Dossier zur Nutzenbewertung gemäß § 35a SGB V

Vericiguat (VERQUVO®)

Bayer Vital GmbH

Separater Anhang 4-G

Erwachsene Patienten mit symptomatischer, chronischer Herzinsuffizienz mit reduzierter Ejektionsfraktion, die nach einem kürzlich aufgetretenen Dekompensationsereignis, das eine i.v.-Therapie erforderte, stabilisiert wurden

Stand: 13.09.2021

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PARTICIPANT DISPOSITION, EXPOSURE, DEMOGRAPHICS, BASELINE CHARACTERISTICS AND MEDICATIONS

1.1 Disposition of Participants

Table 1.1-1
Disposition of Study Participants
ITT Population
Participants with Screening Ejection Fraction < 40%

Disposition	Study: 1242-001[a]	
	Vericiguat N[b] = 2158	**Placebo N[b] = 2158**
Status for Trial, n(%)		
Discontinued	456 (21,1)	476 (22,1)
Death	439 (20,3)	458 (21,2)
Lost To Follow-Up	9 (0,4)	5 (0,2)
Withdrawal By Subject	8 (0,4)	13 (0,6)
Trial Ongoing	1702 (78,9)	1682 (77,9)
Status for Study Medication in Trial, n(%)		
Started	2152	2151
Completed	41 (1,9)	42 (2,0)
Discontinued	815 (37,9)	810 (37,7)
Adverse Event	148 (6,9)	136 (6,3)
Death	309 (14,4)	320 (14,9)
Lost To Follow-Up	7 (0,3)	10 (0,5)
Non-Compliance With Study Drug	42 (2,0)	40 (1,9)
Physician Decision	142 (6,6)	137 (6,4)
Protocol Deviation	7 (0,3)	1 (0,0)
Withdrawal By Subject	160 (7,4)	166 (7,7)
Treatment Ongoing	1296 (60,2)	1299 (60,4)

a: Database Cutoff Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

1.2 Participants Demographic Data

Table 1.2-1
Participants Demographics
ITT Population
Participants with Screening Ejection Fraction < 40%

Characteristic	Study: MK-1242-001[a]	
	Vericiguat N[b]=2158	**Placebo** N[b]=2158
Gender		
Male	1661 (77,0)	1658 (76,8)
Female	497 (23,0)	500 (23,2)
Age (years)		
≤50	203 (9,4)	231 (10,7)
51 to 60	400 (18,5)	386 (17,9)
61 to 70	653 (30,3)	650 (30,1)
71 to 80	612 (28,4)	650 (30,1)
≥81	290 (13,4)	241 (11,2)
Mean (SD)	66,9 (12,2)	66,5 (12,3)
Median (Q1; Q3)	68,0 (59,0; 76,0)	68,0 (59,0; 76,0)
Min; Max	24,0; 98,0	23,0; 97,0
Race		
American Indian Or Alaska Native	21 (1,0)	24 (1,1)
Asian	500 (23,2)	475 (22,0)
Black	111 (5,1)	118 (5,5)
Multi-Racial	172 (8,0)	172 (8,0)
Native Hawaiian Or Other Pacific Islander	3 (0,1)	10 (0,5)
Not Reported	1 (0,0)	0 (0,0)
White	1350 (62,6)	1359 (63,0)
Ethnicity		
Hispanic Or Latino	358 (16,6)	358 (16,6)
Not Hispanic Or Latino	1737 (80,5)	1751 (81,1)
Not Reported	35 (1,6)	25 (1,2)
Unknown	28 (1,3)	24 (1,1)
Geographic Region		
Asia Pacific	511 (23,7)	503 (23,3)
Eastern Europe	722 (33,5)	718 (33,3)
Latin and South America	316 (14,6)	324 (15,0)
North America	243 (11,3)	244 (11,3)
Western Europe	366 (17,0)	369 (17,1)
Race in North America		
Black	54 (2,5)	56 (2,6)
Non-Black	189 (8,8)	188 (8,7)
Outside North America	1915 (88,7)	1914 (88,7)

Participants Demographics
ITT Population
Participants with Screening Ejection Fraction < 40%

Characteristic	Study: MK-1242-001[a]	
	Vericiguat N[b]=2158	**Placebo** N[b]=2158
Race Group		
White	1350 (62,6)	1359 (63,0)
Asian	500 (23,2)	475 (22,0)
Black	111 (5,1)	118 (5,5)
Other	196 (9,1)	206 (9,5)
Missing	1 (0,0)	0 (0,0)

a: Database Cutoff Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

1.3 Participants Baseline Characteristics

Table 1.3-1
Participants Baseline Characteristics
ITT Population
Participants with Screening Ejection Fraction < 40%

Characteristic	Study: MK-1242-001[a]	
	Vericiguat N[b]=2158	**Placebo** N[b]=2158
Height (cm)		
Subjects with data	2145	2135
Mean (SD)	168,1 (10,0)	168,1 (9,8)
Median (Q1; Q3)	168,0 (161,5; 175,0)	168,0 (162,0; 175,0)
Min; Max	130,0; 200,7	114,0; 203,2
Weight (Kg)		
Subjects with data	2151	2143
Mean (SD)	78,4 (20,2)	79,2 (20,8)
Median (Q1; Q3)	76,0 (64,2; 89,0)	76,4 (65,2; 90,2)
Min; Max	32,5; 181,6	34,2; 195,0
Body Mass Index (kg/m^2)		
Subjects with data	2144	2134
Mean (SD)	27,6 (5,8)	27,8 (6,1)
Median (Q1; Q3)	26,7 (23,6; 30,5)	26,8 (23,8; 30,9)
Min; Max	14,2; 55,6	15,4; 63,0
NT-pro BNP at Randomization (pg/mL)		
Subjects with data	2068	2045
Mean (SD)	4951,1 (7915,1)	4814,9 (6225,2)
Median (Q1; Q3)	2932,0 (1610,5; 5506,5)	2913,0 (1575,0; 5425,0)
Min; Max	10,0; 175000,0	97,0; 86155,0
NT-pro BNP Category at Randomization (pg/mL)		
Q1 (≤1556)	489 (22,7)	507 (23,5)
Q2 (1556 - 2816)	520 (24,1)	494 (22,9)
Q3 (2816 - 5314)	511 (23,7)	520 (24,1)
Q4 (>5314)	548 (25,4)	524 (24,3)
Missing	90 (4,2)	113 (5,2)
eGFR at Randomization (mL/min/1.73 m^2)		
Subjects with data	2116	2122
Mean (SD)	62,0 (27,2)	62,2 (27,2)
Median (Q1; Q3)	59,2 (41,7; 77,6)	58,8 (41,8; 78,2)
Min; Max	11,0; 225,5	12,7; 218,7
eGFR Category at Randomization (mL/min/1.73 m^2)		
≤30	213 (9,9)	203 (9,4)
>30 to ≤60	882 (40,9)	895 (41,5)
>60	1021 (47,3)	1024 (47,5)
Missing	42 (1,9)	36 (1,7)

Participants Baseline Characteristics
ITT Population
Participants with Screening Ejection Fraction < 40%

Characteristic	Study: MK-1242-001[a]	
	Vericiguat N[b]=2158	**Placebo** N[b]=2158
Index Event		
HF Hospitalization 3-6 Months	390 (18,1)	365 (16,9)
HF Hospitalization within 3 Months	1441 (66,8)	1478 (68,5)
IV diuretic for HF (without hospitalization) within 3 Months	327 (15,2)	315 (14,6)
Time of Primary Diagnosis of Heart Failure with Reduced Ejection Fraction to Randomization (Year)		
Subjects with data	2158	2156
Mean (SD)	4,8 (5,6)	4,9 (5,4)
Median (Q1; Q3)	3,0 (0,8; 7,1)	3,0 (0,9; 7,1)
Min; Max	0,0; 57,8	0,0; 39,6
Time of Earliest Diagnosis of Heart Failure to Randomization (with or without Reduced Ejection Fraction) (Year)		
Subjects with data	2158	2156
Mean (SD)	5,2 (5,7)	5,3 (5,7)
Median (Q1; Q3)	3,3 (1,0; 7,6)	3,4 (1,1; 7,7)
Min; Max	0,0; 57,8	0,0; 48,3
NYHA Class at Baseline		
NYHA Class I	0 (0,0)	1 (0,0)
NYHA Class II	1241 (57,5)	1270 (58,9)
NYHA Class III	885 (41,0)	861 (39,9)
NYHA Class IV	30 (1,4)	26 (1,2)
Missing	2 (0,1)	0 (0,0)
NYHA Class Group at Baseline		
Class I or II	1241 (57,5)	1271 (58,9)
Class III or IV	915 (42,4)	887 (41,1)
Missing	2 (0,1)	0 (0,0)
CCSA Class at Baseline		
CCSA Class 1	172 (8,0)	167 (7,7)
CCSA Class 2	93 (4,3)	94 (4,4)
CCSA Class 3	42 (1,9)	40 (1,9)
CCSA Class 4	2 (0,1)	1 (0,0)
No Angina	1849 (85,7)	1856 (86,0)
CCSA Class at Baseline Group 1		
No Angina	1849 (85,7)	1856 (86,0)
Angina Class 1 or 2	265 (12,3)	261 (12,1)
Angina Class 3 or 4	44 (2,0)	41 (1,9)
Baseline Ejection Fraction Reduction (%) Group 1		
<35	1725 (79,9)	1741 (80,7)

Participants Baseline Characteristics
ITT Population
Participants with Screening Ejection Fraction < 40%

Characteristic	Study: MK-1242-001[a]	
	Vericiguat N[b]=2158	**Placebo** N[b]=2158
≥35	433 (20,1)	417 (19,3)
Use of Sacubitril /Valsartan at Baseline		
Yes	330 (15,3)	330 (15,3)
No	1824 (84,5)	1825 (84,6)
Missing	4 (0,2)	3 (0,1)
History of Tobacco Use Assessed at Baseline		
Yes	1273 (59,0)	1295 (60,0)
No	885 (41,0)	863 (40,0)
History of Diabetes Mellitus		
Yes	1051 (48,7)	985 (45,6)
No	1107 (51,3)	1173 (54,4)

a: Database Cutoff Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

NT-proBNP and creatinine for eGFR analyzed by central lab

CCSA: Canadian Cardiovascular Society Functional Classification of Angina, HF:Heart Failure; Max: Maximum; Min: Minimum; NYHA: New York Heart Association; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

1.4 Prior Medications

Table 1.4-1
Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
Participants in population	2.152		2.151		4.303	
with one or more prior medications	2.152	(100,0)	2.151	(100,0)	4.303	(100,0)
with no prior medication	0	(0,0)	0	(0,0)	0	(0,0)
ALIMENTARY TRACT AND METABOLISM						
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	**190**	**(8,8)**	**196**	**(9,1)**	**386**	**(9,0)**
ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;ATRACTYLODES LANCEA RHIZOME;CINNAMOMUM CASSIA BARK;POLYPORUS UMBELLATUS SCLEROTIUM;PORIA COCOS SCLEROTIUM	0	(0,0)	1	(0,0)	1	(0,0)
AMPHOTERICIN B	1	(0,0)	1	(0,0)	2	(0,0)
AST 120	3	(0,1)	5	(0,2)	8	(0,2)
ATROPINE SULFATE;DIPHENOXYLATE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
BACILLUS MESENTERICUS;CLOSTRIDIUM BUTYRICUM;ENTEROCOCCUS FAECALIS	0	(0,0)	4	(0,2)	4	(0,1)
BACILLUS SUBTILIS;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	1	(0,0)	1	(0,0)	2	(0,0)
BACILLUS SUBTILIS;ENTEROCOCCUS FAECIUM	1	(0,0)	2	(0,1)	3	(0,1)
BACITRACIN ZINC;NEOMYCIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
BECLOMETASONE DIPROPIONATE	24	(1,1)	13	(0,6)	37	(0,9)
BERBERINE	0	(0,0)	1	(0,0)	1	(0,0)
BERBERINE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
BETAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	**190**	**(8,8)**	**196**	**(9,1)**	**386**	**(9,0)**
BETAMETHASONE BUTYRATE PROPIONATE	4	(0,2)	4	(0,2)	8	(0,2)
BETAMETHASONE DIPROPIONATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE SODIUM PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE VALERATE	3	(0,1)	3	(0,1)	6	(0,1)
BIFIDOBACTERIUM BIFIDUM	2	(0,1)	1	(0,0)	3	(0,1)
BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM INFANTIS;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS;LACTOBACILLUS PARACASEI;LACTOBACILLUS PLANTARUM;STREPTOCOCCUS THERMOPHILUS	2	(0,1)	0	(0,0)	2	(0,0)
BIFIDOBACTERIUM LACTIS	0	(0,0)	2	(0,1)	2	(0,0)
BIFIDOBACTERIUM LACTIS;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS	1	(0,0)	0	(0,0)	1	(0,0)
BISMUTH SUBSALICYLATE	0	(0,0)	2	(0,1)	2	(0,0)
BUDESONIDE	47	(2,2)	61	(2,8)	108	(2,5)
CHARCOAL, ACTIVATED	2	(0,1)	1	(0,0)	3	(0,1)
COLESTYRAMINE	3	(0,1)	0	(0,0)	3	(0,1)
DIOSMECTITE	8	(0,4)	7	(0,3)	15	(0,3)
ELECTROLYTES NOS;GLUCOSE	1	(0,0)	0	(0,0)	1	(0,0)
GLUCOSE;SODIUM CHLORIDE	4	(0,2)	1	(0,0)	5	(0,1)
HOUTTUYNIA CORDATA	0	(0,0)	1	(0,0)	1	(0,0)
HYDROCORTISONE	5	(0,2)	8	(0,4)	13	(0,3)
HYDROCORTISONE ACETATE	2	(0,1)	3	(0,1)	5	(0,1)
HYDROCORTISONE BUTYRATE	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	**190**	**(8,8)**	**196**	**(9,1)**	**386**	**(9,0)**
HYDROCORTISONE PROBUTAT	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE SODIUM SUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
INULIN;LACTOBACILLUS RHAMNOSUS	1	(0,0)	0	(0,0)	1	(0,0)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
LACTOBACILLUS ACIDOPHILUS	5	(0,2)	3	(0,1)	8	(0,2)
LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS CASEI;LACTOBACILLUS RHAMNOSUS	1	(0,0)	0	(0,0)	1	(0,0)
LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS RHAMNOSUS	1	(0,0)	0	(0,0)	1	(0,0)
LACTOBACILLUS DELBRUECKII	1	(0,0)	0	(0,0)	1	(0,0)
LACTOBACILLUS HELVETICUS	0	(0,0)	1	(0,0)	1	(0,0)
LACTOBACILLUS NOS	0	(0,0)	1	(0,0)	1	(0,0)
LACTOBACILLUS NOS;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	0	(0,0)	1	(0,0)	1	(0,0)
LACTOBACILLUS RHAMNOSUS	2	(0,1)	6	(0,3)	8	(0,2)
LEVOMENTHOL	1	(0,0)	0	(0,0)	1	(0,0)
LOPERAMIDE	4	(0,2)	3	(0,1)	7	(0,2)
LOPERAMIDE HYDROCHLORIDE	5	(0,2)	5	(0,2)	10	(0,2)
MENTHOL	0	(0,0)	1	(0,0)	1	(0,0)
MESALAZINE	3	(0,1)	6	(0,3)	9	(0,2)
MICONAZOLE	2	(0,1)	0	(0,0)	2	(0,0)
MICONAZOLE NITRATE	1	(0,0)	3	(0,1)	4	(0,1)
NEOMYCIN	0	(0,0)	1	(0,0)	1	(0,0)
NYSTATIN	1	(0,0)	4	(0,2)	5	(0,1)
PAROMOMYCIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	**190**	**(8,8)**	**196**	**(9,1)**	**386**	**(9,0)**
PLANTAGO OVATA	1	(0,0)	3	(0,1)	4	(0,1)
PLANTAGO OVATA SEED	1	(0,0)	0	(0,0)	1	(0,0)
PREDNISOLONE	28	(1,3)	19	(0,9)	47	(1,1)
PREDNISONE	24	(1,1)	28	(1,3)	52	(1,2)
PREDNISONE ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
PROBIOTICS NOS	3	(0,1)	1	(0,0)	4	(0,1)
PROBIOTICS NOS;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)
SACCHAROMYCES BOULARDII	3	(0,1)	3	(0,1)	6	(0,1)
SULFASALAZINE	0	(0,0)	6	(0,3)	6	(0,1)
VACCINIUM MYRTILLUS EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
VANCOMYCIN	3	(0,1)	5	(0,2)	8	(0,2)
VANCOMYCIN HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
ANTIEMETICS AND ANTINAUSEANTS	**56**	**(2,6)**	**73**	**(3,4)**	**129**	**(3,0)**
ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;ATRACTYLODES LANCEA RHIZOME;CINNAMOMUM CASSIA BARK;POLYPORUS UMBELLATUS SCLEROTIUM;PORIA COCOS SCLEROTIUM	0	(0,0)	1	(0,0)	1	(0,0)
ATRACTYLODES LANCEA RHIZOME;CITRUS RETICULATA PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	2	(0,1)	2	(0,0)
CANNABIS SATIVA	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIEMETICS AND ANTINAUSEANTS	**56**	**(2,6)**	**73**	**(3,4)**	**129**	**(3,0)**
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	7	(0,3)	7	(0,3)	14	(0,3)
CYANOCOBALAMIN;PYRIDOXINE ;THIAMINE	1	(0,0)	6	(0,3)	7	(0,2)
DIFENIDOL	1	(0,0)	1	(0,0)	2	(0,0)
DIFENIDOL HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
DIMENHYDRINATE	0	(0,0)	1	(0,0)	1	(0,0)
DIPHENHYDRAMINE	4	(0,2)	9	(0,4)	13	(0,3)
DIPHENHYDRAMINE HYDROCHLORIDE	2	(0,1)	7	(0,3)	9	(0,2)
ERIOBOTRYA JAPONICA	0	(0,0)	1	(0,0)	1	(0,0)
HYDROXYZINE	11	(0,5)	13	(0,6)	24	(0,6)
HYDROXYZINE HYDROCHLORIDE	6	(0,3)	8	(0,4)	14	(0,3)
HYOSCINE	1	(0,0)	0	(0,0)	1	(0,0)
MECLOZINE	3	(0,1)	3	(0,1)	6	(0,1)
MECLOZINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ONDANSETRON	10	(0,5)	11	(0,5)	21	(0,5)
ONDANSETRON HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
PINELLIA TERNATA	1	(0,0)	0	(0,0)	1	(0,0)
PROCHLORPERAZINE	1	(0,0)	1	(0,0)	2	(0,0)
PROCHLORPERAZINE MALEATE	0	(0,0)	1	(0,0)	1	(0,0)
PROMETHAZINE	3	(0,1)	5	(0,2)	8	(0,2)
PROMETHAZINE HYDROCHLORIDE	5	(0,2)	2	(0,1)	7	(0,2)
TRIMETHOBENZAMIDE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS	**18**	**(0,8)**	**14**	**(0,7)**	**32**	**(0,7)**
ACETYLCARNITINE	1	(0,0)	0	(0,0)	1	(0,0)
ACETYLCARNITINE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS	**18**	**(0,8)**	**14**	**(0,7)**	**32**	**(0,7)**
AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
LIRAGLUTIDE	13	(0,6)	11	(0,5)	24	(0,6)
PLANTAGO OVATA	1	(0,0)	3	(0,1)	4	(0,1)
APPETITE STIMULANTS	**4**	**(0,2)**	**6**	**(0,3)**	**10**	**(0,2)**
ATRACTYLODES LANCEA RHIZOME;CITRUS RETICULATA PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	2	(0,1)	2	(0,0)
CARNITINE HYDROCHLORIDE;CYANOCOBALAMIN;CYPROHEPTADINE OROTATE;LYSINE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
CYPROHEPTADINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
MEGESTROL ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
BILE AND LIVER THERAPY	**65**	**(3,0)**	**59**	**(2,7)**	**124**	**(2,9)**
ADENINE HYDROCHLORIDE;BIFENDATE;CARNITINE OROTATE;CYANOCOBALAMIN;LIVER EXTRACT;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN	1	(0,0)	3	(0,1)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
BILE AND LIVER THERAPY	**65**	**(3,0)**	**59**	**(2,7)**	**124**	**(2,9)**
ARGININE	1	(0,0)	0	(0,0)	1	(0,0)
ARTEMISIA SPP. HERB;BUPLEURUM CHINENSE, ROOT;ISATIS INDIGOTICA ROOT;SCHISANDRA CHINENSIS FRUIT;SWINE BILE;VIGNA RADIATA	1	(0,0)	0	(0,0)	1	(0,0)
BICYCLOL	0	(0,0)	2	(0,1)	2	(0,0)
COENZYME A	0	(0,0)	1	(0,0)	1	(0,0)
CURCUMA LONGA	2	(0,1)	0	(0,0)	2	(0,0)
CYSTEINE HYDROCHLORIDE;GLYCINE;GLYCYRRHIZIC ACID, AMMONIUM SALT	0	(0,0)	1	(0,0)	1	(0,0)
CYSTEINE;GLYCINE;GLYCYRRHIZIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
DIISOPROPYLAMINE DICHLOROACETATE	1	(0,0)	0	(0,0)	1	(0,0)
DIMETHYL 4,4'-BIPHENYLDICARBOXYLATE;URSODEOXYCHOLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
ENZYMES NOS;URSODEOXYCHOLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
GLYCYRRHIZA GLABRA	2	(0,1)	0	(0,0)	2	(0,0)
LACTULOSE	35	(1,6)	33	(1,5)	68	(1,6)
LECITHIN	1	(0,0)	1	(0,0)	2	(0,0)
LEVOGLUTAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
LIVER THERAPY	0	(0,0)	4	(0,2)	4	(0,1)
ORNITHINE ASPARTATE	1	(0,0)	1	(0,0)	2	(0,0)
PHOSPHOLIPIDS	3	(0,1)	0	(0,0)	3	(0,1)
POLYENE PHOSPHATIDYLCHOLINE	5	(0,2)	7	(0,3)	12	(0,3)
REHMANNIA GLUTINOSA	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
BILE AND LIVER THERAPY	**65**	**(3,0)**	**59**	**(2,7)**	**124**	**(2,9)**
SILYBUM MARIANUM	1	(0,0)	1	(0,0)	2	(0,0)
TARAXACUM OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
THIOTRIAZOLINE	1	(0,0)	1	(0,0)	2	(0,0)
TIMONACIC	2	(0,1)	1	(0,0)	3	(0,1)
URSODEOXYCHOLIC ACID	10	(0,5)	7	(0,3)	17	(0,4)
DIGESTIVES, INCL. ENZYMES	**12**	**(0,6)**	**15**	**(0,7)**	**27**	**(0,6)**
AMYLASE;LIPASE;PROTEASE;SIMETICONE	0	(0,0)	1	(0,0)	1	(0,0)
ASPERGILLUS ORYZAE ENZYME;PANCREATIN	1	(0,0)	0	(0,0)	1	(0,0)
AZINTAMIDE;CELLULASE;PANCREATIN;SIMETICONE	2	(0,1)	0	(0,0)	2	(0,0)
BETAINE HYDROCHLORIDE;BROMELAINS;OX BILE;PANCREATIN;PAPAIN;PEPSIN	1	(0,0)	0	(0,0)	1	(0,0)
BIODIASTASE 1000;LIPASE;NEWLASE	0	(0,0)	1	(0,0)	1	(0,0)
BROMELAINS;DIMETICONE;PANCREATIN	1	(0,0)	1	(0,0)	2	(0,0)
CALCIUM CARBONATE;CINNAMOMUM VERUM POWDER;COPTIS TRIFOLIA;DIASTASE, TAKA;FOENICULUM VULGARE;GLYCYRRHIZA GLABRA;MENTHOL;SIMALDRATE;SODIUM BICARBONATE;SYZYGIUM AROMATICUM FLOWER;ZANTHOXYLUM AMERICANUM BARK;ZINGIBER OFFICINALE RHIZOME	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DIGESTIVES, INCL. ENZYMES	**12**	**(0,6)**	**15**	**(0,7)**	**27**	**(0,6)**
CELLULASE AP 3;PANCREATIN;SIMETICONE;URSO DEOXYCHOLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
CELLULASE;DIASTASE;PANCREA TIN;PANCRELIPASE;PAPAIN;PEPSIN ;URSODEOXYCHOLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
DIASTASE;LIPASE;PANCREATIN	0	(0,0)	1	(0,0)	1	(0,0)
ENZYMES NOS	1	(0,0)	2	(0,1)	3	(0,1)
ENZYMES NOS;URSODEOXYCHOLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
MONASCUS PURPUREUS	1	(0,0)	0	(0,0)	1	(0,0)
OPHIOPOGON JAPONICUS	1	(0,0)	0	(0,0)	1	(0,0)
PANCREATIN	2	(0,1)	5	(0,2)	7	(0,2)
PANCRELIPASE	1	(0,0)	0	(0,0)	1	(0,0)
SILYBUM MARIANUM	1	(0,0)	1	(0,0)	2	(0,0)
TARAXACUM OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
DRUGS FOR ACID RELATED DISORDERS	**1.065**	**(49,5)**	**1.063**	**(49,4)**	**2.128**	**(49,5)**
ALDIOXA;METAMAGNESIUM ALUMINOSILICATE	1	(0,0)	0	(0,0)	1	(0,0)
ALGELDRATE;ALGINIC ACID;CALCIUM CARBONATE;MAGNESIUM TRISILICATE;SODIUM BICARBONATE	0	(0,0)	1	(0,0)	1	(0,0)
ALGINIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
ALGINIC ACID;ALUMINIUM HYDROXIDE GEL, DRIED;MAGNESIUM CARBONATE	1	(0,0)	0	(0,0)	1	(0,0)
ALMAGATE	1	(0,0)	0	(0,0)	1	(0,0)
ALUMINIUM HYDROXIDE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR ACID RELATED DISORDERS	**1.065**	**(49,5)**	**1.063**	**(49,4)**	**2.128**	**(49,5)**
ALUMINIUM HYDROXIDE;CALCIUM CARBONATE;MAGNESIUM CARBONATE;OXETACAINE	2	(0,1)	1	(0,0)	3	(0,1)
ALUMINIUM HYDROXIDE;CHONDROITIN SULFATE;HYALURONIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
ALUMINIUM HYDROXIDE;DICYCLOVERINE HYDROCHLORIDE;MAGNESIUM OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE	0	(0,0)	2	(0,1)	2	(0,0)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;OXETACAINE	2	(0,1)	0	(0,0)	2	(0,0)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE	1	(0,0)	3	(0,1)	4	(0,1)
ALUMINIUM PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
ALUMINUM MAGNESIUM HYDRATE	0	(0,0)	1	(0,0)	1	(0,0)
ANTACIDS WITH SODIUM BICARBONATE	1	(0,0)	2	(0,1)	3	(0,1)
ARTEMISIA ARGYI LEAF	2	(0,1)	2	(0,1)	4	(0,1)
BISMUTH SUBCITRATE POTASSIUM	0	(0,0)	2	(0,1)	2	(0,0)
BISMUTH SUBCITRATE POTASSIUM;METRONIDAZOLE;TETRACYCLINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
BISMUTH SUBSALICYLATE	0	(0,0)	2	(0,1)	2	(0,0)
CALCIUM CARBONATE	15	(0,7)	17	(0,8)	32	(0,7)
CALCIUM CARBONATE;CALCIUM LACTATE GLUCONATE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR ACID RELATED DISORDERS	**1.065**	**(49,5)**	**1.063**	**(49,4)**	**2.128**	**(49,5)**
CALCIUM CARBONATE;SODIUM ALGINATE;SODIUM BICARBONATE	2	(0,1)	0	(0,0)	2	(0,0)
CALCIUM;MAGNESIUM	1	(0,0)	1	(0,0)	2	(0,0)
CETRAXATE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CIMETIDINE	1	(0,0)	1	(0,0)	2	(0,0)
CITRIC ACID;SODIUM BICARBONATE;SODIUM CITRATE;TARTARIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
CITRIC ACID;SODIUM CITRATE ACID	1	(0,0)	0	(0,0)	1	(0,0)
DEXLANSOPRAZOLE	5	(0,2)	6	(0,3)	11	(0,3)
DEXRABEPRAZOLE SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
ECABET MONOSODIUM	2	(0,1)	2	(0,1)	4	(0,1)
ESOMEPRAZOLE	37	(1,7)	64	(3,0)	101	(2,3)
ESOMEPRAZOLE MAGNESIUM	43	(2,0)	40	(1,9)	83	(1,9)
ESOMEPRAZOLE SODIUM	2	(0,1)	3	(0,1)	5	(0,1)
ESOMEPRAZOLE STRONTIUM	0	(0,0)	2	(0,1)	2	(0,0)
EVODIA LEPTA;MURRAYA EXOTICA LEAF WITH TWIG;PAEONIA LACTIFLORA ROOT;PORIA COCOS SCLEROTIUM;REHMANNIA GLUTINOSA ROOT TUBER;SAUSSUREA COSTUS ROOT;SCUTELLARIA BAICALENSIS ROOT;ZANTHOXYLUM NITIDUM ROOT	1	(0,0)	0	(0,0)	1	(0,0)
FAMOTIDINE	45	(2,1)	43	(2,0)	88	(2,0)
GLYCYRRHIZA GLABRA	2	(0,1)	0	(0,0)	2	(0,0)
HYDROTALCITE	2	(0,1)	3	(0,1)	5	(0,1)
ILAPRAZOLE	2	(0,1)	3	(0,1)	5	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR ACID RELATED DISORDERS	**1.065**	**(49,5)**	**1.063**	**(49,4)**	**2.128**	**(49,5)**
IRSOGLADINE MALEATE	1	(0,0)	1	(0,0)	2	(0,0)
LAFUTIDINE	1	(0,0)	2	(0,1)	3	(0,1)
LANSOPRAZOLE	133	(6,2)	122	(5,7)	255	(5,9)
LEVOGLUTAMIDE;SODIUM GUALENATE	1	(0,0)	0	(0,0)	1	(0,0)
MAGNESIUM CARBONATE	2	(0,1)	4	(0,2)	6	(0,1)
MAGNESIUM HYDROXIDE	10	(0,5)	10	(0,5)	20	(0,5)
MAGNESIUM OXIDE	60	(2,8)	47	(2,2)	107	(2,5)
MAGNESIUM TRISILICATE	2	(0,1)	3	(0,1)	5	(0,1)
MISOPROSTOL	1	(0,0)	0	(0,0)	1	(0,0)
NIZATIDINE	3	(0,1)	0	(0,0)	3	(0,1)
OMEPRAZOLE	269	(12,5)	303	(14,1)	572	(13,3)
OMEPRAZOLE MAGNESIUM	0	(0,0)	1	(0,0)	1	(0,0)
OMEPRAZOLE SODIUM	4	(0,2)	3	(0,1)	7	(0,2)
OMEPRAZOLE;SODIUM BICARBONATE	1	(0,0)	0	(0,0)	1	(0,0)
PANTOPRAZOLE	229	(10,6)	230	(10,7)	459	(10,7)
PANTOPRAZOLE MAGNESIUM	1	(0,0)	0	(0,0)	1	(0,0)
PANTOPRAZOLE SODIUM SESQUIHYDRATE	195	(9,1)	163	(7,6)	358	(8,3)
PERIPLANETA AMERICANA	0	(0,0)	1	(0,0)	1	(0,0)
POTASSIUM CITRATE;SODIUM CITRATE DIHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
RABEPRAZOLE SODIUM	50	(2,3)	38	(1,8)	88	(2,0)
RANITIDINE	33	(1,5)	32	(1,5)	65	(1,5)
RANITIDINE HYDROCHLORIDE	7	(0,3)	11	(0,5)	18	(0,4)
RANITIDINE HYDROCHLORIDE;SUCRALFATE;TRIPOTASSIUM DICITRATOBISMUTHATE	0	(0,0)	1	(0,0)	1	(0,0)
REBAMIPIDE	6	(0,3)	18	(0,8)	24	(0,6)
SODIUM ALGINATE	1	(0,0)	1	(0,0)	2	(0,0)
SODIUM BICARBONATE	40	(1,9)	34	(1,6)	74	(1,7)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR ACID RELATED DISORDERS	**1.065**	**(49,5)**	**1.063**	**(49,4)**	**2.128**	**(49,5)**
SODIUM CARBONATE ANHYDROUS	0	(0,0)	1	(0,0)	1	(0,0)
SODIUM GUALENATE	1	(0,0)	0	(0,0)	1	(0,0)
SUCRALFATE	4	(0,2)	5	(0,2)	9	(0,2)
SULPIRIDE	0	(0,0)	1	(0,0)	1	(0,0)
TEPRENONE	0	(0,0)	4	(0,2)	4	(0,1)
VONOPRAZAN FUMARATE	10	(0,5)	8	(0,4)	18	(0,4)
DRUGS FOR CONSTIPATION	**285**	**(13,2)**	**263**	**(12,2)**	**548**	**(12,7)**
ALOE VERA;ANGELICA SINENSIS ROOT;ATRACTYLODES MACROCEPHALA;CISTANCHE DESERTICOLA;CITRUS AURANTIUM UNRIPE FRUIT;MORUS ALBA FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM ASCORBATE;SODIUM CHLORIDE;SODIUM SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
BISACODYL	18	(0,8)	22	(1,0)	40	(0,9)
BISACODYL;SENNOSIDE B	0	(0,0)	1	(0,0)	1	(0,0)
CARMELLOSE SODIUM	3	(0,1)	1	(0,0)	4	(0,1)
CASANTHRANOL;DOCUSATE SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
DOCUSATE CALCIUM	0	(0,0)	1	(0,0)	1	(0,0)
DOCUSATE SODIUM	25	(1,2)	25	(1,2)	50	(1,2)
DOCUSATE SODIUM;GLYCEROL	0	(0,0)	1	(0,0)	1	(0,0)
DOCUSATE SODIUM;SENNA ALEXANDRINA	3	(0,1)	0	(0,0)	3	(0,1)
DOCUSATE SODIUM;SENNOSIDE A+B	7	(0,3)	2	(0,1)	9	(0,2)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR CONSTIPATION	**285**	**(13,2)**	**263**	**(12,2)**	**548**	**(12,7)**
FICUS CARICA FRUIT;SENNA ALEXANDRINA FRUIT;SENNOSIDE B	1	(0,0)	0	(0,0)	1	(0,0)
GLYCEROL	8	(0,4)	3	(0,1)	11	(0,3)
INULIN	0	(0,0)	1	(0,0)	1	(0,0)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
LACTULOSE	35	(1,6)	33	(1,5)	68	(1,6)
LINACLOTIDE	0	(0,0)	4	(0,2)	4	(0,1)
LINUM USITATISSIMUM SEED	0	(0,0)	1	(0,0)	1	(0,0)
LUBIPROSTONE	3	(0,1)	2	(0,1)	5	(0,1)
MACROGOL	12	(0,6)	10	(0,5)	22	(0,5)
MACROGOL 3350	3	(0,1)	5	(0,2)	8	(0,2)
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	15	(0,7)	9	(0,4)	24	(0,6)
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE ANHYDROUS	1	(0,0)	0	(0,0)	1	(0,0)
MACROGOL 4000	0	(0,0)	3	(0,1)	3	(0,1)
MACROGOL;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	4	(0,2)	1	(0,0)	5	(0,1)
MACROGOL;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE ANHYDROUS	2	(0,1)	0	(0,0)	2	(0,0)
MAGNESIUM CARBONATE	2	(0,1)	4	(0,2)	6	(0,1)
MAGNESIUM CITRATE	6	(0,3)	5	(0,2)	11	(0,3)
MAGNESIUM HYDROXIDE	10	(0,5)	10	(0,5)	20	(0,5)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR CONSTIPATION	**285**	**(13,2)**	**263**	**(12,2)**	**548**	**(12,7)**
MAGNESIUM OXIDE	60	(2,8)	47	(2,2)	107	(2,5)
MAGNESIUM SULFATE	38	(1,8)	35	(1,6)	73	(1,7)
MANNITOL	1	(0,0)	0	(0,0)	1	(0,0)
NALOXONE HYDROCHLORIDE	2	(0,1)	4	(0,2)	6	(0,1)
PANAX GINSENG ROOT;ZANTHOXYLUM PIPERITUM PERICARP;ZINGIBER OFFICINALE PROCESSED RHIZOME	2	(0,1)	2	(0,1)	4	(0,1)
PARAFFIN	1	(0,0)	1	(0,0)	2	(0,0)
PARAFFIN, LIQUID	1	(0,0)	0	(0,0)	1	(0,0)
PLANTAGO OVATA	1	(0,0)	3	(0,1)	4	(0,1)
PLANTAGO OVATA HUSK	2	(0,1)	1	(0,0)	3	(0,1)
PLANTAGO OVATA SEED	1	(0,0)	0	(0,0)	1	(0,0)
PLANTAGO OVATA;SENNA SPP.	1	(0,0)	0	(0,0)	1	(0,0)
POLYCARBOPHIL CALCIUM	2	(0,1)	5	(0,2)	7	(0,2)
PRUCALOPRIDE SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
PSYLLIUM HYDROPHILIC MUCILLOID	0	(0,0)	1	(0,0)	1	(0,0)
REHMANNIA GLUTINOSA	1	(0,0)	0	(0,0)	1	(0,0)
RHEUM PALMATUM	1	(0,0)	1	(0,0)	2	(0,0)
RICINUS COMMUNIS OIL	0	(0,0)	1	(0,0)	1	(0,0)
SENNA ALEXANDRINA	7	(0,3)	12	(0,6)	19	(0,4)
SENNA ALEXANDRINA EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
SENNOSIDE A+B	48	(2,2)	37	(1,7)	85	(2,0)
SENNOSIDE A+B CALCIUM	4	(0,2)	7	(0,3)	11	(0,3)
SODIUM BICARBONATE;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM CHLORIDE	44	(2,0)	49	(2,3)	93	(2,2)
SODIUM CITRATE;SODIUM LAURYL SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
SODIUM PHOSPHATE DIBASIC	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR CONSTIPATION	**285**	**(13,2)**	**263**	**(12,2)**	**548**	**(12,7)**
SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC	2	(0,1)	1	(0,0)	3	(0,1)
SODIUM PHOSPHATE;SODIUM PHOSPHATE DIBASIC	0	(0,0)	1	(0,0)	1	(0,0)
SODIUM PICOSULFATE	8	(0,4)	6	(0,3)	14	(0,3)
SORBITOL	0	(0,0)	1	(0,0)	1	(0,0)
STERCULIA URENS	1	(0,0)	0	(0,0)	1	(0,0)
TARAXACUM OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	**90**	**(4,2)**	**89**	**(4,1)**	**179**	**(4,2)**
ALIZAPRIDE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ALVERINE CITRATE;SIMETICONE	2	(0,1)	0	(0,0)	2	(0,0)
ATROPINE	1	(0,0)	0	(0,0)	1	(0,0)
ATROPINE SULFATE	1	(0,0)	1	(0,0)	2	(0,0)
BENDAZOL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CARPRONIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CHLORDIAZEPOXIDE HYDROCHLORIDE;CLIDINIUM BROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
CIMETROPIUM BROMIDE	1	(0,0)	1	(0,0)	2	(0,0)
CINITAPRIDE TARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
CINNAMOMUM VERUM	1	(0,0)	0	(0,0)	1	(0,0)
CLEBOPRIDE MALATE;SIMETICONE	1	(0,0)	1	(0,0)	2	(0,0)
CORYDALIS YANHUSUO TUBER;IPOMOEA NIL SEED	0	(0,0)	1	(0,0)	1	(0,0)
CURCUMA LONGA	2	(0,1)	0	(0,0)	2	(0,0)
DEXPANTHENOL	0	(0,0)	1	(0,0)	1	(0,0)
DICYCLOVERINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
DIMETICONE	2	(0,1)	7	(0,3)	9	(0,2)
DOMPERIDONE	9	(0,4)	4	(0,2)	13	(0,3)
DROTAVERINE	1	(0,0)	1	(0,0)	2	(0,0)
DROTAVERINE HYDROCHLORIDE	4	(0,2)	0	(0,0)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	**90**	**(4,2)**	**89**	**(4,1)**	**179**	**(4,2)**
FENPIVERINIUM BROMIDE;METAMIZOLE SODIUM;PITOFENONE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
GLYCOPYRRONIUM	1	(0,0)	2	(0,1)	3	(0,1)
GLYCOPYRRONIUM BROMIDE	5	(0,2)	5	(0,2)	10	(0,2)
GLYCYRRHIZA GLABRA	2	(0,1)	0	(0,0)	2	(0,0)
GLYCYRRHIZA URALENSIS	1	(0,0)	0	(0,0)	1	(0,0)
HYOSCINE	1	(0,0)	0	(0,0)	1	(0,0)
HYOSCINE BUTYLBROMIDE	6	(0,3)	6	(0,3)	12	(0,3)
HYOSCINE BUTYLBROMIDE;PARACETAMOL	1	(0,0)	0	(0,0)	1	(0,0)
ITOPRIDE	1	(0,0)	0	(0,0)	1	(0,0)
ITOPRIDE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
LEVOSULPIRIDE	0	(0,0)	2	(0,1)	2	(0,0)
MEBEVERINE	0	(0,0)	1	(0,0)	1	(0,0)
MEBEVERINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
METOCLOPRAMIDE	10	(0,5)	21	(1,0)	31	(0,7)
METOCLOPRAMIDE HYDROCHLORIDE	18	(0,8)	18	(0,8)	36	(0,8)
MOSAPRIDE	2	(0,1)	4	(0,2)	6	(0,1)
MOSAPRIDE CITRATE	9	(0,4)	11	(0,5)	20	(0,5)
OTILONIUM BROMIDE	1	(0,0)	0	(0,0)	1	(0,0)
PAPAVERINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
PHLOROGLUCINOL	0	(0,0)	1	(0,0)	1	(0,0)
PHLOROGLUCINOL;TRIMETHYLPHLOROGLUCINOL	1	(0,0)	0	(0,0)	1	(0,0)
PIPOXOLAN HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
SIMETICONE	5	(0,2)	3	(0,1)	8	(0,2)
SYZYGIUM AROMATICUM	1	(0,0)	0	(0,0)	1	(0,0)
TRIMEBUTINE	0	(0,0)	1	(0,0)	1	(0,0)
TRIMEBUTINE MALEATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	**90**	**(4,2)**	**89**	**(4,1)**	**179**	**(4,2)**
TRIMETHYLPHLOROGLUCINOL	0	(0,0)	1	(0,0)	1	(0,0)
TROSPIUM	1	(0,0)	0	(0,0)	1	(0,0)
TROSPIUM CHLORIDE	1	(0,0)	4	(0,2)	5	(0,1)
VALERIANA OFFICINALIS	2	(0,1)	0	(0,0)	2	(0,0)
ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
DRUGS USED IN DIABETES	**890**	**(41,4)**	**817**	**(38,0)**	**1.707**	**(39,7)**
ACARBOSE	36	(1,7)	25	(1,2)	61	(1,4)
ALOGLIPTIN	2	(0,1)	0	(0,0)	2	(0,0)
ALOGLIPTIN BENZOATE	3	(0,1)	5	(0,2)	8	(0,2)
ALOGLIPTIN BENZOATE;METFORMIN HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
ANAGLIPTIN	1	(0,0)	1	(0,0)	2	(0,0)
CANAGLIFLOZIN	5	(0,2)	4	(0,2)	9	(0,2)
CANAGLIFLOZIN HEMIHYDRATE;TENELIGLIPTIN HYDROBROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
CHLORPROPAMIDE;PHENFORMIN	1	(0,0)	0	(0,0)	1	(0,0)
CINNAMOMUM VERUM	1	(0,0)	0	(0,0)	1	(0,0)
DAPAGLIFLOZIN	5	(0,2)	6	(0,3)	11	(0,3)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	4	(0,2)	7	(0,3)	11	(0,3)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE;METFORMIN HYDROCHLORIDE	3	(0,1)	0	(0,0)	3	(0,1)
DULAGLUTIDE	8	(0,4)	3	(0,1)	11	(0,3)
EMPAGLIFLOZIN	43	(2,0)	39	(1,8)	82	(1,9)
EMPAGLIFLOZIN;LINAGLIPTIN	1	(0,0)	0	(0,0)	1	(0,0)
EMPAGLIFLOZIN;METFORMIN HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
EPALRESTAT	1	(0,0)	2	(0,1)	3	(0,1)
EVOGLIPTIN TARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
EXENATIDE	6	(0,3)	2	(0,1)	8	(0,2)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS USED IN DIABETES	**890**	**(41,4)**	**817**	**(38,0)**	**1.707**	**(39,7)**
GEMIGLIPTIN TARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
GEMIGLIPTIN TARTRATE;METFORMIN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
GLIBENCLAMIDE	20	(0,9)	15	(0,7)	35	(0,8)
GLIBENCLAMIDE;METFORMIN HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
GLICLAZIDE	92	(4,3)	84	(3,9)	176	(4,1)
GLICLAZIDE;METFORMIN HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
GLIMEPIRIDE	56	(2,6)	50	(2,3)	106	(2,5)
GLIMEPIRIDE;METFORMIN HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
GLIMEPIRIDE;PIOGLITAZONE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
GLIPIZIDE	33	(1,5)	22	(1,0)	55	(1,3)
GLIPIZIDE;METFORMIN HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
GLIQUIDONE	9	(0,4)	5	(0,2)	14	(0,3)
INSULIN	51	(2,4)	53	(2,5)	104	(2,4)
INSULIN ASPART	70	(3,3)	75	(3,5)	145	(3,4)
INSULIN ASPART PROTAMINE	0	(0,0)	1	(0,0)	1	(0,0)
INSULIN ASPART;INSULIN ASPART PROTAMINE	3	(0,1)	0	(0,0)	3	(0,1)
INSULIN ASPART;INSULIN ASPART PROTAMINE (CRYSTALLINE)	24	(1,1)	10	(0,5)	34	(0,8)
INSULIN ASPART;INSULIN DEGLUDEC	3	(0,1)	4	(0,2)	7	(0,2)
INSULIN BOVINE	1	(0,0)	1	(0,0)	2	(0,0)
INSULIN BOVINE;INSULIN PORCINE	0	(0,0)	1	(0,0)	1	(0,0)
INSULIN DEGLUDEC	18	(0,8)	10	(0,5)	28	(0,7)
INSULIN DETEMIR	29	(1,3)	40	(1,9)	69	(1,6)
INSULIN GLARGINE	168	(7,8)	145	(6,7)	313	(7,3)
INSULIN GLULISINE	27	(1,3)	37	(1,7)	64	(1,5)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS USED IN DIABETES	**890**	**(41,4)**	**817**	**(38,0)**	**1.707**	**(39,7)**
INSULIN HUMAN	59	(2,7)	49	(2,3)	108	(2,5)
INSULIN HUMAN INJECTION, ISOPHANE	56	(2,6)	39	(1,8)	95	(2,2)
INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE	46	(2,1)	34	(1,6)	80	(1,9)
INSULIN ISOPHANE PORCINE	5	(0,2)	3	(0,1)	8	(0,2)
INSULIN LISPRO	46	(2,1)	48	(2,2)	94	(2,2)
INSULIN LISPRO PROTAMINE SUSPENSION	0	(0,0)	1	(0,0)	1	(0,0)
INSULIN LISPRO;INSULIN LISPRO PROTAMINE SUSPENSION	8	(0,4)	7	(0,3)	15	(0,3)
INSULIN ZINC PROTAMINE INJECTION	0	(0,0)	1	(0,0)	1	(0,0)
IPRAGLIFLOZIN L-PROLINE	3	(0,1)	3	(0,1)	6	(0,1)
IPRAGLIFLOZIN L-PROLINE;SITAGLIPTIN PHOSPHATE MONOHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
ISOPHANE INSULIN	2	(0,1)	0	(0,0)	2	(0,0)
LINAGLIPTIN	66	(3,1)	48	(2,2)	114	(2,6)
LINAGLIPTIN;METFORMIN HYDROCHLORIDE	6	(0,3)	5	(0,2)	11	(0,3)
LIRAGLUTIDE	13	(0,6)	11	(0,5)	24	(0,6)
LIXISENATIDE	0	(0,0)	1	(0,0)	1	(0,0)
METFORMIN	265	(12,3)	265	(12,3)	530	(12,3)
METFORMIN EMBONATE	0	(0,0)	1	(0,0)	1	(0,0)
METFORMIN HYDROCHLORIDE	135	(6,3)	131	(6,1)	266	(6,2)
METFORMIN HYDROCHLORIDE;SITAGLIPTIN	2	(0,1)	4	(0,2)	6	(0,1)
METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE	2	(0,1)	1	(0,0)	3	(0,1)
METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE	9	(0,4)	6	(0,3)	15	(0,3)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS USED IN DIABETES	**890**	**(41,4)**	**817**	**(38,0)**	**1.707**	**(39,7)**
METFORMIN HYDROCHLORIDE;VILDAGLIPTIN	10	(0,5)	8	(0,4)	18	(0,4)
MIGLITOL	0	(0,0)	3	(0,1)	3	(0,1)
MITIGLINIDE CALCIUM	3	(0,1)	2	(0,1)	5	(0,1)
MITIGLINIDE CALCIUM;VOGLIBOSE	2	(0,1)	0	(0,0)	2	(0,0)
NATEGLINIDE	1	(0,0)	0	(0,0)	1	(0,0)
OPHIOPOGON JAPONICUS	1	(0,0)	0	(0,0)	1	(0,0)
PIOGLITAZONE	1	(0,0)	2	(0,1)	3	(0,1)
PIOGLITAZONE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
PLATYCODON GRANDIFLORUS	1	(0,0)	0	(0,0)	1	(0,0)
REHMANNIA GLUTINOSA	1	(0,0)	0	(0,0)	1	(0,0)
REPAGLINIDE	30	(1,4)	27	(1,3)	57	(1,3)
SAXAGLIPTIN	1	(0,0)	1	(0,0)	2	(0,0)
SAXAGLIPTIN HYDROCHLORIDE	4	(0,2)	4	(0,2)	8	(0,2)
SITAGLIPTIN	26	(1,2)	24	(1,1)	50	(1,2)
SITAGLIPTIN PHOSPHATE	41	(1,9)	33	(1,5)	74	(1,7)
SITAGLIPTIN PHOSPHATE MONOHYDRATE	3	(0,1)	2	(0,1)	5	(0,1)
TENELIGLIPTIN HYDROBROMIDE	13	(0,6)	11	(0,5)	24	(0,6)
TOFOGLIFLOZIN	1	(0,0)	1	(0,0)	2	(0,0)
TOLBUTAMIDE	1	(0,0)	1	(0,0)	2	(0,0)
TRELAGLIPTIN SUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
VILDAGLIPTIN	12	(0,6)	19	(0,9)	31	(0,7)
VOGLIBOSE	8	(0,4)	8	(0,4)	16	(0,4)
MINERAL SUPPLEMENTS	**658**	**(30,6)**	**634**	**(29,5)**	**1.292**	**(30,0)**
ASCORBIC ACID;ASPARTIC ACID;POTASSIUM	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;ASPARTIC ACID;POTASSIUM BICARBONATE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;POTASSIUM BICARBONATE	5	(0,2)	0	(0,0)	5	(0,1)
ASPARTATE CALCIUM	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
MINERAL SUPPLEMENTS	**658**	**(30,6)**	**634**	**(29,5)**	**1.292**	**(30,0)**
BETAINE HYDROCHLORIDE;POTASSIUM BICARBONATE;POTASSIUM CHLORIDE	1	(0,0)	3	(0,1)	4	(0,1)
CALCIUM	15	(0,7)	16	(0,7)	31	(0,7)
CALCIUM ACETATE	1	(0,0)	2	(0,1)	3	(0,1)
CALCIUM CARBONATE	15	(0,7)	17	(0,8)	32	(0,7)
CALCIUM CARBONATE;CALCIUM LACTATE GLUCONATE	1	(0,0)	1	(0,0)	2	(0,0)
CALCIUM CARBONATE;COLECALCIFEROL	6	(0,3)	20	(0,9)	26	(0,6)
CALCIUM CARBONATE;ERGOCALCIFEROL	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM CARBONATE;MAGNESIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CARBONATE;VITAMIN D NOS	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CHLORIDE	2	(0,1)	4	(0,2)	6	(0,1)
CALCIUM CHLORIDE;GLUCOSE	2	(0,1)	3	(0,1)	5	(0,1)
CALCIUM CITRATE	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM CITRATE;COLECALCIFEROL	1	(0,0)	1	(0,0)	2	(0,0)
CALCIUM GLUCONATE	4	(0,2)	7	(0,3)	11	(0,3)
CALCIUM HYDROGENCARBONATE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM LACTATE	1	(0,0)	1	(0,0)	2	(0,0)
CALCIUM PHOSPHATE	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM;COLECALCIFEROL	5	(0,2)	1	(0,0)	6	(0,1)
CALCIUM;MAGNESIUM	1	(0,0)	1	(0,0)	2	(0,0)
CALCIUM;MAGNESIUM;ZINC	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM;VITAMIN D NOS	3	(0,1)	1	(0,0)	4	(0,1)
CITRIC ACID;POTASSIUM BICARBONATE;POTASSIUM CITRATE	4	(0,2)	4	(0,2)	8	(0,2)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
MINERAL SUPPLEMENTS	**658**	**(30,6)**	**634**	**(29,5)**	**1.292**	**(30,0)**
MAGNESIUM	31	(1,4)	34	(1,6)	65	(1,5)
MAGNESIUM ASPARTATE	4	(0,2)	3	(0,1)	7	(0,2)
MAGNESIUM ASPARTATE DIHYDRATE	0	(0,0)	1	(0,0)	1	(0,0)
MAGNESIUM ASPARTATE HYDROCHLORIDE	2	(0,1)	4	(0,2)	6	(0,1)
MAGNESIUM ASPARTATE;POTASSIUM ASPARTATE	16	(0,7)	17	(0,8)	33	(0,8)
MAGNESIUM CARBONATE	2	(0,1)	4	(0,2)	6	(0,1)
MAGNESIUM CARBONATE;MAGNESIUM OXIDE	6	(0,3)	4	(0,2)	10	(0,2)
MAGNESIUM CHLORIDE	4	(0,2)	1	(0,0)	5	(0,1)
MAGNESIUM CITRATE	6	(0,3)	5	(0,2)	11	(0,3)
MAGNESIUM CITRATE;MAGNESIUM GLUTAMATE	1	(0,0)	0	(0,0)	1	(0,0)
MAGNESIUM GLUCONATE	0	(0,0)	3	(0,1)	3	(0,1)
MAGNESIUM GLYCINATE;PYRIDOXINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
MAGNESIUM HYDROXIDE	10	(0,5)	10	(0,5)	20	(0,5)
MAGNESIUM LACTATE	2	(0,1)	4	(0,2)	6	(0,1)
MAGNESIUM LACTATE;PYRIDOXINE HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
MAGNESIUM OXIDE	60	(2,8)	47	(2,2)	107	(2,5)
MAGNESIUM PIDOLATE	2	(0,1)	0	(0,0)	2	(0,0)
MAGNESIUM SULFATE	38	(1,8)	35	(1,6)	73	(1,7)
MINERALS NOS;VITAMINS NOS	4	(0,2)	9	(0,4)	13	(0,3)
POTASSIUM	56	(2,6)	50	(2,3)	106	(2,5)
POTASSIUM ASPARTATE	5	(0,2)	3	(0,1)	8	(0,2)
POTASSIUM BICARBONATE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
MINERAL SUPPLEMENTS	**658**	**(30,6)**	**634**	**(29,5)**	**1.292**	**(30,0)**
POTASSIUM BICARBONATE;POTASSIUM CARBONATE;POTASSIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM BICARBONATE;POTASSIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM BICARBONATE;POTASSIUM CITRATE	4	(0,2)	7	(0,3)	11	(0,3)
POTASSIUM BICARBONATE;POTASSIUM CITRATE MONOHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM CHLORIDE	427	(19,8)	399	(18,5)	826	(19,2)
POTASSIUM CITRATE	15	(0,7)	11	(0,5)	26	(0,6)
POTASSIUM GLUCONATE	14	(0,7)	18	(0,8)	32	(0,7)
SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM CHLORIDE	44	(2,0)	49	(2,3)	93	(2,2)
SODIUM FLUORIDE	0	(0,0)	1	(0,0)	1	(0,0)
SODIUM PHOSPHATE DIBASIC	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC	2	(0,1)	1	(0,0)	3	(0,1)
SODIUM PHOSPHATE;SODIUM PHOSPHATE DIBASIC	0	(0,0)	1	(0,0)	1	(0,0)
ZINC	0	(0,0)	1	(0,0)	1	(0,0)
ZINC SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	**128**	**(5,9)**	**134**	**(6,2)**	**262**	**(6,1)**
ACETYLCYSTEINE	35	(1,6)	48	(2,2)	83	(1,9)
ADEMETIONINE	0	(0,0)	1	(0,0)	1	(0,0)
ADEMETIONINE 1,4-BUTANEDISULFONATE	2	(0,1)	0	(0,0)	2	(0,0)
ADENOSINE;COENZYME A;NADIDE	6	(0,3)	1	(0,0)	7	(0,2)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	**128**	**(5,9)**	**134**	**(6,2)**	**262**	**(6,1)**
AMINO ACIDS NOS	1	(0,0)	1	(0,0)	2	(0,0)
ARGININE	1	(0,0)	0	(0,0)	1	(0,0)
CARNITINE	2	(0,1)	0	(0,0)	2	(0,0)
CLOSTRIDIUM BUTYRICUM	4	(0,2)	4	(0,2)	8	(0,2)
CYSTEINE	1	(0,0)	0	(0,0)	1	(0,0)
FUCOIDAN	3	(0,1)	0	(0,0)	3	(0,1)
GLUCUROLACTONE	1	(0,0)	0	(0,0)	1	(0,0)
GLYCINE	0	(0,0)	1	(0,0)	1	(0,0)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
LEVOCARNITINE	9	(0,4)	7	(0,3)	16	(0,4)
LEVOGLUTAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
OXIDIZED STARCH	1	(0,0)	0	(0,0)	1	(0,0)
PROBIOTICS NOS	3	(0,1)	1	(0,0)	4	(0,1)
QUERCETIN	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM BICARBONATE	40	(1,9)	34	(1,6)	74	(1,7)
SUCRALFATE	4	(0,2)	5	(0,2)	9	(0,2)
THIOCTIC ACID	4	(0,2)	9	(0,4)	13	(0,3)
UBIDECARENONE	25	(1,2)	31	(1,4)	56	(1,3)
ZINC	0	(0,0)	1	(0,0)	1	(0,0)
STOMATOLOGICAL PREPARATIONS	**1.190**	**(55,3)**	**1.112**	**(51,7)**	**2.302**	**(53,5)**
ACETYLSALICYLIC ACID	1.037	(48,2)	978	(45,5)	2.015	(46,8)
AMPHOTERICIN B	1	(0,0)	1	(0,0)	2	(0,0)
BENZYDAMINE HYDROCHLORIDE;CHLORHEXIDINE GLUCONATE	0	(0,0)	1	(0,0)	1	(0,0)
BORIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
CARBOMER	1	(0,0)	1	(0,0)	2	(0,0)
CETYLPYRIDINIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CHLORAMPHENICOL	1	(0,0)	3	(0,1)	4	(0,1)
CHLORHEXIDINE GLUCONATE	0	(0,0)	3	(0,1)	3	(0,1)
CHOLINE SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)
CLOBETASOL PROPIONATE	4	(0,2)	8	(0,4)	12	(0,3)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
STOMATOLOGICAL PREPARATIONS	**1.190**	**(55,3)**	**1.112**	**(51,7)**	**2.302**	**(53,5)**
CLOTRIMAZOLE	1	(0,0)	3	(0,1)	4	(0,1)
DEXAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
DEXAMETHASONE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM PHOSPHATE	3	(0,1)	6	(0,3)	9	(0,2)
DICLOFENAC	7	(0,3)	11	(0,5)	18	(0,4)
DICLOFENAC SODIUM	14	(0,7)	7	(0,3)	21	(0,5)
DIMETICONE	2	(0,1)	7	(0,3)	9	(0,2)
DOMIPHEN BROMIDE	0	(0,0)	2	(0,1)	2	(0,0)
DOXYCYCLINE	6	(0,3)	3	(0,1)	9	(0,2)
DOXYCYCLINE HYCLATE	1	(0,0)	0	(0,0)	1	(0,0)
ELECTROLYTES NOS	1	(0,0)	7	(0,3)	8	(0,2)
EPINEPHRINE	0	(0,0)	2	(0,1)	2	(0,0)
ERIOBOTRYA JAPONICA	0	(0,0)	1	(0,0)	1	(0,0)
FLURBIPROFEN	4	(0,2)	2	(0,1)	6	(0,1)
FLURBIPROFEN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
GLYCEROL	8	(0,4)	3	(0,1)	11	(0,3)
HYALURONATE SODIUM	9	(0,4)	7	(0,3)	16	(0,4)
HYDROCORTISONE	5	(0,2)	8	(0,4)	13	(0,3)
HYDROCORTISONE ACETATE	2	(0,1)	3	(0,1)	5	(0,1)
HYDROCORTISONE PROBUTAT	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE SODIUM SUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
KETOPROFEN	10	(0,5)	19	(0,9)	29	(0,7)
LIDOCAINE	16	(0,7)	19	(0,9)	35	(0,8)
LIDOCAINE HYDROCHLORIDE	14	(0,7)	8	(0,4)	22	(0,5)
LIDOCAINE;PRILOCAINE	0	(0,0)	1	(0,0)	1	(0,0)
METRONIDAZOLE	4	(0,2)	2	(0,1)	6	(0,1)
MICONAZOLE	2	(0,1)	0	(0,0)	2	(0,0)
MICONAZOLE NITRATE	1	(0,0)	3	(0,1)	4	(0,1)
MINOCYCLINE	0	(0,0)	1	(0,0)	1	(0,0)
MINOCYCLINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
NAPROXEN	0	(0,0)	5	(0,2)	5	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
STOMATOLOGICAL PREPARATIONS	**1.190**	**(55,3)**	**1.112**	**(51,7)**	**2.302**	**(53,5)**
NEOMYCIN	0	(0,0)	1	(0,0)	1	(0,0)
NIMESULIDE	1	(0,0)	0	(0,0)	1	(0,0)
NYSTATIN	1	(0,0)	4	(0,2)	5	(0,1)
OPHIOPOGON JAPONICUS	1	(0,0)	0	(0,0)	1	(0,0)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	0	(0,0)	1	(0,0)	1	(0,0)
OXYGEN	6	(0,3)	6	(0,3)	12	(0,3)
POTASSIUM	56	(2,6)	50	(2,3)	106	(2,5)
POTASSIUM CHLORATE	4	(0,2)	0	(0,0)	4	(0,1)
POVIDONE-IODINE	3	(0,1)	1	(0,0)	4	(0,1)
PREDNISOLONE	28	(1,3)	19	(0,9)	47	(1,1)
PREDNISOLONE ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
RIFAMYCIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
SALICYLIC ACID	0	(0,0)	2	(0,1)	2	(0,0)
SODIUM BICARBONATE	40	(1,9)	34	(1,6)	74	(1,7)
SODIUM CHLORIDE	44	(2,0)	49	(2,3)	93	(2,2)
SODIUM FLUORIDE	0	(0,0)	1	(0,0)	1	(0,0)
SUCRALFATE	4	(0,2)	5	(0,2)	9	(0,2)
SYZYGIUM AROMATICUM	1	(0,0)	0	(0,0)	1	(0,0)
TETRACYCLINE	0	(0,0)	1	(0,0)	1	(0,0)
TETRACYCLINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
TRANEXAMIC ACID	4	(0,2)	2	(0,1)	6	(0,1)
TRIAMCINOLONE	0	(0,0)	6	(0,3)	6	(0,1)
TRIAMCINOLONE ACETONIDE	1	(0,0)	4	(0,2)	5	(0,1)
UREA HYDROGEN PEROXIDE	0	(0,0)	1	(0,0)	1	(0,0)
ZINC	0	(0,0)	1	(0,0)	1	(0,0)
TONICS	**12**	**(0,6)**	**19**	**(0,9)**	**31**	**(0,7)**
ALLIUM MACROSTEMON	1	(0,0)	0	(0,0)	1	(0,0)
ALLIUM SATIVUM	1	(0,0)	3	(0,1)	4	(0,1)
ASTRAGALUS PROPINQUUS	1	(0,0)	1	(0,0)	2	(0,0)
CURCUMA LONGA	2	(0,1)	0	(0,0)	2	(0,0)
GLYCYRRHIZA URALENSIS	1	(0,0)	0	(0,0)	1	(0,0)
MINERALS NOS;VITAMINS NOS	4	(0,2)	9	(0,4)	13	(0,3)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
TONICS	**12**	**(0,6)**	**19**	**(0,9)**	**31**	**(0,7)**
OPHIOPOGON JAPONICUS	1	(0,0)	0	(0,0)	1	(0,0)
OPHIOPOGON JAPONICUS ROOT TUBER;PANAX GINSENG ROOT;SCHISANDRA CHINENSIS FRUIT	2	(0,1)	3	(0,1)	5	(0,1)
TOCOPHEROL	3	(0,1)	5	(0,2)	8	(0,2)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
VITAMINS	**238**	**(11,1)**	**242**	**(11,3)**	**480**	**(11,2)**
ALFACALCIDOL	12	(0,6)	7	(0,3)	19	(0,4)
ASCORBIC ACID	19	(0,9)	16	(0,7)	35	(0,8)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CHROMIC CHLORIDE;COLECALCIFEROL;COPPER SULFATE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;LYCOPENE;MAGNESIUM OXIDE;MANGANESE SULFATE;NICOTINAMIDE;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL ACETATE;RIBOFLAVIN;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**238**	**(11,1)**	**242**	**(11,3)**	**480**	**(11,2)**
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM PANTOTHENATE;CHROMIC CHLORIDE;CHROMIUM;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM;CHROMIUM;COLECALCIFEROL;COPPER;FOLIC ACID;IODINE;IRON;LYCOPENE;MAGNESIUM;MANGANESE;NICOTINAMIDE;PANTOTHENIC ACID;PHOSPHORUS;PHYTOMENADIONE;POTASSIUM;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SELENIUM;VITAMIN B1 NOS;VITAMIN B12 NOS;VITAMIN E NOS;XANTOFYL;ZINC	0	(0,0)	2	(0,1)	2	(0,0)
ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;SODIUM SELENATE;TOCOPHERYL ACETATE;XANTOFYL;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;TOCOPHERYL ACETATE;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**238**	**(11,1)**	**242**	**(11,3)**	**480**	**(11,2)**
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE;COPPER SULFATE;CYANOCOBALAMIN;DL-ALPHA TOCOPHERYL ACETATE;ERGOCALCIFEROL;IRON; MAGNESIUM OXIDE;MAGNESIUM PHOSPHATE;MAGNESIUM STEARATE;MANGANESE SULFATE;MOLYBDENUM;NICOTINAMIDE;PHOSPHORUS;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;ZINC SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**238**	**(11,1)**	**242**	**(11,3)**	**480**	**(11,2)**
ASCORBIC ACID;BIOTIN;CALCIUM;CHROMIUM;COPPER;FOLIC ACID;IODINE;LYCOPENE;MAGNESIUM;MANGANESE;MENADIONE;MOLYBDENUM;NICOTINIC ACID;PANTOTHENIC ACID;PHOSPHORUS;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;SELENIUM;THIAMINE;TOCOPHEROL;VITAMIN B12 NOS;VITAMIN D NOS;XANTOFYL;ZEAXANTHIN;ZINC	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;BIOTIN;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;FURSULTIAMINE HYDROCHLORIDE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN TETRABUTYRATE;SELENIUM;TOCOPHERYL ACETATE;ZINC OXIDE	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;CALCIUM PANTOTHENATE	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;CALCIUM PANTOTHENATE;CHROMIUM;COLECALCIFEROL;COPPER;FOLIC ACID;IODINE;IRON;MAGNESIUM;MANGANESE;MOLYBDENUM;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SELENIUM;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE;ZINC	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**238**	**(11,1)**	**242**	**(11,3)**	**480**	**(11,2)**
ASCORBIC ACID;CALCIUM PANTOTHENATE;COPPER;CYANOCOBALAMIN;ERGOCALCIFEROL;IODINE;IRON;MAGNESIUM;MANGANESE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;TOCOPHEROL;ZINC	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;CUPRIC OXIDE;RETINOL;TOCOPHERYL ACETATE;ZINC OXIDE	3	(0,1)	1	(0,0)	4	(0,1)
ASCORBIC ACID;CUPRIC OXIDE;TOCOPHERYL ACID SUCCINATE;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;FERROUS SULFATE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
ASCORBIC ACID;FOLIC ACID;VITAMIN B COMPLEX	2	(0,1)	0	(0,0)	2	(0,0)
ASCORBIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**238**	**(11,1)**	**242**	**(11,3)**	**480**	**(11,2)**
ASCORBIC ACID;VITAMIN B COMPLEX	2	(0,1)	0	(0,0)	2	(0,0)
BENFOTIAMINE;CYANOCOBALAMIN	1	(0,0)	0	(0,0)	1	(0,0)
BENFOTIAMINE;CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
BENFOTIAMINE;PYRIDOXINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
BENMETIAMINE;CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
BIOTIN	5	(0,2)	1	(0,0)	6	(0,1)
CALCIFEDIOL	5	(0,2)	7	(0,3)	12	(0,3)
CALCITRIOL	19	(0,9)	17	(0,8)	36	(0,8)
CALCIUM CARBONATE;VITAMIN D NOS	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM MEFOLINATE;PYRIDOXINE HYDROCHLORIDE;VITAMIN B12 NOS	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM PANTOTHENATE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
COD-LIVER OIL	0	(0,0)	1	(0,0)	1	(0,0)
COLECALCIFEROL	69	(3,2)	63	(2,9)	132	(3,1)
COLECALCIFEROL;FISH OIL	0	(0,0)	1	(0,0)	1	(0,0)
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	7	(0,3)	7	(0,3)	14	(0,3)
CYANOCOBALAMIN;PYRIDOXINE ;THIAMINE	1	(0,0)	6	(0,3)	7	(0,2)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**238**	**(11,1)**	**242**	**(11,3)**	**480**	**(11,2)**
CYANOCOBALAMIN;THIAMINE	1	(0,0)	0	(0,0)	1	(0,0)
DEXPANTHENOL	0	(0,0)	1	(0,0)	1	(0,0)
DEXPANTHENOL;NICOTINAMIDE; PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN SODIUM PHOSPHATE;THIAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ELDECALCITOL	3	(0,1)	1	(0,0)	4	(0,1)
ERGOCALCIFEROL	4	(0,2)	7	(0,3)	11	(0,3)
FOLIC ACID;PYRIDOXINE;VITAMIN B12 NOS	0	(0,0)	1	(0,0)	1	(0,0)
FOLIC ACID;VITAMIN B COMPLEX	1	(0,0)	0	(0,0)	1	(0,0)
FURSULTIAMINE	1	(0,0)	0	(0,0)	1	(0,0)
FURSULTIAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
FURSULTIAMINE;RIBOFLAVIN	1	(0,0)	0	(0,0)	1	(0,0)
MAGNESIUM GLYCINATE;PYRIDOXINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
MAGNESIUM LACTATE;PYRIDOXINE HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
MINERALS NOS;VITAMINS NOS	4	(0,2)	9	(0,4)	13	(0,3)
MINERALS NOS;VITAMINS NOS;XANTOFYL	1	(0,0)	0	(0,0)	1	(0,0)
NICOTINAMIDE	0	(0,0)	1	(0,0)	1	(0,0)
NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	1	(0,0)	0	(0,0)	1	(0,0)
NICOTINIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
PANTETHINE	1	(0,0)	0	(0,0)	1	(0,0)
PROBIOTICS NOS;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)
PYRIDOXINE	9	(0,4)	14	(0,7)	23	(0,5)
PYRIDOXINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**238**	**(11,1)**	**242**	**(11,3)**	**480**	**(11,2)**
PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PYRIDOXINE;THIAMINE	1	(0,0)	0	(0,0)	1	(0,0)
RETINOL	1	(0,0)	0	(0,0)	1	(0,0)
RIBOFLAVIN	0	(0,0)	2	(0,1)	2	(0,0)
SHARK-LIVER OIL	0	(0,0)	1	(0,0)	1	(0,0)
THIAMINE	29	(1,3)	32	(1,5)	61	(1,4)
THIAMINE HYDROCHLORIDE	4	(0,2)	2	(0,1)	6	(0,1)
THIAMINE MONONITRATE	1	(0,0)	2	(0,1)	3	(0,1)
TOCOPHEROL	3	(0,1)	5	(0,2)	8	(0,2)
TOCOPHERYL ACETATE	2	(0,1)	2	(0,1)	4	(0,1)
VITAMIN B COMPLEX	8	(0,4)	13	(0,6)	21	(0,5)
VITAMIN B NOS	4	(0,2)	1	(0,0)	5	(0,1)
VITAMIN D NOS	32	(1,5)	27	(1,3)	59	(1,4)
VITAMINS NOS	36	(1,7)	34	(1,6)	70	(1,6)
VITAMINS, OTHER COMBINATIONS	1	(0,0)	0	(0,0)	1	(0,0)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIBACTERIALS FOR SYSTEMIC USE	**218**	**(10,1)**	**241**	**(11,2)**	**459**	**(10,7)**
ALLIUM SATIVUM	1	(0,0)	3	(0,1)	4	(0,1)
AMIKACIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
AMOXICILLIN	15	(0,7)	14	(0,7)	29	(0,7)
AMOXICILLIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM	1	(0,0)	1	(0,0)	2	(0,0)
AMOXICILLIN TRIHYDRATE	4	(0,2)	0	(0,0)	4	(0,1)
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	7	(0,3)	4	(0,2)	11	(0,3)
AMOXICILLIN;CLAVULANATE POTASSIUM	28	(1,3)	22	(1,0)	50	(1,2)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIBACTERIALS FOR SYSTEMIC USE	**218**	**(10,1)**	**241**	**(11,2)**	**459**	**(10,7)**
AMPICILLIN	2	(0,1)	0	(0,0)	2	(0,0)
AMPICILLIN SODIUM;SULBACTAM SODIUM	6	(0,3)	11	(0,5)	17	(0,4)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
ARTEMISIA ARGYI LEAF	2	(0,1)	2	(0,1)	4	(0,1)
AZITHROMYCIN	9	(0,4)	13	(0,6)	22	(0,5)
BENZYLPENICILLIN	0	(0,0)	1	(0,0)	1	(0,0)
BENZYLPENICILLIN SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
CEFACLOR	0	(0,0)	1	(0,0)	1	(0,0)
CEFADROXIL	1	(0,0)	4	(0,2)	5	(0,1)
CEFALEXIN	9	(0,4)	7	(0,3)	16	(0,4)
CEFALEXIN MONOHYDRATE	1	(0,0)	1	(0,0)	2	(0,0)
CEFAMANDOLE	0	(0,0)	1	(0,0)	1	(0,0)
CEFAZOLIN	9	(0,4)	8	(0,4)	17	(0,4)
CEFAZOLIN SODIUM	9	(0,4)	11	(0,5)	20	(0,5)
CEFAZOLIN SODIUM PENTAHYDRATE	2	(0,1)	0	(0,0)	2	(0,0)
CEFCAPENE PIVOXIL HYDROCHLORIDE	7	(0,3)	1	(0,0)	8	(0,2)
CEFDINIR	1	(0,0)	1	(0,0)	2	(0,0)
CEFDITOREN PIVOXIL	2	(0,1)	0	(0,0)	2	(0,0)
CEFEPIME	2	(0,1)	2	(0,1)	4	(0,1)
CEFIXIME	4	(0,2)	1	(0,0)	5	(0,1)
CEFMETAZOLE SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
CEFOPERAZONE	0	(0,0)	1	(0,0)	1	(0,0)
CEFOPERAZONE SODIUM;SULBACTAM SODIUM	3	(0,1)	4	(0,2)	7	(0,2)
CEFOTAXIME SODIUM	0	(0,0)	4	(0,2)	4	(0,1)
CEFOTIAM HEXETIL HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CEFOXITIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
CEFPODOXIME PROXETIL	3	(0,1)	2	(0,1)	5	(0,1)
CEFPROZIL	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIBACTERIALS FOR SYSTEMIC USE	**218**	**(10,1)**	**241**	**(11,2)**	**459**	**(10,7)**
CEFTAZIDIME	4	(0,2)	5	(0,2)	9	(0,2)
CEFTIBUTEN	0	(0,0)	1	(0,0)	1	(0,0)
CEFTIZOXIME SODIUM	5	(0,2)	1	(0,0)	6	(0,1)
CEFTRIAXONE	11	(0,5)	21	(1,0)	32	(0,7)
CEFTRIAXONE SODIUM	29	(1,3)	19	(0,9)	48	(1,1)
CEFUROXIME	8	(0,4)	9	(0,4)	17	(0,4)
CEFUROXIME AXETIL	2	(0,1)	8	(0,4)	10	(0,2)
CEFUROXIME SODIUM	4	(0,2)	7	(0,3)	11	(0,3)
CHLORAMPHENICOL	1	(0,0)	3	(0,1)	4	(0,1)
CIPROFLOXACIN	9	(0,4)	19	(0,9)	28	(0,7)
CIPROFLOXACIN HYDROCHLORIDE	5	(0,2)	1	(0,0)	6	(0,1)
CIPROFLOXACIN LACTATE	1	(0,0)	0	(0,0)	1	(0,0)
CLARITHROMYCIN	5	(0,2)	5	(0,2)	10	(0,2)
CLARITHROMYCIN LACTOBIONATE	0	(0,0)	1	(0,0)	1	(0,0)
CLAVULANIC ACID	4	(0,2)	2	(0,1)	6	(0,1)
CLINDAMYCIN	1	(0,0)	4	(0,2)	5	(0,1)
CLINDAMYCIN PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
CLOXACILLIN	3	(0,1)	0	(0,0)	3	(0,1)
DAPTOMYCIN	1	(0,0)	0	(0,0)	1	(0,0)
DICLOXACILLIN	1	(0,0)	0	(0,0)	1	(0,0)
DICLOXACILLIN SODIUM MONOHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
DOXYCYCLINE	6	(0,3)	3	(0,1)	9	(0,2)
DOXYCYCLINE HYCLATE	1	(0,0)	0	(0,0)	1	(0,0)
ERIOBOTRYA JAPONICA	0	(0,0)	1	(0,0)	1	(0,0)
ERYTHROMYCIN	1	(0,0)	2	(0,1)	3	(0,1)
FLOMOXEF	0	(0,0)	1	(0,0)	1	(0,0)
FLOMOXEF SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
FLUCLOXACILLIN	2	(0,1)	2	(0,1)	4	(0,1)
FLUCLOXACILLIN SODIUM	0	(0,0)	2	(0,1)	2	(0,0)
FOSFOMYCIN	1	(0,0)	0	(0,0)	1	(0,0)
FOSFOMYCIN TROMETAMOL	0	(0,0)	1	(0,0)	1	(0,0)
FUSIDIC ACID	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIBACTERIALS FOR SYSTEMIC USE	**218**	**(10,1)**	**241**	**(11,2)**	**459**	**(10,7)**
GATIFLOXACIN	1	(0,0)	1	(0,0)	2	(0,0)
GEMIFLOXACIN MESILATE	0	(0,0)	1	(0,0)	1	(0,0)
GENTAMICIN	0	(0,0)	2	(0,1)	2	(0,0)
GENTAMICIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
HOUTTUYNIA CORDATA	0	(0,0)	1	(0,0)	1	(0,0)
LATAMOXEF SODIUM	2	(0,1)	2	(0,1)	4	(0,1)
LEVOFLOXACIN	13	(0,6)	18	(0,8)	31	(0,7)
LEVOFLOXACIN HEMIHYDRATE	1	(0,0)	1	(0,0)	2	(0,0)
LEVOFLOXACIN HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
LEVOFLOXACIN LACTATE;SODIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
LEVOFLOXACIN;SODIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
LINEZOLID	1	(0,0)	0	(0,0)	1	(0,0)
LINUM USITATISSIMUM SEED	0	(0,0)	1	(0,0)	1	(0,0)
MEROPENEM	0	(0,0)	1	(0,0)	1	(0,0)
MEROPENEM TRIHYDRATE	2	(0,1)	0	(0,0)	2	(0,0)
METHENAMINE ANHYDROMETHYLENECITRATE	0	(0,0)	1	(0,0)	1	(0,0)
METHENAMINE HIPPURATE	0	(0,0)	2	(0,1)	2	(0,0)
METRONIDAZOLE	4	(0,2)	2	(0,1)	6	(0,1)
MINOCYCLINE	0	(0,0)	1	(0,0)	1	(0,0)
MINOCYCLINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
MOXIFLOXACIN	4	(0,2)	1	(0,0)	5	(0,1)
MOXIFLOXACIN HYDROCHLORIDE	7	(0,3)	4	(0,2)	11	(0,3)
NEOMYCIN	0	(0,0)	1	(0,0)	1	(0,0)
NITROFURANTOIN	3	(0,1)	0	(0,0)	3	(0,1)
OFLOXACIN	1	(0,0)	7	(0,3)	8	(0,2)
PENICILLIN NOS	2	(0,1)	0	(0,0)	2	(0,0)
PHENOXYMETHYLPENICILLIN	1	(0,0)	1	(0,0)	2	(0,0)
PHENOXYMETHYLPENICILLIN POTASSIUM	1	(0,0)	0	(0,0)	1	(0,0)
PIPERACILLIN	1	(0,0)	3	(0,1)	4	(0,1)

