocol	Sitagliptin N=7,257		Placebo N=7,266			
	n (%)	Events. per 100 person-year	n (%)	Events. per 100 person-year	Hazard Ratio (95%CI)	P Value
CV outcomes						
Primary composite outcome – MACE plus (non inferiority)[1]	695 (9.6)	3.73	695 (9.6%)	3.82	0.98 (0.88, 1.09)	<.001
Secondary composite outcome – MACE (non inferiority)[1]	609 (8.4)	3.24	602 (8.3)	3.28	0.99 (0.89, 1.11)	<.001
Secondary outcomes						
CV death[2]	250 (3.4)	1.29	235 (3.2)	1.24	1.04 (0.87, 1.24)	0.654
Hospitalization for unstable angina[3]	104 (1.4)	0.54	114 (1.6)	0.61	0.90 (0.69, 1.18)	0.445
Fatal or nonfatal MI[4]	269 (3.7)	1.42	276 (3.8)	1.49	0.96 (0.81, 1.13)	0.604
Fatal or nonfatal stroke[5]	157 (2.2)	0.82	165 (2.3)	0.88	0.93 (0.75, 1.16)	0.544
All cause mortality[6]	342 (4.7%)	1.77	315 (4.3%)	1.67	1.06 (0.91, 1.24)	0.435
Hospitalization for CHF[7]	200 (2.8)	1.05	202 (2.8)	1.08	0.98 (0.81, 1.19)	0.858
Hospitalization for CHF or CV death[8]	415 (5.7)	2.18	406 (5.6)	2.18	1.01 (0.88, 1.16)	0.889
Non-CV outcomes						
Acute pancreatitis[9]	20 (0.3)	0.10	11 (0.2%)	0.06	1.80 (0.86, 3.76)	0.118
Charter-defined malignancy[10]	248 (3.4)	1.30	260 (3.6%)	1.40	0.93 (0.78, 1.10)	0.384
Charter-defined pancreatic malignancy[11]	9 (0.1)	0.05	10 (0.1)	0.05	0.91 (0.37, 2.25)	0.846
Severe hypoglycemia[12]	144 (2.0)	0.77	125 (1.7)	0.68	1.13 (0.89, 1.44)	0.310

Source, PP results –
[1] Table 14.2.5, [2] Table 14.2.20, [3] Table 14.2.24, [4] Table 14.2.28, [5] Table 14.2.32, [6]Table 14.2.36, [7]Table 14.2.47, [8]Table 14.2.55, [9]Table 14.3.34, [10]Table 14.3.42, [11]Table 14.3.50, [12]Table 14.3.54.

Intent to Treat	Sitagliptin N=7,332		Placebo N=7,339		Hazard Ratio (95%CI)	P Value
	n (%)	Events. per 100 person-year	n (%)	Events. per 100 person-year		
CV outcomes						
Primary composite outcome – MACE plus (non inferiority)[13]	839 (11.4)	4.06	851 (11.6)0	4.17	0.98 (0.89, 1.08)	<.001
MACE plus (superiority)[14]	839 (11.4)	4.06	851 (11.6)0	4.17	0.98 (0.89, 1.08)	0.645
Secondary composite outcome – MACE (non inferiority)[13]	745 (10.2)	3.58	746 (10.2)	3.62	0.99 (0.89, 1.10)	<.001
MACE (superiority)[14]	745 (10.2)	3.58	746 (10.2)	3.62	0.99 (0.89, 1.10)	0.844
Secondary outcomes						
CV death[15]	380 (5.2)	1.72	366 (5.0)	1.67	1.03 (0.89, 1.19)	0.711
Hospitalization for unstable angina[16]	160 (1.6)	0.54	129 (1.8)	0.61	0.90 (0.70, 1.16)	0.419
Fatal or nonfatal MI[17]	300 (.4.1)	1.42	316 (4.3)	1.51	0.95 (0.81, 1.11)	0.487
Fatal or nonfatal stroke[18]	178 (2.4)	0.83	183 (2.5)	0.87	0.97 (0.79, 1.19)	0.760
All cause mortality[19]	547 (7.5%)	2.48	537 (7.3%)	2.45	1.01 (0.90, 1.140	0.875
Hospitalization for CHF[20]	228 (3.1)	1.07	229 (3.1)	1.09	1.00 (0.83, 1.20)	0.983
Hospitalization for CHF or CV death[21]	538 (7.3)	2.54	525 (7.2)	2.50	1.02 (0.90, 1.15)	0.743
Non-CV outcomes						
Acute pancreatitis[22]	23 (0.3%)	0.11	12 (0.2%)	0.06	1.93 (0.96, 3.88)	0.065
Charter-defined malignancy[23]	268 (3.7)	1.25	290 (4.0%)	1.37	0.91 (0.77, 1.08)	0.272
Charter-defined pancreatic malignancy[24]	9 (0.1)	0.04	14 (0.2)	0.07	0.66 (0.28, 1.51)	0.322
Severe hypoglycemia[25]	160 (2.2)	0.78	43 (1.9)	0.70	1.12 (0.89, 1.40)	0.334

Source: ITT results – [13] Table 14.2.6, [14] Table 14.2.7, [15] Table 14.2.21, [16] Table 14.2.25, [17] Table 14.2.29, [18] Table 14.2.33, [19] Table 14.2.37, [20] Table 14.2.48, [21] Table 14.2.56, [22] Table 14.3.35, [23] Table 14.3.43, [24] Table 14.3.52, [25] Table 14.3.55.