Participants With Specific Prior Medications
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIBACTERIALS FOR SYSTEMIC USE	**218**	**(10,1)**	**241**	**(11,2)**	**459**	**(10,7)**
PIPERACILLIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
PIPERACILLIN SODIUM;SULBACTAM SODIUM	2	(0,1)	2	(0,1)	4	(0,1)
PIPERACILLIN SODIUM;TAZOBACTAM SODIUM	10	(0,5)	10	(0,5)	20	(0,5)
PIVAMPICILLIN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PIVMECILLINAM	1	(0,0)	0	(0,0)	1	(0,0)
PLATYCODON GRANDIFLORUS	1	(0,0)	0	(0,0)	1	(0,0)
ROXITHROMYCIN	5	(0,2)	2	(0,1)	7	(0,2)
SULFADIAZINE SILVER	1	(0,0)	2	(0,1)	3	(0,1)
SULFAMETHOXAZOLE	0	(0,0)	2	(0,1)	2	(0,0)
SULFAMETHOXAZOLE;TRIMETHOPRIM	1	(0,0)	1	(0,0)	2	(0,0)
SULTAMICILLIN	0	(0,0)	3	(0,1)	3	(0,1)
SULTAMICILLIN TOSILATE	0	(0,0)	3	(0,1)	3	(0,1)
TAZOBACTAM	1	(0,0)	2	(0,1)	3	(0,1)
TAZOBACTAM SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
TEICOPLANIN	0	(0,0)	1	(0,0)	1	(0,0)
TETRACYCLINE	0	(0,0)	1	(0,0)	1	(0,0)
TETRACYCLINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
TOBRAMYCIN	1	(0,0)	0	(0,0)	1	(0,0)
TOSUFLOXACIN TOSILATE	1	(0,0)	0	(0,0)	1	(0,0)
TRIMETHOPRIM	2	(0,1)	2	(0,1)	4	(0,1)
VACCINIUM MACROCARPON	0	(0,0)	1	(0,0)	1	(0,0)
VANCOMYCIN	3	(0,1)	5	(0,2)	8	(0,2)
VANCOMYCIN HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
ANTIMYCOBACTERIALS	**7**	**(0,3)**	**1**	**(0,0)**	**8**	**(0,2)**
ETHAMBUTOL DIHYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
ISONIAZID	2	(0,1)	0	(0,0)	2	(0,0)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
PYRAZINAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
RIFAMPICIN	5	(0,2)	1	(0,0)	6	(0,1)
RIFAMYCIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIMYCOTICS FOR SYSTEMIC USE	**7**	**(0,3)**	**12**	**(0,6)**	**19**	**(0,4)**
AMPHOTERICIN B	1	(0,0)	1	(0,0)	2	(0,0)
FLUCONAZOLE	1	(0,0)	1	(0,0)	2	(0,0)
KETOCONAZOLE	2	(0,1)	3	(0,1)	5	(0,1)
MICONAZOLE	2	(0,1)	0	(0,0)	2	(0,0)
MICONAZOLE NITRATE	1	(0,0)	3	(0,1)	4	(0,1)
NYSTATIN	1	(0,0)	4	(0,2)	5	(0,1)
ANTIVIRALS FOR SYSTEMIC USE	**19**	**(0,9)**	**34**	**(1,6)**	**53**	**(1,2)**
ABACAVIR SULFATE;DOLUTEGRAVIR SODIUM;LAMIVUDINE	0	(0,0)	2	(0,1)	2	(0,0)
ACICLOVIR	0	(0,0)	2	(0,1)	2	(0,0)
ADEFOVIR	1	(0,0)	0	(0,0)	1	(0,0)
AMANTADINE	1	(0,0)	0	(0,0)	1	(0,0)
BICTEGRAVIR SODIUM;EMTRICITABINE;TENOFOVIR ALAFENAMIDE FUMARATE	0	(0,0)	1	(0,0)	1	(0,0)
DARUNAVIR	0	(0,0)	1	(0,0)	1	(0,0)
DARUNAVIR ETHANOLATE	0	(0,0)	1	(0,0)	1	(0,0)
DEHYDROANDROGRAPHOLIDE SUCCINATE POTASSIUM SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
EFAVIRENZ	1	(0,0)	1	(0,0)	2	(0,0)
EFAVIRENZ;EMTRICITABINE;TENOFOVIR DISOPROXIL FUMARATE	3	(0,1)	6	(0,3)	9	(0,2)
EMTRICITABINE	0	(0,0)	2	(0,1)	2	(0,0)
EMTRICITABINE;RILPIVIRINE HYDROCHLORIDE;TENOFOVIR ALAFENAMIDE FUMARATE	0	(0,0)	1	(0,0)	1	(0,0)
ENTECAVIR	3	(0,1)	1	(0,0)	4	(0,1)
ERIOBOTRYA JAPONICA	0	(0,0)	1	(0,0)	1	(0,0)
GANCICLOVIR SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
LAMIVUDINE	0	(0,0)	1	(0,0)	1	(0,0)
LANINAMIVIR OCTANOATE	1	(0,0)	0	(0,0)	1	(0,0)
LEDIPASVIR;SOFOSBUVIR	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIVIRALS FOR SYSTEMIC USE	**19**	**(0,9)**	**34**	**(1,6)**	**53**	**(1,2)**
LOPINAVIR	0	(0,0)	1	(0,0)	1	(0,0)
LYSOZYME CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
OSELTAMIVIR	0	(0,0)	4	(0,2)	4	(0,1)
OSELTAMIVIR PHOSPHATE	7	(0,3)	6	(0,3)	13	(0,3)
PERAMIVIR	1	(0,0)	0	(0,0)	1	(0,0)
RALTEGRAVIR	0	(0,0)	1	(0,0)	1	(0,0)
RITONAVIR	0	(0,0)	2	(0,1)	2	(0,0)
TENOFOVIR	0	(0,0)	1	(0,0)	1	(0,0)
TENOFOVIR DISOPROXIL FUMARATE	0	(0,0)	1	(0,0)	1	(0,0)
THYMALFASIN	0	(0,0)	2	(0,1)	2	(0,0)
VALACICLOVIR HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
ZIDOVUDINE	1	(0,0)	0	(0,0)	1	(0,0)
IMMUNE SERA AND IMMUNOGLOBULINS	**0**	**(0,0)**	**1**	**(0,0)**	**1**	**(0,0)**
IMMUNOGLOBULIN HUMAN NORMAL	0	(0,0)	1	(0,0)	1	(0,0)
VACCINES	**8**	**(0,4)**	**11**	**(0,5)**	**19**	**(0,4)**
INFLUENZA A(H1N1)PDM09 VACCINE INACT SPLIT VIRION	1	(0,0)	0	(0,0)	1	(0,0)
INFLUENZA VACCINE	3	(0,1)	6	(0,3)	9	(0,2)
INFLUENZA VACCINE INACT	0	(0,0)	3	(0,1)	3	(0,1)
INFLUENZA VACCINE INACT SPLIT VIRION 3V	0	(0,0)	1	(0,0)	1	(0,0)
INFLUENZA VACCINE INACT SPLIT VIRION 4V	0	(0,0)	1	(0,0)	1	(0,0)
PNEUMOCOCCAL VACCINE	2	(0,1)	0	(0,0)	2	(0,0)
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197)	0	(0,0)	3	(0,1)	3	(0,1)
PNEUMOCOCCAL VACCINE CONJ 7V (CRM197)	3	(0,1)	0	(0,0)	3	(0,1)
PNEUMOCOCCAL VACCINE POLYSACCH 23V	3	(0,1)	1	(0,0)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS						
ANTINEOPLASTIC AGENTS	**17**	**(0,8)**	**32**	**(1,5)**	**49**	**(1,1)**
BEVACIZUMAB	3	(0,1)	1	(0,0)	4	(0,1)
CELECOXIB	3	(0,1)	10	(0,5)	13	(0,3)
CLARITHROMYCIN	5	(0,2)	5	(0,2)	10	(0,2)
CLARITHROMYCIN LACTOBIONATE	0	(0,0)	1	(0,0)	1	(0,0)
HYDROXYCARBAMIDE	1	(0,0)	5	(0,2)	6	(0,1)
IMATINIB MESILATE	1	(0,0)	0	(0,0)	1	(0,0)
METHOTREXATE	2	(0,1)	8	(0,4)	10	(0,2)
METHOTREXATE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
RITUXIMAB	0	(0,0)	1	(0,0)	1	(0,0)
Z 100	1	(0,0)	0	(0,0)	1	(0,0)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
ENDOCRINE THERAPY	**18**	**(0,8)**	**20**	**(0,9)**	**38**	**(0,9)**
ANASTROZOLE	2	(0,1)	2	(0,1)	4	(0,1)
BICALUTAMIDE	4	(0,2)	4	(0,2)	8	(0,2)
ESTRADIOL	3	(0,1)	3	(0,1)	6	(0,1)
ESTROGENS CONJUGATED	0	(0,0)	3	(0,1)	3	(0,1)
EXEMESTANE	1	(0,0)	1	(0,0)	2	(0,0)
GOSERELIN	0	(0,0)	1	(0,0)	1	(0,0)
LETROZOLE	3	(0,1)	0	(0,0)	3	(0,1)
LEUPRORELIN	0	(0,0)	3	(0,1)	3	(0,1)
MEDROXYPROGESTERONE ACETATE	1	(0,0)	3	(0,1)	4	(0,1)
MEGESTROL ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
TAMOXIFEN	1	(0,0)	1	(0,0)	2	(0,0)
TAMOXIFEN CITRATE	1	(0,0)	0	(0,0)	1	(0,0)
TRIPTORELIN ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
IMMUNOSTIMULANTS	**23**	**(1,1)**	**17**	**(0,8)**	**40**	**(0,9)**
ANGELICA SINENSIS ROOT;ASTRAGALUS PROPINQUUS ROOT;EPIMEDIUM BREVICORNU HERB;GELATIN;LESPEDEZA BUERGERI;SOPHORA FLAVESCENS ROOT;ZIZIPHUS JUJUBA FRUIT	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS						
IMMUNOSTIMULANTS	**23**	**(1,1)**	**17**	**(0,8)**	**40**	**(0,9)**
ASTRAGALUS PROPINQUUS	1	(0,0)	1	(0,0)	2	(0,0)
GANODERMA LUCIDUM	0	(0,0)	1	(0,0)	1	(0,0)
GLUTATHIONE	8	(0,4)	2	(0,1)	10	(0,2)
LEUCOGEN	1	(0,0)	1	(0,0)	2	(0,0)
OPHIOPOGON JAPONICUS ROOT TUBER;PANAX GINSENG	12	(0,6)	9	(0,4)	21	(0,5)
OPHIOPOGON JAPONICUS;PANAX GINSENG	2	(0,1)	2	(0,1)	4	(0,1)
THYMALFASIN	0	(0,0)	2	(0,1)	2	(0,0)
IMMUNOSUPPRESSANTS	**11**	**(0,5)**	**21**	**(1,0)**	**32**	**(0,7)**
ABATACEPT	0	(0,0)	1	(0,0)	1	(0,0)
ADALIMUMAB	0	(0,0)	1	(0,0)	1	(0,0)
AZATHIOPRINE	4	(0,2)	1	(0,0)	5	(0,1)
CICLOSPORIN	1	(0,0)	2	(0,1)	3	(0,1)
HYDROXYCHLOROQUINE SULFATE	2	(0,1)	5	(0,2)	7	(0,2)
LEFLUNOMIDE	2	(0,1)	3	(0,1)	5	(0,1)
METHOTREXATE	2	(0,1)	8	(0,4)	10	(0,2)
METHOTREXATE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
MYCOPHENOLATE MOFETIL	0	(0,0)	1	(0,0)	1	(0,0)
MYCOPHENOLATE SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
SECUKINUMAB	1	(0,0)	0	(0,0)	1	(0,0)
SIROLIMUS	1	(0,0)	0	(0,0)	1	(0,0)
TACROLIMUS	1	(0,0)	2	(0,1)	3	(0,1)
USTEKINUMAB	0	(0,0)	1	(0,0)	1	(0,0)
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS						
ANTHELMINTICS	**1**	**(0,0)**	**2**	**(0,1)**	**3**	**(0,1)**
IVERMECTIN	0	(0,0)	1	(0,0)	1	(0,0)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
PIPERAZINE FERULATE	0	(0,0)	1	(0,0)	1	(0,0)
ANTIPROTOZOALS	**12**	**(0,6)**	**17**	**(0,8)**	**29**	**(0,7)**
CLOTRIMAZOLE	1	(0,0)	3	(0,1)	4	(0,1)
HYDROXYCHLOROQUINE SULFATE	2	(0,1)	5	(0,2)	7	(0,2)
MEGLUMINE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS						
ANTIPROTOZOALS	**12**	**(0,6)**	**17**	**(0,8)**	**29**	**(0,7)**
METRONIDAZOLE	4	(0,2)	2	(0,1)	6	(0,1)
MICONAZOLE	2	(0,1)	0	(0,0)	2	(0,0)
MICONAZOLE NITRATE	1	(0,0)	3	(0,1)	4	(0,1)
QUININE	1	(0,0)	3	(0,1)	4	(0,1)
QUININE SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS	**5**	**(0,2)**	**8**	**(0,4)**	**13**	**(0,3)**
CROTAMITON	3	(0,1)	1	(0,0)	4	(0,1)
DIMETICONE	2	(0,1)	7	(0,3)	9	(0,2)
BLOOD AND BLOOD FORMING ORGANS						
ANTIANEMIC PREPARATIONS	**252**	**(11,7)**	**254**	**(11,8)**	**506**	**(11,8)**
ANIMAL FECES NOS;BOMBYX MORI	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;COPPER SULFATE;CYANOCOBALAMIN;FERROUS GLUCONATE;FOLIC ACID;MANGANESE SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;CYANOCOBALAMIN;DOCUSATE SODIUM;FERROUS FUMARATE;FOLIC ACID;TOCOPHERYL ACID SUCCINATE	2	(0,1)	1	(0,0)	3	(0,1)
ASCORBIC ACID;CYANOCOBALAMIN;FERROUS BISGLYCINATE;FOLIC ACID	2	(0,1)	0	(0,0)	2	(0,0)
ASCORBIC ACID;CYANOCOBALAMIN;FERROUS SULFATE;FOLIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
ASCORBIC ACID;CYANOCOBALAMIN;FOLIC ACID;IRON;PYRIDOXINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
ANTIANEMIC PREPARATIONS	**252**	**(11,7)**	**254**	**(11,8)**	**506**	**(11,8)**
ASCORBIC ACID;FERROUS FUMARATE	3	(0,1)	0	(0,0)	3	(0,1)
ASCORBIC ACID;FERROUS SULFATE	3	(0,1)	10	(0,5)	13	(0,3)
ASCORBIC ACID;FERROUS SULFATE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
CALCIUM FERROUS CITRATE	1	(0,0)	1	(0,0)	2	(0,0)
CALCIUM FOLINATE;IRON SUCCINYL-PROTEIN COMPLEX	0	(0,0)	1	(0,0)	1	(0,0)
CEPHARANTHINE	1	(0,0)	0	(0,0)	1	(0,0)
CYANOCOBALAMIN	35	(1,6)	35	(1,6)	70	(1,6)
CYANOCOBALAMIN;FERROUS GLYCINE SULFATE;FOLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
CYANOCOBALAMIN;FOLIC ACID;PYRIDOXINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
DARBEPOETIN ALFA	5	(0,2)	7	(0,3)	12	(0,3)
EPOETIN ALFA	2	(0,1)	2	(0,1)	4	(0,1)
EPOETIN BETA	1	(0,0)	2	(0,1)	3	(0,1)
EPOETIN NOS	3	(0,1)	2	(0,1)	5	(0,1)
EPOETIN THETA	2	(0,1)	0	(0,0)	2	(0,0)
FERRIC ACETYL TRANSFERRIN	0	(0,0)	1	(0,0)	1	(0,0)
FERRIC CARBOXYMALTOSE	17	(0,8)	14	(0,7)	31	(0,7)
FERRIC HYDROXIDE POLYMALTOSE COMPLEX	3	(0,1)	4	(0,2)	7	(0,2)
FERRIC HYDROXIDE POLYMALTOSE COMPLEX;FOLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
FERRIC SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
FERRIC SULFATE;MUCOPROTEOSE	1	(0,0)	0	(0,0)	1	(0,0)
FERRITIN	1	(0,0)	0	(0,0)	1	(0,0)
FERROUS FUMARATE	15	(0,7)	7	(0,3)	22	(0,5)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
ANTIANEMIC PREPARATIONS	**252**	**(11,7)**	**254**	**(11,8)**	**506**	**(11,8)**
FERROUS FUMARATE;FOLIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
FERROUS GLUCONATE	9	(0,4)	6	(0,3)	15	(0,3)
FERROUS GLYCINE SULFATE	3	(0,1)	12	(0,6)	15	(0,3)
FERROUS GLYCINE SULFATE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN SODIUM PHOSPHATE;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
FERROUS SODIUM CITRATE	12	(0,6)	8	(0,4)	20	(0,5)
FERROUS SUCCINATE	2	(0,1)	1	(0,0)	3	(0,1)
FERROUS SULFATE	66	(3,1)	56	(2,6)	122	(2,8)
FERROUS SULFATE;FOLIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
FERROUS SULFATE;FOLIC ACID;SERINE	1	(0,0)	0	(0,0)	1	(0,0)
FERROUS SULFATE;NICOTINAMIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
FERROUS SULFATE;SERINE	0	(0,0)	1	(0,0)	1	(0,0)
FOLIC ACID	56	(2,6)	65	(3,0)	121	(2,8)
FOLIC ACID;IRON	0	(0,0)	1	(0,0)	1	(0,0)
FOLIC ACID;SACCHARATED IRON OXIDE	0	(0,0)	2	(0,1)	2	(0,0)
HYDROXOCOBALAMIN	2	(0,1)	1	(0,0)	3	(0,1)
HYDROXOCOBALAMIN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
IRON	9	(0,4)	12	(0,6)	21	(0,5)
IRON ISOMALTOSIDE 1000	1	(0,0)	0	(0,0)	1	(0,0)
IRON SUCCINYL-PROTEIN COMPLEX	2	(0,1)	0	(0,0)	2	(0,0)
LEVOGLUTAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
MECOBALAMIN	8	(0,4)	7	(0,3)	15	(0,3)
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA	2	(0,1)	3	(0,1)	5	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
ANTIANEMIC PREPARATIONS	**252**	**(11,7)**	**254**	**(11,8)**	**506**	**(11,8)**
MINERALS NOS;VITAMINS NOS	4	(0,2)	9	(0,4)	13	(0,3)
POLYSACCHARIDE-IRON COMPLEX	2	(0,1)	2	(0,1)	4	(0,1)
RECOMBINANT HUMAN THROMBOPOIETIN	0	(0,0)	1	(0,0)	1	(0,0)
SACCHARATED IRON OXIDE	14	(0,7)	14	(0,7)	28	(0,7)
VITAMIN B NOS	4	(0,2)	1	(0,0)	5	(0,1)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
ANTIHEMORRHAGICS	**29**	**(1,3)**	**24**	**(1,1)**	**53**	**(1,2)**
AMINO ACIDS NOS	1	(0,0)	1	(0,0)	2	(0,0)
CAMOSTAT MESILATE	1	(0,0)	0	(0,0)	1	(0,0)
CARBAZOCHROME SODIUM SULFONATE	0	(0,0)	2	(0,1)	2	(0,0)
CORDYCEPS SINENSIS	12	(0,6)	6	(0,3)	18	(0,4)
EPINEPHRINE	0	(0,0)	2	(0,1)	2	(0,0)
ERIOBOTRYA JAPONICA	0	(0,0)	1	(0,0)	1	(0,0)
ETAMSILATE	1	(0,0)	0	(0,0)	1	(0,0)
HAEMOCOAGULASE	2	(0,1)	1	(0,0)	3	(0,1)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
MENATETRENONE	1	(0,0)	1	(0,0)	2	(0,0)
PANAX NOTOGINSENG	2	(0,1)	3	(0,1)	5	(0,1)
PHYTOMENADIONE	4	(0,2)	5	(0,2)	9	(0,2)
THROMBIN	0	(0,0)	1	(0,0)	1	(0,0)
TRANEXAMIC ACID	4	(0,2)	2	(0,1)	6	(0,1)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
ANTITHROMBOTIC AGENTS	**1.908**	**(88,7)**	**1.910**	**(88,8)**	**3.818**	**(88,7)**
ACENOCOUMAROL	116	(5,4)	106	(4,9)	222	(5,2)
ACETYLSALICYLATE LYSINE	8	(0,4)	7	(0,3)	15	(0,3)
ACETYLSALICYLIC ACID	1.037	(48,2)	978	(45,5)	2.015	(46,8)
ACETYLSALICYLIC ACID;ALUMINIUM GLYCINATE;MAGNESIUM CARBONATE	3	(0,1)	1	(0,0)	4	(0,1)
ACETYLSALICYLIC ACID;CLOPIDOGREL BISULFATE	7	(0,3)	5	(0,2)	12	(0,3)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
ANTITHROMBOTIC AGENTS	**1.908**	**(88,7)**	**1.910**	**(88,8)**	**3.818**	**(88,7)**
ACETYLSALICYLIC ACID;GLYCINE	17	(0,8)	14	(0,7)	31	(0,7)
ACETYLSALICYLIC ACID;LANSOPRAZOLE	4	(0,2)	6	(0,3)	10	(0,2)
ACETYLSALICYLIC ACID;MAGNESIUM HYDROXIDE	14	(0,7)	14	(0,7)	28	(0,7)
ACETYLSALICYLIC ACID;MAGNESIUM OXIDE	1	(0,0)	3	(0,1)	4	(0,1)
ALPROSTADIL	8	(0,4)	8	(0,4)	16	(0,4)
APIXABAN	191	(8,9)	212	(9,9)	403	(9,4)
BEMIPARIN SODIUM	1	(0,0)	2	(0,1)	3	(0,1)
BERAPROST SODIUM	3	(0,1)	3	(0,1)	6	(0,1)
CARBASALATE CALCIUM	1	(0,0)	0	(0,0)	1	(0,0)
CERTOPARIN SODIUM	8	(0,4)	11	(0,5)	19	(0,4)
CILOSTAZOL	7	(0,3)	8	(0,4)	15	(0,3)
CILOSTAZOL;GINKGO BILOBA	1	(0,0)	0	(0,0)	1	(0,0)
CLOPIDOGREL	222	(10,3)	230	(10,7)	452	(10,5)
CLOPIDOGREL BESYLATE	3	(0,1)	1	(0,0)	4	(0,1)
CLOPIDOGREL BISULFATE	169	(7,9)	148	(6,9)	317	(7,4)
CLOPIDOGREL RESINATE	1	(0,0)	2	(0,1)	3	(0,1)
DABIGATRAN	35	(1,6)	36	(1,7)	71	(1,7)
DABIGATRAN ETEXILATE	5	(0,2)	7	(0,3)	12	(0,3)
DABIGATRAN ETEXILATE MESILATE	41	(1,9)	43	(2,0)	84	(2,0)
DALTEPARIN SODIUM	8	(0,4)	8	(0,4)	16	(0,4)
DIPYRIDAMOLE	4	(0,2)	5	(0,2)	9	(0,2)
EDOXABAN	6	(0,3)	5	(0,2)	11	(0,3)
EDOXABAN TOSILATE	19	(0,9)	26	(1,2)	45	(1,0)
EDOXABAN TOSILATE MONOHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
ENOXAPARIN SODIUM	111	(5,2)	127	(5,9)	238	(5,5)
FLUINDIONE	6	(0,3)	12	(0,6)	18	(0,4)
FONDAPARINUX SODIUM	6	(0,3)	10	(0,5)	16	(0,4)
HEPARIN	18	(0,8)	27	(1,3)	45	(1,0)
HEPARIN CALCIUM	11	(0,5)	3	(0,1)	14	(0,3)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
ANTITHROMBOTIC AGENTS	**1.908**	**(88,7)**	**1.910**	**(88,8)**	**3.818**	**(88,7)**
HEPARIN SODIUM	25	(1,2)	16	(0,7)	41	(1,0)
HEPARIN SODIUM;SODIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
HEPARINOID	3	(0,1)	2	(0,1)	5	(0,1)
LIMAPROST ALFADEX	3	(0,1)	6	(0,3)	9	(0,2)
LOW MOLECULAR WEIGHT HEPARIN	0	(0,0)	1	(0,0)	1	(0,0)
LOW MOLECULAR WEIGHT HEPARIN, SODIUM SALT	0	(0,0)	1	(0,0)	1	(0,0)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	6	(0,3)	4	(0,2)	10	(0,2)
NADROPARIN CALCIUM	9	(0,4)	10	(0,5)	19	(0,4)
PARNAPARIN SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
PHENPROCOUMON	31	(1,4)	39	(1,8)	70	(1,6)
PRASUGREL HYDROCHLORIDE	19	(0,9)	10	(0,5)	29	(0,7)
RIVAROXABAN	168	(7,8)	187	(8,7)	355	(8,3)
SARPOGRELATE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
STREPTODORNASE;STREPTOKINASE	0	(0,0)	1	(0,0)	1	(0,0)
SULODEXIDE	0	(0,0)	1	(0,0)	1	(0,0)
TICAGRELOR	26	(1,2)	31	(1,4)	57	(1,3)
TICLOPIDINE	1	(0,0)	0	(0,0)	1	(0,0)
TICLOPIDINE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
TINZAPARIN SODIUM	3	(0,1)	1	(0,0)	4	(0,1)
TRIFLUSAL	0	(0,0)	1	(0,0)	1	(0,0)
UROKINASE	1	(0,0)	0	(0,0)	1	(0,0)
WARFARIN	272	(12,6)	270	(12,6)	542	(12,6)
WARFARIN POTASSIUM	20	(0,9)	20	(0,9)	40	(0,9)
WARFARIN SODIUM	94	(4,4)	105	(4,9)	199	(4,6)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**608**	**(28,3)**	**576**	**(26,8)**	**1.184**	**(27,5)**

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**608**	**(28,3)**	**576**	**(26,8)**	**1.184**	**(27,5)**
ALANINE;ARGININE;ASPARTIC ACID;CALCIUM CHLORIDE;GLUCOSE MONOHYDRATE;GLUTAMIC ACID;GLYCINE;GLYCINE MAX SEED OIL;HISTIDINE HYDROCHLORIDE;ISOLEUCINE;LEUCINE;LYSINE HYDROCHLORIDE;MAGNESIUM ACETATE TETRAHYDRATE;MEDIUM-CHAIN TRIGLYCERIDES;METHIONINE;PHENYLALANINE;POTASSIUM ACETATE;PROLINE;SERINE;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM HYDROXIDE;SODIUM PHOSPHATE MONOBASIC	0	(0,0)	1	(0,0)	1	(0,0)
ALBUMIN HUMAN	7	(0,3)	9	(0,4)	16	(0,4)
AMINO ACIDS NOS	1	(0,0)	1	(0,0)	2	(0,0)
AMINO ACIDS NOS;ELECTROLYTES NOS;GLUCOSE;THIAMINE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
ARGININE	1	(0,0)	0	(0,0)	1	(0,0)
ARGININE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**608**	**(28,3)**	**576**	**(26,8)**	**1.184**	**(27,5)**
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	1	(0,0)	0	(0,0)	1	(0,0)
BLOOD, CALF, DEPROT., LMW PORTION	2	(0,1)	0	(0,0)	2	(0,0)
CALCIUM ACETATE;MAGNESIUM ACETATE;POTASSIUM ACETATE;SODIUM ACETATE;SODIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM CHLORIDE	2	(0,1)	4	(0,2)	6	(0,1)
CALCIUM CHLORIDE DIHYDRATE;FRUCTOSE;GLUCOSE; MAGNESIUM CHLORIDE;POTASSIUM PHOSPHATE DIBASIC;SODIUM ACETATE;SODIUM CHLORIDE;XYLITOL;ZINC SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CHLORIDE DIHYDRATE;GLUCOSE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CHLORIDE DIHYDRATE;GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**608**	**(28,3)**	**576**	**(26,8)**	**1.184**	**(27,5)**
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	5	(0,2)	2	(0,1)	7	(0,2)
CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	2	(0,1)	4	(0,2)	6	(0,1)
CALCIUM CHLORIDE;GLUCOSE	2	(0,1)	3	(0,1)	5	(0,1)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE;SORBITOL	2	(0,1)	4	(0,2)	6	(0,1)
CALCIUM GLUCONATE	4	(0,2)	7	(0,3)	11	(0,3)
CALCIUM GLUCONATE MONOHYDRATE;GLUCOSE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE DIHYDRATE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**608**	**(28,3)**	**576**	**(26,8)**	**1.184**	**(27,5)**
CALCIUM GLUCONATE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE	0	(0,0)	1	(0,0)	1	(0,0)
CARBOHYDRATES NOS;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	4	(0,2)	6	(0,3)	10	(0,2)
CARTHAMUS TINCTORIUS	1	(0,0)	0	(0,0)	1	(0,0)
CETYLPYRIDINIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CHLORHEXIDINE GLUCONATE	0	(0,0)	3	(0,1)	3	(0,1)
CYSTEINE HYDROCHLORIDE;GLYCINE;GLYCYRRHIZIC ACID, AMMONIUM SALT	0	(0,0)	1	(0,0)	1	(0,0)
CYSTEINE HYDROCHLORIDE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE ACETATE;METHIONINE;PHENYLALANINE;THREONINE;TRYPTOPHAN, L-;VALINE	1	(0,0)	0	(0,0)	1	(0,0)
CYSTEINE;GLYCINE;GLYCYRRHIZIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
ELECTROLYTES NOS	1	(0,0)	7	(0,3)	8	(0,2)
ELECTROLYTES NOS;GLUCOSE	1	(0,0)	0	(0,0)	1	(0,0)
ELECTROLYTES NOS;SODIUM LACTATE	1	(0,0)	2	(0,1)	3	(0,1)
FISH OIL;GLYCINE MAX SEED OIL;OLEA EUROPAEA OIL;TRIGLYCERIDES	1	(0,0)	0	(0,0)	1	(0,0)
FOSFRUCTOSE TRISODIUM	1	(0,0)	0	(0,0)	1	(0,0)
FRUCTOSE	0	(0,0)	2	(0,1)	2	(0,0)

Participants With Specific Prior Medications
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**608**	**(28,3)**	**576**	**(26,8)**	**1.184**	**(27,5)**
GLUCOSE	27	(1,3)	23	(1,1)	50	(1,2)
GLUCOSE;MAGNESIUM SULFATE	1	(0,0)	1	(0,0)	2	(0,0)
GLUCOSE;POTASSIUM CHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
GLUCOSE;SODIUM CHLORIDE	4	(0,2)	1	(0,0)	5	(0,1)
GLUCOSE;SODIUM CHLORIDE;SODIUM LACTATE	6	(0,3)	4	(0,2)	10	(0,2)
GLYCEROL	8	(0,4)	3	(0,1)	11	(0,3)
GLYCINE	0	(0,0)	1	(0,0)	1	(0,0)
INVERT SUGAR;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;POTASSIUM PHOSPHATE DIBASIC;SODIUM CHLORIDE;SODIUM LACTATE;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	1	(0,0)	0	(0,0)	1	(0,0)
ISOSORBIDE	3	(0,1)	3	(0,1)	6	(0,1)
MAGNESIUM ASPARTATE;POTASSIUM ASPARTATE;SORBITOL	1	(0,0)	0	(0,0)	1	(0,0)
MAGNESIUM CHLORIDE	4	(0,2)	1	(0,0)	5	(0,1)
MAGNESIUM CITRATE	6	(0,3)	5	(0,2)	11	(0,3)
MAGNESIUM SULFATE	38	(1,8)	35	(1,6)	73	(1,7)
MANNITOL	1	(0,0)	0	(0,0)	1	(0,0)
MINERALS NOS;VITAMINS NOS	4	(0,2)	9	(0,4)	13	(0,3)
NEOMYCIN	0	(0,0)	1	(0,0)	1	(0,0)
PHOSPHOLIPIDS	3	(0,1)	0	(0,0)	3	(0,1)
POTASSIUM	56	(2,6)	50	(2,3)	106	(2,5)
POTASSIUM CHLORIDE	427	(19,8)	399	(18,5)	826	(19,2)
POTASSIUM CHLORIDE;SODIUM CHLORIDE	3	(0,1)	0	(0,0)	3	(0,1)
RED BLOOD CELLS	3	(0,1)	0	(0,0)	3	(0,1)
SODIUM BICARBONATE	40	(1,9)	34	(1,6)	74	(1,7)
SODIUM CHLORIDE	44	(2,0)	49	(2,3)	93	(2,2)

Participants With Specific Prior Medications
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All Subjects as Treated Population
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**608**	**(28,3)**	**576**	**(26,8)**	**1.184**	**(27,5)**
SODIUM PHOSPHATE DIBASIC	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC	2	(0,1)	1	(0,0)	3	(0,1)
SODIUM PHOSPHATE;SODIUM PHOSPHATE DIBASIC	0	(0,0)	1	(0,0)	1	(0,0)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	0	(0,0)	1	(0,0)	1	(0,0)
SORBITOL	0	(0,0)	1	(0,0)	1	(0,0)
UREA	8	(0,4)	4	(0,2)	12	(0,3)
VITAMINS NOS	36	(1,7)	34	(1,6)	70	(1,6)
ZINC	0	(0,0)	1	(0,0)	1	(0,0)
ZINC SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
OTHER HEMATOLOGICAL AGENTS	**40**	**(1,9)**	**37**	**(1,7)**	**77**	**(1,8)**
ENZYMES NOS	1	(0,0)	2	(0,1)	3	(0,1)
PRONASE	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM BICARBONATE	40	(1,9)	34	(1,6)	74	(1,7)
STREPTODORNASE;STREPTOKINASE	0	(0,0)	1	(0,0)	1	(0,0)
CARDIOVASCULAR SYSTEM						
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	**1.918**	**(89,1)**	**1.939**	**(90,1)**	**3.857**	**(89,6)**
ALISKIREN FUMARATE	0	(0,0)	1	(0,0)	1	(0,0)
ALLISARTAN ISOPROXIL	1	(0,0)	1	(0,0)	2	(0,0)
AMLODIPINE ADIPATE;VALSARTAN	0	(0,0)	1	(0,0)	1	(0,0)
AMLODIPINE BESILATE;AZILSARTAN	1	(0,0)	1	(0,0)	2	(0,0)
AMLODIPINE BESILATE;HYDROCHLOROTHIAZIDE;OLMESARTAN MEDOXOMIL	0	(0,0)	1	(0,0)	1	(0,0)
AMLODIPINE BESILATE;IRBESARTAN	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	**1.918**	**(89,1)**	**1.939**	**(90,1)**	**3.857**	**(89,6)**
AMLODIPINE BESILATE;OLMESARTAN MEDOXOMIL	1	(0,0)	1	(0,0)	2	(0,0)
AMLODIPINE BESILATE;PERINDOPRIL ARGININE	4	(0,2)	1	(0,0)	5	(0,1)
AMLODIPINE BESILATE;RAMIPRIL	1	(0,0)	1	(0,0)	2	(0,0)
AMLODIPINE BESILATE;TELMISARTAN	1	(0,0)	2	(0,1)	3	(0,1)
AMLODIPINE BESILATE;VALSARTAN	3	(0,1)	6	(0,3)	9	(0,2)
AZILSARTAN	3	(0,1)	4	(0,2)	7	(0,2)
AZILSARTAN KAMEDOXOMIL	1	(0,0)	0	(0,0)	1	(0,0)
BENAZEPRIL HYDROCHLORIDE	25	(1,2)	22	(1,0)	47	(1,1)
BISOPROLOL FUMARATE;PERINDOPRIL ARGININE	1	(0,0)	1	(0,0)	2	(0,0)
CANDESARTAN	53	(2,5)	57	(2,6)	110	(2,6)
CANDESARTAN CILEXETIL	45	(2,1)	44	(2,0)	89	(2,1)
CANDESARTAN CILEXETIL;HYDROCHLOROTHIAZIDE	2	(0,1)	1	(0,0)	3	(0,1)
CAPTOPRIL	28	(1,3)	24	(1,1)	52	(1,2)
CILAZAPRIL	17	(0,8)	14	(0,7)	31	(0,7)
ENALAPRIL	284	(13,2)	311	(14,5)	595	(13,8)
ENALAPRIL MALEATE	84	(3,9)	70	(3,3)	154	(3,6)
ENALAPRIL MALEATE;HYDROCHLOROTHIAZIDE	2	(0,1)	1	(0,0)	3	(0,1)
ENALAPRIL MALEATE;LERCANIDIPINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ENALAPRILAT	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	**1.918**	**(89,1)**	**1.939**	**(90,1)**	**3.857**	**(89,6)**
EPROSARTAN MESILATE	0	(0,0)	1	(0,0)	1	(0,0)
FIMASARTAN POTASSIUM TRIHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
FOSINOPRIL SODIUM	24	(1,1)	16	(0,7)	40	(0,9)
FOSINOPRIL SODIUM;HYDROCHLOROTHIAZIDE	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCHLOROTHIAZIDE;IRBESARTAN	2	(0,1)	5	(0,2)	7	(0,2)
HYDROCHLOROTHIAZIDE;LISINOPRIL DIHYDRATE	2	(0,1)	0	(0,0)	2	(0,0)
HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM	10	(0,5)	7	(0,3)	17	(0,4)
HYDROCHLOROTHIAZIDE;OLMESARTAN MEDOXOMIL	0	(0,0)	1	(0,0)	1	(0,0)
HYDROCHLOROTHIAZIDE;QUINAPRIL HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCHLOROTHIAZIDE;RAMIPRIL	4	(0,2)	0	(0,0)	4	(0,1)
HYDROCHLOROTHIAZIDE;TELMISARTAN	1	(0,0)	2	(0,1)	3	(0,1)
HYDROCHLOROTHIAZIDE;VALSARTAN	6	(0,3)	5	(0,2)	11	(0,3)
IMIDAPRIL	1	(0,0)	2	(0,1)	3	(0,1)
IMIDAPRIL HYDROCHLORIDE	12	(0,6)	7	(0,3)	19	(0,4)
INDAPAMIDE;PERINDOPRIL	1	(0,0)	1	(0,0)	2	(0,0)
INDAPAMIDE;PERINDOPRIL ARGININE	1	(0,0)	2	(0,1)	3	(0,1)
INDAPAMIDE;PERINDOPRIL ERBUMINE	0	(0,0)	2	(0,1)	2	(0,0)
IRBESARTAN	28	(1,3)	35	(1,6)	63	(1,5)
LISINOPRIL	108	(5,0)	106	(4,9)	214	(5,0)
LISINOPRIL DIHYDRATE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	**1.918**	**(89,1)**	**1.939**	**(90,1)**	**3.857**	**(89,6)**
LOSARTAN	184	(8,6)	184	(8,6)	368	(8,6)
LOSARTAN POTASSIUM	91	(4,2)	77	(3,6)	168	(3,9)
OLMESARTAN	1	(0,0)	0	(0,0)	1	(0,0)
OLMESARTAN MEDOXOMIL	13	(0,6)	11	(0,5)	24	(0,6)
PERINDOPRIL	104	(4,8)	113	(5,3)	217	(5,0)
PERINDOPRIL ARGININE	47	(2,2)	43	(2,0)	90	(2,1)
PERINDOPRIL ERBUMINE	28	(1,3)	45	(2,1)	73	(1,7)
QUINAPRIL HYDROCHLORIDE	3	(0,1)	9	(0,4)	12	(0,3)
RAMIPRIL	372	(17,3)	379	(17,6)	751	(17,5)
SACUBITRIL VALSARTAN SODIUM HYDRATE	244	(11,3)	258	(12,0)	502	(11,7)
SACUBITRIL;VALSARTAN	98	(4,6)	82	(3,8)	180	(4,2)
TELMISARTAN	25	(1,2)	36	(1,7)	61	(1,4)
TRANDOLAPRIL	10	(0,5)	7	(0,3)	17	(0,4)
TRANDOLAPRIL;VERAPAMIL HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
VALSARTAN	142	(6,6)	148	(6,9)	290	(6,7)
ZOFENOPRIL CALCIUM	5	(0,2)	11	(0,5)	16	(0,4)
ANTIHYPERTENSIVES	**155**	**(7,2)**	**158**	**(7,3)**	**313**	**(7,3)**
CLONIDINE	3	(0,1)	2	(0,1)	5	(0,1)
CLONIDINE HYDROCHLORIDE	1	(0,0)	4	(0,2)	5	(0,1)
DIHYDRALAZINE MESILATE	1	(0,0)	0	(0,0)	1	(0,0)
DIHYDRALAZINE SULFATE	4	(0,2)	9	(0,4)	13	(0,3)
DOXAZOSIN	10	(0,5)	17	(0,8)	27	(0,6)
DOXAZOSIN MESILATE	18	(0,8)	13	(0,6)	31	(0,7)
HYDRALAZINE	36	(1,7)	44	(2,0)	80	(1,9)
HYDRALAZINE HYDROCHLORIDE	11	(0,5)	4	(0,2)	15	(0,3)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
MAGNESIUM SULFATE	38	(1,8)	35	(1,6)	73	(1,7)
METHYLDOPA	0	(0,0)	1	(0,0)	1	(0,0)
MOXONIDINE	5	(0,2)	10	(0,5)	15	(0,3)
NAFTOPIDIL	2	(0,1)	1	(0,0)	3	(0,1)
NITROPRUSSIDE SODIUM	12	(0,6)	8	(0,4)	20	(0,5)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
ANTIHYPERTENSIVES	**155**	**(7,2)**	**158**	**(7,3)**	**313**	**(7,3)**
OPHIOPOGON JAPONICUS	1	(0,0)	0	(0,0)	1	(0,0)
PRAZOSIN	4	(0,2)	2	(0,1)	6	(0,1)
PRAZOSIN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
REHMANNIA GLUTINOSA	1	(0,0)	0	(0,0)	1	(0,0)
RILMENIDINE	2	(0,1)	1	(0,0)	3	(0,1)
RILMENIDINE PHOSPHATE	2	(0,1)	2	(0,1)	4	(0,1)
SILDENAFIL CITRATE	3	(0,1)	3	(0,1)	6	(0,1)
TADALAFIL	2	(0,1)	0	(0,0)	2	(0,0)
TERAZOSIN	3	(0,1)	4	(0,2)	7	(0,2)
TERAZOSIN HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
URAPIDIL	7	(0,3)	3	(0,1)	10	(0,2)
BETA BLOCKING AGENTS	**2.030**	**(94,3)**	**2.031**	**(94,4)**	**4.061**	**(94,4)**
ATENOLOL	19	(0,9)	19	(0,9)	38	(0,9)
ATENOLOL;CHLORTALIDONE;NIFEDIPINE	0	(0,0)	1	(0,0)	1	(0,0)
BETAXOLOL HYDROCHLORIDE	4	(0,2)	3	(0,1)	7	(0,2)
BISOPROLOL	431	(20,0)	440	(20,5)	871	(20,2)
BISOPROLOL FUMARATE	337	(15,7)	318	(14,8)	655	(15,2)
CARTEOLOL HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CARVEDILOL	821	(38,2)	838	(39,0)	1.659	(38,6)
CARVEDILOL;HYDROCHLOROTHIAZIDE	0	(0,0)	1	(0,0)	1	(0,0)
CELIPROLOL HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ESMOLOL HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
LANDIOLOL HYDROCHLORIDE	1	(0,0)	3	(0,1)	4	(0,1)
METOPROLOL	176	(8,2)	175	(8,1)	351	(8,2)
METOPROLOL SUCCINATE	224	(10,4)	203	(9,4)	427	(9,9)
METOPROLOL TARTRATE	94	(4,4)	80	(3,7)	174	(4,0)
NEBIVOLOL	44	(2,0)	42	(2,0)	86	(2,0)
NEBIVOLOL HYDROCHLORIDE	21	(1,0)	23	(1,1)	44	(1,0)
NIPRADOLOL	0	(0,0)	1	(0,0)	1	(0,0)
PINDOLOL	1	(0,0)	0	(0,0)	1	(0,0)
PROPRANOLOL	0	(0,0)	1	(0,0)	1	(0,0)
PROPRANOLOL HYDROCHLORIDE	0	(0,0)	4	(0,2)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
BETA BLOCKING AGENTS	**2.030**	**(94,3)**	**2.031**	**(94,4)**	**4.061**	**(94,4)**
SOTALOL	8	(0,4)	12	(0,6)	20	(0,5)
SOTALOL HYDROCHLORIDE	5	(0,2)	4	(0,2)	9	(0,2)
TIMOLOL	3	(0,1)	2	(0,1)	5	(0,1)
TIMOLOL MALEATE	2	(0,1)	0	(0,0)	2	(0,0)
CALCIUM CHANNEL BLOCKERS	**233**	**(10,8)**	**229**	**(10,6)**	**462**	**(10,7)**
AMLODIPINE	114	(5,3)	112	(5,2)	226	(5,3)
AMLODIPINE BESILATE	47	(2,2)	41	(1,9)	88	(2,0)
AMLODIPINE CAMSILATE	0	(0,0)	1	(0,0)	1	(0,0)
AMLODIPINE MALEATE	3	(0,1)	2	(0,1)	5	(0,1)
AMLODIPINE MESILATE	1	(0,0)	0	(0,0)	1	(0,0)
AZELNIDIPINE	1	(0,0)	2	(0,1)	3	(0,1)
BENIDIPINE HYDROCHLORIDE	7	(0,3)	1	(0,0)	8	(0,2)
BEPRIDIL HYDROCHLORIDE MONOHYDRATE	5	(0,2)	0	(0,0)	5	(0,1)
CILNIDIPINE	5	(0,2)	0	(0,0)	5	(0,1)
DILTIAZEM	7	(0,3)	9	(0,4)	16	(0,4)
DILTIAZEM HYDROCHLORIDE	14	(0,7)	14	(0,7)	28	(0,7)
EFONIDIPINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
FELODIPINE	2	(0,1)	4	(0,2)	6	(0,1)
LACIDIPINE	1	(0,0)	0	(0,0)	1	(0,0)
LERCANIDIPINE	4	(0,2)	3	(0,1)	7	(0,2)
LERCANIDIPINE HYDROCHLORIDE	8	(0,4)	16	(0,7)	24	(0,6)
LEVAMLODIPINE	0	(0,0)	1	(0,0)	1	(0,0)
LEVAMLODIPINE BESILATE	2	(0,1)	1	(0,0)	3	(0,1)
LEVAMLODIPINE MALEATE	0	(0,0)	1	(0,0)	1	(0,0)
NICARDIPINE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
NIFEDIPINE	13	(0,6)	20	(0,9)	33	(0,8)
NIMODIPINE	1	(0,0)	1	(0,0)	2	(0,0)
NITRENDIPINE	5	(0,2)	1	(0,0)	6	(0,1)
PERHEXILINE MALEATE	0	(0,0)	2	(0,1)	2	(0,0)
S AMLODIPINE NICOTINATE	1	(0,0)	0	(0,0)	1	(0,0)
VERAPAMIL	5	(0,2)	4	(0,2)	9	(0,2)
VERAPAMIL HYDROCHLORIDE	1	(0,0)	3	(0,1)	4	(0,1)
CARDIAC THERAPY	**1.222**	**(56,8)**	**1.188**	**(55,2)**	**2.410**	**(56,0)**

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
CARDIAC THERAPY	**1.222**	**(56,8)**	**1.188**	**(55,2)**	**2.410**	**(56,0)**
ACEGLUTAMIDE;CARTHAMUS TINCTORIUS	1	(0,0)	2	(0,1)	3	(0,1)
ACETYLDIGOXIN	1	(0,0)	0	(0,0)	1	(0,0)
ACONITUM CARMICHAELII	1	(0,0)	0	(0,0)	1	(0,0)
ADENOSINE	3	(0,1)	2	(0,1)	5	(0,1)
ADENOSINE TRIPHOSPHATE	0	(0,0)	1	(0,0)	1	(0,0)
ADENOSINE TRIPHOSPHATE, DISODIUM SALT	2	(0,1)	2	(0,1)	4	(0,1)
ALGINIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
ALLIUM MACROSTEMON BULB;BUXUS SPP.;GINKGO BILOBA LEAF;LITSEA LANCILIMBA;SALVIA MILTIORRHIZA ROOT WITH RHIZOME	1	(0,0)	0	(0,0)	1	(0,0)
ALPROSTADIL	8	(0,4)	8	(0,4)	16	(0,4)
AMBER;CODONOPSIS PILOSULA ROOT;NARDOSTACHYS JATAMANSI ROOT WITH RHIZOME;PANAX NOTOGINSENG ROOT;POLYGONATUM SIBIRICUM ROOT	2	(0,1)	0	(0,0)	2	(0,0)
AMIODARONE	195	(9,1)	193	(9,0)	388	(9,0)
AMIODARONE HYDROCHLORIDE	153	(7,1)	168	(7,8)	321	(7,5)
ARGININE HYDROCHLORIDE;LEVOCARNITINE	1	(0,0)	1	(0,0)	2	(0,0)
ASTRAGALUS MONGHOLICUS ROOT;DALBERGIA ODORIFERA OIL;PANAX NOTOGINSENG ROOT;SALVIA MILTIORRHIZA ROOT	3	(0,1)	4	(0,2)	7	(0,2)
ATROPINE	1	(0,0)	0	(0,0)	1	(0,0)
ATROPINE SULFATE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
CARDIAC THERAPY	**1.222**	**(56,8)**	**1.188**	**(55,2)**	**2.410**	**(56,0)**
BETA-ACETYLDIGOXIN	0	(0,0)	1	(0,0)	1	(0,0)
BORNEOL;BOSWELLIA SACRA RESIN;CENTIPEDE;CICADA SLOUGH;DALBERGIA ODORIFERA;EUPOLYPHAGA STELEOPHAGA;LEECH EXTRACT;MESOBUTHUS MARTENSII;PAEONIA SPP. ROOT;PANAX GINSENG ROOT;SANTALUM ALBUM HEARTWOOD;ZIZIPHUS JUJUBA VAR. SPINOSA SEED	0	(0,0)	1	(0,0)	1	(0,0)
BORNEOL;CINNAMOMUM CASSIA BARK;COW BEZOAR;LIQUIDAMBAR ORIENTALIS RESIN;MUSK;PANAX GINSENG EXTRACT;TOAD VENOM	1	(0,0)	3	(0,1)	4	(0,1)
BORNEOL;PANAX NOTOGINSENG ROOT;SALVIA MILTIORRHIZA ROOT	2	(0,1)	1	(0,0)	3	(0,1)
BUCLADESINE CALCIUM	7	(0,3)	6	(0,3)	13	(0,3)
CAFFEINE	0	(0,0)	1	(0,0)	1	(0,0)
CAMPHOR	0	(0,0)	1	(0,0)	1	(0,0)
CARNITINE	2	(0,1)	0	(0,0)	2	(0,0)
CARPERITIDE	23	(1,1)	11	(0,5)	34	(0,8)
CARTHAMUS TINCTORIUS	1	(0,0)	0	(0,0)	1	(0,0)
CARTHAMUS TINCTORIUS FLOWER;SALVIA MILTIORRHIZA ROOT	5	(0,2)	3	(0,1)	8	(0,2)
CONVALLATOXIN	2	(0,1)	0	(0,0)	2	(0,0)
CRATAEGUS SPP. EXTRACT	1	(0,0)	1	(0,0)	2	(0,0)
CREATINE PHOSPHATE	0	(0,0)	1	(0,0)	1	(0,0)
CYCLIC AMP	2	(0,1)	4	(0,2)	6	(0,1)
DENOPAMINE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
CARDIAC THERAPY	**1.222**	**(56,8)**	**1.188**	**(55,2)**	**2.410**	**(56,0)**
DESLANOSIDE	31	(1,4)	19	(0,9)	50	(1,2)
DIGITALIS GLYCOSIDES	0	(0,0)	1	(0,0)	1	(0,0)
DIGITALIS PURPUREA	2	(0,1)	0	(0,0)	2	(0,0)
DIGITOXIN	24	(1,1)	22	(1,0)	46	(1,1)
DIGOXIN	432	(20,1)	417	(19,4)	849	(19,7)
DOBUTAMINE	11	(0,5)	17	(0,8)	28	(0,7)
DOBUTAMINE HYDROCHLORIDE	15	(0,7)	18	(0,8)	33	(0,8)
DOBUTAMINE HYDROCHLORIDE;GLUCOSE	2	(0,1)	0	(0,0)	2	(0,0)
DOCARPAMINE	0	(0,0)	1	(0,0)	1	(0,0)
DOFETILIDE	5	(0,2)	1	(0,0)	6	(0,1)
DOPAMINE	10	(0,5)	18	(0,8)	28	(0,7)
DOPAMINE HYDROCHLORIDE	19	(0,9)	23	(1,1)	42	(1,0)
DRONEDARONE	0	(0,0)	1	(0,0)	1	(0,0)
EPINEPHRINE	0	(0,0)	2	(0,1)	2	(0,0)
FLECAINIDE ACETATE	0	(0,0)	5	(0,2)	5	(0,1)
FOSFRUCTOSE TRISODIUM	1	(0,0)	0	(0,0)	1	(0,0)
GLYCERYL TRINITRATE	183	(8,5)	153	(7,1)	336	(7,8)
IBUPROFEN	14	(0,7)	9	(0,4)	23	(0,5)
INDOMETACIN	2	(0,1)	2	(0,1)	4	(0,1)
IPRATROPIUM BROMIDE	93	(4,3)	97	(4,5)	190	(4,4)
ISOPRENALINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
ISOSORBIDE DINITRATE	75	(3,5)	59	(2,7)	134	(3,1)
ISOSORBIDE MONONITRATE	122	(5,7)	98	(4,6)	220	(5,1)
ISOSORBIDE MONONITRATE;SODIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
IVABRADINE	87	(4,0)	71	(3,3)	158	(3,7)
IVABRADINE HYDROCHLORIDE	65	(3,0)	75	(3,5)	140	(3,3)
LAPPACONITINE HYDROBROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
LEVOCARNITINE	9	(0,4)	7	(0,3)	16	(0,4)
LEVOSIMENDAN	27	(1,3)	27	(1,3)	54	(1,3)
LIDOCAINE	16	(0,7)	19	(0,9)	35	(0,8)
LIDOCAINE HYDROCHLORIDE	14	(0,7)	8	(0,4)	22	(0,5)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
CARDIAC THERAPY	**1.222**	**(56,8)**	**1.188**	**(55,2)**	**2.410**	**(56,0)**
LIGUSTICUM STRIATUM	1	(0,0)	0	(0,0)	1	(0,0)
LIGUSTRAZINE HYDROCHLORIDE;SALVIA MILTIORRHIZA	6	(0,3)	3	(0,1)	9	(0,2)
LIMAPROST ALFADEX	3	(0,1)	6	(0,3)	9	(0,2)
MAGNESIUM ASPARTATE;POTASSIUM ASPARTATE	16	(0,7)	17	(0,8)	33	(0,8)
MAGNESIUM TANSHINOATE B	4	(0,2)	2	(0,1)	6	(0,1)
MEGLUMINE ADENOSINE CYCLOPHOSPHATE	4	(0,2)	3	(0,1)	7	(0,2)
MELDONIUM	3	(0,1)	2	(0,1)	5	(0,1)
METARAMINOL TARTRATE	0	(0,0)	1	(0,0)	1	(0,0)
METILDIGOXIN	14	(0,7)	14	(0,7)	28	(0,7)
MEXILETINE	6	(0,3)	3	(0,1)	9	(0,2)
MEXILETINE HYDROCHLORIDE	3	(0,1)	3	(0,1)	6	(0,1)
MIDODRINE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
MILRINONE	23	(1,1)	17	(0,8)	40	(0,9)
MILRINONE LACTATE	5	(0,2)	2	(0,1)	7	(0,2)
MOLSIDOMINE	5	(0,2)	7	(0,3)	12	(0,3)
NESIRITIDE	10	(0,5)	9	(0,4)	19	(0,4)
NICORANDIL	16	(0,7)	16	(0,7)	32	(0,7)
NICOTINAMIDE	0	(0,0)	1	(0,0)	1	(0,0)
NOREPINEPHRINE	1	(0,0)	3	(0,1)	4	(0,1)
NOREPINEPHRINE BITARTRATE	1	(0,0)	1	(0,0)	2	(0,0)
OPHIOPOGON JAPONICUS ROOT TUBER;PANAX GINSENG	12	(0,6)	9	(0,4)	21	(0,5)
OPHIOPOGON JAPONICUS ROOT TUBER;PANAX GINSENG ROOT;SCHISANDRA CHINENSIS FRUIT	2	(0,1)	3	(0,1)	5	(0,1)
OPHIOPOGON JAPONICUS;PANAX GINSENG	2	(0,1)	2	(0,1)	4	(0,1)
PANAX NOTOGINSENG	2	(0,1)	3	(0,1)	5	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
CARDIAC THERAPY	**1.222**	**(56,8)**	**1.188**	**(55,2)**	**2.410**	**(56,0)**
PHOSPHOCREATINE SODIUM	12	(0,6)	6	(0,3)	18	(0,4)
PILSICAINIDE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
PIMOBENDAN	21	(1,0)	21	(1,0)	42	(1,0)
PINELLIA TERNATA	1	(0,0)	0	(0,0)	1	(0,0)
PROPAFENONE HYDROCHLORIDE	0	(0,0)	5	(0,2)	5	(0,1)
RANOLAZINE	12	(0,6)	15	(0,7)	27	(0,6)
RANOLAZINE HYDROCHLORIDE	5	(0,2)	10	(0,5)	15	(0,3)
RELAXIN	1	(0,0)	0	(0,0)	1	(0,0)
SALVIA MILTIORRHIZA	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM ALGINATE	1	(0,0)	1	(0,0)	2	(0,0)
SODIUM CHLORIDE;UBIDECARENONE	0	(0,0)	1	(0,0)	1	(0,0)
STROPHANTHIN-K	1	(0,0)	1	(0,0)	2	(0,0)
TANSHINONE IIA SODIUM SULFONATE	1	(0,0)	1	(0,0)	2	(0,0)
THIOTRIAZOLINE	1	(0,0)	1	(0,0)	2	(0,0)
TIAZOTIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
TRIMETAZIDINE	62	(2,9)	37	(1,7)	99	(2,3)
TRIMETAZIDINE HYDROCHLORIDE	93	(4,3)	90	(4,2)	183	(4,3)
UBIDECARENONE	25	(1,2)	31	(1,4)	56	(1,3)
XINMAILONG	4	(0,2)	2	(0,1)	6	(0,1)
ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
DIURETICS	**2.129**	**(98,9)**	**2.137**	**(99,3)**	**4.266**	**(99,1)**
ACETAZOLAMIDE	6	(0,3)	6	(0,3)	12	(0,3)
ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;ATRACTYLODES LANCEA RHIZOME;CINNAMOMUM CASSIA BARK;POLYPORUS UMBELLATUS SCLEROTIUM;PORIA COCOS SCLEROTIUM	0	(0,0)	1	(0,0)	1	(0,0)
ALLIUM MACROSTEMON	1	(0,0)	0	(0,0)	1	(0,0)
AMILORIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
DIURETICS	**2.129**	**(98,9)**	**2.137**	**(99,3)**	**4.266**	**(99,1)**
AMILORIDE HYDROCHLORIDE;HYDROCHLOROTHIAZIDE	4	(0,2)	2	(0,1)	6	(0,1)
ASTRAGALUS PROPINQUUS	1	(0,0)	1	(0,0)	2	(0,0)
AZOSEMIDE	48	(2,2)	42	(2,0)	90	(2,1)
BENDROFLUMETHIAZIDE	3	(0,1)	2	(0,1)	5	(0,1)
BENDROFLUMETHIAZIDE;POTASSIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
BUMETANIDE	113	(5,3)	107	(5,0)	220	(5,1)
BUTIZIDE;SPIRONOLACTONE	1	(0,0)	0	(0,0)	1	(0,0)
CANRENONE	13	(0,6)	18	(0,8)	31	(0,7)
CHLOROTHIAZIDE	0	(0,0)	1	(0,0)	1	(0,0)
CHLOROTHIAZIDE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
CHLORTALIDONE	23	(1,1)	18	(0,8)	41	(1,0)
CHLORTALIDONE;SPIRONOLACTONE	0	(0,0)	1	(0,0)	1	(0,0)
CLOPAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
EPLERENONE	270	(12,5)	302	(14,0)	572	(13,3)
ERIOBOTRYA JAPONICA	0	(0,0)	1	(0,0)	1	(0,0)
ETACRYNIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
FUROSEMIDE	1.791	(83,2)	1.788	(83,1)	3.579	(83,2)
FUROSEMIDE SODIUM	209	(9,7)	196	(9,1)	405	(9,4)
FUROSEMIDE;POTASSIUM CHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
FUROSEMIDE;SPIRONOLACTONE	2	(0,1)	1	(0,0)	3	(0,1)
HYDROCHLOROTHIAZIDE	80	(3,7)	82	(3,8)	162	(3,8)
HYDROCHLOROTHIAZIDE;SPIRONOLACTONE	13	(0,6)	15	(0,7)	28	(0,7)
INDAPAMIDE	23	(1,1)	21	(1,0)	44	(1,0)
ISOSORBIDE	3	(0,1)	3	(0,1)	6	(0,1)
MANNITOL	1	(0,0)	0	(0,0)	1	(0,0)
METOLAZONE	64	(3,0)	62	(2,9)	126	(2,9)
POTASSIUM CANRENOATE	11	(0,5)	15	(0,7)	26	(0,6)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
DIURETICS	**2.129**	**(98,9)**	**2.137**	**(99,3)**	**4.266**	**(99,1)**
POTASSIUM CANRENOATE;TROMETAMOL	2	(0,1)	0	(0,0)	2	(0,0)
REHMANNIA GLUTINOSA	1	(0,0)	0	(0,0)	1	(0,0)
SPIRONOLACTONE	1.297	(60,3)	1.302	(60,5)	2.599	(60,4)
TARAXACUM OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
THEOBROMINE	0	(0,0)	1	(0,0)	1	(0,0)
TOLVAPTAN	72	(3,3)	50	(2,3)	122	(2,8)
TORASEMIDE	363	(16,9)	392	(18,2)	755	(17,5)
TRIAMTERENE	2	(0,1)	0	(0,0)	2	(0,0)
TRICHLORMETHIAZIDE	12	(0,6)	15	(0,7)	27	(0,6)
XIPAMIDE	21	(1,0)	13	(0,6)	34	(0,8)
LIPID MODIFYING AGENTS	**1.441**	**(67,0)**	**1.437**	**(66,8)**	**2.878**	**(66,9)**
ACETYLSALICYLIC ACID;ATORVASTATIN CALCIUM;RAMIPRIL	1	(0,0)	0	(0,0)	1	(0,0)
ALIROCUMAB	1	(0,0)	0	(0,0)	1	(0,0)
ALLIUM SATIVUM	1	(0,0)	3	(0,1)	4	(0,1)
AMLODIPINE BESILATE;ATORVASTATIN CALCIUM	1	(0,0)	3	(0,1)	4	(0,1)
AMLODIPINE BESILATE;ATORVASTATIN CALCIUM TRIHYDRATE	0	(0,0)	1	(0,0)	1	(0,0)
ATORVASTATIN	605	(28,1)	609	(28,3)	1.214	(28,2)
ATORVASTATIN CALCIUM	286	(13,3)	293	(13,6)	579	(13,5)
ATORVASTATIN CALCIUM TRIHYDRATE	2	(0,1)	0	(0,0)	2	(0,0)
ATORVASTATIN CALCIUM TRIHYDRATE;EZETIMIBE	0	(0,0)	1	(0,0)	1	(0,0)
ATORVASTATIN CALCIUM;EZETIMIBE	7	(0,3)	11	(0,5)	18	(0,4)
ATORVASTATIN CALCIUM;IRBESARTAN	1	(0,0)	0	(0,0)	1	(0,0)
BERBERINE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
LIPID MODIFYING AGENTS	**1.441**	**(67,0)**	**1.437**	**(66,8)**	**2.878**	**(66,9)**
BEZAFIBRATE	4	(0,2)	8	(0,4)	12	(0,3)
BORAGO OFFICINALIS;DL-ALPHA TOCOPHEROL;FISH OIL;LINUM USITATISSIMUM	0	(0,0)	1	(0,0)	1	(0,0)
CARNITINE	2	(0,1)	0	(0,0)	2	(0,0)
CARTHAMUS TINCTORIUS	1	(0,0)	0	(0,0)	1	(0,0)
CERIVASTATIN SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
CHOLINE FENOFIBRATE	1	(0,0)	0	(0,0)	1	(0,0)
COLECALCIFEROL;FISH OIL	0	(0,0)	1	(0,0)	1	(0,0)
COLESEVELAM HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
COLESTIPOL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
COLESTYRAMINE	3	(0,1)	0	(0,0)	3	(0,1)
EICOSAPENTAENOIC ACID ETHYL ESTER	4	(0,2)	4	(0,2)	8	(0,2)
EVOLOCUMAB	0	(0,0)	3	(0,1)	3	(0,1)
EZETIMIBE	62	(2,9)	58	(2,7)	120	(2,8)
EZETIMIBE;ROSUVASTATIN CALCIUM	1	(0,0)	1	(0,0)	2	(0,0)
EZETIMIBE;ROSUVASTATIN ZINC	0	(0,0)	1	(0,0)	1	(0,0)
EZETIMIBE;SIMVASTATIN	8	(0,4)	11	(0,5)	19	(0,4)
FENOFIBRATE	24	(1,1)	13	(0,6)	37	(0,9)
FENOFIBRATE;SIMVASTATIN	0	(0,0)	1	(0,0)	1	(0,0)
FIBRATES	1	(0,0)	1	(0,0)	2	(0,0)
FLUVASTATIN SODIUM	10	(0,5)	9	(0,4)	19	(0,4)
GEMFIBROZIL	4	(0,2)	1	(0,0)	5	(0,1)
LECITHIN	1	(0,0)	1	(0,0)	2	(0,0)
LINUM USITATISSIMUM SEED	0	(0,0)	1	(0,0)	1	(0,0)
LOVASTATIN	3	(0,1)	8	(0,4)	11	(0,3)
LOVASTATIN;NICOTINIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
MONASCUS PURPUREUS	1	(0,0)	0	(0,0)	1	(0,0)
NICERITROL	1	(0,0)	0	(0,0)	1	(0,0)
NICOTINIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
OMEGA-3 MARINE TRIGLYCERIDES	22	(1,0)	13	(0,6)	35	(0,8)
OMEGA-3 TRIGLYCERIDES	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
LIPID MODIFYING AGENTS	**1.441**	**(67,0)**	**1.437**	**(66,8)**	**2.878**	**(66,9)**
OMEGA-3-ACID ETHYL ESTER	7	(0,3)	5	(0,2)	12	(0,3)
OTHER LIPID MODIFYING AGENTS	1	(0,0)	0	(0,0)	1	(0,0)
PHOSPHOLIPIDS	3	(0,1)	0	(0,0)	3	(0,1)
PITAVASTATIN CALCIUM	23	(1,1)	17	(0,8)	40	(0,9)
POLYENE PHOSPHATIDYLCHOLINE	5	(0,2)	7	(0,3)	12	(0,3)
PRAVASTATIN	27	(1,3)	20	(0,9)	47	(1,1)
PRAVASTATIN SODIUM	14	(0,7)	12	(0,6)	26	(0,6)
PROBUCOL	0	(0,0)	1	(0,0)	1	(0,0)
ROSUVASTATIN	106	(4,9)	115	(5,3)	221	(5,1)
ROSUVASTATIN CALCIUM	139	(6,5)	132	(6,1)	271	(6,3)
ROSUVASTATIN CALCIUM;TELMISARTAN	2	(0,1)	0	(0,0)	2	(0,0)
ROSUVASTATIN ZINC	1	(0,0)	1	(0,0)	2	(0,0)
SIMVASTATIN	206	(9,6)	218	(10,1)	424	(9,9)
TOCOPHERYL NICOTINATE	1	(0,0)	1	(0,0)	2	(0,0)
PERIPHERAL VASODILATORS	**37**	**(1,7)**	**47**	**(2,2)**	**84**	**(2,0)**
ACONITUM CARMICHAELII	1	(0,0)	0	(0,0)	1	(0,0)
ACONITUM SPP. PROCESSED ROOT;ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;CINNAMOMUM CASSIA BARK;CORNUS OFFICINALIS FRUIT;DIOSCOREA SPP. RHIZOME;PAEONIA X SUFFRUTICOSA ROOT BARK;PORIA COCOS SCLEROTIUM;REHMANNIA GLUTINOSA ROOT	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
PERIPHERAL VASODILATORS	**37**	**(1,7)**	**47**	**(2,2)**	**84**	**(2,0)**
AKEBIA SPP. STEM;ANGELICA ACUTILOBA ROOT;ASARUM SPP. ROOT;CINNAMOMUM CASSIA BARK;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;TETRADIUM RUTICARPUM FRUIT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
BENCYCLANE FUMARATE	1	(0,0)	3	(0,1)	4	(0,1)
BENDAZOL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CILOSTAZOL	7	(0,3)	8	(0,4)	15	(0,3)
CINEPAZIDE	1	(0,0)	2	(0,1)	3	(0,1)
CINEPAZIDE MALEATE	3	(0,1)	2	(0,1)	5	(0,1)
DIHYDROERGOTOXINE MESILATE	0	(0,0)	1	(0,0)	1	(0,0)
DIISOPROPYLAMINE DICHLOROACETATE	1	(0,0)	0	(0,0)	1	(0,0)
ENZYMES NOS	1	(0,0)	2	(0,1)	3	(0,1)
GINKGO BILOBA	2	(0,1)	2	(0,1)	4	(0,1)
GINKGO BILOBA EXTRACT	2	(0,1)	3	(0,1)	5	(0,1)
IFENPRODIL TARTRATE	1	(0,0)	1	(0,0)	2	(0,0)
KALLIDINOGENASE	0	(0,0)	2	(0,1)	2	(0,0)
METHYLETHYLPIRIDINOL SUCCINATE	2	(0,1)	0	(0,0)	2	(0,0)
NAFTIDROFURYL OXALATE	2	(0,1)	2	(0,1)	4	(0,1)
NICERGOLINE	4	(0,2)	1	(0,0)	5	(0,1)
NICOTINIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
PAPAVERINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
PENTOXIFYLLINE	6	(0,3)	14	(0,7)	20	(0,5)
PHENOXYBENZAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PIRIBEDIL	0	(0,0)	1	(0,0)	1	(0,0)
VASOPROTECTIVES	**394**	**(18,3)**	**346**	**(16,1)**	**740**	**(17,2)**