Safety Results

Prespecified diabetes complications and expected events

There was no notable difference between sitagliptin and placebo with respect to the incidence of any prespecified diabetes complications, based on the prospectively planned collection of all events of peripheral arterial disease, amputation, gangrene, hyperglycemia requiring hospitalization, hypoglycemia requiring assistance, blindness due to diabetes, diabetic neuropathy, retinopathy, microalbuminuria, renal failure, infections, gastrointestinal (GI) conditions associated with diabetes, pancreatitis, and metabolic conditions associated with diabetes. There was no apparent difference between treatment groups with respect to the percentage of patients having 1, 2, or ≥3 post baseline diabetes complications.

There was no notable difference between sitagliptin and placebo with respect to the incidence of any prespecified expected events, not classified as diabetic complications. These events included blindness not due to diabetes, percutaneous coronary intervention, coronary artery bypass graft surgery, atrial fibrillation/flutter, ventricular fibrillation/tachycardia requiring intervention, deep vein thrombosis, pulmonary embolism, shock/hypotension, cardiac catheterization, macroalbuminuria, and allergic reaction attributed to study drug.

Adverse event data includes events that were not on the Protocol's clinical events list which met SAE reporting criteria, and/or any AEs that resulted in early cessation of study medication. Other non-serious AEs were not captured in this trial. The clinical events listed in the Protocol were collected and presented separately from the adverse event data.

Estimates reflect the difference in percentage of subjects with the event (sitagliptin vs. placebo). 95% confidence intervals are based on Miettinen & Nurminen method in accordance with the statistical analysis plan. P values are based on Fisher's Exact mid-P in accordance with the statistical analysis plan.

Treatment Emergent Adverse Events – APaT				
Subjects with one or more:	**Sitagliptin N=7,266**	**Placebo N=7,274**	**Estimate (95% CI)**	**P value**
Adverse event (AE)	1,015 (14.0%)	995 (13.7%)	0.29 (-0.83, 1.41)	0.606
Serious adverse event (SAE)	928 (12.8%)	909 (12.5%)	0.28 (-0.81, 1.36)	0.609
AE related to study treatment	101 (1.4%)	111 (1.5%)	-0.14 (-0.53, 0.26)	0.512
AE with fatal outcome	54 (0.7%)	57 (0.8%)	-0.04 (-0.33, 0.25)	0.812
AE resulting in permanent treatment discontinuation	176 (2.4%)	173 (2.4%)	0.04 (-0.46, 0.54)	0.850
AE related to study treatment resulting in permanent treatment discontinuation	79 (1.1%)	88 (1.2%)	-0.12 (-0.47, 0.23)	0.509
Source: Table 14.3.6.				

Serious Adverse Events: There was no notable difference between the sitagliptin group and the placebo group with respect to the incidence of SAEs within any SOC or for any Preferred Term.

Treatment Emergent Serious Adverse Events in at Least 1% of Patients in Either Group by System Organ Class – APaT				
	Sitagliptin N=7266		**Placebo N=7274**	
	Patients n (%)	**Events n**	**Patients n (%)**	**Events n**
Neoplasms benign, malignant and unspecified (including cysts and polyps)	341 (4.7%)	405	371 (5.1%)	470
Injury, poisoning and procedural complications	146 (2.0%)	165	133 (1.8%)	153
Gastrointestinal disorders	130 (1.8%)	143	102 (1.4%)	121
Musculoskeletal and connective tissue disorders	118 (1.6%)	136	93 (1.3%)	102
Respiratory, thoracic and mediastinal disorders	66 (0.9%)	81	77 (1.1%)	95
Source: Table 14.3.26.				