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
VASOPROTECTIVES	**394**	**(18,3)**	**346**	**(16,1)**	**740**	**(17,2)**
AESCULUS HIPPOCASTANUM EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
ALLANTOIN;CHLORHEXIDINE HYDROCHLORIDE;CHLORPHENAMINE MALEATE;HYDROCORTISONE ACETATE;LIDOCAINE;TETRYZOLINE HYDROCHLORIDE;TOCOPHERYL ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;HESPERIDIN METHYL CHALCONE;RUSCUS ACULEATUS	0	(0,0)	1	(0,0)	1	(0,0)
BECLOMETASONE DIPROPIONATE	24	(1,1)	13	(0,6)	37	(0,9)
BENZOCAINE;BISMUTH SUBGALLATE;DIPHENHYDRAMINE HYDROCHLORIDE;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
BETAMETHASONE BUTYRATE PROPIONATE	4	(0,2)	4	(0,2)	8	(0,2)
BETAMETHASONE DIPROPIONATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE SODIUM PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE VALERATE	3	(0,1)	3	(0,1)	6	(0,1)
BISMUTH OXIDE;BISMUTH SUBGALLATE;MYROXYLON BALSAMUM VAR. PEREIRAE BALSAM;ZINC OXIDE	1	(0,0)	0	(0,0)	1	(0,0)
BISMUTH OXIDE;MYROXYLON BALSAMUM VAR. PEREIRAE BALSAM;ZINC OXIDE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM DOBESILATE	2	(0,1)	3	(0,1)	5	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
VASOPROTECTIVES	**394**	**(18,3)**	**346**	**(16,1)**	**740**	**(17,2)**
CHONDRUS CRISPUS;TITANIUM DIOXIDE;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
CINCHOCAINE HYDROCHLORIDE;POLICRESULEN	0	(0,0)	1	(0,0)	1	(0,0)
CINCHOCAINE HYDROCHLORIDE;PREDNISOLONE CAPROATE	0	(0,0)	1	(0,0)	1	(0,0)
CROTAMITON;HYDROCORTISONE	2	(0,1)	0	(0,0)	2	(0,0)
DEXAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
DEXAMETHASONE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM PHOSPHATE	3	(0,1)	6	(0,3)	9	(0,2)
DILTIAZEM	7	(0,3)	9	(0,4)	16	(0,4)
DILTIAZEM HYDROCHLORIDE	14	(0,7)	14	(0,7)	28	(0,7)
DIOSMIN	2	(0,1)	1	(0,0)	3	(0,1)
DIOSMIN;HESPERIDIN	3	(0,1)	2	(0,1)	5	(0,1)
ERIGERON BREVISCAPUS HERB	1	(0,0)	0	(0,0)	1	(0,0)
ESCHERICHIA COLI;HYDROCORTISONE	1	(0,0)	0	(0,0)	1	(0,0)
FLUOCINOLONE ACETONIDE	0	(0,0)	2	(0,1)	2	(0,0)
FLUOCINONIDE	1	(0,0)	1	(0,0)	2	(0,0)
FLUOROMETHOLONE	4	(0,2)	0	(0,0)	4	(0,1)
GLUCOSE;SODIUM CHLORIDE	4	(0,2)	1	(0,0)	5	(0,1)
GLYCERYL TRINITRATE	183	(8,5)	153	(7,1)	336	(7,8)
HEPARIN	18	(0,8)	27	(1,3)	45	(1,0)
HEPARIN CALCIUM	11	(0,5)	3	(0,1)	14	(0,3)
HEPARIN SODIUM	25	(1,2)	16	(0,7)	41	(1,0)
HEPARINOID	3	(0,1)	2	(0,1)	5	(0,1)
HESPERIDIN	1	(0,0)	0	(0,0)	1	(0,0)
HYALURONATE SODIUM	9	(0,4)	7	(0,3)	16	(0,4)
HYDROCORTISONE	5	(0,2)	8	(0,4)	13	(0,3)
HYDROCORTISONE ACETATE	2	(0,1)	3	(0,1)	5	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
VASOPROTECTIVES	**394**	**(18,3)**	**346**	**(16,1)**	**740**	**(17,2)**
HYDROCORTISONE ACETATE;PRAMOCAINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
HYDROCORTISONE PROBUTAT	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE SODIUM SUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
ISOSORBIDE DINITRATE	75	(3,5)	59	(2,7)	134	(3,1)
LIDOCAINE	16	(0,7)	19	(0,9)	35	(0,8)
LIDOCAINE HYDROCHLORIDE	14	(0,7)	8	(0,4)	22	(0,5)
LIDOCAINE;TRIBENOSIDE	1	(0,0)	0	(0,0)	1	(0,0)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	6	(0,3)	4	(0,2)	10	(0,2)
NIFEDIPINE	13	(0,6)	20	(0,9)	33	(0,8)
PRAMOCAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PREDNISOLONE	28	(1,3)	19	(0,9)	47	(1,1)
PREDNISOLONE ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
PREDNISOLONE SODIUM SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE VALEROACETATE	3	(0,1)	0	(0,0)	3	(0,1)
PROCAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
QUERCETIN	1	(0,0)	0	(0,0)	1	(0,0)
THIOTRIAZOLINE	1	(0,0)	1	(0,0)	2	(0,0)
TRIAMCINOLONE	0	(0,0)	6	(0,3)	6	(0,1)
TRIAMCINOLONE ACETONIDE	1	(0,0)	4	(0,2)	5	(0,1)
VITIS VINIFERA EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
ZINC	0	(0,0)	1	(0,0)	1	(0,0)
ZINC SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
OTHER	**2**	**(0,1)**	**3**	**(0,1)**	**5**	**(0,1)**
ALLIUM SATIVUM	1	(0,0)	3	(0,1)	4	(0,1)
ARGININE	1	(0,0)	0	(0,0)	1	(0,0)
DERMATOLOGICALS						
ANTI-ACNE PREPARATIONS	**47**	**(2,2)**	**62**	**(2,9)**	**109**	**(2,5)**
AZELAIC ACID	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
ANTI-ACNE PREPARATIONS	**47**	**(2,2)**	**62**	**(2,9)**	**109**	**(2,5)**
AZITHROMYCIN	9	(0,4)	13	(0,6)	22	(0,5)
CHLORAMPHENICOL	1	(0,0)	3	(0,1)	4	(0,1)
CHLORHEXIDINE GLUCONATE	0	(0,0)	3	(0,1)	3	(0,1)
CLINDAMYCIN	1	(0,0)	4	(0,2)	5	(0,1)
CLINDAMYCIN PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
DEXAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
DEXAMETHASONE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM PHOSPHATE	3	(0,1)	6	(0,3)	9	(0,2)
DIMETICONE	2	(0,1)	7	(0,3)	9	(0,2)
DOXYCYCLINE	6	(0,3)	3	(0,1)	9	(0,2)
ERYTHROMYCIN	1	(0,0)	2	(0,1)	3	(0,1)
FLUOROMETHOLONE	4	(0,2)	0	(0,0)	4	(0,1)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
MATRICARIA RECUTITA;MELALEUCA ALTERNIFOLIA	0	(0,0)	1	(0,0)	1	(0,0)
METHYLPREDNISOLONE	12	(0,6)	14	(0,7)	26	(0,6)
METHYLPREDNISOLONE HEMISUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
METHYLPREDNISOLONE SODIUM SUCCINATE	10	(0,5)	2	(0,1)	12	(0,3)
NICOTINAMIDE	0	(0,0)	1	(0,0)	1	(0,0)
RETINOL	1	(0,0)	0	(0,0)	1	(0,0)
SALICYLIC ACID	0	(0,0)	2	(0,1)	2	(0,0)
SULFACETAMIDE	0	(0,0)	1	(0,0)	1	(0,0)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	**44**	**(2,0)**	**53**	**(2,5)**	**97**	**(2,3)**
ACICLOVIR	0	(0,0)	2	(0,1)	2	(0,0)
AMIKACIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
BACITRACIN ZINC;NEOMYCIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	**44**	**(2,0)**	**53**	**(2,5)**	**97**	**(2,3)**
BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	1	(0,0)	1	(0,0)	2	(0,0)
BENZYLPENICILLIN	0	(0,0)	1	(0,0)	1	(0,0)
CHLORAMPHENICOL	1	(0,0)	3	(0,1)	4	(0,1)
CIPROFLOXACIN	9	(0,4)	19	(0,9)	28	(0,7)
CIPROFLOXACIN HYDROCHLORIDE	5	(0,2)	1	(0,0)	6	(0,1)
CLARITHROMYCIN	5	(0,2)	5	(0,2)	10	(0,2)
DOXYCYCLINE	6	(0,3)	3	(0,1)	9	(0,2)
ERYTHROMYCIN	1	(0,0)	2	(0,1)	3	(0,1)
FUSIDIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
GANCICLOVIR SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
GENTAMICIN	0	(0,0)	2	(0,1)	2	(0,0)
GENTAMICIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
LYSOZYME CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
METRONIDAZOLE	4	(0,2)	2	(0,1)	6	(0,1)
MUPIROCIN	2	(0,1)	3	(0,1)	5	(0,1)
NEOMYCIN	0	(0,0)	1	(0,0)	1	(0,0)
RIFAMPICIN	5	(0,2)	1	(0,0)	6	(0,1)
RIFAMYCIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
SULFADIAZINE SILVER	1	(0,0)	2	(0,1)	3	(0,1)
TETRACYCLINE	0	(0,0)	1	(0,0)	1	(0,0)
TETRACYCLINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
ANTIFUNGALS FOR DERMATOLOGICAL USE	**13**	**(0,6)**	**22**	**(1,0)**	**35**	**(0,8)**
AMPHOTERICIN B	1	(0,0)	1	(0,0)	2	(0,0)
BETAMETHASONE DIPROPIONATE;CLOTRIMAZOLE	2	(0,1)	0	(0,0)	2	(0,0)
CICLOPIROX	0	(0,0)	1	(0,0)	1	(0,0)
CLOBETASOL PROPIONATE;KETOCONAZOLE	1	(0,0)	0	(0,0)	1	(0,0)
CLOTRIMAZOLE	1	(0,0)	3	(0,1)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
ANTIFUNGALS FOR DERMATOLOGICAL USE	**13**	**(0,6)**	**22**	**(1,0)**	**35**	**(0,8)**
DIFLUCORTOLONE VALERATE;ISOCONAZOLE NITRATE	1	(0,0)	0	(0,0)	1	(0,0)
ECONAZOLE NITRATE;TRIAMCINOLONE ACETONIDE	0	(0,0)	1	(0,0)	1	(0,0)
FLUCONAZOLE	1	(0,0)	1	(0,0)	2	(0,0)
HYDROCORTISONE;MICONAZOLE NITRATE	0	(0,0)	1	(0,0)	1	(0,0)
ISOCONAZOLE NITRATE	2	(0,1)	0	(0,0)	2	(0,0)
KETOCONAZOLE	2	(0,1)	3	(0,1)	5	(0,1)
LULICONAZOLE	0	(0,0)	1	(0,0)	1	(0,0)
MICONAZOLE	2	(0,1)	0	(0,0)	2	(0,0)
MICONAZOLE NITRATE	1	(0,0)	3	(0,1)	4	(0,1)
NAFTIFINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
NYSTATIN	1	(0,0)	4	(0,2)	5	(0,1)
SALICYLIC ACID	0	(0,0)	2	(0,1)	2	(0,0)
TERBINAFINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	**65**	**(3,0)**	**69**	**(3,2)**	**134**	**(3,1)**
ANTIHISTAMINES FOR TOPICAL USE	1	(0,0)	1	(0,0)	2	(0,0)
CALAMINE	0	(0,0)	1	(0,0)	1	(0,0)
CALAMINE;ZINC OXIDE	2	(0,1)	0	(0,0)	2	(0,0)
CAMPHOR	0	(0,0)	1	(0,0)	1	(0,0)
CINCHOCAINE HYDROCHLORIDE;DIPHENHYDRAMINE;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
CLEMASTINE FUMARATE	1	(0,0)	0	(0,0)	1	(0,0)
CROTAMITON	3	(0,1)	1	(0,0)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	**65**	**(3,0)**	**69**	**(3,2)**	**134**	**(3,1)**
CYSTEINE HYDROCHLORIDE;GLYCINE;GLYCYRRHIZIC ACID, AMMONIUM SALT	0	(0,0)	1	(0,0)	1	(0,0)
CYSTEINE;GLYCINE;GLYCYRRHIZIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
DEXCHLORPHENIRAMINE MALEATE	1	(0,0)	0	(0,0)	1	(0,0)
DIPHENHYDRAMINE	4	(0,2)	9	(0,4)	13	(0,3)
DIPHENHYDRAMINE HYDROCHLORIDE	2	(0,1)	7	(0,3)	9	(0,2)
DIPHENHYDRAMINE HYDROCHLORIDE;ZINC ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
DOXEPIN HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
HYDROXYZINE	11	(0,5)	13	(0,6)	24	(0,6)
KETOTIFEN FUMARATE	1	(0,0)	1	(0,0)	2	(0,0)
LEVOMENTHOL	1	(0,0)	0	(0,0)	1	(0,0)
LIDOCAINE	16	(0,7)	19	(0,9)	35	(0,8)
LIDOCAINE HYDROCHLORIDE	14	(0,7)	8	(0,4)	22	(0,5)
LIDOCAINE;PRILOCAINE	0	(0,0)	1	(0,0)	1	(0,0)
MENTHOL	0	(0,0)	1	(0,0)	1	(0,0)
OTHER ANTIPRURITICS	1	(0,0)	0	(0,0)	1	(0,0)
OXYBUPROCAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PHENIRAMINE MALEATE	1	(0,0)	1	(0,0)	2	(0,0)
PRAMOCAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PROMETHAZINE	3	(0,1)	5	(0,2)	8	(0,2)
PROMETHAZINE HYDROCHLORIDE	5	(0,2)	2	(0,1)	7	(0,2)
ANTIPSORIATICS	**24**	**(1,1)**	**21**	**(1,0)**	**45**	**(1,0)**
ACITRETIN	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
ANTIPSORIATICS	**24**	**(1,1)**	**21**	**(1,0)**	**45**	**(1,0)**
BETAMETHASONE BUTYRATE PROPIONATE;MAXACALCITOL	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE DIPROPIONATE;CALCIPOTRIOL	0	(0,0)	3	(0,1)	3	(0,1)
CALCIPOTRIOL	2	(0,1)	0	(0,0)	2	(0,0)
CALCITRIOL	19	(0,9)	17	(0,8)	36	(0,8)
DISODIUM FUMARATE	0	(0,0)	1	(0,0)	1	(0,0)
MAXACALCITOL	1	(0,0)	1	(0,0)	2	(0,0)
ANTISEPTICS AND DISINFECTANTS	**9**	**(0,4)**	**10**	**(0,5)**	**19**	**(0,4)**
BENZETHONIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
BORIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
CETYLPYRIDINIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CHLORHEXIDINE GLUCONATE	0	(0,0)	3	(0,1)	3	(0,1)
CHLORHEXIDINE GLUCONATE;PHENYLEPHRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
DEQUALINIUM CHLORIDE	3	(0,1)	4	(0,2)	7	(0,2)
OCTENIDINE HYDROCHLORIDE;PHENOXYETHANOL	0	(0,0)	1	(0,0)	1	(0,0)
OLANEXIDINE GLUCONATE	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM PERMANGANATE	1	(0,0)	1	(0,0)	2	(0,0)
POVIDONE-IODINE	3	(0,1)	1	(0,0)	4	(0,1)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	**190**	**(8,8)**	**193**	**(9,0)**	**383**	**(8,9)**
AMCINONIDE	1	(0,0)	0	(0,0)	1	(0,0)
BACTERIA NOS;HYDROCORTISONE	1	(0,0)	0	(0,0)	1	(0,0)
BECLOMETASONE DIPROPIONATE	24	(1,1)	13	(0,6)	37	(0,9)
BETAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
BETAMETHASONE BUTYRATE PROPIONATE	4	(0,2)	4	(0,2)	8	(0,2)
BETAMETHASONE DIPROPIONATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	**190**	**(8,8)**	**193**	**(9,0)**	**383**	**(8,9)**
BETAMETHASONE DIPROPIONATE;BETAMETHASONE SODIUM PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE DIPROPIONATE;CLOTRIMAZOLE;GENTAMICIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE DIPROPIONATE;GENTAMICIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE DIPROPIONATE;SALICYLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE SODIUM PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE VALERATE	3	(0,1)	3	(0,1)	6	(0,1)
BETAMETHASONE VALERATE;CLIOQUINOL	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE VALERATE;FUSIDIC ACID	0	(0,0)	3	(0,1)	3	(0,1)
BETAMETHASONE VALERATE;GENTAMICIN SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
BETAMETHASONE VALERATE;SALICYLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
BUDESONIDE	47	(2,2)	61	(2,8)	108	(2,5)
CHLORQUINALDOL;DIFLUCORTOLONE VALERATE	1	(0,0)	0	(0,0)	1	(0,0)
CLOBETASOL PROPIONATE	4	(0,2)	8	(0,4)	12	(0,3)
CLOBETASONE BUTYRATE	1	(0,0)	0	(0,0)	1	(0,0)
CLOCORTOLONE PIVALATE	1	(0,0)	0	(0,0)	1	(0,0)
CROTAMITON;HYDROCORTISONE	2	(0,1)	0	(0,0)	2	(0,0)
DESONIDE	1	(0,0)	1	(0,0)	2	(0,0)
DEXAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	**190**	**(8,8)**	**193**	**(9,0)**	**383**	**(8,9)**
DEXAMETHASONE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM PHOSPHATE	3	(0,1)	6	(0,3)	9	(0,2)
DIFLORASONE DIACETATE	1	(0,0)	0	(0,0)	1	(0,0)
DIFLUCORTOLONE VALERATE	1	(0,0)	1	(0,0)	2	(0,0)
DIFLUPREDNATE	2	(0,1)	0	(0,0)	2	(0,0)
FLUOCINOLONE ACETONIDE	0	(0,0)	2	(0,1)	2	(0,0)
FLUOCINONIDE	1	(0,0)	1	(0,0)	2	(0,0)
FLUOROMETHOLONE	4	(0,2)	0	(0,0)	4	(0,1)
FLUTICASONE	21	(1,0)	17	(0,8)	38	(0,9)
FLUTICASONE PROPIONATE	16	(0,7)	28	(1,3)	44	(1,0)
HALOMETASONE	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE	5	(0,2)	8	(0,4)	13	(0,3)
HYDROCORTISONE ACETATE	2	(0,1)	3	(0,1)	5	(0,1)
HYDROCORTISONE ACETATE;PRAMOCAINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
HYDROCORTISONE BUTYRATE	1	(0,0)	2	(0,1)	3	(0,1)
HYDROCORTISONE PROBUTAT	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE SODIUM SUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
METHYLPREDNISOLONE	12	(0,6)	14	(0,7)	26	(0,6)
METHYLPREDNISOLONE ACEPONATE	2	(0,1)	1	(0,0)	3	(0,1)
METHYLPREDNISOLONE HEMISUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
METHYLPREDNISOLONE SODIUM SUCCINATE	10	(0,5)	2	(0,1)	12	(0,3)
METHYLPREDNISOLONE;NEOMYCIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
MOMETASONE FUROATE	9	(0,4)	9	(0,4)	18	(0,4)
PREDNISOLONE	28	(1,3)	19	(0,9)	47	(1,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	**190**	**(8,8)**	**193**	**(9,0)**	**383**	**(8,9)**
PREDNISOLONE ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
PREDNISOLONE SODIUM SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE VALEROACETATE	3	(0,1)	0	(0,0)	3	(0,1)
TRIAMCINOLONE	0	(0,0)	6	(0,3)	6	(0,1)
TRIAMCINOLONE ACETONIDE	1	(0,0)	4	(0,2)	5	(0,1)
EMOLLIENTS AND PROTECTIVES	**57**	**(2,6)**	**61**	**(2,8)**	**118**	**(2,7)**
AMMONIUM LACTATE	1	(0,0)	0	(0,0)	1	(0,0)
BORIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
BUTYROSPERMUM PARKII;DIMETHICONOL;DIMETICONE;GLYCEROL;GLYCERYL MONOSTEARATE;NICOTINAMIDE;PARAFFIN, LIQUID	0	(0,0)	1	(0,0)	1	(0,0)
CALAMINE;ZINC OXIDE	2	(0,1)	0	(0,0)	2	(0,0)
CAMPHOR;CAPSICUM SPP.;METHYL SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)
CAMPHOR;MENTHOL;METHYL SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)
CETOMACROGOL;PARAFFIN, LIQUID;PROPYLENE GLYCOL;WHITE SOFT PARAFFIN	0	(0,0)	1	(0,0)	1	(0,0)
CETOSTEARYL ALCOHOL;SODIUM LAURYL SULFATE	6	(0,3)	4	(0,2)	10	(0,2)
DIMETICONE	2	(0,1)	7	(0,3)	9	(0,2)
GLUCONOLACTONE	0	(0,0)	1	(0,0)	1	(0,0)
GLYCEROL	8	(0,4)	3	(0,1)	11	(0,3)
GLYCEROL;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	3	(0,1)	3	(0,1)	6	(0,1)
GLYCERYL MONOSTEARATE	0	(0,0)	1	(0,0)	1	(0,0)
HEPARINOID	3	(0,1)	2	(0,1)	5	(0,1)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
EMOLLIENTS AND PROTECTIVES	**57**	**(2,6)**	**61**	**(2,8)**	**118**	**(2,7)**
LINOLEIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
LINUM USITATISSIMUM SEED	0	(0,0)	1	(0,0)	1	(0,0)
METHYL SALICYLATE	2	(0,1)	1	(0,0)	3	(0,1)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	6	(0,3)	4	(0,2)	10	(0,2)
OTHER EMOLLIENTS AND PROTECTIVES	0	(0,0)	1	(0,0)	1	(0,0)
PANICUM MILIACEUM	1	(0,0)	0	(0,0)	1	(0,0)
PARAFFIN	1	(0,0)	1	(0,0)	2	(0,0)
PARAFFIN, LIQUID	1	(0,0)	0	(0,0)	1	(0,0)
PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	1	(0,0)	1	(0,0)	2	(0,0)
PETROLATUM	0	(0,0)	1	(0,0)	1	(0,0)
PETROLATUM;WOOL FAT	0	(0,0)	1	(0,0)	1	(0,0)
RICINUS COMMUNIS OIL	0	(0,0)	1	(0,0)	1	(0,0)
SALICYLIC ACID	0	(0,0)	2	(0,1)	2	(0,0)
THIOCTIC ACID	4	(0,2)	9	(0,4)	13	(0,3)
TOCOPHEROL	3	(0,1)	5	(0,2)	8	(0,2)
TOCOPHERYL ACETATE	2	(0,1)	2	(0,1)	4	(0,1)
UREA	8	(0,4)	4	(0,2)	12	(0,3)
WHITE SOFT PARAFFIN	6	(0,3)	4	(0,2)	10	(0,2)
ZINC	0	(0,0)	1	(0,0)	1	(0,0)
ZINC OXIDE	0	(0,0)	2	(0,1)	2	(0,0)
ZINC SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
MEDICATED DRESSINGS	**53**	**(2,5)**	**59**	**(2,7)**	**112**	**(2,6)**
ALGINIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
CALAMINE;ZINC OXIDE	2	(0,1)	0	(0,0)	2	(0,0)
CARMELLOSE SODIUM	3	(0,1)	1	(0,0)	4	(0,1)
CETYLPYRIDINIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CHLORHEXIDINE GLUCONATE	0	(0,0)	3	(0,1)	3	(0,1)
FUSIDIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
PARAFFIN	1	(0,0)	1	(0,0)	2	(0,0)
POVIDONE-IODINE	3	(0,1)	1	(0,0)	4	(0,1)
SODIUM ALGINATE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
MEDICATED DRESSINGS	**53**	**(2,5)**	**59**	**(2,7)**	**112**	**(2,6)**
SODIUM CHLORIDE	44	(2,0)	49	(2,3)	93	(2,2)
ZINC	0	(0,0)	1	(0,0)	1	(0,0)
ZINC OXIDE	0	(0,0)	2	(0,1)	2	(0,0)
OTHER DERMATOLOGICAL PREPARATIONS	**222**	**(10,3)**	**225**	**(10,5)**	**447**	**(10,4)**
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID	19	(0,9)	16	(0,7)	35	(0,8)
BIMATOPROST	2	(0,1)	1	(0,0)	3	(0,1)
BRIMONIDINE TARTRATE	2	(0,1)	6	(0,3)	8	(0,2)
CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM GLUCONATE	4	(0,2)	7	(0,3)	11	(0,3)
CARPRONIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;PUERARIA LOBATA ROOT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
CORNUS OFFICINALIS	1	(0,0)	0	(0,0)	1	(0,0)
DICLOFENAC	7	(0,3)	11	(0,5)	18	(0,4)
DICLOFENAC SODIUM	14	(0,7)	7	(0,3)	21	(0,5)
ESTRADIOL	3	(0,1)	3	(0,1)	6	(0,1)
ETOFESALAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
FATTY ACIDS NOS	1	(0,0)	1	(0,0)	2	(0,0)
FINASTERIDE	33	(1,5)	38	(1,8)	71	(1,7)
GLYCEROL	8	(0,4)	3	(0,1)	11	(0,3)
GLYCOPYRRONIUM	1	(0,0)	2	(0,1)	3	(0,1)
GLYCOPYRRONIUM BROMIDE	5	(0,2)	5	(0,2)	10	(0,2)
GUAIAZULENE	1	(0,0)	2	(0,1)	3	(0,1)
HYALURONATE SODIUM	9	(0,4)	7	(0,3)	16	(0,4)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
OTHER DERMATOLOGICAL PREPARATIONS	**222**	**(10,3)**	**225**	**(10,5)**	**447**	**(10,4)**
IVERMECTIN	0	(0,0)	1	(0,0)	1	(0,0)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
MAGNESIUM SULFATE	38	(1,8)	35	(1,6)	73	(1,7)
OXYGEN	6	(0,3)	6	(0,3)	12	(0,3)
OXYMETAZOLINE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
PANICUM MILIACEUM	1	(0,0)	0	(0,0)	1	(0,0)
PHYTOMENADIONE	4	(0,2)	5	(0,2)	9	(0,2)
POVIDONE-IODINE	3	(0,1)	1	(0,0)	4	(0,1)
PYRIDOXINE	9	(0,4)	14	(0,7)	23	(0,5)
PYRIDOXINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
SALICYLIC ACID	0	(0,0)	2	(0,1)	2	(0,0)
SILDENAFIL CITRATE	3	(0,1)	3	(0,1)	6	(0,1)
SIROLIMUS	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM BICARBONATE	40	(1,9)	34	(1,6)	74	(1,7)
SUCRALFATE	4	(0,2)	5	(0,2)	9	(0,2)
SULFACETAMIDE	0	(0,0)	1	(0,0)	1	(0,0)
TACROLIMUS	1	(0,0)	2	(0,1)	3	(0,1)
THIOTRIAZOLINE	1	(0,0)	1	(0,0)	2	(0,0)
UBIDECARENONE	25	(1,2)	31	(1,4)	56	(1,3)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	**65**	**(3,0)**	**76**	**(3,5)**	**141**	**(3,3)**
ALLIUM MACROSTEMON	1	(0,0)	0	(0,0)	1	(0,0)
CARMELLOSE SODIUM	3	(0,1)	1	(0,0)	4	(0,1)
COD-LIVER OIL	0	(0,0)	1	(0,0)	1	(0,0)
COLLAGENASE	1	(0,0)	2	(0,1)	3	(0,1)
DEXPANTHENOL	0	(0,0)	1	(0,0)	1	(0,0)
DIMETICONE	2	(0,1)	7	(0,3)	9	(0,2)
FIBRONECTIN	0	(0,0)	1	(0,0)	1	(0,0)
HONEY	1	(0,0)	0	(0,0)	1	(0,0)
HOUTTUYNIA CORDATA	0	(0,0)	1	(0,0)	1	(0,0)
HYALURONATE SODIUM	9	(0,4)	7	(0,3)	16	(0,4)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	**65**	**(3,0)**	**76**	**(3,5)**	**141**	**(3,3)**
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
NEPIDERMIN	0	(0,0)	1	(0,0)	1	(0,0)
PANICUM MILIACEUM	1	(0,0)	0	(0,0)	1	(0,0)
PERIPLANETA AMERICANA	0	(0,0)	1	(0,0)	1	(0,0)
PINELLIA TERNATA	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM CHLORIDE	44	(2,0)	49	(2,3)	93	(2,2)
STREPTODORNASE;STREPTOKINASE	0	(0,0)	1	(0,0)	1	(0,0)
TOCOPHEROL	3	(0,1)	5	(0,2)	8	(0,2)
TOCOPHERYL ACETATE	2	(0,1)	2	(0,1)	4	(0,1)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
OTHER	**8**	**(0,4)**	**7**	**(0,3)**	**15**	**(0,3)**
DIOSMECTITE	8	(0,4)	7	(0,3)	15	(0,3)
GENITO URINARY SYSTEM AND SEX HORMONES						
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	**105**	**(4,9)**	**116**	**(5,4)**	**221**	**(5,1)**
AMPHOTERICIN B	1	(0,0)	1	(0,0)	2	(0,0)
ASCORBIC ACID	19	(0,9)	16	(0,7)	35	(0,8)
BORIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
CHLORAMPHENICOL	1	(0,0)	3	(0,1)	4	(0,1)
CHLORHEXIDINE GLUCONATE	0	(0,0)	3	(0,1)	3	(0,1)
CICLOPIROX	0	(0,0)	1	(0,0)	1	(0,0)
CIPROFLOXACIN	9	(0,4)	19	(0,9)	28	(0,7)
CIPROFLOXACIN LACTATE	1	(0,0)	0	(0,0)	1	(0,0)
CLINDAMYCIN	1	(0,0)	4	(0,2)	5	(0,1)
CLINDAMYCIN PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
CLOTRIMAZOLE	1	(0,0)	3	(0,1)	4	(0,1)
DEQUALINIUM CHLORIDE	3	(0,1)	4	(0,2)	7	(0,2)
FLUCONAZOLE	1	(0,0)	1	(0,0)	2	(0,0)
ISOCONAZOLE NITRATE	2	(0,1)	0	(0,0)	2	(0,0)
KETOCONAZOLE	2	(0,1)	3	(0,1)	5	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
GENITO URINARY SYSTEM AND SEX HORMONES						
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	**105**	**(4,9)**	**116**	**(5,4)**	**221**	**(5,1)**
LACTOBACILLUS RHAMNOSUS	2	(0,1)	6	(0,3)	8	(0,2)
METRONIDAZOLE	4	(0,2)	2	(0,1)	6	(0,1)
MICONAZOLE	2	(0,1)	0	(0,0)	2	(0,0)
MICONAZOLE NITRATE	1	(0,0)	3	(0,1)	4	(0,1)
NYSTATIN	1	(0,0)	4	(0,2)	5	(0,1)
OCTENIDINE HYDROCHLORIDE;PHENOXYETHANOL	0	(0,0)	1	(0,0)	1	(0,0)
POTASSIUM	56	(2,6)	50	(2,3)	106	(2,5)
POVIDONE-IODINE	3	(0,1)	1	(0,0)	4	(0,1)
OTHER GYNECOLOGICALS	**113**	**(5,3)**	**113**	**(5,3)**	**226**	**(5,3)**
AKEBIA SPP. STEM;ANGELICA ACUTILOBA ROOT;ASARUM SPP. ROOT;CINNAMOMUM CASSIA BARK;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;TETRADIUM RUTICARPUM FRUIT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
ALLIUM MACROSTEMON	1	(0,0)	0	(0,0)	1	(0,0)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
ARTEMISIA ARGYI LEAF	2	(0,1)	2	(0,1)	4	(0,1)
CABERGOLINE	1	(0,0)	1	(0,0)	2	(0,0)
CARBOMER	1	(0,0)	1	(0,0)	2	(0,0)
CARTHAMUS TINCTORIUS	1	(0,0)	0	(0,0)	1	(0,0)
FENOTEROL	5	(0,2)	8	(0,4)	13	(0,3)
FENOTEROL HYDROBROMIDE	1	(0,0)	2	(0,1)	3	(0,1)
GLUCOSE;MAGNESIUM SULFATE	1	(0,0)	1	(0,0)	2	(0,0)
GLYCEROL	8	(0,4)	3	(0,1)	11	(0,3)
HYALURONATE SODIUM	9	(0,4)	7	(0,3)	16	(0,4)
IBUPROFEN	14	(0,7)	9	(0,4)	23	(0,5)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
GENITO URINARY SYSTEM AND SEX HORMONES						
OTHER GYNECOLOGICALS	**113**	**(5,3)**	**113**	**(5,3)**	**226**	**(5,3)**
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
LACTOBACILLUS ACIDOPHILUS	5	(0,2)	3	(0,1)	8	(0,2)
LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS CASEI;LACTOBACILLUS RHAMNOSUS	1	(0,0)	0	(0,0)	1	(0,0)
LACTOBACILLUS NOS	0	(0,0)	1	(0,0)	1	(0,0)
LEVONORGESTREL	1	(0,0)	0	(0,0)	1	(0,0)
LIGUSTICUM STRIATUM	1	(0,0)	0	(0,0)	1	(0,0)
METHOTREXATE	2	(0,1)	8	(0,4)	10	(0,2)
MISOPROSTOL	1	(0,0)	0	(0,0)	1	(0,0)
NAPROXEN	0	(0,0)	5	(0,2)	5	(0,1)
NAPROXEN SODIUM	0	(0,0)	2	(0,1)	2	(0,0)
NIFEDIPINE	13	(0,6)	20	(0,9)	33	(0,8)
PAROXETINE	6	(0,3)	3	(0,1)	9	(0,2)
PROGESTERONE	1	(0,0)	0	(0,0)	1	(0,0)
REHMANNIA GLUTINOSA	1	(0,0)	0	(0,0)	1	(0,0)
SALVIA MILTIORRHIZA	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM BICARBONATE	40	(1,9)	34	(1,6)	74	(1,7)
STREPTODORNASE;STREPTOKINASE	0	(0,0)	1	(0,0)	1	(0,0)
TERBUTALINE SULFATE	6	(0,3)	7	(0,3)	13	(0,3)
THIOTRIAZOLINE	1	(0,0)	1	(0,0)	2	(0,0)
TRICHOSANTHES KIRILOWII	1	(0,0)	1	(0,0)	2	(0,0)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	**16**	**(0,7)**	**17**	**(0,8)**	**33**	**(0,8)**
CYPROTERONE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
DESOGESTREL;ETHINYLESTRADIOL	1	(0,0)	0	(0,0)	1	(0,0)
ESTRADIOL	3	(0,1)	3	(0,1)	6	(0,1)
ESTRIOL	2	(0,1)	0	(0,0)	2	(0,0)
ESTROGENS CONJUGATED	0	(0,0)	3	(0,1)	3	(0,1)
ETHINYLESTRADIOL;GESTODENE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
GENITO URINARY SYSTEM AND SEX HORMONES						
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	**16**	**(0,7)**	**17**	**(0,8)**	**33**	**(0,8)**
ETHINYLESTRADIOL;LEVONORGESTREL	1	(0,0)	0	(0,0)	1	(0,0)
LEVONORGESTREL	1	(0,0)	0	(0,0)	1	(0,0)
MEDROXYPROGESTERONE ACETATE	1	(0,0)	3	(0,1)	4	(0,1)
MEGESTROL ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
NORETHISTERONE ENANTATE	2	(0,1)	2	(0,1)	4	(0,1)
PROGESTERONE	1	(0,0)	0	(0,0)	1	(0,0)
RALOXIFENE	0	(0,0)	1	(0,0)	1	(0,0)
TESTOSTERONE	1	(0,0)	2	(0,1)	3	(0,1)
TESTOSTERONE CIPIONATE	0	(0,0)	1	(0,0)	1	(0,0)
TESTOSTERONE ENANTHATE	1	(0,0)	0	(0,0)	1	(0,0)
TESTOSTERONE PROPIONATE	1	(0,0)	0	(0,0)	1	(0,0)
UROLOGICALS	**323**	**(15,0)**	**330**	**(15,3)**	**653**	**(15,2)**
ABELMOSCHUS MANIHOT FLOWER	1	(0,0)	0	(0,0)	1	(0,0)
ACONITUM SPP. PROCESSED ROOT;ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;CINNAMOMUM CASSIA BARK;CORNUS OFFICINALIS FRUIT;DIOSCOREA SPP. RHIZOME;PAEONIA X SUFFRUTICOSA ROOT BARK;PORIA COCOS SCLEROTIUM;REHMANNIA GLUTINOSA ROOT	0	(0,0)	1	(0,0)	1	(0,0)
AESCULUS HIPPOCASTANUM SEED;SERENOA REPENS;SOLIDAGO VIRGAUREA	0	(0,0)	1	(0,0)	1	(0,0)
ALFUZOSIN HYDROCHLORIDE	11	(0,5)	16	(0,7)	27	(0,6)
ALPROSTADIL	8	(0,4)	8	(0,4)	16	(0,4)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
GENITO URINARY SYSTEM AND SEX HORMONES						
UROLOGICALS	**323**	**(15,0)**	**330**	**(15,3)**	**653**	**(15,2)**
BORON;CHROMIUM;COPPER;GERMANIUM;IODINE;MANGANESE;MOLYBDENUM;SELENIUM;SILICON;SITOSTEROL;VANADIUM;VITAMIN D NOS;ZINC	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CHLORIDE	2	(0,1)	4	(0,2)	6	(0,1)
CHONDROITIN SULFATE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
CITRIC ACID;SODIUM BICARBONATE;SODIUM CITRATE;TARTARIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
CITRIC ACID;SODIUM CITRATE ACID	1	(0,0)	0	(0,0)	1	(0,0)
CORDYCEPS SINENSIS	12	(0,6)	6	(0,3)	18	(0,4)
CORNUS OFFICINALIS	1	(0,0)	0	(0,0)	1	(0,0)
DOXAZOSIN	10	(0,5)	17	(0,8)	27	(0,6)
DOXAZOSIN MESILATE	18	(0,8)	13	(0,6)	31	(0,7)
DULOXETINE HYDROCHLORIDE	11	(0,5)	13	(0,6)	24	(0,6)
DUTASTERIDE	18	(0,8)	17	(0,8)	35	(0,8)
DUTASTERIDE;TAMSULOSIN HYDROCHLORIDE	4	(0,2)	9	(0,4)	13	(0,3)
FESOTERODINE FUMARATE	0	(0,0)	1	(0,0)	1	(0,0)
FINASTERIDE	33	(1,5)	38	(1,8)	71	(1,7)
HYALURONATE SODIUM	9	(0,4)	7	(0,3)	16	(0,4)
LIDOCAINE	16	(0,7)	19	(0,9)	35	(0,8)
LIDOCAINE HYDROCHLORIDE	14	(0,7)	8	(0,4)	22	(0,5)
MAGNESIUM CITRATE	6	(0,3)	5	(0,2)	11	(0,3)
MAGNESIUM HYDROXIDE	10	(0,5)	10	(0,5)	20	(0,5)
MIRABEGRON	6	(0,3)	8	(0,4)	14	(0,3)
NAFTOPIDIL	2	(0,1)	1	(0,0)	3	(0,1)
OPHIOPOGON JAPONICUS	1	(0,0)	0	(0,0)	1	(0,0)
OXYBUTYNIN	3	(0,1)	1	(0,0)	4	(0,1)
OXYBUTYNIN HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
PANICUM MILIACEUM	1	(0,0)	0	(0,0)	1	(0,0)
PAPAVERINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
GENITO URINARY SYSTEM AND SEX HORMONES						
UROLOGICALS	**323**	**(15,0)**	**330**	**(15,3)**	**653**	**(15,2)**
PHENAZOPYRIDINE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
POTASSIUM CITRATE	15	(0,7)	11	(0,5)	26	(0,6)
POTASSIUM CITRATE;SODIUM CITRATE DIHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
SERENOA REPENS	6	(0,3)	1	(0,0)	7	(0,2)
SERENOA REPENS EXTRACT	4	(0,2)	2	(0,1)	6	(0,1)
SERENOA REPENS EXTRACT;URTICA DIOICA EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
SILDENAFIL CITRATE	3	(0,1)	3	(0,1)	6	(0,1)
SILODOSIN	14	(0,7)	17	(0,8)	31	(0,7)
SODIUM BICARBONATE	40	(1,9)	34	(1,6)	74	(1,7)
SOLIFENACIN SUCCINATE	3	(0,1)	5	(0,2)	8	(0,2)
TADALAFIL	2	(0,1)	0	(0,0)	2	(0,0)
TAMSULOSIN HYDROCHLORIDE	109	(5,1)	115	(5,3)	224	(5,2)
TARAXACUM OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
TERAZOSIN	3	(0,1)	4	(0,2)	7	(0,2)
TERAZOSIN HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
TOLTERODINE	0	(0,0)	1	(0,0)	1	(0,0)
TOLTERODINE L-TARTRATE	2	(0,1)	3	(0,1)	5	(0,1)
TROSPIUM	1	(0,0)	0	(0,0)	1	(0,0)
TROSPIUM CHLORIDE	1	(0,0)	4	(0,2)	5	(0,1)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
OTHER	**1**	**(0,0)**	**1**	**(0,0)**	**2**	**(0,0)**
ARGININE	1	(0,0)	0	(0,0)	1	(0,0)
ARGININE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
MUSCULO-SKELETAL SYSTEM						
ANTIGOUT PREPARATIONS	**482**	**(22,4)**	**465**	**(21,6)**	**947**	**(22,0)**
ALLOPURINOL	326	(15,1)	313	(14,6)	639	(14,9)
BENZBROMARONE	15	(0,7)	26	(1,2)	41	(1,0)
COLCHICINE	58	(2,7)	55	(2,6)	113	(2,6)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
ANTIGOUT PREPARATIONS	**482**	**(22,4)**	**465**	**(21,6)**	**947**	**(22,0)**
COLCHICINE;DICYCLOVERINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
COLCHICINE;PROBENECID	1	(0,0)	0	(0,0)	1	(0,0)
FEBUXOSTAT	119	(5,5)	111	(5,2)	230	(5,3)
SULFINPYRAZONE	2	(0,1)	1	(0,0)	3	(0,1)
TOPIROXOSTAT	4	(0,2)	1	(0,0)	5	(0,1)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	**115**	**(5,3)**	**123**	**(5,7)**	**238**	**(5,5)**
ACECLOFENAC	1	(0,0)	1	(0,0)	2	(0,0)
ACEMETACIN	0	(0,0)	1	(0,0)	1	(0,0)
ACONITUM CARMICHAELII	1	(0,0)	0	(0,0)	1	(0,0)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
APRONAL;CAFFEINE;IBUPROFEN	0	(0,0)	1	(0,0)	1	(0,0)
ARGININE HYDROCHLORIDE;IBUPROFEN	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;CHONDROITIN SULFATE;GLUCOSAMINE SULFATE;MANGANESE SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
BAICALIN;BUFFALO HORN;CHOLIC ACID;CONCHA MARGARITIFERA;GARDENIA JASMINOIDES FRUIT;HYODEOXYCHOLIC ACID;ISATIS INDIGOTICA ROOT;LONICERA JAPONICA FLOWER	1	(0,0)	0	(0,0)	1	(0,0)
BOSWELLIA SERRATA;CURCUMA LONGA	1	(0,0)	0	(0,0)	1	(0,0)
BROMFENAC SODIUM	2	(0,1)	2	(0,1)	4	(0,1)
BUCILLAMINE	0	(0,0)	1	(0,0)	1	(0,0)
BUCOLOME	0	(0,0)	1	(0,0)	1	(0,0)
CELECOXIB	3	(0,1)	10	(0,5)	13	(0,3)
CHONDROITIN SULFATE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	**115**	**(5,3)**	**123**	**(5,7)**	**238**	**(5,5)**
CHONDROITIN SULFATE SODIUM;GLUCOSAMINE HYDROCHLORIDE;HYALURONIC ACID;METHYLSULFONYLMETHANE	1	(0,0)	0	(0,0)	1	(0,0)
CHONDROITIN SULFATE SODIUM;GLUCOSAMINE SULFATE;METHYLSULFONYLMETHANE	1	(0,0)	0	(0,0)	1	(0,0)
CHONDROITIN;GLUCOSAMINE	3	(0,1)	3	(0,1)	6	(0,1)
CORNUS OFFICINALIS	1	(0,0)	0	(0,0)	1	(0,0)
CORYDALIS BUNGEANA HERB;ISATIS INDIGOTICA ROOT;SCUTELLARIA BAICALENSIS ROOT;TARAXACUM MONGOLICUM HERB	2	(0,1)	0	(0,0)	2	(0,0)
CURCUMA LONGA	2	(0,1)	0	(0,0)	2	(0,0)
DEXIBUPROFEN	0	(0,0)	1	(0,0)	1	(0,0)
DEXKETOPROFEN TROMETAMOL	2	(0,1)	0	(0,0)	2	(0,0)
DIACEREIN;MELOXICAM	0	(0,0)	1	(0,0)	1	(0,0)
DICLOFENAC	7	(0,3)	11	(0,5)	18	(0,4)
DICLOFENAC DIETHYLAMINE	2	(0,1)	4	(0,2)	6	(0,1)
DICLOFENAC EPOLAMINE	1	(0,0)	0	(0,0)	1	(0,0)
DICLOFENAC POTASSIUM	1	(0,0)	4	(0,2)	5	(0,1)
DICLOFENAC SODIUM	14	(0,7)	7	(0,3)	21	(0,5)
DICLOFENAC SODIUM;MISOPROSTOL	1	(0,0)	0	(0,0)	1	(0,0)
EDETIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
ETOFENAMATE	1	(0,0)	0	(0,0)	1	(0,0)
ETORICOXIB	2	(0,1)	3	(0,1)	5	(0,1)
FLURBIPROFEN	4	(0,2)	2	(0,1)	6	(0,1)
FLURBIPROFEN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
GELATINE HYDROLYSATE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	**115**	**(5,3)**	**123**	**(5,7)**	**238**	**(5,5)**
GLUCOSAMINE	0	(0,0)	3	(0,1)	3	(0,1)
GLUCOSAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
GLUCOSAMINE SULFATE	1	(0,0)	1	(0,0)	2	(0,0)
GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT	1	(0,0)	5	(0,2)	6	(0,1)
GUAIAZULENE	1	(0,0)	2	(0,1)	3	(0,1)
HEPARINOID	3	(0,1)	2	(0,1)	5	(0,1)
HYDROXYCHLOROQUINE SULFATE	2	(0,1)	5	(0,2)	7	(0,2)
IBUPROFEN	14	(0,7)	9	(0,4)	23	(0,5)
INDOMETACIN	2	(0,1)	2	(0,1)	4	(0,1)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
KETOPROFEN	10	(0,5)	19	(0,9)	29	(0,7)
KETOROLAC TROMETHAMINE	2	(0,1)	2	(0,1)	4	(0,1)
LORNOXICAM	1	(0,0)	0	(0,0)	1	(0,0)
LOXOPROFEN SODIUM	23	(1,1)	14	(0,7)	37	(0,9)
LOXOPROFEN SODIUM DIHYDRATE	0	(0,0)	1	(0,0)	1	(0,0)
MEFENAMIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
MELOXICAM	2	(0,1)	6	(0,3)	8	(0,2)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	6	(0,3)	4	(0,2)	10	(0,2)
NAPROXEN	0	(0,0)	5	(0,2)	5	(0,1)
NAPROXEN SODIUM	0	(0,0)	2	(0,1)	2	(0,0)
NIMESULIDE	1	(0,0)	0	(0,0)	1	(0,0)
PELUBIPROFEN	1	(0,0)	0	(0,0)	1	(0,0)
PIROXICAM	2	(0,1)	0	(0,0)	2	(0,0)
PIROXICAM BETADEX	0	(0,0)	1	(0,0)	1	(0,0)
PRANOPROFEN	3	(0,1)	1	(0,0)	4	(0,1)
RABBIT VACCINIA EXTRACT	2	(0,1)	1	(0,0)	3	(0,1)
SULFASALAZINE	0	(0,0)	6	(0,3)	6	(0,1)
TENOXICAM	1	(0,0)	1	(0,0)	2	(0,0)
TRICHOSANTHES KIRILOWII	1	(0,0)	1	(0,0)	2	(0,0)
VACCINIUM MACROCARPON	0	(0,0)	1	(0,0)	1	(0,0)
ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
DRUGS FOR TREATMENT OF BONE DISEASES	**14**	**(0,7)**	**16**	**(0,7)**	**30**	**(0,7)**
ALENDRONATE SODIUM	5	(0,2)	8	(0,4)	13	(0,3)
ALENDRONIC ACID	1	(0,0)	3	(0,1)	4	(0,1)
DENOSUMAB	5	(0,2)	2	(0,1)	7	(0,2)
PAMIDRONATE DISODIUM	1	(0,0)	0	(0,0)	1	(0,0)
RISEDRONATE SODIUM	3	(0,1)	2	(0,1)	5	(0,1)
ZOLEDRONIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
MUSCLE RELAXANTS	**33**	**(1,5)**	**31**	**(1,4)**	**64**	**(1,5)**
ATRACURIUM BESILATE	0	(0,0)	1	(0,0)	1	(0,0)
BACLOFEN	2	(0,1)	0	(0,0)	2	(0,0)
CHLORZOXAZONE	0	(0,0)	2	(0,1)	2	(0,0)
CHLORZOXAZONE;PARACETAMOL	0	(0,0)	1	(0,0)	1	(0,0)
CYCLOBENZAPRINE HYDROCHLORIDE	2	(0,1)	6	(0,3)	8	(0,2)
DIAZEPAM	17	(0,8)	10	(0,5)	27	(0,6)
EPERISONE	1	(0,0)	0	(0,0)	1	(0,0)
EPERISONE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
METHOCARBAMOL	1	(0,0)	0	(0,0)	1	(0,0)
ORPHENADRINE CITRATE	1	(0,0)	1	(0,0)	2	(0,0)
ORPHENADRINE CITRATE;PARACETAMOL	1	(0,0)	1	(0,0)	2	(0,0)
ROCURONIUM BROMIDE	1	(0,0)	2	(0,1)	3	(0,1)
SUXAMETHONIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
TIZANIDINE HYDROCHLORIDE	4	(0,2)	3	(0,1)	7	(0,2)
TOLPERISONE	1	(0,0)	0	(0,0)	1	(0,0)
TOLPERISONE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	**23**	**(1,1)**	**18**	**(0,8)**	**41**	**(1,0)**
ENZYMES NOS	1	(0,0)	2	(0,1)	3	(0,1)
HEPARINOID	3	(0,1)	2	(0,1)	5	(0,1)
HYALURONATE SODIUM	9	(0,4)	7	(0,3)	16	(0,4)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	6	(0,3)	4	(0,2)	10	(0,2)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	**23**	**(1,1)**	**18**	**(0,8)**	**41**	**(1,0)**
PRONASE	1	(0,0)	0	(0,0)	1	(0,0)
QUININE	1	(0,0)	3	(0,1)	4	(0,1)
QUININE SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	**1.100**	**(51,1)**	**1.058**	**(49,2)**	**2.158**	**(50,2)**
ACECLOFENAC	1	(0,0)	1	(0,0)	2	(0,0)
ACETYLSALICYLIC ACID	1.037	(48,2)	978	(45,5)	2.015	(46,8)
CAMPHOR	0	(0,0)	1	(0,0)	1	(0,0)
CAMPHOR;CAPSICUM SPP.;METHYL SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)
CAMPHOR;MENTHOL;METHYL SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)
CAPSAICIN	1	(0,0)	2	(0,1)	3	(0,1)
CHONDROITIN SULFATE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
CHONDROITIN SULFATE SODIUM;GLUCOSAMINE SULFATE;METHYLSULFONYLMETHANE	1	(0,0)	0	(0,0)	1	(0,0)
CHONDROITIN;GLUCOSAMINE	3	(0,1)	3	(0,1)	6	(0,1)
CINEOLE;MELALEUCA LEUCADENDRA OIL;MENTHOL;METHYL SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)
DEXIBUPROFEN	0	(0,0)	1	(0,0)	1	(0,0)
DEXKETOPROFEN TROMETAMOL	2	(0,1)	0	(0,0)	2	(0,0)
DICLOFENAC	7	(0,3)	11	(0,5)	18	(0,4)
DICLOFENAC DIETHYLAMINE	2	(0,1)	4	(0,2)	6	(0,1)
DICLOFENAC EPOLAMINE	1	(0,0)	0	(0,0)	1	(0,0)
DICLOFENAC SODIUM	14	(0,7)	7	(0,3)	21	(0,5)
ESFLURBIPROFEN;MENTHA SPP. OIL	1	(0,0)	2	(0,1)	3	(0,1)
ETOFENAMATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	**1.100**	**(51,1)**	**1.058**	**(49,2)**	**2.158**	**(50,2)**
FELBINAC	3	(0,1)	8	(0,4)	11	(0,3)
FLURBIPROFEN	4	(0,2)	2	(0,1)	6	(0,1)
FLURBIPROFEN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
FOLIC ACID	56	(2,6)	65	(3,0)	121	(2,8)
GLUCOSAMINE	0	(0,0)	3	(0,1)	3	(0,1)
GLUCOSAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
GLUCOSAMINE SULFATE	1	(0,0)	1	(0,0)	2	(0,0)
HEPARINOID	3	(0,1)	2	(0,1)	5	(0,1)
IBUPROFEN	14	(0,7)	9	(0,4)	23	(0,5)
INDOMETACIN	2	(0,1)	2	(0,1)	4	(0,1)
KETOPROFEN	10	(0,5)	19	(0,9)	29	(0,7)
LOXOPROFEN SODIUM	23	(1,1)	14	(0,7)	37	(0,9)
LOXOPROFEN SODIUM DIHYDRATE	0	(0,0)	1	(0,0)	1	(0,0)
MAGNESIUM CHLORIDE	4	(0,2)	1	(0,0)	5	(0,1)
MELOXICAM	2	(0,1)	6	(0,3)	8	(0,2)
MENTHOL	0	(0,0)	1	(0,0)	1	(0,0)
METHYL SALICYLATE	2	(0,1)	1	(0,0)	3	(0,1)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	6	(0,3)	4	(0,2)	10	(0,2)
NAPROXEN	0	(0,0)	5	(0,2)	5	(0,1)
NAPROXEN SODIUM	0	(0,0)	2	(0,1)	2	(0,0)
NICOTINIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
NIMESULIDE	1	(0,0)	0	(0,0)	1	(0,0)
PHOSPHOLIPIDS	3	(0,1)	0	(0,0)	3	(0,1)
PIROXICAM	2	(0,1)	0	(0,0)	2	(0,0)
PIROXICAM BETADEX	0	(0,0)	1	(0,0)	1	(0,0)
SALICYLIC ACID	0	(0,0)	2	(0,1)	2	(0,0)
TOLPERISONE	1	(0,0)	0	(0,0)	1	(0,0)
TOLPERISONE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
TROLAMINE SALICYLATE	1	(0,0)	0	(0,0)	1	(0,0)
VACCINIUM MACROCARPON	0	(0,0)	1	(0,0)	1	(0,0)
ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANALGESICS	**1.447**	**(67,2)**	**1.423**	**(66,2)**	**2.870**	**(66,7)**
ACETYLSALICYLATE LYSINE	8	(0,4)	7	(0,3)	15	(0,3)
ACETYLSALICYLIC ACID	1.037	(48,2)	978	(45,5)	2.015	(46,8)
ACETYLSALICYLIC ACID;ALUMINIUM GLYCINATE;MAGNESIUM CARBONATE	3	(0,1)	1	(0,0)	4	(0,1)
ACETYLSALICYLIC ACID;GLYCINE	17	(0,8)	14	(0,7)	31	(0,7)
ACETYLSALICYLIC ACID;MAGNESIUM HYDROXIDE	14	(0,7)	14	(0,7)	28	(0,7)
ACETYLSALICYLIC ACID;MAGNESIUM OXIDE	1	(0,0)	3	(0,1)	4	(0,1)
ACONITUM CARMICHAELII	1	(0,0)	0	(0,0)	1	(0,0)
AMITRIPTYLINE HYDROCHLORIDE	22	(1,0)	10	(0,5)	32	(0,7)
ARTEMISIA ARGYI LEAF	2	(0,1)	2	(0,1)	4	(0,1)
ASCORBIC ACID;PARACETAMOL;PHENIRAMINE MALEATE	1	(0,0)	0	(0,0)	1	(0,0)
BIDENS BITERNATA;CAFFEINE;CHLORPHENAMINE MALEATE;CHRYSANTHEMUM INDICUM FLOWER;ILEX ASPRELLA ROOT;MELICOPE PTELEIFOLIA;MENTHA CANADENSIS OIL;PARACETAMOL	1	(0,0)	0	(0,0)	1	(0,0)
BUPRENORPHINE	0	(0,0)	2	(0,1)	2	(0,0)
BUTALBITAL;CAFFEINE;PARACETAMOL	1	(0,0)	0	(0,0)	1	(0,0)
CAFFEINE;CODEINE PHOSPHATE;PARACETAMOL	2	(0,1)	3	(0,1)	5	(0,1)
CAFFEINE;PARACETAMOL;PROMETHAZINE METHYLENE DISALICYLATE;SALICYLAMIDE	5	(0,2)	3	(0,1)	8	(0,2)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANALGESICS	**1.447**	**(67,2)**	**1.423**	**(66,2)**	**2.870**	**(66,7)**
CAFFEINE;PARACETAMOL;PROPYPHENAZONE	1	(0,0)	1	(0,0)	2	(0,0)
CALCIUM BROMIDE;CINCHOCAINE HYDROCHLORIDE;SALICYLATE SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
CANNABIS SATIVA	1	(0,0)	0	(0,0)	1	(0,0)
CARBAMAZEPINE	5	(0,2)	5	(0,2)	10	(0,2)
CARBASALATE CALCIUM	1	(0,0)	0	(0,0)	1	(0,0)
CARTHAMUS TINCTORIUS	1	(0,0)	0	(0,0)	1	(0,0)
CHOLINE SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)
CLONIDINE	3	(0,1)	2	(0,1)	5	(0,1)
CLONIDINE HYDROCHLORIDE	1	(0,0)	4	(0,2)	5	(0,1)
CODEINE	7	(0,3)	5	(0,2)	12	(0,3)
CODEINE PHOSPHATE	7	(0,3)	5	(0,2)	12	(0,3)
CODEINE PHOSPHATE;IBUPROFEN;PARACETAMOL	1	(0,0)	0	(0,0)	1	(0,0)
CODEINE PHOSPHATE;PARACETAMOL	5	(0,2)	7	(0,3)	12	(0,3)
CODEINE;PARACETAMOL	1	(0,0)	2	(0,1)	3	(0,1)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
DIHYDROCODEINE	1	(0,0)	2	(0,1)	3	(0,1)
DIHYDROCODEINE BITARTRATE;PARACETAMOL	1	(0,0)	1	(0,0)	2	(0,0)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1	(0,0)	2	(0,1)	3	(0,1)

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(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANALGESICS	**1.447**	**(67,2)**	**1.423**	**(66,2)**	**2.870**	**(66,7)**
DULOXETINE HYDROCHLORIDE	11	(0,5)	13	(0,6)	24	(0,6)
ERIOBOTRYA JAPONICA	0	(0,0)	1	(0,0)	1	(0,0)
FENPIVERINIUM BROMIDE;METAMIZOLE SODIUM;PITOFENONE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
FENTANYL	10	(0,5)	8	(0,4)	18	(0,4)
FENTANYL CITRATE	3	(0,1)	0	(0,0)	3	(0,1)
FLUNARIZINE	2	(0,1)	0	(0,0)	2	(0,0)
FLUNARIZINE DIHYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
GABAPENTIN	49	(2,3)	58	(2,7)	107	(2,5)
GLUCUROLACTONE	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCODONE	2	(0,1)	4	(0,2)	6	(0,1)
HYDROCODONE BITARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCODONE BITARTRATE;PARACETAMOL	7	(0,3)	12	(0,6)	19	(0,4)
HYDROMORPHONE	2	(0,1)	4	(0,2)	6	(0,1)
HYDROMORPHONE HYDROCHLORIDE	5	(0,2)	3	(0,1)	8	(0,2)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
LIGUSTICUM STRIATUM	1	(0,0)	0	(0,0)	1	(0,0)
METAMIZOLE MAGNESIUM	1	(0,0)	1	(0,0)	2	(0,0)
METAMIZOLE SODIUM	37	(1,7)	33	(1,5)	70	(1,6)
METHADONE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
METOPROLOL	176	(8,2)	175	(8,1)	351	(8,2)
METOPROLOL SUCCINATE	224	(10,4)	203	(9,4)	427	(9,9)
METOPROLOL TARTRATE	94	(4,4)	80	(3,7)	174	(4,0)
MILNACIPRAN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
MORPHINE	17	(0,8)	15	(0,7)	32	(0,7)
MORPHINE HYDROCHLORIDE	3	(0,1)	1	(0,0)	4	(0,1)
MORPHINE SULFATE	2	(0,1)	3	(0,1)	5	(0,1)
NALOXONE HYDROCHLORIDE;OXYCODONE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANALGESICS	**1.447**	**(67,2)**	**1.423**	**(66,2)**	**2.870**	**(66,7)**
NALOXONE HYDROCHLORIDE;TILIDINE HYDROCHLORIDE	4	(0,2)	4	(0,2)	8	(0,2)
OPHIOPOGON JAPONICUS	1	(0,0)	0	(0,0)	1	(0,0)
OXCARBAZEPINE	2	(0,1)	0	(0,0)	2	(0,0)
OXYCODONE	5	(0,2)	6	(0,3)	11	(0,3)
OXYCODONE HYDROCHLORIDE	4	(0,2)	9	(0,4)	13	(0,3)
OXYCODONE HYDROCHLORIDE;PARACETAMOL	6	(0,3)	5	(0,2)	11	(0,3)
OXYMORPHONE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
PARACETAMOL	175	(8,1)	217	(10,1)	392	(9,1)
PARACETAMOL;PHENYLPROPANOLAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PARACETAMOL;TRAMADOL HYDROCHLORIDE	9	(0,4)	9	(0,4)	18	(0,4)
PENTAZOCINE	1	(0,0)	1	(0,0)	2	(0,0)
PETHIDINE HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
PLATYCODON GRANDIFLORUS	1	(0,0)	0	(0,0)	1	(0,0)
PREGABALIN	28	(1,3)	39	(1,8)	67	(1,6)
PROPACETAMOL	0	(0,0)	1	(0,0)	1	(0,0)
PROPACETAMOL HYDROCHLORIDE	3	(0,1)	0	(0,0)	3	(0,1)
PROPRANOLOL	0	(0,0)	1	(0,0)	1	(0,0)
PROPRANOLOL HYDROCHLORIDE	0	(0,0)	4	(0,2)	4	(0,1)
SALICYLIC ACID	0	(0,0)	2	(0,1)	2	(0,0)
SUMATRIPTAN	1	(0,0)	0	(0,0)	1	(0,0)
TAPENTADOL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
TOPIRAMATE	3	(0,1)	1	(0,0)	4	(0,1)
TRAMADOL HYDROCHLORIDE	56	(2,6)	59	(2,7)	115	(2,7)
VALPROATE SEMISODIUM	1	(0,0)	2	(0,1)	3	(0,1)
VALPROIC ACID	2	(0,1)	0	(0,0)	2	(0,0)
VENLAFAXINE HYDROCHLORIDE	12	(0,6)	11	(0,5)	23	(0,5)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANALGESICS	**1.447**	**(67,2)**	**1.423**	**(66,2)**	**2.870**	**(66,7)**
VERAPAMIL	5	(0,2)	4	(0,2)	9	(0,2)
VERAPAMIL HYDROCHLORIDE	1	(0,0)	3	(0,1)	4	(0,1)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
ANESTHETICS	**47**	**(2,2)**	**38**	**(1,8)**	**85**	**(2,0)**
ACONITUM CARMICHAELII	1	(0,0)	0	(0,0)	1	(0,0)
CAMPHORSULFONIC ACID;PROCAINE	0	(0,0)	1	(0,0)	1	(0,0)
CAPSAICIN	1	(0,0)	2	(0,1)	3	(0,1)
EPINEPHRINE HYDROCHLORIDE;LIDOCAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ETOMIDATE	1	(0,0)	1	(0,0)	2	(0,0)
FENTANYL	10	(0,5)	8	(0,4)	18	(0,4)
FENTANYL CITRATE	3	(0,1)	0	(0,0)	3	(0,1)
LIDOCAINE	16	(0,7)	19	(0,9)	35	(0,8)
LIDOCAINE CARBONATE	1	(0,0)	0	(0,0)	1	(0,0)
LIDOCAINE HYDROCHLORIDE	14	(0,7)	8	(0,4)	22	(0,5)
LIDOCAINE;PRILOCAINE	0	(0,0)	1	(0,0)	1	(0,0)
MEPIVACAINE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
PRILOCAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PROCAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PROPOFOL	5	(0,2)	4	(0,2)	9	(0,2)
SYZYGIUM AROMATICUM	1	(0,0)	0	(0,0)	1	(0,0)
TRIMECAINE	0	(0,0)	1	(0,0)	1	(0,0)
ANTI-PARKINSON DRUGS	**21**	**(1,0)**	**31**	**(1,4)**	**52**	**(1,2)**
AMANTADINE	1	(0,0)	0	(0,0)	1	(0,0)
BENSERAZIDE	0	(0,0)	1	(0,0)	1	(0,0)
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	4	(0,2)	1	(0,0)	5	(0,1)
BENZATROPINE MESILATE	0	(0,0)	1	(0,0)	1	(0,0)
CABERGOLINE	1	(0,0)	1	(0,0)	2	(0,0)
CARBIDOPA	2	(0,1)	0	(0,0)	2	(0,0)
CARBIDOPA;LEVODOPA	1	(0,0)	2	(0,1)	3	(0,1)
DIPHENHYDRAMINE	4	(0,2)	9	(0,4)	13	(0,3)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANTI-PARKINSON DRUGS	**21**	**(1,0)**	**31**	**(1,4)**	**52**	**(1,2)**
DIPHENHYDRAMINE HYDROCHLORIDE	2	(0,1)	7	(0,3)	9	(0,2)
LEVODOPA	3	(0,1)	2	(0,1)	5	(0,1)
PIRIBEDIL	0	(0,0)	1	(0,0)	1	(0,0)
PRAMIPEXOLE	2	(0,1)	4	(0,2)	6	(0,1)
PRAMIPEXOLE DIHYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
ROPINIROLE	1	(0,0)	1	(0,0)	2	(0,0)
ROPINIROLE HYDROCHLORIDE	1	(0,0)	3	(0,1)	4	(0,1)
ROTIGOTINE	1	(0,0)	1	(0,0)	2	(0,0)
SELEGILINE	1	(0,0)	0	(0,0)	1	(0,0)
SELEGILINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ANTIEPILEPTICS	**209**	**(9,7)**	**224**	**(10,4)**	**433**	**(10,1)**
ACETAZOLAMIDE	6	(0,3)	6	(0,3)	12	(0,3)
CARBAMAZEPINE	5	(0,2)	5	(0,2)	10	(0,2)
CLOBAZAM	3	(0,1)	0	(0,0)	3	(0,1)
CLONAZEPAM	22	(1,0)	25	(1,2)	47	(1,1)
DIAZEPAM	17	(0,8)	10	(0,5)	27	(0,6)
GABAPENTIN	49	(2,3)	58	(2,7)	107	(2,5)
LACOSAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
LAMOTRIGINE	4	(0,2)	3	(0,1)	7	(0,2)
LEVETIRACETAM	4	(0,2)	11	(0,5)	15	(0,3)
LORAZEPAM	33	(1,5)	35	(1,6)	68	(1,6)
MAGNESIUM SULFATE	38	(1,8)	35	(1,6)	73	(1,7)
OXCARBAZEPINE	2	(0,1)	0	(0,0)	2	(0,0)
PHENYTOIN	0	(0,0)	1	(0,0)	1	(0,0)
PHENYTOIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
PREGABALIN	28	(1,3)	39	(1,8)	67	(1,6)
PRIMIDONE	4	(0,2)	5	(0,2)	9	(0,2)
TIAGABINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
TOPIRAMATE	3	(0,1)	1	(0,0)	4	(0,1)
VALPROATE SEMISODIUM	1	(0,0)	2	(0,1)	3	(0,1)
VALPROATE SODIUM	4	(0,2)	7	(0,3)	11	(0,3)
VALPROATE SODIUM;VALPROIC ACID	1	(0,0)	1	(0,0)	2	(0,0)