CONCLUSIONS:	• Sitagliptin, when used as part of usual diabetes care among patients with type 2 diabetes and preexisting CVD, is noninferior to usual diabetes care without sitagliptin with regard to the risk of developing confirmed MACE plus, a composite of CV-related death, nonfatal MI, nonfatal stroke, or unstable angina requiring hospitalization. • Sitagliptin, when used as part of usual diabetes care among patients with type 2 diabetes and preexisting CVD, is noninferior to usual diabetes care without sitagliptin with regard to the risk of developing confirmed MACE, a composite of CV-related death, nonfatal MI or nonfatal stroke. • The addition of sitagliptin to usual diabetes care results in no notable difference in rates of any component of MACE plus or MACE. • The addition of sitagliptin to usual diabetes care compared to usual diabetes care without sitagliptin does not change rates of hospitalization for CHF, nor rates of the composite of hospitalization for CHF or CV death. • The addition of sitagliptin to usual diabetes care compared to usual diabetes care without sitagliptin does not change the long-term rates of death from any cause, CV death, or non-CV death; and does not impact the rates of specific causes of death, including infection. • Among patients treated with sitagliptin in addition to usual diabetes care compared to usual diabetes care without sitagliptin, over a median of three years of follow-up, no clinically relevant differences occur in the long-term incidence of diabetic complications, including diabetic eye disease, neuropathy, microalbuminuria, renal failure, peripheral vascular disease, gangrene, infections, GI conditions, and metabolic conditions. • No increase in the rate of severe hypoglycemia is seen among patients treated with sitagliptin plus usual diabetes care compared to usual diabetes care without sitagliptin. • Among patients treated with sitagliptin plus usual diabetes care, fewer require additional antihyperglycemic agents or the initiation of chronic insulin therapy compared with patients treated with usual diabetes care without sitagliptin.

PUBLICATION(S):	Green JB, Bethel MA, Paul SK, Ring A, Kaufman KD, Shapiro DR, Califf RM, Holman RR. Rationale, design, and organization of a randomized, controlled Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS) in patients with type 2 diabetes and established cardiovascular disease. Am Heart J 2013;166(6):983–989. Bethel MA, Green JB, Milton J, Tajar A, Engel SS, Califf RM, Holman RR and on behalf of the TECOS executive committee. Regional, age and sex differences in baseline characteristics of patients enrolled in the Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS). Diabetes Obes Metab 2015;17:395-402. Green JB, Bethel MA, Armstrong MD, Buse JB, Engel SS, Garg J, et al. for the TECOS Study Group. Effect of sitagliptin on cardiovascular outcomes in type 2 diabetes. N Engl J Med; July16, 2015. 373(3):232-242. Copies of these publications are provided in [16.1.11].
REPORT DATE:	**28 September, 2015**

Bulk Product Description	**Manufacturing Lot Numbers**
FCT MK-0431 100 mg, Beige (MMD)	WL00044434, WL00047019, WL00047018, WL00043661, WL00049684, WL00049679, WL00051370, WL00051363, WL00050364, WL00053111, WL00053108, WL00055473, WL00055806, WL00030298, WL00030300, WL00032414, WL00035566, WL00035529, WL00037083, WL00037072, WL00038212, WL00038181, WL00040265, WL00040261, WL00040265, WL00042357, WL00042275, WL00042357, WL00044434, WL00044414
FCT MK-0431 100 mg Placebo, Beige (MMD)	WL00040654, WL00045919, WL00045898, WL00036886, WL00048175, WL00048174, WL00050127, WL00050126, WL00050128, WL00050127, WL00052989, WL00052986, WL00054525, WL00052993, WL00014503, WL00033815, WL00033880, WL00033852, WL00036800, WL00036785, WL00036862, WL00036843, WL00038595, WL00038582, WL00040486, WL00038555, WL00040486, WL00040654, WL00040632
FCT Sitagliptin Phosphate 25 mg (MMD)	WL00044634, WL00047321, WL00047320, WL00044634, WL00049115, WL00051362, WL00053102, WL00055501, WL00030935, WL00032241, WL00036380, WL00038196, WL00040351, WL00042260, WL00042258, WL00044634
FCT Sitagliptin Phosphate 25 mg Placebo	WL00045249, WL00037248, WL00051627, WL00022836, WL00037248

Product: MK-0431
Protocol/Amendment No.: 082-01

SUMMARY OF CHANGES

PRIMARY REASON FOR THIS AMENDMENT:

Revised eligibility criteria to include patients on insulin and reduced the minimum number of patients to be recruited on pioglitazone (either as monotherapy or combination therapy) from 2000 to 1000.

Product: MK-0431
Protocol/Amendment No.: 082-02

SUMMARY OF CHANGES

PRIMARY REASON FOR THIS AMENDMENT:

The non-inferiority margin was revised from 1.20 to 1.30 to provide consistency with current regulatory guidance.

Product: MK-0431
Protocol/Amendment No.: 082-03

SUMMARY OF CHANGES

PRIMARY REASON(S) FOR THIS AMENDMENT

Section Number(s)	Section Title(s)	Description of Change(s)
		The secondary objective related to the analysis of each of the components of the primary composite endpoint was revised to include fatal myocardial infarctions and fatal strokes when analyzing the time to these individual categories of events.

Product: MK-0431
Protocol/Amendment No.: 082-04

SUMMARY OF CHANGES

PRIMARY REASON(S) FOR THIS AMENDMENT

Section Number(s)	Section Title(s)	Description of Change(s)
		The protocol was amended to • allow for the collection of new or worsening malignancy and pancreatitis information beyond 28 days after discontinuation of study drug. • indicate that reported events of basal and/or squamous cell carcinoma of the skin will not undergo adjudication by the CECC.

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