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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANTIEPILEPTICS	**209**	**(9,7)**	**224**	**(10,4)**	**433**	**(10,1)**
VALPROIC ACID	2	(0,1)	0	(0,0)	2	(0,0)
VALPROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
ZONISAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
OTHER NERVOUS SYSTEM DRUGS	**252**	**(11,7)**	**235**	**(10,9)**	**487**	**(11,3)**
ANTIVERTIGO PREPARATIONS	1	(0,0)	0	(0,0)	1	(0,0)
BETAHISTINE	4	(0,2)	3	(0,1)	7	(0,2)
BETAHISTINE HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
BETAHISTINE MESILATE	3	(0,1)	1	(0,0)	4	(0,1)
BETHANECHOL CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
BUPRENORPHINE	0	(0,0)	2	(0,1)	2	(0,0)
BUPROPION	3	(0,1)	0	(0,0)	3	(0,1)
BUPROPION HYDROCHLORIDE	6	(0,3)	4	(0,2)	10	(0,2)
CEREBROPROTEIN HYDROLYSATE	1	(0,0)	0	(0,0)	1	(0,0)
CHOLINE ALFOSCERATE	1	(0,0)	0	(0,0)	1	(0,0)
CORNUS OFFICINALIS	1	(0,0)	0	(0,0)	1	(0,0)
DIMENHYDRINATE	0	(0,0)	1	(0,0)	1	(0,0)
DISTIGMINE BROMIDE	1	(0,0)	1	(0,0)	2	(0,0)
ERIGERON BREVISCAPUS HERB;OPHIOPOGON JAPONICUS;PANAX GINSENG ROOT;SCHISANDRA CHINENSIS FRUIT	3	(0,1)	1	(0,0)	4	(0,1)
FLUNARIZINE	2	(0,1)	0	(0,0)	2	(0,0)
FLUNARIZINE DIHYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
FLUOXETINE	9	(0,4)	11	(0,5)	20	(0,5)
FLUOXETINE HYDROCHLORIDE	3	(0,1)	2	(0,1)	5	(0,1)
GABAPENTIN	49	(2,3)	58	(2,7)	107	(2,5)
GASTRODIN	1	(0,0)	0	(0,0)	1	(0,0)
GINKGO BILOBA	2	(0,1)	2	(0,1)	4	(0,1)
ISOPRENALINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
MECLOZINE	3	(0,1)	3	(0,1)	6	(0,1)
MECLOZINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
MELDONIUM	3	(0,1)	2	(0,1)	5	(0,1)
METHADONE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
OTHER NERVOUS SYSTEM DRUGS	**252**	**(11,7)**	**235**	**(10,9)**	**487**	**(11,3)**
METHYLETHYLPIRIDINOL SUCCINATE	2	(0,1)	0	(0,0)	2	(0,0)
NALOXONE HYDROCHLORIDE	2	(0,1)	4	(0,2)	6	(0,1)
NALOXONE HYDROCHLORIDE;OXYCODONE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
NERVE GROWTH FACTOR, MOUSE	0	(0,0)	1	(0,0)	1	(0,0)
NICOTINE	7	(0,3)	6	(0,3)	13	(0,3)
NICOTINE POLACRILEX	0	(0,0)	2	(0,1)	2	(0,0)
PHOSPHOLIPIDS	3	(0,1)	0	(0,0)	3	(0,1)
PYRIDOSTIGMINE BROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
THIOCTIC ACID	4	(0,2)	9	(0,4)	13	(0,3)
TRIMETAZIDINE	62	(2,9)	37	(1,7)	99	(2,3)
TRIMETAZIDINE HYDROCHLORIDE	93	(4,3)	90	(4,2)	183	(4,3)
PSYCHOANALEPTICS	**237**	**(11,0)**	**214**	**(9,9)**	**451**	**(10,5)**
ACEGLUTAMIDE;CARTHAMUS TINCTORIUS	1	(0,0)	2	(0,1)	3	(0,1)
ACETYLCARNITINE	1	(0,0)	0	(0,0)	1	(0,0)
ACETYLCARNITINE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
ACONITUM CARMICHAELII ROOT;PANAX GINSENG ROOT	6	(0,3)	2	(0,1)	8	(0,2)
ACONITUM CARMICHAELII;PANAX GINSENG	1	(0,0)	0	(0,0)	1	(0,0)
ADEMETIONINE	0	(0,0)	1	(0,0)	1	(0,0)
ADEMETIONINE 1,4-BUTANEDISULFONATE	2	(0,1)	0	(0,0)	2	(0,0)
AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
AMITRIPTYLINE HYDROCHLORIDE	22	(1,0)	10	(0,5)	32	(0,7)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
PSYCHOANALEPTICS	**237**	**(11,0)**	**214**	**(9,9)**	**451**	**(10,5)**
AMITRIPTYLINE HYDROCHLORIDE;PERPHENAZINE	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	0	(0,0)	1	(0,0)	1	(0,0)
BUPROPION	3	(0,1)	0	(0,0)	3	(0,1)
BUPROPION HYDROCHLORIDE	6	(0,3)	4	(0,2)	10	(0,2)
CAFFEINE	0	(0,0)	1	(0,0)	1	(0,0)
CITALOPRAM	12	(0,6)	15	(0,7)	27	(0,6)
CITALOPRAM HYDROBROMIDE	5	(0,2)	7	(0,3)	12	(0,3)
CITICOLINE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
CLOMIPRAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CLONIDINE	3	(0,1)	2	(0,1)	5	(0,1)
CLONIDINE HYDROCHLORIDE	1	(0,0)	4	(0,2)	5	(0,1)
CORDYCEPS SINENSIS	12	(0,6)	6	(0,3)	18	(0,4)
DESVENLAFAXINE	0	(0,0)	1	(0,0)	1	(0,0)
DONEPEZIL	1	(0,0)	1	(0,0)	2	(0,0)
DONEPEZIL HYDROCHLORIDE	2	(0,1)	4	(0,2)	6	(0,1)
DOXEPIN HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
DULOXETINE HYDROCHLORIDE	11	(0,5)	13	(0,6)	24	(0,6)
ENZYMES NOS	1	(0,0)	2	(0,1)	3	(0,1)
ESCITALOPRAM	15	(0,7)	11	(0,5)	26	(0,6)
ESCITALOPRAM OXALATE	11	(0,5)	20	(0,9)	31	(0,7)
FLUOXETINE	9	(0,4)	11	(0,5)	20	(0,5)
FLUOXETINE HYDROCHLORIDE	3	(0,1)	2	(0,1)	5	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
PSYCHOANALEPTICS	**237**	**(11,0)**	**214**	**(9,9)**	**451**	**(10,5)**
FLUPENTIXOL DIHYDROCHLORIDE;MELITRACEN HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
FLUVOXAMINE MALEATE	0	(0,0)	1	(0,0)	1	(0,0)
GALANTAMINE	2	(0,1)	0	(0,0)	2	(0,0)
GALANTAMINE HYDROBROMIDE	1	(0,0)	0	(0,0)	1	(0,0)
GINKGO BILOBA	2	(0,1)	2	(0,1)	4	(0,1)
GINKGO BILOBA EXTRACT	2	(0,1)	3	(0,1)	5	(0,1)
IMIPRAMINE	1	(0,0)	0	(0,0)	1	(0,0)
LAMOTRIGINE	4	(0,2)	3	(0,1)	7	(0,2)
MEMANTINE	1	(0,0)	0	(0,0)	1	(0,0)
MEMANTINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
METHYLETHYLPIRIDINOL SUCCINATE	2	(0,1)	0	(0,0)	2	(0,0)
METHYLPHENIDATE	0	(0,0)	1	(0,0)	1	(0,0)
MIANSERIN HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
MILNACIPRAN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
MIRTAZAPINE	18	(0,8)	11	(0,5)	29	(0,7)
NIMODIPINE	1	(0,0)	1	(0,0)	2	(0,0)
NORTRIPTYLINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
OPIPRAMOL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
PANAX GINSENG	1	(0,0)	0	(0,0)	1	(0,0)
PANAX GINSENG TOTAL GINSENOSIDE EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
PAROXETINE	6	(0,3)	3	(0,1)	9	(0,2)
PAROXETINE HYDROCHLORIDE	5	(0,2)	2	(0,1)	7	(0,2)
PEMOLINE	1	(0,0)	0	(0,0)	1	(0,0)
PIRACETAM	10	(0,5)	6	(0,3)	16	(0,4)
RIVASTIGMINE	1	(0,0)	0	(0,0)	1	(0,0)
SELEGILINE	1	(0,0)	0	(0,0)	1	(0,0)
SERTRALINE HYDROCHLORIDE	40	(1,9)	35	(1,6)	75	(1,7)
TIANEPTINE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
TRAZODONE HYDROCHLORIDE	27	(1,3)	34	(1,6)	61	(1,4)
TRIMIPRAMINE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
PSYCHOANALEPTICS	**237**	**(11,0)**	**214**	**(9,9)**	**451**	**(10,5)**
VENLAFAXINE HYDROCHLORIDE	12	(0,6)	11	(0,5)	23	(0,5)
VINPOCETINE	5	(0,2)	2	(0,1)	7	(0,2)
PSYCHOLEPTICS	**402**	**(18,7)**	**434**	**(20,2)**	**836**	**(19,4)**
ALPHA-CASOZEPINE;MAGNESIUM;MELISSA OFFICINALIS;PYRIDOXINE HYDROCHLORIDE;ZINC	1	(0,0)	0	(0,0)	1	(0,0)
ALPRAZOLAM	47	(2,2)	45	(2,1)	92	(2,1)
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	0	(0,0)	1	(0,0)	1	(0,0)
ARIPIPRAZOLE	0	(0,0)	3	(0,1)	3	(0,1)
BROMAZEPAM	5	(0,2)	9	(0,4)	14	(0,3)
BROTIZOLAM	29	(1,3)	25	(1,2)	54	(1,3)
BUSPIRONE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
CARBAMAZEPINE	5	(0,2)	5	(0,2)	10	(0,2)
CHLORDIAZEPOXIDE	1	(0,0)	0	(0,0)	1	(0,0)
CHLORDIAZEPOXIDE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CHLORPROMAZINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
CHLORPROTHIXENE	1	(0,0)	0	(0,0)	1	(0,0)
CINNAMOMUM VERUM;CITRUS AURANTIUM;MELISSA OFFICINALIS;PASSIFLORA ALATA	1	(0,0)	0	(0,0)	1	(0,0)
CLOBAZAM	3	(0,1)	0	(0,0)	3	(0,1)
CLONAZEPAM	22	(1,0)	25	(1,2)	47	(1,1)
CLORAZEPATE DIPOTASSIUM	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
PSYCHOLEPTICS	**402**	**(18,7)**	**434**	**(20,2)**	**836**	**(19,4)**
CLOTIAZEPAM	3	(0,1)	1	(0,0)	4	(0,1)
DELORAZEPAM	2	(0,1)	0	(0,0)	2	(0,0)
DEXMEDETOMIDINE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
DIAZEPAM	17	(0,8)	10	(0,5)	27	(0,6)
DIPHENHYDRAMINE	4	(0,2)	9	(0,4)	13	(0,3)
DIPHENHYDRAMINE HYDROCHLORIDE	2	(0,1)	7	(0,3)	9	(0,2)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1	(0,0)	2	(0,1)	3	(0,1)
DOXEPIN HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
DULOXETINE HYDROCHLORIDE	11	(0,5)	13	(0,6)	24	(0,6)
ERIOBOTRYA JAPONICA	0	(0,0)	1	(0,0)	1	(0,0)
ESCITALOPRAM	15	(0,7)	11	(0,5)	26	(0,6)
ESCITALOPRAM OXALATE	11	(0,5)	20	(0,9)	31	(0,7)
ESTAZOLAM	10	(0,5)	14	(0,7)	24	(0,6)
ESZOPICLONE	7	(0,3)	4	(0,2)	11	(0,3)
ETHYL 2-BROMOISOVALERATE;MENTHYL VALERATE;PHENOBARBITAL	0	(0,0)	1	(0,0)	1	(0,0)
ETHYL LOFLAZEPATE	1	(0,0)	0	(0,0)	1	(0,0)
ETIZOLAM	10	(0,5)	3	(0,1)	13	(0,3)
FLUNITRAZEPAM	2	(0,1)	1	(0,0)	3	(0,1)
FLUOXETINE	9	(0,4)	11	(0,5)	20	(0,5)
FLUOXETINE HYDROCHLORIDE	3	(0,1)	2	(0,1)	5	(0,1)
FLURAZEPAM	0	(0,0)	1	(0,0)	1	(0,0)
GLYCINE	0	(0,0)	1	(0,0)	1	(0,0)
HALOPERIDOL	6	(0,3)	5	(0,2)	11	(0,3)
HUMULUS LUPULUS EXTRACT;PASSIFLORA INCARNATA EXTRACT;VALERIANA OFFICINALIS EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
PSYCHOLEPTICS	**402**	**(18,7)**	**434**	**(20,2)**	**836**	**(19,4)**
HYDROXYZINE	11	(0,5)	13	(0,6)	24	(0,6)
HYDROXYZINE EMBONATE	0	(0,0)	1	(0,0)	1	(0,0)
HYDROXYZINE HYDROCHLORIDE	6	(0,3)	8	(0,4)	14	(0,3)
HYOSCINE	1	(0,0)	0	(0,0)	1	(0,0)
LEVOSULPIRIDE	0	(0,0)	2	(0,1)	2	(0,0)
LIGUSTICUM STRIATUM	1	(0,0)	0	(0,0)	1	(0,0)
LOPRAZOLAM MESILATE	0	(0,0)	1	(0,0)	1	(0,0)
LORAZEPAM	33	(1,5)	35	(1,6)	68	(1,6)
LORMETAZEPAM	6	(0,3)	4	(0,2)	10	(0,2)
MEDAZEPAM	1	(0,0)	0	(0,0)	1	(0,0)
MELATONIN	9	(0,4)	8	(0,4)	17	(0,4)
MELPERONE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
MIDAZOLAM	10	(0,5)	15	(0,7)	25	(0,6)
MIDAZOLAM HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
NITRAZEPAM	5	(0,2)	4	(0,2)	9	(0,2)
OLANZAPINE	1	(0,0)	0	(0,0)	1	(0,0)
OPHIOPOGON JAPONICUS	1	(0,0)	0	(0,0)	1	(0,0)
OXAZEPAM	8	(0,4)	9	(0,4)	17	(0,4)
PANAX NOTOGINSENG	2	(0,1)	3	(0,1)	5	(0,1)
PAROXETINE	6	(0,3)	3	(0,1)	9	(0,2)
PAROXETINE HYDROCHLORIDE	5	(0,2)	2	(0,1)	7	(0,2)
PEROSPIRONE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
PERPHENAZINE	0	(0,0)	1	(0,0)	1	(0,0)
PIPAMPERONE	0	(0,0)	1	(0,0)	1	(0,0)
PLATYCODON GRANDIFLORUS	1	(0,0)	0	(0,0)	1	(0,0)
PRAZEPAM	1	(0,0)	0	(0,0)	1	(0,0)
PREGABALIN	28	(1,3)	39	(1,8)	67	(1,6)
PROCHLORPERAZINE	1	(0,0)	1	(0,0)	2	(0,0)
PROCHLORPERAZINE MALEATE	0	(0,0)	1	(0,0)	1	(0,0)
PROMAZINE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
PROMETHAZINE	3	(0,1)	5	(0,2)	8	(0,2)
PROMETHAZINE HYDROCHLORIDE	5	(0,2)	2	(0,1)	7	(0,2)
PROPIOMAZINE MALEATE	0	(0,0)	1	(0,0)	1	(0,0)
PROTHIPENDYL HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
PSYCHOLEPTICS	**402**	**(18,7)**	**434**	**(20,2)**	**836**	**(19,4)**
QUETIAPINE FUMARATE	15	(0,7)	9	(0,4)	24	(0,6)
RAMELTEON	3	(0,1)	2	(0,1)	5	(0,1)
RILMAZAFONE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
RISPERIDONE	0	(0,0)	3	(0,1)	3	(0,1)
SERTRALINE HYDROCHLORIDE	40	(1,9)	35	(1,6)	75	(1,7)
SULPIRIDE	0	(0,0)	1	(0,0)	1	(0,0)
SUVOREXANT	6	(0,3)	6	(0,3)	12	(0,3)
TANDOSPIRONE CITRATE	1	(0,0)	1	(0,0)	2	(0,0)
TEMAZEPAM	3	(0,1)	8	(0,4)	11	(0,3)
THIORIDAZINE	2	(0,1)	4	(0,2)	6	(0,1)
THIORIDAZINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
TIAPRIDE	0	(0,0)	1	(0,0)	1	(0,0)
TIAPRIDE HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
TRIAZOLAM	7	(0,3)	10	(0,5)	17	(0,4)
TRIFLUOPERAZINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
VALERIANA OFFICINALIS	2	(0,1)	0	(0,0)	2	(0,0)
VALPROATE SEMISODIUM	1	(0,0)	2	(0,1)	3	(0,1)
VALPROIC ACID	2	(0,1)	0	(0,0)	2	(0,0)
VENLAFAXINE HYDROCHLORIDE	12	(0,6)	11	(0,5)	23	(0,5)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
ZOLPIDEM	11	(0,5)	12	(0,6)	23	(0,5)
ZOLPIDEM TARTRATE	25	(1,2)	24	(1,1)	49	(1,1)
ZOPICLONE	30	(1,4)	27	(1,3)	57	(1,3)
ZOTEPINE	1	(0,0)	0	(0,0)	1	(0,0)
RESPIRATORY SYSTEM						
ANTIHISTAMINES FOR SYSTEMIC USE	**114**	**(5,3)**	**103**	**(4,8)**	**217**	**(5,0)**
ALIMEMAZINE TARTRATE	0	(0,0)	2	(0,1)	2	(0,0)
AZELASTINE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
BEPOTASTINE BESILATE	2	(0,1)	1	(0,0)	3	(0,1)
BETAMETHASONE;EBASTINE	0	(0,0)	1	(0,0)	1	(0,0)
BILASTINE	2	(0,1)	2	(0,1)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
ANTIHISTAMINES FOR SYSTEMIC USE	**114**	**(5,3)**	**103**	**(4,8)**	**217**	**(5,0)**
CETIRIZINE HYDROCHLORIDE	17	(0,8)	12	(0,6)	29	(0,7)
CHLORPHENAMINE	1	(0,0)	3	(0,1)	4	(0,1)
CHLORPHENAMINE MALEATE	8	(0,4)	4	(0,2)	12	(0,3)
CLEMASTINE FUMARATE	1	(0,0)	0	(0,0)	1	(0,0)
CYPROHEPTADINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
DESLORATADINE	8	(0,4)	5	(0,2)	13	(0,3)
DEXCHLORPHENIRAMINE MALEATE	1	(0,0)	0	(0,0)	1	(0,0)
DIMENHYDRINATE	0	(0,0)	1	(0,0)	1	(0,0)
DIPHENHYDRAMINE	4	(0,2)	9	(0,4)	13	(0,3)
DIPHENHYDRAMINE HYDROCHLORIDE	2	(0,1)	7	(0,3)	9	(0,2)
EBASTINE	1	(0,0)	5	(0,2)	6	(0,1)
EMEDASTINE FUMARATE	0	(0,0)	1	(0,0)	1	(0,0)
EPINASTINE HYDROCHLORIDE	4	(0,2)	0	(0,0)	4	(0,1)
FEXOFENADINE HYDROCHLORIDE	11	(0,5)	11	(0,5)	22	(0,5)
FEXOFENADINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
HYDROXYZINE	11	(0,5)	13	(0,6)	24	(0,6)
HYDROXYZINE EMBONATE	0	(0,0)	1	(0,0)	1	(0,0)
HYDROXYZINE HYDROCHLORIDE	6	(0,3)	8	(0,4)	14	(0,3)
KETOTIFEN FUMARATE	1	(0,0)	1	(0,0)	2	(0,0)
LEVOCETIRIZINE	1	(0,0)	3	(0,1)	4	(0,1)
LEVOCETIRIZINE DIHYDROCHLORIDE	7	(0,3)	5	(0,2)	12	(0,3)
LORATADINE	20	(0,9)	16	(0,7)	36	(0,8)
MECLOZINE	3	(0,1)	3	(0,1)	6	(0,1)
MECLOZINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
OLOPATADINE HYDROCHLORIDE	7	(0,3)	1	(0,0)	8	(0,2)
PHENIRAMINE MALEATE	1	(0,0)	1	(0,0)	2	(0,0)
PROMETHAZINE	3	(0,1)	5	(0,2)	8	(0,2)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
ANTIHISTAMINES FOR SYSTEMIC USE	**114**	**(5,3)**	**103**	**(4,8)**	**217**	**(5,0)**
PROMETHAZINE HYDROCHLORIDE	5	(0,2)	2	(0,1)	7	(0,2)
QUERCETIN	1	(0,0)	0	(0,0)	1	(0,0)
TRIMETHOBENZAMIDE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
COUGH AND COLD PREPARATIONS	**180**	**(8,4)**	**188**	**(8,7)**	**368**	**(8,6)**
ACETYLCYSTEINE	35	(1,6)	48	(2,2)	83	(1,9)
ACETYLCYSTEINE;ASCORBIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
AMBROXOL	5	(0,2)	8	(0,4)	13	(0,3)
AMBROXOL ACEFYLLINATE	1	(0,0)	0	(0,0)	1	(0,0)
AMBROXOL HYDROCHLORIDE	19	(0,9)	20	(0,9)	39	(0,9)
AMMONIA;CAMPHOR;GLYCEROL; GLYCYRRHIZA GLABRA;GUAIFENESIN	6	(0,3)	2	(0,1)	8	(0,2)
AMMONIUM BICARBONATE;AMMONIUM CHLORIDE;DRIMIA MARITIMA;GLYCYRRHIZA GLABRA;POLYGALA SENEGA;SODIUM CITRATE	0	(0,0)	1	(0,0)	1	(0,0)
AMMONIUM BICARBONATE;CEPHAELIS SPP.	3	(0,1)	0	(0,0)	3	(0,1)
AMMONIUM CHLORIDE;CHLORPHENAMINE MALEATE;DIHYDROCODEINE BITARTRATE;METHYLEPHEDRINE HYDROCHLORIDE-DL	2	(0,1)	5	(0,2)	7	(0,2)
AMMONIUM CHLORIDE;DIPHENHYDRAMINE HYDROCHLORIDE;SODIUM CITRATE	1	(0,0)	0	(0,0)	1	(0,0)
AMMONIUM CHLORIDE;GLYCYRRHIZA GLABRA	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**180**	**(8,4)**	**188**	**(8,7)**	**368**	**(8,6)**
ANTIMONY POTASSIUM TARTRATE;GLYCEROL;GLYCYRRHIZA GLABRA LIQUID EXTRACT;NITROUS ETHER SPIRIT;PAPAVER SOMNIFERUM TINCTURE	1	(0,0)	1	(0,0)	2	(0,0)
ANTIMONY POTASSIUM TARTRATE;GLYCYRRHIZA SPP.;PAPAVER SOMNIFERUM TINCTURE	2	(0,1)	1	(0,0)	3	(0,1)
ARCTIUM LAPPA FRUIT;CICADA SLOUGH;EPHEDRA SPP. HERB;ERIOBOTRYA JAPONICA LEAF;PERILLA FRUTESCENS FRUIT;PERILLA FRUTESCENS LEAF;PEUCEDANUM PRAERUPTORUM ROOT;PHERETIMA SPP.;SCHISANDRA CHINENSIS FRUIT	1	(0,0)	2	(0,1)	3	(0,1)
ARCTIUM LAPPA FRUIT;CITRUS RETICULATA FRUIT PEEL;HIBISCUS MUTABILIS LEAF;MAGNOLIA OFFICINALIS STEM BARK	2	(0,1)	2	(0,1)	4	(0,1)
BENPROPERINE PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)
BENZONATATE	1	(0,0)	5	(0,2)	6	(0,1)
BROMHEXINE HYDROCHLORIDE	7	(0,3)	6	(0,3)	13	(0,3)
BUTAMIRATE CITRATE;GUAIFENESIN	1	(0,0)	0	(0,0)	1	(0,0)
CAMPHOR	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**180**	**(8,4)**	**188**	**(8,7)**	**368**	**(8,6)**
CAMPHOR;GLYCYRRHIZA GLABRA;ILLICIUM VERUM OIL;PAPAVER SOMNIFERUM;SODIUM BENZOATE	1	(0,0)	0	(0,0)	1	(0,0)
CARBOCISTEINE	7	(0,3)	7	(0,3)	14	(0,3)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CHLORPHENAMINE MALEATE;DIHYDROCODEINE BITARTRATE;GUAIFENESIN;METHYLEPHEDRINE HYDROCHLORIDE-DL	0	(0,0)	1	(0,0)	1	(0,0)
CHLORPHENAMINE MALEATE;DIHYDROCODEINE PHOSPHATE;METHYLEPHEDRINE HYDROCHLORIDE-DL	1	(0,0)	1	(0,0)	2	(0,0)
CINEOLE;DIPENTEN;PINENE	1	(0,0)	0	(0,0)	1	(0,0)
CINEOLE;LIMONENE, (+)-;PINENE	1	(0,0)	4	(0,2)	5	(0,1)
CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;PUERARIA LOBATA ROOT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
CLOPERASTINE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
CODEINE	7	(0,3)	5	(0,2)	12	(0,3)
CODEINE PHOSPHATE	7	(0,3)	5	(0,2)	12	(0,3)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**180**	**(8,4)**	**188**	**(8,7)**	**368**	**(8,6)**
CODEINE PHOSPHATE;EPHEDRINE HYDROCHLORIDE;PROMETHAZINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CODEINE PHOSPHATE;GUAIFENESIN	1	(0,0)	0	(0,0)	1	(0,0)
CODEINE PHOSPHATE;PLATYCODON GRANDIFLORUS	1	(0,0)	0	(0,0)	1	(0,0)
CODEINE PHOSPHATE;PROMETHAZINE HYDROCHLORIDE	6	(0,3)	1	(0,0)	7	(0,2)
CODEINE PHOSPHATE;PSEUDOEPHEDRINE HYDROCHLORIDE;TRIPROLIDINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
CODEINE PHOSPHATE;SULFOGAIACOL	2	(0,1)	0	(0,0)	2	(0,0)
COPTIS SPP. RHIZOME;HEDERA HELIX LEAF	1	(0,0)	0	(0,0)	1	(0,0)
COUGH AND COLD PREPARATIONS	0	(0,0)	2	(0,1)	2	(0,0)
CYSTEINE HYDROCHLORIDE;GLYCINE;GLYCYRRHIZIC ACID, AMMONIUM SALT	0	(0,0)	1	(0,0)	1	(0,0)
CYSTEINE;GLYCINE;GLYCYRRHIZIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
DEXTROMETHORPHAN	3	(0,1)	4	(0,2)	7	(0,2)
DEXTROMETHORPHAN HYDROBROMIDE	10	(0,5)	5	(0,2)	15	(0,3)
DEXTROMETHORPHAN HYDROBROMIDE;EPHEDRINE HYDROCHLORIDE;PROMETHAZINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**180**	**(8,4)**	**188**	**(8,7)**	**368**	**(8,6)**
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN	0	(0,0)	2	(0,1)	2	(0,0)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PSEUDOEPHEDRINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
DEXTROMETHORPHAN HYDROBROMIDE;LYSOZYME CHLORIDE;POTASSIUM CRESOLSULFONATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXTROMETHORPHAN HYDROBROMIDE;LYSOZYME HYDROCHLORIDE;POTASSIUM CRESOLSULFONATE	3	(0,1)	5	(0,2)	8	(0,2)
DIHYDROCODEINE	1	(0,0)	2	(0,1)	3	(0,1)
DIHYDROCODEINE THIOCYANATE	2	(0,1)	1	(0,0)	3	(0,1)
DIMEMORFAN PHOSPHATE	0	(0,0)	1	(0,0)	1	(0,0)
DRIMIA MARITIMA;MORPHINE	0	(0,0)	1	(0,0)	1	(0,0)
DROPROPIZINE	0	(0,0)	1	(0,0)	1	(0,0)
ELECTROLYTES NOS	1	(0,0)	7	(0,3)	8	(0,2)
EPRAZINONE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ERDOSTEINE	7	(0,3)	1	(0,0)	8	(0,2)
ERIOBOTRYA JAPONICA	0	(0,0)	1	(0,0)	1	(0,0)
ETHYLMORPHINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
FUDOSTEINE	0	(0,0)	1	(0,0)	1	(0,0)
GLYCEROL	8	(0,4)	3	(0,1)	11	(0,3)
GLYCYRRHIZA GLABRA	2	(0,1)	0	(0,0)	2	(0,0)
GLYCYRRHIZA URALENSIS	1	(0,0)	0	(0,0)	1	(0,0)
GUAIFENESIN	8	(0,4)	3	(0,1)	11	(0,3)
GUAIFENESIN;PSEUDOEPHEDRINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
HOUTTUYNIA CORDATA	0	(0,0)	1	(0,0)	1	(0,0)
HYDROCODONE	2	(0,1)	4	(0,2)	6	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**180**	**(8,4)**	**188**	**(8,7)**	**368**	**(8,6)**
HYDROCODONE BITARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
LEVOCLOPERASTINE FENDIZOATE	0	(0,0)	1	(0,0)	1	(0,0)
LEVODROPROPIZINE	1	(0,0)	1	(0,0)	2	(0,0)
LEVOMENTHOL	1	(0,0)	0	(0,0)	1	(0,0)
LINUM USITATISSIMUM SEED	0	(0,0)	1	(0,0)	1	(0,0)
MANNITOL	1	(0,0)	0	(0,0)	1	(0,0)
MENTHOL	0	(0,0)	1	(0,0)	1	(0,0)
OPHIOPOGON JAPONICUS	1	(0,0)	0	(0,0)	1	(0,0)
PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PINELLIA TERNATA	1	(0,0)	0	(0,0)	1	(0,0)
PLATYCODON GRANDIFLORUS	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM IODIDE	0	(0,0)	1	(0,0)	1	(0,0)
QUININE	1	(0,0)	3	(0,1)	4	(0,1)
QUININE SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
SODIUM CHLORIDE	44	(2,0)	49	(2,3)	93	(2,2)
TERPIN HYDRATE	1	(0,0)	1	(0,0)	2	(0,0)
TIPEPIDINE HIBENZATE	3	(0,1)	1	(0,0)	4	(0,1)
TRICHOSANTHES KIRILOWII	1	(0,0)	1	(0,0)	2	(0,0)
ZINC	0	(0,0)	1	(0,0)	1	(0,0)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	**385**	**(17,9)**	**412**	**(19,2)**	**797**	**(18,5)**
ACLIDINIUM BROMIDE	11	(0,5)	4	(0,2)	15	(0,3)
ACLIDINIUM BROMIDE;FORMOTEROL FUMARATE	2	(0,1)	2	(0,1)	4	(0,1)
AMINOPHYLLINE	8	(0,4)	10	(0,5)	18	(0,4)
AMINOPHYLLINE;CHLORPHENAMINE MALEATE;METHOXYPHENAMINE HYDROCHLORIDE;NOSCAPINE	0	(0,0)	4	(0,2)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	**385**	**(17,9)**	**412**	**(19,2)**	**797**	**(18,5)**
ARCTIUM LAPPA FRUIT;CICADA SLOUGH;EPHEDRA SPP. HERB;ERIOBOTRYA JAPONICA LEAF;PERILLA FRUTESCENS FRUIT;PERILLA FRUTESCENS LEAF;PEUCEDANUM PRAERUPTORUM ROOT;PHERETIMA SPP.;SCHISANDRA CHINENSIS FRUIT	1	(0,0)	2	(0,1)	3	(0,1)
ARTEMISIA ARGYI LEAF	2	(0,1)	2	(0,1)	4	(0,1)
BAMBUTEROL	0	(0,0)	1	(0,0)	1	(0,0)
BECLOMETASONE DIPROPIONATE	24	(1,1)	13	(0,6)	37	(0,9)
BECLOMETASONE DIPROPIONATE;FORMOTEROL FUMARATE	10	(0,5)	5	(0,2)	15	(0,3)
BECLOMETASONE DIPROPIONATE;FORMOTEROL FUMARATE;GLYCOPYRRONIUM BROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
BETAMETHASONE DIPROPIONATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE SODIUM PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE VALERATE	3	(0,1)	3	(0,1)	6	(0,1)
BUDESONIDE	47	(2,2)	61	(2,8)	108	(2,5)
BUDESONIDE;FORMOTEROL FUMARATE	30	(1,4)	26	(1,2)	56	(1,3)
CICLESONIDE	3	(0,1)	2	(0,1)	5	(0,1)
CORDYCEPS SINENSIS	12	(0,6)	6	(0,3)	18	(0,4)
DESLORATADINE;MONTELUKAST SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
DEXAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	**385**	**(17,9)**	**412**	**(19,2)**	**797**	**(18,5)**
DIPROPHYLLINE	2	(0,1)	2	(0,1)	4	(0,1)
DOXOFYLLINE	7	(0,3)	7	(0,3)	14	(0,3)
EPINEPHRINE	0	(0,0)	2	(0,1)	2	(0,0)
ERIOBOTRYA JAPONICA	0	(0,0)	1	(0,0)	1	(0,0)
FENOTEROL	5	(0,2)	8	(0,4)	13	(0,3)
FENOTEROL HYDROBROMIDE	1	(0,0)	2	(0,1)	3	(0,1)
FENOTEROL HYDROBROMIDE;IPRATROPIUM BROMIDE	28	(1,3)	17	(0,8)	45	(1,0)
FENOTEROL;IPRATROPIUM BROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
FLUTICASONE	21	(1,0)	17	(0,8)	38	(0,9)
FLUTICASONE FUROATE	2	(0,1)	8	(0,4)	10	(0,2)
FLUTICASONE FUROATE;VILANTEROL TRIFENATATE	8	(0,4)	9	(0,4)	17	(0,4)
FLUTICASONE PROPIONATE	16	(0,7)	28	(1,3)	44	(1,0)
FLUTICASONE PROPIONATE;FORMOTEROL FUMARATE	1	(0,0)	3	(0,1)	4	(0,1)
FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE	41	(1,9)	29	(1,3)	70	(1,6)
FORMOTEROL FUMARATE	27	(1,3)	23	(1,1)	50	(1,2)
FORMOTEROL FUMARATE;MOMETASONE FUROATE	2	(0,1)	1	(0,0)	3	(0,1)
GLYCOPYRRONIUM	1	(0,0)	2	(0,1)	3	(0,1)
GLYCOPYRRONIUM BROMIDE	5	(0,2)	5	(0,2)	10	(0,2)
GLYCOPYRRONIUM BROMIDE;INDACATEROL MALEATE	9	(0,4)	10	(0,5)	19	(0,4)
INDACATEROL	2	(0,1)	1	(0,0)	3	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	**385**	**(17,9)**	**412**	**(19,2)**	**797**	**(18,5)**
INDACATEROL MALEATE	2	(0,1)	0	(0,0)	2	(0,0)
IPRATROPIUM BROMIDE	93	(4,3)	97	(4,5)	190	(4,4)
IPRATROPIUM BROMIDE MONOHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
IPRATROPIUM BROMIDE;SALBUTAMOL	3	(0,1)	9	(0,4)	12	(0,3)
IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE	22	(1,0)	25	(1,2)	47	(1,1)
ISOPRENALINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
LEVOCETIRIZINE DIHYDROCHLORIDE;MONTELUKAST SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
LEVOSALBUTAMOL HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
MOMETASONE FUROATE	9	(0,4)	9	(0,4)	18	(0,4)
MONTELUKAST	7	(0,3)	6	(0,3)	13	(0,3)
MONTELUKAST SODIUM	14	(0,7)	12	(0,6)	26	(0,6)
OLODATEROL	2	(0,1)	3	(0,1)	5	(0,1)
OLODATEROL HYDROCHLORIDE;TIOTROPIUM BROMIDE MONOHYDRATE	4	(0,2)	3	(0,1)	7	(0,2)
OMALIZUMAB	1	(0,0)	0	(0,0)	1	(0,0)
PRANLUKAST	2	(0,1)	1	(0,0)	3	(0,1)
PROCATEROL HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
ROFLUMILAST	0	(0,0)	1	(0,0)	1	(0,0)
SALBUTAMOL	100	(4,6)	90	(4,2)	190	(4,4)
SALBUTAMOL SULFATE	25	(1,2)	33	(1,5)	58	(1,3)
SALMETEROL	8	(0,4)	7	(0,3)	15	(0,3)
SALMETEROL XINAFOATE	3	(0,1)	2	(0,1)	5	(0,1)
TERBUTALINE SULFATE	6	(0,3)	7	(0,3)	13	(0,3)
THEOBROMINE	0	(0,0)	1	(0,0)	1	(0,0)
THEOPHYLLINE	25	(1,2)	23	(1,1)	48	(1,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	**385**	**(17,9)**	**412**	**(19,2)**	**797**	**(18,5)**
TIOTROPIUM BROMIDE	67	(3,1)	68	(3,2)	135	(3,1)
TRIAMCINOLONE	0	(0,0)	6	(0,3)	6	(0,1)
TRIAMCINOLONE ACETONIDE	1	(0,0)	4	(0,2)	5	(0,1)
TULOBUTEROL	0	(0,0)	1	(0,0)	1	(0,0)
UMECLIDINIUM	2	(0,1)	0	(0,0)	2	(0,0)
UMECLIDINIUM BROMIDE	1	(0,0)	2	(0,1)	3	(0,1)
UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	4	(0,2)	5	(0,2)	9	(0,2)
VILANTEROL	0	(0,0)	1	(0,0)	1	(0,0)
VILANTEROL TRIFENATATE	0	(0,0)	1	(0,0)	1	(0,0)
NASAL PREPARATIONS	**309**	**(14,4)**	**333**	**(15,5)**	**642**	**(14,9)**
ACETYLCYSTEINE	35	(1,6)	48	(2,2)	83	(1,9)
AZELASTINE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE	0	(0,0)	1	(0,0)	1	(0,0)
BECLOMETASONE DIPROPIONATE	24	(1,1)	13	(0,6)	37	(0,9)
BETAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
BETAMETHASONE DIPROPIONATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE SODIUM PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE VALERATE	3	(0,1)	3	(0,1)	6	(0,1)
BUDESONIDE	47	(2,2)	61	(2,8)	108	(2,5)
CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CAMPHOR;MENTHOL;METHYL SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)
CICLESONIDE	3	(0,1)	2	(0,1)	5	(0,1)
DEXAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
DEXAMETHASONE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
NASAL PREPARATIONS	**309**	**(14,4)**	**333**	**(15,5)**	**642**	**(14,9)**
DEXAMETHASONE ISONICOTINATE;NEOMYCIN SULFATE;TRAMAZOLINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM PHOSPHATE	3	(0,1)	6	(0,3)	9	(0,2)
DEXPANTHENOL	0	(0,0)	1	(0,0)	1	(0,0)
EPINEPHRINE	0	(0,0)	2	(0,1)	2	(0,0)
FEXOFENADINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
FLUTICASONE	21	(1,0)	17	(0,8)	38	(0,9)
FLUTICASONE FUROATE	2	(0,1)	8	(0,4)	10	(0,2)
FLUTICASONE PROPIONATE	16	(0,7)	28	(1,3)	44	(1,0)
HYALURONATE SODIUM	9	(0,4)	7	(0,3)	16	(0,4)
IPRATROPIUM BROMIDE	93	(4,3)	97	(4,5)	190	(4,4)
KETOTIFEN FUMARATE	1	(0,0)	1	(0,0)	2	(0,0)
LEVOCABASTINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
LORATADINE;PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
MOMETASONE FUROATE	9	(0,4)	9	(0,4)	18	(0,4)
MUPIROCIN	2	(0,1)	3	(0,1)	5	(0,1)
OLOPATADINE HYDROCHLORIDE	7	(0,3)	1	(0,0)	8	(0,2)
OXYMETAZOLINE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
POTASSIUM CHLORIDE;SODIUM CHLORIDE	3	(0,1)	0	(0,0)	3	(0,1)
PREDNISOLONE	28	(1,3)	19	(0,9)	47	(1,1)
RETINOL	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM BICARBONATE	40	(1,9)	34	(1,6)	74	(1,7)
SODIUM CHLORIDE	44	(2,0)	49	(2,3)	93	(2,2)
TRIAMCINOLONE	0	(0,0)	6	(0,3)	6	(0,1)
TRIAMCINOLONE ACETONIDE	1	(0,0)	4	(0,2)	5	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
NASAL PREPARATIONS	**309**	**(14,4)**	**333**	**(15,5)**	**642**	**(14,9)**
XYLOMETAZOLINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
ZINC	0	(0,0)	1	(0,0)	1	(0,0)
OTHER RESPIRATORY SYSTEM PRODUCTS	**36**	**(1,7)**	**40**	**(1,9)**	**76**	**(1,8)**
AMBROXOL	5	(0,2)	8	(0,4)	13	(0,3)
AMBROXOL HYDROCHLORIDE	19	(0,9)	20	(0,9)	39	(0,9)
BETAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
CAFFEINE	0	(0,0)	1	(0,0)	1	(0,0)
DEXAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
OXYGEN	6	(0,3)	6	(0,3)	12	(0,3)
PENTETRAZOL	1	(0,0)	0	(0,0)	1	(0,0)
PHOSPHOLIPIDS	3	(0,1)	0	(0,0)	3	(0,1)
THROAT PREPARATIONS	**91**	**(4,2)**	**107**	**(5,0)**	**198**	**(4,6)**
AMBROXOL	5	(0,2)	8	(0,4)	13	(0,3)
AMBROXOL HYDROCHLORIDE	19	(0,9)	20	(0,9)	39	(0,9)
AMMONIUM CHLORIDE;GLYCYRRHIZA GLABRA	1	(0,0)	0	(0,0)	1	(0,0)
BACITRACIN ZINC;NEOMYCIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
BENZETHONIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
BENZYDAMINE HYDROCHLORIDE;CHLORHEXIDINE GLUCONATE	0	(0,0)	1	(0,0)	1	(0,0)
CETYLPYRIDINIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CHLORHEXIDINE GLUCONATE	0	(0,0)	3	(0,1)	3	(0,1)
DEQUALINIUM CHLORIDE	3	(0,1)	4	(0,2)	7	(0,2)
DICHLOROBENZYL ALCOHOL	1	(0,0)	0	(0,0)	1	(0,0)
DICLOFENAC	7	(0,3)	11	(0,5)	18	(0,4)
DICLOFENAC SODIUM	14	(0,7)	7	(0,3)	21	(0,5)
DOMIPHEN BROMIDE	0	(0,0)	2	(0,1)	2	(0,0)
FLURBIPROFEN	4	(0,2)	2	(0,1)	6	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
THROAT PREPARATIONS	**91**	**(4,2)**	**107**	**(5,0)**	**198**	**(4,6)**
GARDENIA JASMINOIDES FRUIT;ISATIS INDIGOTICA ROOT;PHELLODENDRON CHINENSE BARK;SCUTELLARIA BAICALENSIS ROOT;STERCULIA LYCHNOPHORA SEED	0	(0,0)	2	(0,1)	2	(0,0)
IBUPROFEN	14	(0,7)	9	(0,4)	23	(0,5)
KETOPROFEN	10	(0,5)	19	(0,9)	29	(0,7)
LIDOCAINE	16	(0,7)	19	(0,9)	35	(0,8)
LIDOCAINE HYDROCHLORIDE	14	(0,7)	8	(0,4)	22	(0,5)
NEOMYCIN	0	(0,0)	1	(0,0)	1	(0,0)
POVIDONE-IODINE	3	(0,1)	1	(0,0)	4	(0,1)
TETRACYCLINE	0	(0,0)	1	(0,0)	1	(0,0)
TETRACYCLINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
SENSORY ORGANS						
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	**70**	**(3,3)**	**88**	**(4,1)**	**158**	**(3,7)**
BACITRACIN ZINC;NEOMYCIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
BETAMETHASONE DIPROPIONATE;GENTAMICIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE SODIUM PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE VALERATE;GENTAMICIN SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
CHLORAMPHENICOL	1	(0,0)	3	(0,1)	4	(0,1)
CHLORHEXIDINE GLUCONATE	0	(0,0)	3	(0,1)	3	(0,1)
CIPROFLOXACIN	9	(0,4)	19	(0,9)	28	(0,7)
CIPROFLOXACIN HYDROCHLORIDE	5	(0,2)	1	(0,0)	6	(0,1)
CIPROFLOXACIN LACTATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	**70**	**(3,3)**	**88**	**(4,1)**	**158**	**(3,7)**
DEXAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
DEXAMETHASONE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM PHOSPHATE	3	(0,1)	6	(0,3)	9	(0,2)
DEXAMETHASONE;TOBRAMYCIN	1	(0,0)	2	(0,1)	3	(0,1)
GATIFLOXACIN	1	(0,0)	1	(0,0)	2	(0,0)
GENTAMICIN	0	(0,0)	2	(0,1)	2	(0,0)
GENTAMICIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
LEVOFLOXACIN	13	(0,6)	18	(0,8)	31	(0,7)
LEVOFLOXACIN HEMIHYDRATE	1	(0,0)	1	(0,0)	2	(0,0)
METHYLPREDNISOLONE;NEOMYCIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
NEOMYCIN	0	(0,0)	1	(0,0)	1	(0,0)
OFLOXACIN	1	(0,0)	7	(0,3)	8	(0,2)
PREDNISOLONE	28	(1,3)	19	(0,9)	47	(1,1)
PREDNISOLONE ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
PREDNISOLONE SODIUM SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE VALEROACETATE	3	(0,1)	0	(0,0)	3	(0,1)
TETRACYCLINE	0	(0,0)	1	(0,0)	1	(0,0)
TETRACYCLINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
OPHTHALMOLOGICALS	**773**	**(35,9)**	**765**	**(35,6)**	**1.538**	**(35,7)**
ACETAZOLAMIDE	6	(0,3)	6	(0,3)	12	(0,3)
ACETYLCYSTEINE	35	(1,6)	48	(2,2)	83	(1,9)
ACICLOVIR	0	(0,0)	2	(0,1)	2	(0,0)
ADENOSINE	3	(0,1)	2	(0,1)	5	(0,1)
ADENOSINE TRIPHOSPHATE	0	(0,0)	1	(0,0)	1	(0,0)
ALBUMIN HUMAN	7	(0,3)	9	(0,4)	16	(0,4)
ALGINIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
AMIKACIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
AMINO ACIDS NOS	1	(0,0)	1	(0,0)	2	(0,0)
AMPICILLIN	2	(0,1)	0	(0,0)	2	(0,0)
ASCORBIC ACID	19	(0,9)	16	(0,7)	35	(0,8)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**773**	**(35,9)**	**765**	**(35,6)**	**1.538**	**(35,7)**
ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;SODIUM SELENATE;TOCOPHERYL ACETATE;XANTOFYL;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;TOCOPHERYL ACETATE;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;COPPER CITRATE;TOCOPHERYL ACETATE;XANTOFYL;ZEAXANTHIN;ZINC OXIDE	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;COPPER;OMEGA-3 FATTY ACIDS;VITAMIN E NOS;XANTOFYL;ZEAXANTHIN;ZINC	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;CUPRIC OXIDE;RETINOL;TOCOPHERYL ACETATE;ZINC OXIDE	3	(0,1)	1	(0,0)	4	(0,1)
ATROPINE	1	(0,0)	0	(0,0)	1	(0,0)
ATROPINE SULFATE	1	(0,0)	1	(0,0)	2	(0,0)
AZELASTINE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
AZITHROMYCIN	9	(0,4)	13	(0,6)	22	(0,5)
BACITRACIN ZINC;NEOMYCIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	1	(0,0)	1	(0,0)	2	(0,0)
BENZYLPENICILLIN	0	(0,0)	1	(0,0)	1	(0,0)
BENZYLPENICILLIN SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
BEPOTASTINE BESILATE	2	(0,1)	1	(0,0)	3	(0,1)
BETAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
BETAMETHASONE DIPROPIONATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**773**	**(35,9)**	**765**	**(35,6)**	**1.538**	**(35,7)**
BETAMETHASONE DIPROPIONATE;GENTAMICIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE SODIUM PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE VALERATE	3	(0,1)	3	(0,1)	6	(0,1)
BETAMETHASONE VALERATE;GENTAMICIN SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
BETAXOLOL HYDROCHLORIDE	4	(0,2)	3	(0,1)	7	(0,2)
BEVACIZUMAB	3	(0,1)	1	(0,0)	4	(0,1)
BIMATOPROST	2	(0,1)	1	(0,0)	3	(0,1)
BLOOD, CALF, DEPROT., LMW PORTION	2	(0,1)	0	(0,0)	2	(0,0)
BORIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
BORIC ACID;POTASSIUM CHLORIDE;SODIUM CARBONATE ANHYDROUS;SODIUM CHLORIDE;SODIUM PHOSPHATE DIBASIC	1	(0,0)	0	(0,0)	1	(0,0)
BORIC ACID;TOBRAMYCIN	1	(0,0)	0	(0,0)	1	(0,0)
BRIMONIDINE TARTRATE	2	(0,1)	6	(0,3)	8	(0,2)
BRIMONIDINE TARTRATE;TIMOLOL MALEATE	1	(0,0)	2	(0,1)	3	(0,1)
BRINZOLAMIDE;TIMOLOL MALEATE	1	(0,0)	1	(0,0)	2	(0,0)
BROMFENAC SODIUM	2	(0,1)	2	(0,1)	4	(0,1)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CARBOMER	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**773**	**(35,9)**	**765**	**(35,6)**	**1.538**	**(35,7)**
CARMELLOSE SODIUM	3	(0,1)	1	(0,0)	4	(0,1)
CARTEOLOL HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CARTEOLOL HYDROCHLORIDE;LATANOPROST	1	(0,0)	0	(0,0)	1	(0,0)
CEFUROXIME	8	(0,4)	9	(0,4)	17	(0,4)
CEFUROXIME SODIUM	4	(0,2)	7	(0,3)	11	(0,3)
CETIRIZINE HYDROCHLORIDE	17	(0,8)	12	(0,6)	29	(0,7)
CETYLPYRIDINIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CHLORAMPHENICOL	1	(0,0)	3	(0,1)	4	(0,1)
CHLORHEXIDINE GLUCONATE	0	(0,0)	3	(0,1)	3	(0,1)
CHLORHEXIDINE GLUCONATE;PHENYLEPHRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CHLORPHENAMINE MALEATE;CHONDROITIN SULFATE SODIUM;NEOSTIGMINE METILSULFATE;POTASSIUM ASPARTATE;PYRIDOXINE HYDROCHLORIDE;TOCOPHERYL ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
CHONDROITIN SULFATE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
CHONDROITIN SULFATE SODIUM;FLAVINE ADENINE DINUCLEOTIDE DISODIUM	0	(0,0)	1	(0,0)	1	(0,0)
CICLOSPORIN	1	(0,0)	2	(0,1)	3	(0,1)
CIPROFLOXACIN	9	(0,4)	19	(0,9)	28	(0,7)
CIPROFLOXACIN HYDROCHLORIDE	5	(0,2)	1	(0,0)	6	(0,1)
CIPROFLOXACIN LACTATE	1	(0,0)	0	(0,0)	1	(0,0)
CLOBETASONE BUTYRATE	1	(0,0)	0	(0,0)	1	(0,0)
CLONIDINE	3	(0,1)	2	(0,1)	5	(0,1)
CLONIDINE HYDROCHLORIDE	1	(0,0)	4	(0,2)	5	(0,1)
CLOTRIMAZOLE	1	(0,0)	3	(0,1)	4	(0,1)
CORTISONE	1	(0,0)	0	(0,0)	1	(0,0)
CROTAMITON;HYDROCORTISONE	2	(0,1)	0	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**773**	**(35,9)**	**765**	**(35,6)**	**1.538**	**(35,7)**
CYANOCOBALAMIN	35	(1,6)	35	(1,6)	70	(1,6)
DESONIDE	1	(0,0)	1	(0,0)	2	(0,0)
DEXAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
DEXAMETHASONE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM PHOSPHATE	3	(0,1)	6	(0,3)	9	(0,2)
DEXAMETHASONE;TOBRAMYCIN	1	(0,0)	2	(0,1)	3	(0,1)
DEXPANTHENOL	0	(0,0)	1	(0,0)	1	(0,0)
DEXTRAN 70;HYPROMELLOSE	3	(0,1)	0	(0,0)	3	(0,1)
DICLOFENAC	7	(0,3)	11	(0,5)	18	(0,4)
DICLOFENAC DIETHYLAMINE	2	(0,1)	4	(0,2)	6	(0,1)
DICLOFENAC EPOLAMINE	1	(0,0)	0	(0,0)	1	(0,0)
DICLOFENAC SODIUM	14	(0,7)	7	(0,3)	21	(0,5)
DIFLUPREDNATE	2	(0,1)	0	(0,0)	2	(0,0)
DIGITALIS PURPUREA LEAF;ESCULOSIDE	1	(0,0)	0	(0,0)	1	(0,0)
DIGITALIS PURPUREA;ESCULOSIDE	1	(0,0)	0	(0,0)	1	(0,0)
DIMETICONE	2	(0,1)	7	(0,3)	9	(0,2)
DIQUAFOSOL TETRASODIUM	1	(0,0)	3	(0,1)	4	(0,1)
DORZOLAMIDE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
DORZOLAMIDE HYDROCHLORIDE;TIMOLOL MALEATE	1	(0,0)	0	(0,0)	1	(0,0)
EDETIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
EMEDASTINE FUMARATE	0	(0,0)	1	(0,0)	1	(0,0)
EPINASTINE HYDROCHLORIDE	4	(0,2)	0	(0,0)	4	(0,1)
EPINEPHRINE	0	(0,0)	2	(0,1)	2	(0,0)
ERYTHROMYCIN	1	(0,0)	2	(0,1)	3	(0,1)
ETHYLMORPHINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
FLUCONAZOLE	1	(0,0)	1	(0,0)	2	(0,0)
FLUDROCORTISONE ACETATE	2	(0,1)	0	(0,0)	2	(0,0)
FLUOCINOLONE ACETONIDE	0	(0,0)	2	(0,1)	2	(0,0)
FLURESCEIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**773**	**(35,9)**	**765**	**(35,6)**	**1.538**	**(35,7)**
FLUOROMETHOLONE	4	(0,2)	0	(0,0)	4	(0,1)
FLURBIPROFEN	4	(0,2)	2	(0,1)	6	(0,1)
FLURBIPROFEN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
FUSIDIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
GATIFLOXACIN	1	(0,0)	1	(0,0)	2	(0,0)
GENTAMICIN	0	(0,0)	2	(0,1)	2	(0,0)
GENTAMICIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
GLUTATHIONE	8	(0,4)	2	(0,1)	10	(0,2)
GLYCEROL	8	(0,4)	3	(0,1)	11	(0,3)
GUAIAZULENE	1	(0,0)	2	(0,1)	3	(0,1)
HEPARIN	18	(0,8)	27	(1,3)	45	(1,0)
HEPARIN CALCIUM	11	(0,5)	3	(0,1)	14	(0,3)
HEPARIN SODIUM	25	(1,2)	16	(0,7)	41	(1,0)
HEPARINOID	3	(0,1)	2	(0,1)	5	(0,1)
HYALURONATE SODIUM	9	(0,4)	7	(0,3)	16	(0,4)
HYDROCORTISONE	5	(0,2)	8	(0,4)	13	(0,3)
HYDROCORTISONE ACETATE	2	(0,1)	3	(0,1)	5	(0,1)
HYDROCORTISONE PROBUTAT	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE SODIUM SUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
HYETELLOSE;POVIDONE	1	(0,0)	1	(0,0)	2	(0,0)
HYOSCINE	1	(0,0)	0	(0,0)	1	(0,0)
HYPROMELLOSE	1	(0,0)	2	(0,1)	3	(0,1)
INDOMETACIN	2	(0,1)	2	(0,1)	4	(0,1)
IODOLECITHIN	0	(0,0)	1	(0,0)	1	(0,0)
ISOSORBIDE	3	(0,1)	3	(0,1)	6	(0,1)
KETOROLAC TROMETHAMINE	2	(0,1)	2	(0,1)	4	(0,1)
KETOTIFEN FUMARATE	1	(0,0)	1	(0,0)	2	(0,0)
LATANOPROST	14	(0,7)	7	(0,3)	21	(0,5)
LEVOBUNOLOL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
LEVOCABASTINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
LEVOFLOXACIN	13	(0,6)	18	(0,8)	31	(0,7)
LEVOFLOXACIN HEMIHYDRATE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**773**	**(35,9)**	**765**	**(35,6)**	**1.538**	**(35,7)**
LIDOCAINE	16	(0,7)	19	(0,9)	35	(0,8)
LIDOCAINE HYDROCHLORIDE	14	(0,7)	8	(0,4)	22	(0,5)
MACROGOL	12	(0,6)	10	(0,5)	22	(0,5)
MACROGOL 4000	0	(0,0)	3	(0,1)	3	(0,1)
MELOXICAM	2	(0,1)	6	(0,3)	8	(0,2)
MESO ZEAXANTHIN;XANTOFYL;ZEAXANTHIN	0	(0,0)	1	(0,0)	1	(0,0)
METHYLPREDNISOLONE	12	(0,6)	14	(0,7)	26	(0,6)
MINERALS NOS;VITAMINS NOS	4	(0,2)	9	(0,4)	13	(0,3)
MOXIFLOXACIN	4	(0,2)	1	(0,0)	5	(0,1)
MOXIFLOXACIN HYDROCHLORIDE	7	(0,3)	4	(0,2)	11	(0,3)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	6	(0,3)	4	(0,2)	10	(0,2)
NAPROXEN	0	(0,0)	5	(0,2)	5	(0,1)
NAPROXEN SODIUM	0	(0,0)	2	(0,1)	2	(0,0)
NEOMYCIN	0	(0,0)	1	(0,0)	1	(0,0)
NEPAFENAC	0	(0,0)	1	(0,0)	1	(0,0)
NERVE GROWTH FACTOR, MOUSE	0	(0,0)	1	(0,0)	1	(0,0)
NETARSUDIL MESILATE	0	(0,0)	1	(0,0)	1	(0,0)
NIPRADOLOL	0	(0,0)	1	(0,0)	1	(0,0)
OFLOXACIN	1	(0,0)	7	(0,3)	8	(0,2)
OLOPATADINE HYDROCHLORIDE	7	(0,3)	1	(0,0)	8	(0,2)
OXYBUPROCAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
OXYMETAZOLINE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
PANCREATIN	2	(0,1)	5	(0,2)	7	(0,2)
PARAFFIN	1	(0,0)	1	(0,0)	2	(0,0)
PARAFFIN, LIQUID	1	(0,0)	0	(0,0)	1	(0,0)
PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	1	(0,0)	1	(0,0)	2	(0,0)
PERFLUTREN	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**773**	**(35,9)**	**765**	**(35,6)**	**1.538**	**(35,7)**
PHENYLEPHRINE HYDROCHLORIDE;TROPICAMIDE	1	(0,0)	2	(0,1)	3	(0,1)
PICLOXYDINE DIHYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
PINDOLOL	1	(0,0)	0	(0,0)	1	(0,0)
PIRENOXINE	4	(0,2)	3	(0,1)	7	(0,2)
PIROXICAM	2	(0,1)	0	(0,0)	2	(0,0)
PIROXICAM BETADEX	0	(0,0)	1	(0,0)	1	(0,0)
POLYVINYL ALCOHOL	0	(0,0)	1	(0,0)	1	(0,0)
POLYVINYL ALCOHOL;POVIDONE	2	(0,1)	0	(0,0)	2	(0,0)
POTASSIUM	56	(2,6)	50	(2,3)	106	(2,5)
POTASSIUM CHLORIDE	427	(19,8)	399	(18,5)	826	(19,2)
POTASSIUM CHLORIDE;SODIUM CHLORIDE	3	(0,1)	0	(0,0)	3	(0,1)
POTASSIUM IODIDE	0	(0,0)	1	(0,0)	1	(0,0)
POVIDONE-IODINE	3	(0,1)	1	(0,0)	4	(0,1)
PRANOPROFEN	3	(0,1)	1	(0,0)	4	(0,1)
PREDNISOLONE	28	(1,3)	19	(0,9)	47	(1,1)
PREDNISOLONE ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
PREDNISOLONE SODIUM SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE VALEROACETATE	3	(0,1)	0	(0,0)	3	(0,1)
PREDNISONE	24	(1,1)	28	(1,3)	52	(1,2)
PREDNISONE ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
PROCAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
REBAMIPIDE	6	(0,3)	18	(0,8)	24	(0,6)
RETINOL	1	(0,0)	0	(0,0)	1	(0,0)
RIBOFLAVIN	0	(0,0)	2	(0,1)	2	(0,0)
RICINUS COMMUNIS OIL	0	(0,0)	1	(0,0)	1	(0,0)
RIFAMPICIN	5	(0,2)	1	(0,0)	6	(0,1)
RIFAMYCIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
RIPASUDIL HYDROCHLORIDE DIHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
SALICYLIC ACID	0	(0,0)	2	(0,1)	2	(0,0)
SIROLIMUS	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**773**	**(35,9)**	**765**	**(35,6)**	**1.538**	**(35,7)**
SODIUM CHLORIDE	44	(2,0)	49	(2,3)	93	(2,2)
SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC	2	(0,1)	1	(0,0)	3	(0,1)
SODIUM PHOSPHATE;SODIUM PHOSPHATE DIBASIC	0	(0,0)	1	(0,0)	1	(0,0)
SULFACETAMIDE	0	(0,0)	1	(0,0)	1	(0,0)
SULFADIAZINE SILVER	1	(0,0)	2	(0,1)	3	(0,1)
SULFAMETHOXAZOLE	0	(0,0)	2	(0,1)	2	(0,0)
TAFLUPROST	1	(0,0)	0	(0,0)	1	(0,0)
TETRACYCLINE	0	(0,0)	1	(0,0)	1	(0,0)
TETRACYCLINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
THIOTRIAZOLINE	1	(0,0)	1	(0,0)	2	(0,0)
TIMOLOL	3	(0,1)	2	(0,1)	5	(0,1)
TIMOLOL MALEATE	2	(0,1)	0	(0,0)	2	(0,0)
TOBRAMYCIN	1	(0,0)	0	(0,0)	1	(0,0)
TOSUFLOXACIN TOSILATE	1	(0,0)	0	(0,0)	1	(0,0)
TRAVOPROST	4	(0,2)	4	(0,2)	8	(0,2)
TRIAMCINOLONE	0	(0,0)	6	(0,3)	6	(0,1)
TRIAMCINOLONE ACETONIDE	1	(0,0)	4	(0,2)	5	(0,1)
UBIDECARENONE	25	(1,2)	31	(1,4)	56	(1,3)
UNOPROSTONE ISOPROPYL	0	(0,0)	1	(0,0)	1	(0,0)
VACCINIUM MYRTILLUS EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
VANCOMYCIN	3	(0,1)	5	(0,2)	8	(0,2)
VANCOMYCIN HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
XANTOFYL	1	(0,0)	0	(0,0)	1	(0,0)
XYLOMETAZOLINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
ZINC	0	(0,0)	1	(0,0)	1	(0,0)
ZINC SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
OTOLOGICALS	**201**	**(9,3)**	**224**	**(10,4)**	**425**	**(9,9)**
BETAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
BETAMETHASONE DIPROPIONATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OTOLOGICALS	**201**	**(9,3)**	**224**	**(10,4)**	**425**	**(9,9)**
BETAMETHASONE SODIUM PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE VALERATE	3	(0,1)	3	(0,1)	6	(0,1)
BORIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
CHLORAMPHENICOL	1	(0,0)	3	(0,1)	4	(0,1)
CHLORHEXIDINE GLUCONATE	0	(0,0)	3	(0,1)	3	(0,1)
CHOLINE SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)
CIPROFLOXACIN	9	(0,4)	19	(0,9)	28	(0,7)
CIPROFLOXACIN HYDROCHLORIDE	5	(0,2)	1	(0,0)	6	(0,1)
CLOTRIMAZOLE	1	(0,0)	3	(0,1)	4	(0,1)
CROTAMITON;HYDROCORTISONE	2	(0,1)	0	(0,0)	2	(0,0)
DEXAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
DEXAMETHASONE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM PHOSPHATE	3	(0,1)	6	(0,3)	9	(0,2)
DEXAMETHASONE;TOBRAMYCIN	1	(0,0)	2	(0,1)	3	(0,1)
DOCUSATE SODIUM	25	(1,2)	25	(1,2)	50	(1,2)
FLUOCINOLONE ACETONIDE	0	(0,0)	2	(0,1)	2	(0,0)
GENTAMICIN	0	(0,0)	2	(0,1)	2	(0,0)
GENTAMICIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
GLYCEROL	8	(0,4)	3	(0,1)	11	(0,3)
HYDROCORTISONE	5	(0,2)	8	(0,4)	13	(0,3)
HYDROCORTISONE ACETATE	2	(0,1)	3	(0,1)	5	(0,1)
HYDROCORTISONE PROBUTAT	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE SODIUM SUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
LEVOFLOXACIN	13	(0,6)	18	(0,8)	31	(0,7)
LEVOFLOXACIN HEMIHYDRATE	1	(0,0)	1	(0,0)	2	(0,0)
LIDOCAINE	16	(0,7)	19	(0,9)	35	(0,8)
LIDOCAINE HYDROCHLORIDE	14	(0,7)	8	(0,4)	22	(0,5)
MICONAZOLE	2	(0,1)	0	(0,0)	2	(0,0)
MICONAZOLE NITRATE	1	(0,0)	3	(0,1)	4	(0,1)
NEOMYCIN	0	(0,0)	1	(0,0)	1	(0,0)
OFLOXACIN	1	(0,0)	7	(0,3)	8	(0,2)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OTOLOGICALS	**201**	**(9,3)**	**224**	**(10,4)**	**425**	**(9,9)**
PARAFFIN, LIQUID	1	(0,0)	0	(0,0)	1	(0,0)
PREDNISOLONE	28	(1,3)	19	(0,9)	47	(1,1)
PREDNISOLONE ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
PREDNISOLONE SODIUM SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE VALEROACETATE	3	(0,1)	0	(0,0)	3	(0,1)
RIFAMYCIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
SALICYLIC ACID	0	(0,0)	2	(0,1)	2	(0,0)
SODIUM BICARBONATE	40	(1,9)	34	(1,6)	74	(1,7)
SODIUM CHLORIDE	44	(2,0)	49	(2,3)	93	(2,2)
TETRACYCLINE	0	(0,0)	1	(0,0)	1	(0,0)
TETRACYCLINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
UREA HYDROGEN PEROXIDE	0	(0,0)	1	(0,0)	1	(0,0)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS						
CALCIUM HOMEOSTASIS	**3**	**(0,1)**	**6**	**(0,3)**	**9**	**(0,2)**
CALCITONIN, SALMON	0	(0,0)	1	(0,0)	1	(0,0)
CINACALCET	0	(0,0)	1	(0,0)	1	(0,0)
ELCATONIN	1	(0,0)	0	(0,0)	1	(0,0)
MAXACALCITOL	1	(0,0)	1	(0,0)	2	(0,0)
PARICALCITOL	1	(0,0)	3	(0,1)	4	(0,1)
CORTICOSTEROIDS FOR SYSTEMIC USE	**121**	**(5,6)**	**113**	**(5,3)**	**234**	**(5,4)**
ALDOSTERONE	1	(0,0)	0	(0,0)	1	(0,0)
BECLOMETASONE DIPROPIONATE	24	(1,1)	13	(0,6)	37	(0,9)
BETAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
BETAMETHASONE BUTYRATE PROPIONATE	4	(0,2)	4	(0,2)	8	(0,2)
BETAMETHASONE DIPROPIONATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE DIPROPIONATE;BETAMETHASONE SODIUM PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE SODIUM PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS						
CORTICOSTEROIDS FOR SYSTEMIC USE	**121**	**(5,6)**	**113**	**(5,3)**	**234**	**(5,4)**
BETAMETHASONE VALERATE	3	(0,1)	3	(0,1)	6	(0,1)
BETAMETHASONE;DEXCHLORPH ENIRAMINE MALEATE	1	(0,0)	0	(0,0)	1	(0,0)
CORTISONE	1	(0,0)	0	(0,0)	1	(0,0)
CROTAMITON;HYDROCORTISONE	2	(0,1)	0	(0,0)	2	(0,0)
DEFLAZACORT	1	(0,0)	2	(0,1)	3	(0,1)
DEXAMETHASONE	1	(0,0)	3	(0,1)	4	(0,1)
DEXAMETHASONE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM PHOSPHATE	3	(0,1)	6	(0,3)	9	(0,2)
FLUDROCORTISONE ACETATE	2	(0,1)	0	(0,0)	2	(0,0)
HYDROCORTISONE	5	(0,2)	8	(0,4)	13	(0,3)
HYDROCORTISONE ACETATE	2	(0,1)	3	(0,1)	5	(0,1)
HYDROCORTISONE BUTYRATE	1	(0,0)	2	(0,1)	3	(0,1)
HYDROCORTISONE PROBUTAT	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE SODIUM SUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
KETOCONAZOLE	2	(0,1)	3	(0,1)	5	(0,1)
METHYLPREDNISOLONE	12	(0,6)	14	(0,7)	26	(0,6)
METHYLPREDNISOLONE HEMISUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
METHYLPREDNISOLONE SODIUM SUCCINATE	10	(0,5)	2	(0,1)	12	(0,3)
PREDNISOLONE	28	(1,3)	19	(0,9)	47	(1,1)
PREDNISOLONE ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
PREDNISOLONE SODIUM SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE VALEROACETATE	3	(0,1)	0	(0,0)	3	(0,1)
PREDNISONE	24	(1,1)	28	(1,3)	52	(1,2)
PREDNISONE ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
TRIAMCINOLONE	0	(0,0)	6	(0,3)	6	(0,1)
TRIAMCINOLONE ACETONIDE	1	(0,0)	4	(0,2)	5	(0,1)
PANCREATIC HORMONES	**0**	**(0,0)**	**2**	**(0,1)**	**2**	**(0,0)**

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS						
PANCREATIC HORMONES	**0**	**(0,0)**	**2**	**(0,1)**	**2**	**(0,0)**
GLUCAGON	0	(0,0)	2	(0,1)	2	(0,0)
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES	**2**	**(0,1)**	**1**	**(0,0)**	**3**	**(0,1)**
SOMATROPIN	1	(0,0)	0	(0,0)	1	(0,0)
TETRACOSACTIDE	1	(0,0)	0	(0,0)	1	(0,0)
VASOPRESSIN	0	(0,0)	1	(0,0)	1	(0,0)
THYROID THERAPY	**243**	**(11,3)**	**242**	**(11,3)**	**485**	**(11,3)**
CARBIMAZOLE	4	(0,2)	1	(0,0)	5	(0,1)
LEVOTHYROXINE SODIUM	218	(10,1)	221	(10,3)	439	(10,2)
LEVOTHYROXINE SODIUM;LIOTHYRONINE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
LEVOTHYROXINE SODIUM;POTASSIUM IODIDE	0	(0,0)	1	(0,0)	1	(0,0)
LIOTHYRONINE SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM IODIDE	0	(0,0)	1	(0,0)	1	(0,0)
PROPRANOLOL	0	(0,0)	1	(0,0)	1	(0,0)
PROPYLTHIOURACIL	0	(0,0)	1	(0,0)	1	(0,0)
THIAMAZOLE	21	(1,0)	14	(0,7)	35	(0,8)
THYROID	0	(0,0)	1	(0,0)	1	(0,0)
VARIOUS						
ALL OTHER NON-THERAPEUTIC PRODUCTS	**68**	**(3,2)**	**68**	**(3,2)**	**136**	**(3,2)**
ASCORBIC ACID	19	(0,9)	16	(0,7)	35	(0,8)
GLUCOSE;POTASSIUM CHLORIDE;POTASSIUM PHOSPHATE DIBASIC;POTASSIUM PHOSPHATE MONOBASIC;SODIUM CHLORIDE;SODIUM LACTATE	1	(0,0)	0	(0,0)	1	(0,0)
HYPROMELLOSE	1	(0,0)	2	(0,1)	3	(0,1)
MENTHOL	0	(0,0)	1	(0,0)	1	(0,0)
OTHER NON-THERAPEUTIC AUXILIARY PRODUCTS	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
ALL OTHER NON-THERAPEUTIC PRODUCTS	**68**	**(3,2)**	**68**	**(3,2)**	**136**	**(3,2)**
PENICILLIN NOS	2	(0,1)	0	(0,0)	2	(0,0)
SODIUM CHLORIDE	44	(2,0)	49	(2,3)	93	(2,2)
WATER FOR INJECTION	1	(0,0)	0	(0,0)	1	(0,0)
ALL OTHER THERAPEUTIC PRODUCTS	**158**	**(7,3)**	**176**	**(8,2)**	**334**	**(7,8)**
ACETYLCYSTEINE	35	(1,6)	48	(2,2)	83	(1,9)
ACHYRANTHES BIDENTATA ROOT;CARTHAMUS TINCTORIUS FLOWER;CITRUS RETICULATA FRUIT PEEL;COPTIS CHINENSIS RHIZOME;GLYCYRRHIZA URALENSIS ROOT;PINELLIA TERNATA RHIZOME;PORIA COCOS;PSEUDOSTELLARIA HETEROPHYLLA ROOT;RHEUM PALMATUM ROOT WITH RHIZOME;SALVIA MILTIORRHIZA ROOT	2	(0,1)	2	(0,1)	4	(0,1)
ADENOSINE	3	(0,1)	2	(0,1)	5	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**158**	**(7,3)**	**176**	**(8,2)**	**334**	**(7,8)**
ALBIZIA JULIBRISSIN FLOWER;CALCIUM SULFATE;ELEUTHEROCOCCUS SENTICOSUS ROOT WITH RHIZOME;FALLOPIA MULTIFLORA STEM;JUNCUS EFFUSUS STEM PITH;LILIUM SPP.;OPHIOPOGON JAPONICUS ROOT TUBER;OYSTER SHELL;POLYGALA TENUIFOLIA ROOT;PORIA COCOS;REHMANNIA GLUTINOSA ROOT;SALVIA MILTIORRHIZA ROOT WITH RHIZOME;SCHISANDRA CHINENSIS FRUIT;SCROPHULARIA NINGPOENSIS ROOT;ZIZIPHUS JUJUBA SEED	0	(0,0)	1	(0,0)	1	(0,0)
ALUMINIUM HYDROXIDE	1	(0,0)	1	(0,0)	2	(0,0)
ANEMARRHENA ASPHODELOIDES RHIZOME;ARCTIUM LAPPA FRUIT;ARTEMISIA ANNUA HERB;CALCIUM SULFATE;EPHEDRA SINICA HERB;FORSYTHIA SUSPENSA FRUIT;FRITILLARIA THUNBERGII BULB;GLYCYRRHIZA URALENSIS ROOT WITH RHIZOME;LONICERA JAPONICA FLOWER;MENTHA CANADENSIS HERB;PRUNUS ARMENIACA SEED;SCUTELLARIA BAICALENSIS ROOT	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**158**	**(7,3)**	**176**	**(8,2)**	**334**	**(7,8)**
ANGELICA ACUTILOBA ROOT;ATRACTYLODES SPP. RHIZOME;CALCIUM SULFATE;CNIDIUM OFFICINALE RHIZOME;EPHEDRA SPP. HERB;FORSYTHIA SPP. FRUIT;GARDENIA JASMINOIDES FRUIT;GLYCYRRHIZA SPP. ROOT;MENTHA CANADENSIS HERB;PAEONIA LACTIFLORA ROOT;PLATYCODON GRANDIFLORUS ROOT;RHEUM SPP. RHIZOME;SAPOSHNIKOVIA DIVARICATA ROOT;SCHIZONEPETA TENUIFOLIA SPIKE;SCUTELLARIA BAICALENSIS ROOT;SODIUM SULFATE;TALC;ZINGIBER	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA DAHURICA ROOT;ANGELICA SINENSIS ROOT;BOSWELLIA SPP. RESIN;CAPSICUM ANNUUM FRUIT;CINNAMOMUM CAMPHORA;CINNAMOMUM CASSIA ESSENTIAL OIL;CURCUMA LONGA RHIZOME;EPHEDRA SPP. HERB;ERYCIBE OBTUSIFOLIA STEM;MENTHOL;OCIMUM BASILICUM;PANAX NOTOGINSENG ROOT;PIPER KADSURA STEM;ZINGIBER OFFICINALE RHIZOME	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**158**	**(7,3)**	**176**	**(8,2)**	**334**	**(7,8)**
ANGELICA DAHURICA ROOT;ARMENIACA VULGARIS VAR. ANSU SEED;BUPLEURUM CHINENSE, ROOT;CORYDALIS BUNGEANA HERB;MENTHA CANADENSIS HERB;PERILLA FRUTESCENS VAR. CRISPA LEAF;PHRAGMITES COMMUNIS RHIZOME;PLATYCODON GRANDIFLORUS ROOT;PUERARIA LOBATA ROOT;SAPOSHNIKOVIA DIVARICATA ROOT;SCHIZONEPETA SPP.	2	(0,1)	1	(0,0)	3	(0,1)
ASCORBIC ACID	19	(0,9)	16	(0,7)	35	(0,8)
ASTRAGALUS PROPINQUUS	1	(0,0)	1	(0,0)	2	(0,0)
ATROPINE	1	(0,0)	0	(0,0)	1	(0,0)
BORNEOL	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM ACETATE	1	(0,0)	2	(0,1)	3	(0,1)
CALCIUM CARBONATE	15	(0,7)	17	(0,8)	32	(0,7)
CALCIUM POLYSTYRENE SULFONATE	19	(0,9)	26	(1,2)	45	(1,0)
CALCIUM;MAGNESIUM	1	(0,0)	1	(0,0)	2	(0,0)
CALCIUM;VITAMIN D NOS	3	(0,1)	1	(0,0)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**158**	**(7,3)**	**176**	**(8,2)**	**334**	**(7,8)**
CARTHAMUS TINCTORIUS;CINNAMOMUM CASSIA;CISTANCHE DESERTICOLA;CURCUMA LONGA;EPIMEDIUM SAGITTATUM;EUCOMMIA ULMOIDES;GLOYDIUS HALYS;LEONURUS JAPONICUS;LINDERA SPP.;PAEONIA LACTIFLORA;PANAX GINSENG;REHMANNIA GLUTINOSA;SAPOSHNIKOVIA DIVARICATA;SYZYGIUM AROMATICUM	0	(0,0)	1	(0,0)	1	(0,0)
CHONDROITIN SULFATE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
COBICISTAT	0	(0,0)	1	(0,0)	1	(0,0)
COPTIS SPP. RHIZOME;CORNUS OFFICINALIS FRUIT;EUPOLYPHAGA STELEOPHAGA;FOSSILIA OSSIS MASTODI;NARDOSTACHYS JATAMANSI ROOT WITH RHIZOME;OPHIOPOGON JAPONICUS ROOT TUBER;PAEONIA SPP. ROOT;PANAX GINSENG ROOT;SALVIA MILTIORRHIZA ROOT WITH RHIZOME;SCHISANDRA SPHENANTHERA FRUIT;TAXILLUS CHINENSIS HERB;ZIZIPHUS JUJUBA VAR. SPINOSA SEED	2	(0,1)	2	(0,1)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**158**	**(7,3)**	**176**	**(8,2)**	**334**	**(7,8)**
CYSTEINE	1	(0,0)	0	(0,0)	1	(0,0)
DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
EDETIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
GLUCOSE;INSULIN	1	(0,0)	0	(0,0)	1	(0,0)
GLUTATHIONE	8	(0,4)	2	(0,1)	10	(0,2)
GLYCOPYRRONIUM	1	(0,0)	2	(0,1)	3	(0,1)
GLYCOPYRRONIUM BROMIDE	5	(0,2)	5	(0,2)	10	(0,2)
HONEY	1	(0,0)	0	(0,0)	1	(0,0)
HYDROXOCOBALAMIN	2	(0,1)	1	(0,0)	3	(0,1)
HYDROXOCOBALAMIN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
IRON	9	(0,4)	12	(0,6)	21	(0,5)
LACTOBACILLUS RHAMNOSUS	2	(0,1)	6	(0,3)	8	(0,2)
NALOXONE HYDROCHLORIDE	2	(0,1)	4	(0,2)	6	(0,1)
NALOXONE HYDROCHLORIDE;TILIDINE HYDROCHLORIDE	4	(0,2)	4	(0,2)	8	(0,2)
OTHER THERAPEUTIC PRODUCTS	3	(0,1)	5	(0,2)	8	(0,2)
OXYGEN	6	(0,3)	6	(0,3)	12	(0,3)
PANICUM MILIACEUM	1	(0,0)	0	(0,0)	1	(0,0)
PATIROMER	1	(0,0)	0	(0,0)	1	(0,0)
PINELLIA TERNATA	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM IODIDE	0	(0,0)	1	(0,0)	1	(0,0)
POTASSIUM PERMANGANATE	1	(0,0)	1	(0,0)	2	(0,0)
PROTAMINE SULFATE	2	(0,1)	1	(0,0)	3	(0,1)
SEVELAMER	1	(0,0)	0	(0,0)	1	(0,0)
SEVELAMER HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
SIROLIMUS	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM POLYSTYRENE SULFONATE	14	(0,7)	12	(0,6)	26	(0,6)
WATER	3	(0,1)	1	(0,0)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
CONTRAST MEDIA	**17**	**(0,8)**	**11**	**(0,5)**	**28**	**(0,7)**
GADOBUTROL	1	(0,0)	0	(0,0)	1	(0,0)
IODIXANOL	3	(0,1)	3	(0,1)	6	(0,1)
IOHEXOL	4	(0,2)	1	(0,0)	5	(0,1)
IOMEPROL	0	(0,0)	3	(0,1)	3	(0,1)
IOPAMIDOL	5	(0,2)	2	(0,1)	7	(0,2)
IOPROMIDE	0	(0,0)	2	(0,1)	2	(0,0)
IOVERSOL	3	(0,1)	0	(0,0)	3	(0,1)
MEGLUMINE	0	(0,0)	1	(0,0)	1	(0,0)
MEGLUMINE GADOPENTETATE	1	(0,0)	0	(0,0)	1	(0,0)
PERFLUTREN	0	(0,0)	1	(0,0)	1	(0,0)
DIAGNOSTIC AGENTS	**119**	**(5,5)**	**124**	**(5,8)**	**243**	**(5,6)**
CAFFEINE	0	(0,0)	1	(0,0)	1	(0,0)
FLUORESCEIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
FOLIC ACID	56	(2,6)	65	(3,0)	121	(2,8)
GLUCOSE	27	(1,3)	23	(1,1)	50	(1,2)
INULIN	0	(0,0)	1	(0,0)	1	(0,0)
MAGNESIUM SULFATE	38	(1,8)	35	(1,6)	73	(1,7)
MANNITOL	1	(0,0)	0	(0,0)	1	(0,0)
SORBITOL	0	(0,0)	1	(0,0)	1	(0,0)
TOLBUTAMIDE	1	(0,0)	1	(0,0)	2	(0,0)
TUBERCULIN PPD	0	(0,0)	1	(0,0)	1	(0,0)
DIAGNOSTIC RADIOPHARMACEUTICALS	**2**	**(0,1)**	**0**	**(0,0)**	**2**	**(0,0)**
TECHNETIUM TC 99M TETROFOSMIN	2	(0,1)	0	(0,0)	2	(0,0)
GENERAL NUTRIENTS	**46**	**(2,1)**	**53**	**(2,5)**	**99**	**(2,3)**

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
GENERAL NUTRIENTS	**46**	**(2,1)**	**53**	**(2,5)**	**99**	**(2,3)**
(RS)-3 METHYL-2-OXOVALERIANIC ACID CALCIUM;(RS)-3-METHYL-2-OXOBUTYRIC ACID CALCIUM;CALCIUM (RS)-4-METHYL-2-OXOVALERIANAT;CALCIUM 2-OXO-3-PHENYLPROPIONAT;DESMENINOL CALCIUM;HISTIDINE;LYSINE ACETATE;THREONINE;TRYPTOPHAN, L-;TYROSINE	3	(0,1)	8	(0,4)	11	(0,3)
AMINO ACIDS NOS	1	(0,0)	1	(0,0)	2	(0,0)
ARGININE	1	(0,0)	0	(0,0)	1	(0,0)
ARGININE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;BIOTIN;CALCIUM;CARBOHYDRATES NOS;CHLORIDE;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;FATS NOS;FOLIC ACID;IRON;MAGNESIUM;MANGANESE;NICOTINAMIDE;PANTOTHENIC ACID;PHOSPHORUS;POTASSIUM;PROTEINS NOS;PYRIDOXINE;RETINOL;RIBOFLAVIN;SODIUM;THIAMINE;TOCOPHEROL;ZINC	0	(0,0)	1	(0,0)	1	(0,0)
ASPARTATE CALCIUM	1	(0,0)	0	(0,0)	1	(0,0)
CYSTEINE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
GENERAL NUTRIENTS	**46**	**(2,1)**	**53**	**(2,5)**	**99**	**(2,3)**
CYSTEINE HYDROCHLORIDE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE ACETATE;METHIONINE;PHENYLALANINE;THREONINE;TRYPTOPHAN, L-;VALINE	1	(0,0)	0	(0,0)	1	(0,0)
FATTY ACIDS NOS	1	(0,0)	1	(0,0)	2	(0,0)
FRUCTOSE	0	(0,0)	2	(0,1)	2	(0,0)
GELATINE HYDROLYSATE	0	(0,0)	1	(0,0)	1	(0,0)
GLUCOSE	27	(1,3)	23	(1,1)	50	(1,2)
GLYCINE	0	(0,0)	1	(0,0)	1	(0,0)
INULIN	0	(0,0)	1	(0,0)	1	(0,0)
LECITHIN	1	(0,0)	1	(0,0)	2	(0,0)
LINOLEIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
MESO ZEAXANTHIN;XANTOFYL;ZEAXANTHIN	0	(0,0)	1	(0,0)	1	(0,0)
MINERALS NOS;VITAMINS NOS	4	(0,2)	9	(0,4)	13	(0,3)
POTASSIUM ASPARTATE	5	(0,2)	3	(0,1)	8	(0,2)
HOMEOPATHIC PREPARATION	**558**	**(25,9)**	**534**	**(24,8)**	**1.092**	**(25,4)**
ASCORBIC ACID	19	(0,9)	16	(0,7)	35	(0,8)
BORIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM PHOSPHATE	0	(0,0)	1	(0,0)	1	(0,0)
CAPSAICIN	1	(0,0)	2	(0,1)	3	(0,1)
CHARCOAL, ACTIVATED	2	(0,1)	1	(0,0)	3	(0,1)
CORTISONE	1	(0,0)	0	(0,0)	1	(0,0)
CYANOCOBALAMIN	35	(1,6)	35	(1,6)	70	(1,6)
CYSTEINE	1	(0,0)	0	(0,0)	1	(0,0)
EPINEPHRINE	0	(0,0)	2	(0,1)	2	(0,0)
ESTRIOL	2	(0,1)	0	(0,0)	2	(0,0)
GINKGO BILOBA	2	(0,1)	2	(0,1)	4	(0,1)
IRON	9	(0,4)	12	(0,6)	21	(0,5)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
PARAFFIN, LIQUID	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
HOMEOPATHIC PREPARATION	**558**	**(25,9)**	**534**	**(24,8)**	**1.092**	**(25,4)**
POTASSIUM	56	(2,6)	50	(2,3)	106	(2,5)
POTASSIUM CHLORIDE	427	(19,8)	399	(18,5)	826	(19,2)
RIBOFLAVIN	0	(0,0)	2	(0,1)	2	(0,0)
SILYBUM MARIANUM	1	(0,0)	1	(0,0)	2	(0,0)
SODIUM CHLORIDE	44	(2,0)	49	(2,3)	93	(2,2)
SYZYGIUM AROMATICUM	1	(0,0)	0	(0,0)	1	(0,0)
TARAXACUM OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
THYROID	0	(0,0)	1	(0,0)	1	(0,0)
UBIDECARENONE	25	(1,2)	31	(1,4)	56	(1,3)
UREA	8	(0,4)	4	(0,2)	12	(0,3)
VACCINIUM MYRTILLUS EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
ZINC	0	(0,0)	1	(0,0)	1	(0,0)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**121**	**(5,6)**	**115**	**(5,3)**	**236**	**(5,5)**
ABELMOSCHUS MANIHOT FLOWER	1	(0,0)	0	(0,0)	1	(0,0)
ACONITUM CARMICHAELII	1	(0,0)	0	(0,0)	1	(0,0)
ACONITUM CARMICHAELII ROOT;PANAX GINSENG ROOT	6	(0,3)	2	(0,1)	8	(0,2)
ACONITUM CARMICHAELII;PANAX GINSENG	1	(0,0)	0	(0,0)	1	(0,0)
ACONITUM PENDULUM;BENZOIN;OXYTROPIS FALCATA;PHYLLANTHUS EMBLICA;RHEUM SPP.;TERMINALIA BELLIRICA;TERMINALIA CHEBULA;TINOSPORA SINENSIS	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**121**	**(5,6)**	**115**	**(5,3)**	**236**	**(5,5)**
ACONITUM SPP. PROCESSED ROOT;ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;CINNAMOMUM CASSIA BARK;CORNUS OFFICINALIS FRUIT;DIOSCOREA SPP. RHIZOME;PAEONIA X SUFFRUTICOSA ROOT BARK;PORIA COCOS SCLEROTIUM;REHMANNIA GLUTINOSA ROOT	0	(0,0)	1	(0,0)	1	(0,0)
AESCULUS HIPPOCASTANUM EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
AESCULUS HIPPOCASTANUM SEED;SERENOA REPENS;SOLIDAGO VIRGAUREA	0	(0,0)	1	(0,0)	1	(0,0)
AGASTACHE RUGOSA HERB;IMPERATA CYLINDRICA VAR. MAJOR RHIZOME;LEONURUS JAPONICUS HERB;SMILAX GLABRA RHIZOME;STYPHNOLOBIUM JAPONICUM FLOWER	1	(0,0)	0	(0,0)	1	(0,0)
AKEBIA SPP. STEM;ANGELICA ACUTILOBA ROOT;ASARUM SPP. ROOT;CINNAMOMUM CASSIA BARK;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;TETRADIUM RUTICARPUM FRUIT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**121**	**(5,6)**	**115**	**(5,3)**	**236**	**(5,5)**
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;ATRACTYLODES MACROCEPHALA;CINNAMOMUM CASSIA;POLYPORUS UMBELLATUS;PORIA COCOS	1	(0,0)	0	(0,0)	1	(0,0)
ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;ATRACTYLODES LANCEA RHIZOME;CINNAMOMUM CASSIA BARK;POLYPORUS UMBELLATUS SCLEROTIUM;PORIA COCOS SCLEROTIUM	0	(0,0)	1	(0,0)	1	(0,0)
ALLIUM MACROSTEMON	1	(0,0)	0	(0,0)	1	(0,0)
ALLIUM MACROSTEMON BULB;BUXUS SPP.;GINKGO BILOBA LEAF;LITSEA LANCILIMBA;SALVIA MILTIORRHIZA ROOT WITH RHIZOME	1	(0,0)	0	(0,0)	1	(0,0)
ALLIUM SATIVUM	1	(0,0)	3	(0,1)	4	(0,1)
ALOE VERA;ANGELICA SINENSIS ROOT;ATRACTYLODES MACROCEPHALA;CISTANCHE DESERTICOLA;CITRUS AURANTIUM UNRIPE FRUIT;MORUS ALBA FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
AMBER;CODONOPSIS PILOSULA ROOT;NARDOSTACHYS JATAMANSI ROOT WITH RHIZOME;PANAX NOTOGINSENG ROOT;POLYGONATUM SIBIRICUM ROOT	2	(0,1)	0	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**121**	**(5,6)**	**115**	**(5,3)**	**236**	**(5,5)**
ANDROGRAPHIS PANICULATA HERB;ISODON LOPHANTHOIDES HERB;PICRASMA QUASSIOIDES LEAF WITH TWIG	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
ANGELICA SINENSIS ROOT;ASTRAGALUS PROPINQUUS ROOT;EPIMEDIUM BREVICORNU HERB;GELATIN;LESPEDEZA BUERGERI;SOPHORA FLAVESCENS ROOT;ZIZIPHUS JUJUBA FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA SINENSIS ROOT;CISTANCHE DESERTICOLA STEM;SENNA ALEXANDRINA LEAF	1	(0,0)	0	(0,0)	1	(0,0)
ANGELICA SPP.	0	(0,0)	1	(0,0)	1	(0,0)
ANIMAL FECES NOS;BOMBYX MORI	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**121**	**(5,6)**	**115**	**(5,3)**	**236**	**(5,5)**
ARCTIUM LAPPA FRUIT;CICADA SLOUGH;EPHEDRA SPP. HERB;ERIOBOTRYA JAPONICA LEAF;PERILLA FRUTESCENS FRUIT;PERILLA FRUTESCENS LEAF;PEUCEDANUM PRAERUPTORUM ROOT;PHERETIMA SPP.;SCHISANDRA CHINENSIS FRUIT	1	(0,0)	2	(0,1)	3	(0,1)
ARCTIUM LAPPA FRUIT;CITRUS RETICULATA FRUIT PEEL;HIBISCUS MUTABILIS LEAF;MAGNOLIA OFFICINALIS STEM BARK	2	(0,1)	2	(0,1)	4	(0,1)
ARECA CATECHU	1	(0,0)	0	(0,0)	1	(0,0)
ARECA CATECHU SEED;CITRUS AURANTIUM UNRIPE FRUIT;LINDERA AGGREGATA ROOT;SAUSSUREA COSTUS ROOT	1	(0,0)	0	(0,0)	1	(0,0)
ARTEMISIA ARGYI LEAF	2	(0,1)	2	(0,1)	4	(0,1)
ARTEMISIA SPP. HERB;BUPLEURUM CHINENSE, ROOT;ISATIS INDIGOTICA ROOT;SCHISANDRA CHINENSIS FRUIT;SWINE BILE;VIGNA RADIATA	1	(0,0)	0	(0,0)	1	(0,0)
ASINI CORII COLLA	1	(0,0)	0	(0,0)	1	(0,0)
ASTRAGALUS MONGHOLICUS ROOT;ATRACTYLODES MACROCEPHALA, RHIZOMA;SAPOSHNIKOVIA DIVARICATA ROOT	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**121**	**(5,6)**	**115**	**(5,3)**	**236**	**(5,5)**
ASTRAGALUS MONGHOLICUS ROOT;CRATAEGUS PINNATIFIDA FRUIT;LIGUSTICUM CHUANXIONG RHIZOME;OPHIOPOGON JAPONICUS ROOT TUBER;PANAX GINSENG ROOT;SALVIA MILTIORRHIZA ROOT;SCHISANDRA CHINENSIS FRUIT	2	(0,1)	0	(0,0)	2	(0,0)
ASTRAGALUS MONGHOLICUS ROOT;DALBERGIA ODORIFERA OIL;PANAX NOTOGINSENG ROOT;SALVIA MILTIORRHIZA ROOT	3	(0,1)	4	(0,2)	7	(0,2)
ASTRAGALUS MONGHOLICUS ROOT;PANAX NOTOGINSENG ROOT;SALVIA MILTIORRHIZA ROOT;SCROPHULARIA NINGPOENSIS ROOT	1	(0,0)	0	(0,0)	1	(0,0)
ASTRAGALUS PROPINQUUS	1	(0,0)	1	(0,0)	2	(0,0)
ATRACTYLODES LANCEA RHIZOME;CITRUS RETICULATA PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	2	(0,1)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**121**	**(5,6)**	**115**	**(5,3)**	**236**	**(5,5)**
BAICALIN;BUFFALO HORN;CHOLIC ACID;CONCHA MARGARITIFERA;GARDENIA JASMINOIDES FRUIT;HYODEOXYCHOLIC ACID;ISATIS INDIGOTICA ROOT;LONICERA JAPONICA FLOWER	1	(0,0)	0	(0,0)	1	(0,0)
BIDENS BITERNATA;CAFFEINE;CHLORPHENAMINE MALEATE;CHRYSANTHEMUM INDICUM FLOWER;ILEX ASPRELLA ROOT;MELICOPE PTELEIFOLIA;MENTHA CANADENSIS OIL;PARACETAMOL	1	(0,0)	0	(0,0)	1	(0,0)
BORNEOL;BOSWELLIA SACRA RESIN;CENTIPEDE;CICADA SLOUGH;DALBERGIA ODORIFERA;EUPOLYPHAGA STELEOPHAGA;LEECH EXTRACT;MESOBUTHUS MARTENSII;PAEONIA SPP. ROOT;PANAX GINSENG ROOT;SANTALUM ALBUM HEARTWOOD;ZIZIPHUS JUJUBA VAR. SPINOSA SEED	0	(0,0)	1	(0,0)	1	(0,0)
BORNEOL;CINNAMOMUM CASSIA BARK;COW BEZOAR;LIQUIDAMBAR ORIENTALIS RESIN;MUSK;PANAX GINSENG EXTRACT;TOAD VENOM	1	(0,0)	3	(0,1)	4	(0,1)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**121**	**(5,6)**	**115**	**(5,3)**	**236**	**(5,5)**
BORNEOL;LIGUSTICUM CHUANXIONG RHIZOME	3	(0,1)	0	(0,0)	3	(0,1)
BORNEOL;PANAX NOTOGINSENG ROOT;SALVIA MILTIORRHIZA ROOT	2	(0,1)	1	(0,0)	3	(0,1)
BOSWELLIA SERRATA;CURCUMA LONGA	1	(0,0)	0	(0,0)	1	(0,0)
CANNABIS SATIVA	1	(0,0)	0	(0,0)	1	(0,0)
CANNABIS SATIVA OIL	0	(0,0)	1	(0,0)	1	(0,0)
CARTHAMUS TINCTORIUS	1	(0,0)	0	(0,0)	1	(0,0)
CARTHAMUS TINCTORIUS FLOWER;SALVIA MILTIORRHIZA ROOT	5	(0,2)	3	(0,1)	8	(0,2)
CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;PUERARIA LOBATA ROOT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
CINNAMOMUM VERUM	1	(0,0)	0	(0,0)	1	(0,0)
CINNAMOMUM VERUM;CITRUS AURANTIUM;MELISSA OFFICINALIS;PASSIFLORA ALATA	1	(0,0)	0	(0,0)	1	(0,0)
CISTANCHE DESERTICOLA STEM;CITRUS AURANTIUM SUBMATURE FRUIT;FALLOPIA MULTIFLORA ROOT TUBER;HONEY	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**121**	**(5,6)**	**115**	**(5,3)**	**236**	**(5,5)**
CITRUS AURANTIUM;CRATAEGUS MONOGYNA FRUIT;CYMBOPOGON CITRATUS;MATRICARIA RECUTITA FLOWER;MENTHA SPICATA LEAF;ROSA CENTIFOLIA;RUBUS FRUTICOSUS LEAF;TILIA SPP. FLOWER	1	(0,0)	0	(0,0)	1	(0,0)
CITRUS RETICULATA PEEL;CRATAEGUS PINNATIFIDA FRUIT;DIOSCOREA POLYSTACHYA RHIZOME;HORDEUM VULGARE SPROUT;PSEUDOSTELLARIA HETEROPHYLLA RHIZOME	1	(0,0)	0	(0,0)	1	(0,0)
COLCHICUM AUTUMNALE BULB;CONVOLVULUS SCAMMONIA RESIN;CROCUS SATIVUS STYLE;OPERCULINA TURPETHUM HERB;SENNA ALEXANDRINA LEAF;TERMINALIA CHEBULA FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
COPTIS SPP. RHIZOME;HEDERA HELIX LEAF	1	(0,0)	0	(0,0)	1	(0,0)
CORDYCEPS SINENSIS	12	(0,6)	6	(0,3)	18	(0,4)
CORNUS OFFICINALIS	1	(0,0)	0	(0,0)	1	(0,0)
CORYDALIS BUNGEANA HERB;ISATIS INDIGOTICA ROOT;SCUTELLARIA BAICALENSIS ROOT;TARAXACUM MONGOLICUM HERB	2	(0,1)	0	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**121**	**(5,6)**	**115**	**(5,3)**	**236**	**(5,5)**
CORYDALIS YANHUSUO TUBER;IPOMOEA NIL SEED	0	(0,0)	1	(0,0)	1	(0,0)
CRATAEGUS SPP. EXTRACT	1	(0,0)	1	(0,0)	2	(0,0)
CURCUMA LONGA	2	(0,1)	0	(0,0)	2	(0,0)
CYNANCHUM STAUNTONII ROOT WITH RHIZOME;ERIOBOTRYA JAPONICA LEAF;MENTHOL;MORUS ALBA ROOT BARK;PAPAVER SOMNIFERUM PEEL;PLATYCODON GRANDIFLORUS ROOT;STEMONA SESSILIFOLIA ROOT TUBER	0	(0,0)	3	(0,1)	3	(0,1)
DIGITALIS PURPUREA	2	(0,1)	0	(0,0)	2	(0,0)
ERIGERON BREVISCAPUS HERB	1	(0,0)	0	(0,0)	1	(0,0)
ERIGERON BREVISCAPUS HERB;OPHIOPOGON JAPONICUS;PANAX GINSENG ROOT;SCHISANDRA CHINENSIS FRUIT	3	(0,1)	1	(0,0)	4	(0,1)
ERIOBOTRYA JAPONICA	0	(0,0)	1	(0,0)	1	(0,0)
EVODIA LEPTA;MURRAYA EXOTICA LEAF WITH TWIG;PAEONIA LACTIFLORA ROOT;PORIA COCOS SCLEROTIUM;REHMANNIA GLUTINOSA ROOT TUBER;SAUSSUREA COSTUS ROOT;SCUTELLARIA BAICALENSIS ROOT;ZANTHOXYLUM NITIDUM ROOT	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**121**	**(5,6)**	**115**	**(5,3)**	**236**	**(5,5)**
FORSYTHIA SUSPENSA FRUIT;OPHIOPOGON JAPONICUS ROOT TUBER;REHMANNIA GLUTINOSA ROOT TUBER;SCROPHULARIA NINGPOENSIS ROOT;SCUTELLARIA BAICALENSIS ROOT	1	(0,0)	0	(0,0)	1	(0,0)
GANODERMA CAPENSE	1	(0,0)	0	(0,0)	1	(0,0)
GANODERMA LUCIDUM	0	(0,0)	1	(0,0)	1	(0,0)
GARDENIA JASMINOIDES FRUIT;ISATIS INDIGOTICA ROOT;PHELLODENDRON CHINENSE BARK;SCUTELLARIA BAICALENSIS ROOT;STERCULIA LYCHNOPHORA SEED	0	(0,0)	2	(0,1)	2	(0,0)
GINKGO BILOBA	2	(0,1)	2	(0,1)	4	(0,1)
GINKGO BILOBA EXTRACT	2	(0,1)	3	(0,1)	5	(0,1)
GINSENG NOS	1	(0,0)	0	(0,0)	1	(0,0)
GLYCYRRHIZA GLABRA	2	(0,1)	0	(0,0)	2	(0,0)
GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT	1	(0,0)	5	(0,2)	6	(0,1)
GLYCYRRHIZA URALENSIS	1	(0,0)	0	(0,0)	1	(0,0)
HERBAL NOS	2	(0,1)	0	(0,0)	2	(0,0)
HOUTTUYNIA CORDATA	0	(0,0)	1	(0,0)	1	(0,0)
HUMULUS LUPULUS EXTRACT;PASSIFLORA INCARNATA EXTRACT;VALERIANA OFFICINALIS EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
ISATIS INDIGOTICA	1	(0,0)	0	(0,0)	1	(0,0)
JUGLANS REGIA	1	(0,0)	0	(0,0)	1	(0,0)
LIGUSTICUM STRIATUM	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**121**	**(5,6)**	**115**	**(5,3)**	**236**	**(5,5)**
LINUM USITATISSIMUM SEED	0	(0,0)	1	(0,0)	1	(0,0)
LONICERA CONFUSA	1	(0,0)	0	(0,0)	1	(0,0)
LONICERA JAPONICA;SCUTELLARIA BAICALENSIS	0	(0,0)	1	(0,0)	1	(0,0)
MATRICARIA RECUTITA;MELALEUCA ALTERNIFOLIA	0	(0,0)	1	(0,0)	1	(0,0)
MONASCUS PURPUREUS	1	(0,0)	0	(0,0)	1	(0,0)
OPHIOPOGON JAPONICUS	1	(0,0)	0	(0,0)	1	(0,0)
OPHIOPOGON JAPONICUS ROOT TUBER;PANAX GINSENG	12	(0,6)	9	(0,4)	21	(0,5)
OPHIOPOGON JAPONICUS ROOT TUBER;PANAX GINSENG ROOT;SCHISANDRA CHINENSIS FRUIT	2	(0,1)	3	(0,1)	5	(0,1)
OPHIOPOGON JAPONICUS;PANAX GINSENG	2	(0,1)	2	(0,1)	4	(0,1)
PANAX GINSENG	1	(0,0)	0	(0,0)	1	(0,0)
PANAX GINSENG ROOT;ZANTHOXYLUM PIPERITUM PERICARP;ZINGIBER OFFICINALE PROCESSED RHIZOME	2	(0,1)	2	(0,1)	4	(0,1)
PANAX GINSENG TOTAL GINSENOSIDE EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
PANAX NOTOGINSENG	2	(0,1)	3	(0,1)	5	(0,1)
PANAX NOTOGINSENG ROOT	1	(0,0)	0	(0,0)	1	(0,0)
PANICUM MILIACEUM	1	(0,0)	0	(0,0)	1	(0,0)
PEARL	1	(0,0)	0	(0,0)	1	(0,0)
PERIPLANETA AMERICANA	0	(0,0)	1	(0,0)	1	(0,0)
PHERETIMA SPP.	1	(0,0)	0	(0,0)	1	(0,0)
PINELLIA TERNATA	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**121**	**(5,6)**	**115**	**(5,3)**	**236**	**(5,5)**
PLANTAGO OVATA	1	(0,0)	3	(0,1)	4	(0,1)
PLANTAGO OVATA HUSK	2	(0,1)	1	(0,0)	3	(0,1)
PLANTAGO OVATA SEED	1	(0,0)	0	(0,0)	1	(0,0)
PLANTAGO OVATA;SENNA SPP.	1	(0,0)	0	(0,0)	1	(0,0)
PLATYCODON GRANDIFLORUS	1	(0,0)	0	(0,0)	1	(0,0)
PLATYCODON GRANDIFLORUS ROOT FLUID EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
PORIA COCOS	1	(0,0)	0	(0,0)	1	(0,0)
PSEUDOSTELLARIA HETEROPHYLLA	1	(0,0)	0	(0,0)	1	(0,0)
REHMANNIA GLUTINOSA	1	(0,0)	0	(0,0)	1	(0,0)
RHEUM PALMATUM	1	(0,0)	1	(0,0)	2	(0,0)
RICINUS COMMUNIS OIL	0	(0,0)	1	(0,0)	1	(0,0)
SALVIA MILTIORRHIZA	1	(0,0)	0	(0,0)	1	(0,0)
SENNA ALEXANDRINA	7	(0,3)	12	(0,6)	19	(0,4)
SENNA ALEXANDRINA EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
SERENOA REPENS	6	(0,3)	1	(0,0)	7	(0,2)
SERENOA REPENS EXTRACT	4	(0,2)	2	(0,1)	6	(0,1)
SERENOA REPENS EXTRACT;URTICA DIOICA EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
SILYBUM MARIANUM	1	(0,0)	1	(0,0)	2	(0,0)
STERCULIA URENS	1	(0,0)	0	(0,0)	1	(0,0)
SYZYGIUM AROMATICUM	1	(0,0)	0	(0,0)	1	(0,0)
TARAXACUM OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
TRICHOSANTHES KIRILOWII	1	(0,0)	1	(0,0)	2	(0,0)
TRICHOSANTHES KIRILOWII EXTRACT	1	(0,0)	1	(0,0)	2	(0,0)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	26	(1,2)	30	(1,4)	56	(1,3)
VACCINIUM MACROCARPON	0	(0,0)	1	(0,0)	1	(0,0)
VACCINIUM MYRTILLUS EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
VALERIANA OFFICINALIS	2	(0,1)	0	(0,0)	2	(0,0)

Participants With Specific Prior Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**121**	**(5,6)**	**115**	**(5,3)**	**236**	**(5,5)**
VITIS VINIFERA EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)

Every participant is counted a single time for each applicable specific prior medication. A participant with multiple prior medications within a medication category is counted a single time for that category. Each specific prior medication is listed under all relevant medication classes based on the medication's generic name, regardless of route of administration or reason for use. A medication that is not mapped to a second level therapeutic subgroup is classified under Other

A medication class or specific medication appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding

a: Database Cutoff Date: 18JUN2019

1.5 Concomitant Medications

Table 1.5-1
Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
Participants in population	2.152		2.151		4.303	
with one or more concomitant medications	2.152	(100,0)	2.151	(100,0)	4.303	(100,0)
with no concomitant medication	0	(0,0)	0	(0,0)	0	(0,0)
ALIMENTARY TRACT AND METABOLISM						
ANABOLIC AGENTS FOR SYSTEMIC USE	**2**	**(0,1)**	**0**	**(0,0)**	**2**	**(0,0)**
COBAMAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
NANDROLONE DECANOATE	1	(0,0)	0	(0,0)	1	(0,0)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	**460**	**(21,4)**	**487**	**(22,6)**	**947**	**(22,0)**
ALBUMIN TANNATE	0	(0,0)	2	(0,1)	2	(0,0)
ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;ATRACTYLODES LANCEA RHIZOME;CINNAMOMUM CASSIA BARK;POLYPORUS UMBELLATUS SCLEROTIUM;PORIA COCOS SCLEROTIUM	0	(0,0)	1	(0,0)	1	(0,0)
ALLIUM SATIVUM;CHARCOAL, ACTIVATED;URTICA SPP. EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
AMINO ACIDS NOS;ENTEROCOCCUS FAECIUM;ESCHERICHIA COLI;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS HELVETICUS;MINERALS NOS	1	(0,0)	0	(0,0)	1	(0,0)
AMPHOTERICIN B	2	(0,1)	1	(0,0)	3	(0,1)
ANTIBIOTICS-RESISTANT LACTIC ACID BACTERIAE	0	(0,0)	1	(0,0)	1	(0,0)
ANTIDIARRHEAL MICROORGANISMS	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	**460**	**(21,4)**	**487**	**(22,6)**	**947**	**(22,0)**
ASCORBIC ACID;BIFIDOBACTERIUM LACTIS;FRUCTOOLIGOSACCHARIDES;LACTOBACILLUS PLANTARUM;LACTOBACILLUS RHAMNOSUS;STREPTOCOCCUS THERMOPHILUS	0	(0,0)	2	(0,1)	2	(0,0)
AST 120	3	(0,1)	8	(0,4)	11	(0,3)
ATROPINE SULFATE;DIPHENOXYLATE HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
BACILLUS CLAUSII	0	(0,0)	1	(0,0)	1	(0,0)
BACILLUS COAGULANS;CALCIUM CARBONATE	0	(0,0)	1	(0,0)	1	(0,0)
BACILLUS LICHENFORMIS	2	(0,1)	1	(0,0)	3	(0,1)
BACILLUS MESENTERICUS;CLOSTRIDIUM BUTYRICUM;ENTEROCOCCUS FAECALIS	2	(0,1)	6	(0,3)	8	(0,2)
BACILLUS SUBTILIS;ENTEROCOCCUS FAECALIS	1	(0,0)	0	(0,0)	1	(0,0)
BACILLUS SUBTILIS;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	3	(0,1)	3	(0,1)	6	(0,1)
BACILLUS SUBTILIS;ENTEROCOCCUS FAECIUM	0	(0,0)	5	(0,2)	5	(0,1)
BACITRACIN	2	(0,1)	5	(0,2)	7	(0,2)
BACITRACIN ZINC;NEOMYCIN SULFATE	0	(0,0)	2	(0,1)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	**460**	**(21,4)**	**487**	**(22,6)**	**947**	**(22,0)**
BECLOMETASONE DIPROPIONATE	42	(2,0)	26	(1,2)	68	(1,6)
BERBERINE	0	(0,0)	1	(0,0)	1	(0,0)
BERBERINE HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
BETAMETHASONE	6	(0,3)	9	(0,4)	15	(0,3)
BETAMETHASONE ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE BUTYRATE PROPIONATE	9	(0,4)	7	(0,3)	16	(0,4)
BETAMETHASONE DIPROPIONATE	4	(0,2)	2	(0,1)	6	(0,1)
BETAMETHASONE SODIUM PHOSPHATE	5	(0,2)	6	(0,3)	11	(0,3)
BETAMETHASONE VALERATE	11	(0,5)	9	(0,4)	20	(0,5)
BIFIDOBACTERIUM ANIMALIS;LACTOBACILLUS ACIDOPHILUS	1	(0,0)	0	(0,0)	1	(0,0)
BIFIDOBACTERIUM ANIMALIS;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS	1	(0,0)	0	(0,0)	1	(0,0)
BIFIDOBACTERIUM BIFIDUM	1	(0,0)	4	(0,2)	5	(0,1)
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM INFANTIS;BIFIDOBACTERIUM LACTIS;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS PLANTARUM	0	(0,0)	1	(0,0)	1	(0,0)
BIFIDOBACTERIUM BIFIDUM;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	2	(0,1)	2	(0,1)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
ALIMENTARY TRACT AND METABOLISM						
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	**460**	**(21,4)**	**487**	**(22,6)**	**947**	**(22,0)**
BIFIDOBACTERIUM BIFIDUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS	0	(0,0)	1	(0,0)	1	(0,0)
BIFIDOBACTERIUM BIFIDUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS;STREPTOCOCCUS THERMOPHILUS	1	(0,0)	0	(0,0)	1	(0,0)
BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM INFANTIS;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS;LACTOBACILLUS PARACASEI;LACTOBACILLUS PLANTARUM;STREPTOCOCCUS THERMOPHILUS	2	(0,1)	1	(0,0)	3	(0,1)
BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM LONGUM;FRUCTOOLIGOSACCHARIDES;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS;LACTOBACILLUS CASEI;LACTOBACILLUS RHAMNOSUS;STREPTOCOCCUS THERMOPHILUS	1	(0,0)	1	(0,0)	2	(0,0)
BIFIDOBACTERIUM INFANTIS	0	(0,0)	1	(0,0)	1	(0,0)
BIFIDOBACTERIUM LACTIS	2	(0,1)	5	(0,2)	7	(0,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	**460**	**(21,4)**	**487**	**(22,6)**	**947**	**(22,0)**
BIFIDOBACTERIUM LACTIS;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS	1	(0,0)	0	(0,0)	1	(0,0)
BIFIDOBACTERIUM LACTIS;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS PARACASEI	0	(0,0)	1	(0,0)	1	(0,0)
BIFIDOBACTERIUM LONGUM	1	(0,0)	0	(0,0)	1	(0,0)
BIFIDOBACTERIUM LONGUM;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	1	(0,0)	0	(0,0)	1	(0,0)
BIFIDOBACTERIUM LONGUM;LACTOBACILLUS BULGARICUS;STREPTOCOCCUS THERMOPHILUS	0	(0,0)	2	(0,1)	2	(0,0)
BIFIDOBACTERIUM NOS	2	(0,1)	0	(0,0)	2	(0,0)
BIFIDOBACTERIUM NOS;CLOSTRIDIUM BUTYRICUM	1	(0,0)	0	(0,0)	1	(0,0)
BISMUTH	0	(0,0)	1	(0,0)	1	(0,0)
BISMUTH SUBSALICYLATE	1	(0,0)	2	(0,1)	3	(0,1)
BUDESONIDE	71	(3,3)	80	(3,7)	151	(3,5)
CALCIUM CHLORIDE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	0	(0,0)	1	(0,0)	1	(0,0)
CHARCOAL, ACTIVATED	6	(0,3)	4	(0,2)	10	(0,2)
CHLOROXINE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	**460**	**(21,4)**	**487**	**(22,6)**	**947**	**(22,0)**
CITRUS RETICULATA PEEL;CREOSOTE;GLYCYRRHIZA SPP. ROOT;PHELLODENDRON SPP. BARK;UNCARIA GAMBIR LEAF WITH TWIG	3	(0,1)	0	(0,0)	3	(0,1)
COLESTYRAMINE	4	(0,2)	2	(0,1)	6	(0,1)
COLISTIMETHATE SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
COLISTIN	2	(0,1)	1	(0,0)	3	(0,1)
CROMOGLICATE SODIUM	3	(0,1)	0	(0,0)	3	(0,1)
DIOSMECTITE	17	(0,8)	27	(1,3)	44	(1,0)
ELECTROLYTES NOS;GLUCOSE	4	(0,2)	5	(0,2)	9	(0,2)
ENTEROCOCCUS FAECALIS	2	(0,1)	6	(0,3)	8	(0,2)
ENTEROCOCCUS FAECALIS;ESCHERICHIA COLI;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS HELVETICUS	2	(0,1)	0	(0,0)	2	(0,0)
ENTEROCOCCUS FAECIUM	0	(0,0)	3	(0,1)	3	(0,1)
ETHACRIDINE LACTATE	0	(0,0)	2	(0,1)	2	(0,0)
FALLOPIA MULTIFLORA	1	(0,0)	0	(0,0)	1	(0,0)
FIDAXOMICIN	1	(0,0)	0	(0,0)	1	(0,0)
GELATIN TANNATE	0	(0,0)	1	(0,0)	1	(0,0)
GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	0	(0,0)	3	(0,1)	3	(0,1)
GLUCOSE;POTASSIUM;SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
GLUCOSE;SODIUM CHLORIDE	13	(0,6)	13	(0,6)	26	(0,6)
HOUTTUYNIA CORDATA	0	(0,0)	1	(0,0)	1	(0,0)
HYDROCORTISONE	38	(1,8)	37	(1,7)	75	(1,7)
HYDROCORTISONE ACETATE	15	(0,7)	9	(0,4)	24	(0,6)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	**460**	**(21,4)**	**487**	**(22,6)**	**947**	**(22,0)**
HYDROCORTISONE BUTYRATE	5	(0,2)	8	(0,4)	13	(0,3)
HYDROCORTISONE HYDROGEN SUCCINATE	1	(0,0)	3	(0,1)	4	(0,1)
HYDROCORTISONE PROBUTAT	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE SODIUM PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
HYDROCORTISONE SODIUM SUCCINATE	5	(0,2)	13	(0,6)	18	(0,4)
INULIN;LACTOBACILLUS RHAMNOSUS	1	(0,0)	0	(0,0)	1	(0,0)
KAOLIN	1	(0,0)	0	(0,0)	1	(0,0)
KAOLIN;NEOMYCIN SULFATE;PECTIN	1	(0,0)	0	(0,0)	1	(0,0)
LACTOBACILLUS ACIDOPHILUS	9	(0,4)	14	(0,7)	23	(0,5)
LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS	1	(0,0)	3	(0,1)	4	(0,1)
LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS CASEI;LACTOBACILLUS RHAMNOSUS	2	(0,1)	1	(0,0)	3	(0,1)
LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS RHAMNOSUS	1	(0,0)	7	(0,3)	8	(0,2)
LACTOBACILLUS NOS	1	(0,0)	0	(0,0)	1	(0,0)
LACTOBACILLUS NOS;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	0	(0,0)	1	(0,0)	1	(0,0)
LACTOBACILLUS REUTERI	1	(0,0)	0	(0,0)	1	(0,0)
LACTOBACILLUS RHAMNOSUS	6	(0,3)	5	(0,2)	11	(0,3)
LEVOMENTHOL	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	**460**	**(21,4)**	**487**	**(22,6)**	**947**	**(22,0)**
LOPERAMIDE	14	(0,7)	18	(0,8)	32	(0,7)
LOPERAMIDE HYDROCHLORIDE	15	(0,7)	14	(0,7)	29	(0,7)
MACROGOL 4000;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
MACROGOL 4000;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE ANHYDROUS	1	(0,0)	0	(0,0)	1	(0,0)
MENTHOL	1	(0,0)	1	(0,0)	2	(0,0)
MESALAZINE	4	(0,2)	9	(0,4)	13	(0,3)
MICONAZOLE	6	(0,3)	4	(0,2)	10	(0,2)
MICONAZOLE NITRATE	6	(0,3)	3	(0,1)	9	(0,2)
NEOMYCIN	4	(0,2)	2	(0,1)	6	(0,1)
NIFUROXAZIDE	2	(0,1)	1	(0,0)	3	(0,1)
NYSTATIN	17	(0,8)	15	(0,7)	32	(0,7)
PAROMOMYCIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
PECTIN	1	(0,0)	0	(0,0)	1	(0,0)
PLANTAGO OVATA	1	(0,0)	7	(0,3)	8	(0,2)
POLYMETHYLSILOXANE POLYHYDRATE	1	(0,0)	1	(0,0)	2	(0,0)
POLYMYXIN B SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
POVIDONE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE	84	(3,9)	73	(3,4)	157	(3,6)
PREDNISOLONE HEMISUCCINATE	0	(0,0)	2	(0,1)	2	(0,0)
PREDNISONE	96	(4,5)	97	(4,5)	193	(4,5)
PREDNISONE ACETATE	0	(0,0)	3	(0,1)	3	(0,1)
PROBIOTICS NOS	8	(0,4)	10	(0,5)	18	(0,4)
PROBIOTICS NOS;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)
PRUNUS SEROTINA BARK	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	**460**	**(21,4)**	**487**	**(22,6)**	**947**	**(22,0)**
RACECADOTRIL	1	(0,0)	1	(0,0)	2	(0,0)
RIFAXIMIN	5	(0,2)	7	(0,3)	12	(0,3)
SACCHAROMYCES BOULARDII	15	(0,7)	20	(0,9)	35	(0,8)
SILICON DIOXIDE	1	(0,0)	1	(0,0)	2	(0,0)
SILICON DIOXIDE, COLLOIDAL	1	(0,0)	0	(0,0)	1	(0,0)
SULFASALAZINE	2	(0,1)	7	(0,3)	9	(0,2)
TANNIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
VACCINIUM MYRTILLUS EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
VANCOMYCIN	58	(2,7)	60	(2,8)	118	(2,7)
VANCOMYCIN HYDROCHLORIDE	14	(0,7)	18	(0,8)	32	(0,7)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
ANTIEMETICS AND ANTINAUSEANTS	**217**	**(10,1)**	**219**	**(10,2)**	**436**	**(10,1)**
ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;ATRACTYLODES LANCEA RHIZOME;CINNAMOMUM CASSIA BARK;POLYPORUS UMBELLATUS SCLEROTIUM;PORIA COCOS SCLEROTIUM	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA DAHURICA ROOT;ARECA CATECHU PEEL;ATRACTYLODES SPP. RHIZOME;CITRUS RETICULATA FRUIT PEEL;GLYCYRRHIZA URALENSIS;MAGNOLIA OFFICINALIS BARK;PERILLA FRUTESCENS;PINELLIA TERNATA RHIZOME;POGOSTEMON CABLIN HERB OIL;PORIA COCOS	1	(0,0)	1	(0,0)	2	(0,0)
APREPITANT	2	(0,1)	0	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIEMETICS AND ANTINAUSEANTS	**217**	**(10,1)**	**219**	**(10,2)**	**436**	**(10,1)**
ATRACTYLODES LANCEA RHIZOME;CITRUS RETICULATA PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	1	(0,0)	3	(0,1)	4	(0,1)
BROMISOVAL;PHENOL;PROCAINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CITRUS RETICULATA;GLYCYRRHIZA SPP.;PINELLIA TERNATA;PORIA COCOS;ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
CROCUS SATIVUS	0	(0,0)	1	(0,0)	1	(0,0)
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE DISULFIDE	7	(0,3)	7	(0,3)	14	(0,3)
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	14	(0,7)	15	(0,7)	29	(0,7)
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE MONONITRATE	0	(0,0)	2	(0,1)	2	(0,0)
CYANOCOBALAMIN;PYRIDOXINE ;THIAMINE	5	(0,2)	8	(0,4)	13	(0,3)
CYCLIZINE	3	(0,1)	3	(0,1)	6	(0,1)
DIFENIDOL	5	(0,2)	4	(0,2)	9	(0,2)
DIFENIDOL HYDROCHLORIDE	3	(0,1)	2	(0,1)	5	(0,1)
DIMENHYDRINATE	7	(0,3)	7	(0,3)	14	(0,3)
DIPHENHYDRAMINE	20	(0,9)	18	(0,8)	38	(0,9)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIEMETICS AND ANTINAUSEANTS	**217**	**(10,1)**	**219**	**(10,2)**	**436**	**(10,1)**
DIPHENHYDRAMINE HYDROCHLORIDE	16	(0,7)	21	(1,0)	37	(0,9)
DOXYLAMINE SUCCINATE;FOLIC ACID;PYRIDOXINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
DROPERIDOL	0	(0,0)	2	(0,1)	2	(0,0)
ERIOBOTRYA JAPONICA	0	(0,0)	2	(0,1)	2	(0,0)
GRANISETRON	2	(0,1)	2	(0,1)	4	(0,1)
GRANISETRON HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
HYDROXYZINE	21	(1,0)	21	(1,0)	42	(1,0)
HYDROXYZINE HYDROCHLORIDE	21	(1,0)	24	(1,1)	45	(1,0)
HYOSCINE	2	(0,1)	7	(0,3)	9	(0,2)
HYOSCINE BUTYLBROMIDE;METAMIZOLE SODIUM	1	(0,0)	2	(0,1)	3	(0,1)
HYOSCINE HYDROBROMIDE	0	(0,0)	2	(0,1)	2	(0,0)
MECLOZINE	3	(0,1)	6	(0,3)	9	(0,2)
MECLOZINE HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
ONDANSETRON	58	(2,7)	66	(3,1)	124	(2,9)
ONDANSETRON HYDROCHLORIDE	8	(0,4)	2	(0,1)	10	(0,2)
PALONOSETRON HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
PROCHLORPERAZINE	11	(0,5)	2	(0,1)	13	(0,3)
PROCHLORPERAZINE EDISYLATE	1	(0,0)	0	(0,0)	1	(0,0)
PROCHLORPERAZINE MALEATE	3	(0,1)	10	(0,5)	13	(0,3)
PROCHLORPERAZINE MESILATE	1	(0,0)	3	(0,1)	4	(0,1)
PROMETHAZINE	16	(0,7)	14	(0,7)	30	(0,7)
PROMETHAZINE HYDROCHLORIDE	20	(0,9)	7	(0,3)	27	(0,6)
RAMOSETRON	1	(0,0)	0	(0,0)	1	(0,0)
RAMOSETRON HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
TRIMETHOBENZAMIDE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
TROPISETRON HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS	**28**	**(1,3)**	**26**	**(1,2)**	**54**	**(1,3)**
ACETYLCARNITINE	1	(0,0)	0	(0,0)	1	(0,0)
ACETYLCARNITINE HYDROCHLORIDE	3	(0,1)	0	(0,0)	3	(0,1)
AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
BENZOCAINE	3	(0,1)	0	(0,0)	3	(0,1)
COLLAGEN	2	(0,1)	2	(0,1)	4	(0,1)
LIRAGLUTIDE	18	(0,8)	17	(0,8)	35	(0,8)
PLANTAGO OVATA	1	(0,0)	7	(0,3)	8	(0,2)
APPETITE STIMULANTS	**13**	**(0,6)**	**17**	**(0,8)**	**30**	**(0,7)**
ATRACTYLODES LANCEA RHIZOME;CITRUS RETICULATA PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	1	(0,0)	3	(0,1)	4	(0,1)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
CARNITINE HYDROCHLORIDE;CYANOCOBALAMIN;CYPROHEPTADINE OROTATE;LYSINE HYDROCHLORIDE	4	(0,2)	4	(0,2)	8	(0,2)
CITRUS RETICULATA;GLYCYRRHIZA SPP.;PINELLIA TERNATA;PORIA COCOS;ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
APPETITE STIMULANTS	**13**	**(0,6)**	**17**	**(0,8)**	**30**	**(0,7)**
CYPROHEPTADINE HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
MEGESTROL ACETATE	5	(0,2)	7	(0,3)	12	(0,3)
TRIGONELLA FOENUM-GRAECUM	0	(0,0)	1	(0,0)	1	(0,0)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
BILE AND LIVER THERAPY	**151**	**(7,0)**	**152**	**(7,1)**	**303**	**(7,0)**
ADENINE HYDROCHLORIDE;BIFENDATE;CARNITINE OROTATE;CYANOCOBALAMIN;LIVER EXTRACT;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN	0	(0,0)	1	(0,0)	1	(0,0)
ALLIUM SATIVUM OIL;BIFENDATE	0	(0,0)	2	(0,1)	2	(0,0)
ARTEMISIA SPP. HERB;BUPLEURUM CHINENSE, ROOT;ISATIS INDIGOTICA ROOT;SCHISANDRA CHINENSIS FRUIT;SWINE BILE;VIGNA RADIATA	1	(0,0)	0	(0,0)	1	(0,0)
AZINTAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
BEAR BILE	0	(0,0)	1	(0,0)	1	(0,0)
BICYCLOL	0	(0,0)	1	(0,0)	1	(0,0)
CHOLINE;VITAMIN B NOS	0	(0,0)	1	(0,0)	1	(0,0)
CURCUMA LONGA	3	(0,1)	1	(0,0)	4	(0,1)
CURCUMA LONGA;CYNARA CARDUNCULUS;SILYBUM MARIANUM	0	(0,0)	1	(0,0)	1	(0,0)
CYANOCOBALAMIN;NICOTINAMIDE;PHOSPHOLIPIDS;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE	2	(0,1)	1	(0,0)	3	(0,1)
CYNARA CARDUNCULUS	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
BILE AND LIVER THERAPY	**151**	**(7,0)**	**152**	**(7,1)**	**303**	**(7,0)**
CYSTEINE;GLYCINE;GLYCYRRHIZIC ACID	2	(0,1)	0	(0,0)	2	(0,0)
DIAMMONIUM GLYCYRRHIZINATE	1	(0,0)	0	(0,0)	1	(0,0)
DIISOPROPYLAMINE DICHLOROACETATE	1	(0,0)	0	(0,0)	1	(0,0)
DIMECROTIC ACID MAGNESIUM SALT	0	(0,0)	1	(0,0)	1	(0,0)
DIMETHYL 4,4'-BIPHENYLDICARBOXYLATE;URSODEOXYCHOLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
ENZYMES NOS;URSODEOXYCHOLIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
EUCOMMIA ULMOIDES	1	(0,0)	0	(0,0)	1	(0,0)
GASTRODIA ELATA	0	(0,0)	2	(0,1)	2	(0,0)
GLYCYRRHIZA GLABRA	1	(0,0)	2	(0,1)	3	(0,1)
GLYCYRRHIZIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
HYMECROMONE	0	(0,0)	1	(0,0)	1	(0,0)
INOSINE	0	(0,0)	1	(0,0)	1	(0,0)
LACTULOSE	105	(4,9)	101	(4,7)	206	(4,8)
LECITHIN	1	(0,0)	1	(0,0)	2	(0,0)
LEVOGLUTAMIDE	2	(0,1)	0	(0,0)	2	(0,0)
LIVER HYDROLYSATE	0	(0,0)	1	(0,0)	1	(0,0)
LIVER THERAPY	0	(0,0)	4	(0,2)	4	(0,1)
MAGNESIUM ISOGLYCYRRHIZINATE	0	(0,0)	1	(0,0)	1	(0,0)
ORNITHINE	1	(0,0)	0	(0,0)	1	(0,0)
ORNITHINE ASPARTATE	2	(0,1)	6	(0,3)	8	(0,2)
PHOSPHATIDYL CHOLINE	0	(0,0)	1	(0,0)	1	(0,0)
PHOSPHOLIPIDS	2	(0,1)	2	(0,1)	4	(0,1)
POLYENE PHOSPHATIDYLCHOLINE	8	(0,4)	12	(0,6)	20	(0,5)
RIFAXIMIN	5	(0,2)	7	(0,3)	12	(0,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
BILE AND LIVER THERAPY	**151**	**(7,0)**	**152**	**(7,1)**	**303**	**(7,0)**
SILIBININ MEGLUMINE	1	(0,0)	1	(0,0)	2	(0,0)
SILYBUM MARIANUM	0	(0,0)	5	(0,2)	5	(0,1)
THIOTRIAZOLINE	2	(0,1)	3	(0,1)	5	(0,1)
TIMONACIC	1	(0,0)	2	(0,1)	3	(0,1)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
URSODEOXYCHOLIC ACID	18	(0,8)	11	(0,5)	29	(0,7)
DIGESTIVES, INCL. ENZYMES	**32**	**(1,5)**	**29**	**(1,3)**	**61**	**(1,4)**
AMYLASE;CELLULASE;GLUCOAMYLASE;LIPASE;PROTEASE;PROZYME	1	(0,0)	0	(0,0)	1	(0,0)
AMYLASE;LIPASE;PROTEASE;SIMETICONE	1	(0,0)	3	(0,1)	4	(0,1)
AMYLASE;PANCREATIN;PEPSIN	1	(0,0)	1	(0,0)	2	(0,0)
ANGELICA DAHURICA ROOT;ARECA CATECHU PEEL;ATRACTYLODES SPP. RHIZOME;CITRUS RETICULATA FRUIT PEEL;GLYCYRRHIZA URALENSIS;MAGNOLIA OFFICINALIS BARK;PERILLA FRUTESCENS;PINELLIA TERNATA RHIZOME;POGOSTEMON CABLIN HERB OIL;PORIA COCOS	1	(0,0)	1	(0,0)	2	(0,0)
ASPERGILLUS ORYZAE ENZYME;PANCREATIN	1	(0,0)	3	(0,1)	4	(0,1)
ATRACTYLODES MACROCEPHALA	1	(0,0)	0	(0,0)	1	(0,0)
AZINTAMIDE;CELLULASE;PANCREATIN;SIMETICONE	2	(0,1)	0	(0,0)	2	(0,0)
BETAINE HYDROCHLORIDE;BROMELAINS;OX BILE;PANCREATIN;PAPAIN;PEPSIN	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DIGESTIVES, INCL. ENZYMES	**32**	**(1,5)**	**29**	**(1,3)**	**61**	**(1,4)**
BIODIASTASE 1000;CELLULASE;LIPASE;PANCREATIN;PANPROSIN;SIMETICONE;URSODEOXYCHOLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
BIODIASTASE;CELLULASE;LIPASE;PROMELASE	0	(0,0)	1	(0,0)	1	(0,0)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
BROMELAINS;DIMETICONE;PANCREATIN	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CARBONATE;CINNAMOMUM VERUM POWDER;COPTIS TRIFOLIA;DIASTASE, TAKA;FOENICULUM VULGARE;GLYCYRRHIZA GLABRA;MENTHOL;SIMALDRATE;SODIUM BICARBONATE;SYZYGIUM AROMATICUM FLOWER;ZANTHOXYLUM AMERICANUM BARK;ZINGIBER OFFICINALE RHIZOME	1	(0,0)	0	(0,0)	1	(0,0)
CELLULASE;ENZYMES NOS;PANCREATIC DIGESTIVE ENZYME TA;PROCTASE;SANACTASE	0	(0,0)	1	(0,0)	1	(0,0)
CITRIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
CROCUS SATIVUS	0	(0,0)	1	(0,0)	1	(0,0)
DIASTASE;LIPASE;PANCREATIN	0	(0,0)	1	(0,0)	1	(0,0)
ENZYMES NOS	5	(0,2)	3	(0,1)	8	(0,2)
ENZYMES NOS;URSODEOXYCHOLIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
MONASCUS PURPUREUS	1	(0,0)	0	(0,0)	1	(0,0)
PANCREATIN	11	(0,5)	8	(0,4)	19	(0,4)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DIGESTIVES, INCL. ENZYMES	**32**	**(1,5)**	**29**	**(1,3)**	**61**	**(1,4)**
PANCREATIN;SIMETICONE;URSO DEOXYCHOLIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
PANCRELIPASE	1	(0,0)	1	(0,0)	2	(0,0)
PAPAIN	1	(0,0)	0	(0,0)	1	(0,0)
SILYBUM MARIANUM	0	(0,0)	5	(0,2)	5	(0,1)
ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
DRUGS FOR ACID RELATED DISORDERS	**1.297**	**(60,3)**	**1.268**	**(58,9)**	**2.565**	**(59,6)**
ALDIOXA	1	(0,0)	1	(0,0)	2	(0,0)
ALDIOXA;METAMAGNESIUM ALUMINOSILICATE	3	(0,1)	3	(0,1)	6	(0,1)
ALGELDRATE;ALGINIC ACID;CALCIUM CARBONATE;MAGNESIUM TRISILICATE;SODIUM BICARBONATE	0	(0,0)	1	(0,0)	1	(0,0)
ALGINIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
ALGINIC ACID;ALUMINIUM HYDROXIDE GEL, DRIED;MAGNESIUM CARBONATE	1	(0,0)	2	(0,1)	3	(0,1)
ALMAGATE	1	(0,0)	2	(0,1)	3	(0,1)
ALUMINIUM GLYCINATE;MAGNESIUM OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
ALUMINIUM HYDROXIDE	4	(0,2)	4	(0,2)	8	(0,2)
ALUMINIUM HYDROXIDE GEL, DRIED;AMYLASE;CALCIUM CARBONATE;HERBAL EXTRACT NOS;MAGNESIUM CARBONATE;SODIUM BICARBONATE	1	(0,0)	0	(0,0)	1	(0,0)
ALUMINIUM HYDROXIDE GEL, DRIED;MAGNESIUM HYDROXIDE;SIMETICONE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR ACID RELATED DISORDERS	**1.297**	**(60,3)**	**1.268**	**(58,9)**	**2.565**	**(59,6)**
ALUMINIUM HYDROXIDE;ALUMINIUM MAGNESIUM SILICATE;MAGNESIUM HYDROXIDE;MAGNESIUM OXIDE;RANITIDINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
ALUMINIUM HYDROXIDE;CALCIUM CARBONATE;MAGNESIUM CARBONATE;OXETACAINE	6	(0,3)	6	(0,3)	12	(0,3)
ALUMINIUM HYDROXIDE;CHONDROITIN SULFATE;HYALURONIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
ALUMINIUM HYDROXIDE;DICYCLOVERINE HYDROCHLORIDE;MAGNESIUM OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
ALUMINIUM HYDROXIDE;HOMATROPINE METHYLBROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
ALUMINIUM HYDROXIDE;MAGNESIUM CARBONATE	1	(0,0)	0	(0,0)	1	(0,0)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE	6	(0,3)	5	(0,2)	11	(0,3)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;OXETACAINE	2	(0,1)	3	(0,1)	5	(0,1)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE	7	(0,3)	11	(0,5)	18	(0,4)
ALUMINIUM PHOSPHATE	0	(0,0)	2	(0,1)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR ACID RELATED DISORDERS	**1.297**	**(60,3)**	**1.268**	**(58,9)**	**2.565**	**(59,6)**
ALUMINIUM SILICATE	0	(0,0)	1	(0,0)	1	(0,0)
ALUMINIUM SILICATE;OXETACAINE	0	(0,0)	1	(0,0)	1	(0,0)
ALUMINUM MAGNESIUM HYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
ALUMINUM MAGNESIUM HYDRATE;GLYCYRRHIZIC ACID;OXETACAINE	0	(0,0)	1	(0,0)	1	(0,0)
ANTACIDS WITH SODIUM BICARBONATE	2	(0,1)	2	(0,1)	4	(0,1)
ARTEMISIA ARGYI LEAF	4	(0,2)	4	(0,2)	8	(0,2)
BIODIASTASE;CALCIUM CARBONATE;LIPASE;MAGNESIUM CARBONATE;PERILLA SPP. HERB;SCOPOLIA SPP.;SODIUM BICARBONATE;SWERTIA SPP. HERB;VITAMIN U	1	(0,0)	0	(0,0)	1	(0,0)
BISMUTH	0	(0,0)	1	(0,0)	1	(0,0)
BISMUTH PECTIN	0	(0,0)	1	(0,0)	1	(0,0)
BISMUTH SUBCITRATE POTASSIUM	0	(0,0)	2	(0,1)	2	(0,0)
BISMUTH SUBCITRATE POTASSIUM;METRONIDAZOLE;TETRACYCLINE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
BISMUTH SUBSALICYLATE	1	(0,0)	2	(0,1)	3	(0,1)
CALCIUM CARBONATE	35	(1,6)	42	(2,0)	77	(1,8)
CALCIUM CARBONATE;CALCIUM LACTATE GLUCONATE	3	(0,1)	0	(0,0)	3	(0,1)
CALCIUM CARBONATE;MAGNESIUM CARBONATE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CARBONATE;MAGNESIUM HYDROXIDE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR ACID RELATED DISORDERS	**1.297**	**(60,3)**	**1.268**	**(58,9)**	**2.565**	**(59,6)**
CALCIUM CARBONATE;SODIUM ALGINATE;SODIUM BICARBONATE	7	(0,3)	1	(0,0)	8	(0,2)
CALCIUM;MAGNESIUM	2	(0,1)	1	(0,0)	3	(0,1)
CETRAXATE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CIMETIDINE	2	(0,1)	3	(0,1)	5	(0,1)
CITRIC ACID;SODIUM BICARBONATE;SODIUM CITRATE;TARTARIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
CITRIC ACID;SODIUM CITRATE ACID	1	(0,0)	0	(0,0)	1	(0,0)
DEXLANSOPRAZOLE	10	(0,5)	10	(0,5)	20	(0,5)
ECABET MONOSODIUM	1	(0,0)	2	(0,1)	3	(0,1)
ESOMEPRAZOLE	66	(3,1)	97	(4,5)	163	(3,8)
ESOMEPRAZOLE MAGNESIUM	57	(2,6)	60	(2,8)	117	(2,7)
ESOMEPRAZOLE SODIUM	11	(0,5)	4	(0,2)	15	(0,3)
ESOMEPRAZOLE STRONTIUM	3	(0,1)	1	(0,0)	4	(0,1)
FAMOTIDINE	88	(4,1)	64	(3,0)	152	(3,5)
GLYCYRRHIZA GLABRA	1	(0,0)	2	(0,1)	3	(0,1)
HYDROTALCITE	6	(0,3)	7	(0,3)	13	(0,3)
ILAPRAZOLE	3	(0,1)	1	(0,0)	4	(0,1)
IRSOGLADINE MALEATE	0	(0,0)	1	(0,0)	1	(0,0)
LAFUTIDINE	4	(0,2)	3	(0,1)	7	(0,2)
LANSOPRAZOLE	174	(8,1)	157	(7,3)	331	(7,7)
LEVOGLUTAMIDE;SODIUM GUALENATE	2	(0,1)	0	(0,0)	2	(0,0)
LEVOGLUTAMIDE;SODIUM GUALENATE HYDRATE	0	(0,0)	1	(0,0)	1	(0,0)
MAGALDRATE	0	(0,0)	2	(0,1)	2	(0,0)
MAGNESIUM CARBONATE	4	(0,2)	6	(0,3)	10	(0,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR ACID RELATED DISORDERS	**1.297**	**(60,3)**	**1.268**	**(58,9)**	**2.565**	**(59,6)**
MAGNESIUM CARBONATE;MAGNESIUM TRISILICATE;SODIUM BICARBONATE	1	(0,0)	0	(0,0)	1	(0,0)
MAGNESIUM COMPOUNDS	1	(0,0)	0	(0,0)	1	(0,0)
MAGNESIUM HYDROXIDE	17	(0,8)	25	(1,2)	42	(1,0)
MAGNESIUM OXIDE	83	(3,9)	73	(3,4)	156	(3,6)
MAGNESIUM TRISILICATE	8	(0,4)	8	(0,4)	16	(0,4)
MISOPROSTOL	1	(0,0)	0	(0,0)	1	(0,0)
NIZATIDINE	3	(0,1)	0	(0,0)	3	(0,1)
OMEPRAZOLE	377	(17,5)	366	(17,0)	743	(17,3)
OMEPRAZOLE MAGNESIUM	0	(0,0)	1	(0,0)	1	(0,0)
OMEPRAZOLE SODIUM	12	(0,6)	7	(0,3)	19	(0,4)
OMEPRAZOLE;SODIUM BICARBONATE	1	(0,0)	0	(0,0)	1	(0,0)
PANTOPRAZOLE	308	(14,3)	306	(14,2)	614	(14,3)
PANTOPRAZOLE MAGNESIUM	1	(0,0)	0	(0,0)	1	(0,0)
PANTOPRAZOLE SODIUM SESQUIHYDRATE	242	(11,2)	231	(10,7)	473	(11,0)
PERIPLANETA AMERICANA	1	(0,0)	1	(0,0)	2	(0,0)
POLAPREZINC	0	(0,0)	2	(0,1)	2	(0,0)
POTASSIUM BICARBONATE;SODIUM ALGINATE	0	(0,0)	1	(0,0)	1	(0,0)
POTASSIUM CITRATE;SODIUM CITRATE DIHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
RABEPRAZOLE SODIUM	60	(2,8)	55	(2,6)	115	(2,7)
RANITIDINE	74	(3,4)	70	(3,3)	144	(3,3)
RANITIDINE HYDROCHLORIDE	37	(1,7)	36	(1,7)	73	(1,7)
RANITIDINE HYDROCHLORIDE;SUCRALFATE;TRIPOTASSIUM DICITRATOBISMUTHATE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR ACID RELATED DISORDERS	**1.297**	**(60,3)**	**1.268**	**(58,9)**	**2.565**	**(59,6)**
REBAMIPIDE	19	(0,9)	29	(1,3)	48	(1,1)
ROXATIDINE ACETATE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM ALGINATE	5	(0,2)	4	(0,2)	9	(0,2)
SODIUM ALGINATE;SODIUM BICARBONATE	2	(0,1)	1	(0,0)	3	(0,1)
SODIUM BICARBONATE	104	(4,8)	109	(5,1)	213	(5,0)
SODIUM CARBONATE ANHYDROUS	0	(0,0)	2	(0,1)	2	(0,0)
SODIUM CITRATE	1	(0,0)	2	(0,1)	3	(0,1)
SODIUM GUALENATE	7	(0,3)	2	(0,1)	9	(0,2)
SUCRALFATE	22	(1,0)	24	(1,1)	46	(1,1)
SULGLICOTIDE	1	(0,0)	0	(0,0)	1	(0,0)
SULPIRIDE	0	(0,0)	2	(0,1)	2	(0,0)
TEPRENONE	5	(0,2)	5	(0,2)	10	(0,2)
TRIPOTASSIUM DICITRATOBISMUTHATE	0	(0,0)	1	(0,0)	1	(0,0)
VONOPRAZAN FUMARATE	17	(0,8)	11	(0,5)	28	(0,7)
DRUGS FOR CONSTIPATION	**556**	**(25,8)**	**526**	**(24,5)**	**1.082**	**(25,1)**
ALOE FEROX;CARUM CARVI;CICHORIUM INTYBUS;CUMINUM CYMINUM;FOENICULUM VULGARE;SENNA ALEXANDRINA;TARAXACUM OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
ALOE VERA;ANGELICA SINENSIS ROOT;ATRACTYLODES MACROCEPHALA;CISTANCHE DESERTICOLA;CITRUS AURANTIUM UNRIPE FRUIT;MORUS ALBA FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
ALVIMOPAN	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR CONSTIPATION	**556**	**(25,8)**	**526**	**(24,5)**	**1.082**	**(25,1)**
ASARUM HETEROTROPOIDES	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM ASCORBATE;SODIUM CHLORIDE;SODIUM SULFATE	3	(0,1)	4	(0,2)	7	(0,2)
BISACODYL	53	(2,5)	57	(2,6)	110	(2,6)
BISACODYL;DOCUSATE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
BISACODYL;SENNOSIDE B	0	(0,0)	1	(0,0)	1	(0,0)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
CANNABIS SATIVA FRUIT;CITRUS SPP. UNRIPE FRUIT;MAGNOLIA SPP. BARK;PAEONIA LACTIFLORA ROOT;PRUNUS SPP. SEED;RHEUM SPP. RHIZOME	0	(0,0)	2	(0,1)	2	(0,0)
CARMELLOSE	1	(0,0)	0	(0,0)	1	(0,0)
CARMELLOSE SODIUM	6	(0,3)	1	(0,0)	7	(0,2)
CASANTHRANOL;DOCUSATE SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
CINNAMOMUM CASSIA BARK;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;RHEUM SPP. RHIZOME;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
CYAMOPSIS TETRAGONOLOBA GUM	0	(0,0)	1	(0,0)	1	(0,0)
DOCUSATE CALCIUM	1	(0,0)	1	(0,0)	2	(0,0)
DOCUSATE SODIUM	40	(1,9)	42	(2,0)	82	(1,9)
DOCUSATE SODIUM;SENNA ALEXANDRINA	8	(0,4)	2	(0,1)	10	(0,2)
DOCUSATE SODIUM;SENNOSIDE A+B	13	(0,6)	5	(0,2)	18	(0,4)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR CONSTIPATION	**556**	**(25,8)**	**526**	**(24,5)**	**1.082**	**(25,1)**
DOCUSATE SODIUM;SORBITOL	0	(0,0)	1	(0,0)	1	(0,0)
ELECTROLYTES NOS;MACROGOL	1	(0,0)	0	(0,0)	1	(0,0)
ELOBIXIBAT	1	(0,0)	0	(0,0)	1	(0,0)
FALLOPIA MULTIFLORA	1	(0,0)	0	(0,0)	1	(0,0)
FIBRE, DIETARY	1	(0,0)	1	(0,0)	2	(0,0)
FRUCTOSE;GLYCEROL	1	(0,0)	0	(0,0)	1	(0,0)
GLYCEROL	21	(1,0)	20	(0,9)	41	(1,0)
GLYCEROL;PARAFFIN, LIQUID	1	(0,0)	0	(0,0)	1	(0,0)
GLYCEROL;POLYSORBATE 80;SODIUM CITRATE;SORBITOL	1	(0,0)	0	(0,0)	1	(0,0)
GLYCEROL;SODIUM CITRATE DIHYDRATE;SORBITOL	1	(0,0)	0	(0,0)	1	(0,0)
GLYCEROL;SODIUM CITRATE;SODIUM LAURYL SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
GLYCEROL;SODIUM CITRATE;SODIUM LAURYL SULFOACETATE	0	(0,0)	1	(0,0)	1	(0,0)
GLYCYRRHIZA SPP. ROOT;RHEUM SPP. RHIZOME	0	(0,0)	1	(0,0)	1	(0,0)
INULIN	0	(0,0)	1	(0,0)	1	(0,0)
LACTITOL	1	(0,0)	1	(0,0)	2	(0,0)
LACTULOSE	105	(4,9)	101	(4,7)	206	(4,8)
LINACLOTIDE	0	(0,0)	5	(0,2)	5	(0,1)
LINUM USITATISSIMUM	1	(0,0)	0	(0,0)	1	(0,0)
LINUM USITATISSIMUM SEED	0	(0,0)	1	(0,0)	1	(0,0)
LUBIPROSTONE	8	(0,4)	6	(0,3)	14	(0,3)
MACROGOL	29	(1,3)	29	(1,3)	58	(1,3)
MACROGOL 3350	16	(0,7)	11	(0,5)	27	(0,6)
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	33	(1,5)	31	(1,4)	64	(1,5)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR CONSTIPATION	**556**	**(25,8)**	**526**	**(24,5)**	**1.082**	**(25,1)**
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE ANHYDROUS	2	(0,1)	1	(0,0)	3	(0,1)
MACROGOL 4000	1	(0,0)	7	(0,3)	8	(0,2)
MACROGOL 4000;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
MACROGOL 4000;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE ANHYDROUS	1	(0,0)	0	(0,0)	1	(0,0)
MACROGOL;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	9	(0,4)	5	(0,2)	14	(0,3)
MACROGOL;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE ANHYDROUS	1	(0,0)	6	(0,3)	7	(0,2)
MAGNESIUM CARBONATE	4	(0,2)	6	(0,3)	10	(0,2)
MAGNESIUM CITRATE	6	(0,3)	8	(0,4)	14	(0,3)
MAGNESIUM HYDROXIDE	17	(0,8)	25	(1,2)	42	(1,0)
MAGNESIUM OXIDE	83	(3,9)	73	(3,4)	156	(3,6)
MAGNESIUM SULFATE	87	(4,0)	92	(4,3)	179	(4,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR CONSTIPATION	**556**	**(25,8)**	**526**	**(24,5)**	**1.082**	**(25,1)**
MAGNESIUM SULFATE;POTASSIUM SULFATE;SODIUM SULFATE	0	(0,0)	2	(0,1)	2	(0,0)
MANNITOL	17	(0,8)	12	(0,6)	29	(0,7)
METHYLNALTREXONE BROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
NALOXEGOL OXALATE	0	(0,0)	2	(0,1)	2	(0,0)
NALOXONE HYDROCHLORIDE	12	(0,6)	10	(0,5)	22	(0,5)
PANAX GINSENG ROOT;ZANTHOXYLUM PIPERITUM PERICARP;ZINGIBER OFFICINALE PROCESSED RHIZOME	4	(0,2)	3	(0,1)	7	(0,2)
PARAFFIN	3	(0,1)	2	(0,1)	5	(0,1)
PARAFFIN, LIQUID	2	(0,1)	4	(0,2)	6	(0,1)
PHENOLPHTHALEIN	1	(0,0)	0	(0,0)	1	(0,0)
PLANTAGO OVATA	1	(0,0)	7	(0,3)	8	(0,2)
PLANTAGO OVATA HUSK	3	(0,1)	1	(0,0)	4	(0,1)
PLANTAGO OVATA;SENNA SPP.	1	(0,0)	0	(0,0)	1	(0,0)
PLANTAGO OVATA;SENNOSIDE A+B	1	(0,0)	0	(0,0)	1	(0,0)
POLYCARBOPHIL CALCIUM	1	(0,0)	5	(0,2)	6	(0,1)
POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
POTASSIUM PHOSPHATE DIBASIC	4	(0,2)	5	(0,2)	9	(0,2)
POTASSIUM PHOSPHATE DIBASIC;POTASSIUM PHOSPHATE MONOBASIC	1	(0,0)	1	(0,0)	2	(0,0)
PRUCALOPRIDE SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
PSYLLIUM HYDROPHILIC MUCILLOID	0	(0,0)	1	(0,0)	1	(0,0)
REHMANNIA GLUTINOSA ROOT TUBER	0	(0,0)	1	(0,0)	1	(0,0)
RHEUM PALMATUM	0	(0,0)	1	(0,0)	1	(0,0)
RICINUS COMMUNIS OIL	1	(0,0)	1	(0,0)	2	(0,0)
SENNA ALEXANDRINA	16	(0,7)	25	(1,2)	41	(1,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR CONSTIPATION	**556**	**(25,8)**	**526**	**(24,5)**	**1.082**	**(25,1)**
SENNA ALEXANDRINA EXTRACT	1	(0,0)	1	(0,0)	2	(0,0)
SENNOSIDE A+B	88	(4,1)	74	(3,4)	162	(3,8)
SENNOSIDE A+B CALCIUM	6	(0,3)	11	(0,5)	17	(0,4)
SODIUM BICARBONATE;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	4	(0,2)	2	(0,1)	6	(0,1)
SODIUM CHLORIDE	203	(9,4)	196	(9,1)	399	(9,3)
SODIUM CITRATE ACID;SODIUM LAURYL SULFATE	1	(0,0)	1	(0,0)	2	(0,0)
SODIUM CITRATE;SODIUM LAURYL SULFOACETATE;SORBITOL	1	(0,0)	1	(0,0)	2	(0,0)
SODIUM PHOSPHATE DIBASIC	3	(0,1)	4	(0,2)	7	(0,2)
SODIUM PHOSPHATE DIBASIC DODECAHYDRATE;SODIUM PHOSPHATE MONOBASIC (DIHYDRATE)	4	(0,2)	2	(0,1)	6	(0,1)
SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC	5	(0,2)	5	(0,2)	10	(0,2)
SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	0	(0,0)	1	(0,0)	1	(0,0)
SODIUM PHOSPHATE MONOBASIC	0	(0,0)	4	(0,2)	4	(0,1)
SODIUM PHOSPHATE;SODIUM PHOSPHATE DIBASIC	3	(0,1)	2	(0,1)	5	(0,1)
SODIUM PICOSULFATE	19	(0,9)	19	(0,9)	38	(0,9)
SORBITOL	1	(0,0)	0	(0,0)	1	(0,0)
STERCULIA URENS	1	(0,0)	0	(0,0)	1	(0,0)
STERCULIA URENS GUM	0	(0,0)	2	(0,1)	2	(0,0)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	**280**	**(13,0)**	**268**	**(12,5)**	**548**	**(12,7)**

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	**280**	**(13,0)**	**268**	**(12,5)**	**548**	**(12,7)**
ACORUS CALAMUS RHIZOME;MENTHA X PIPERITA LEAF;RHAMNUS FRANGULA BARK;URTICA DIOICA LEAF;VALERIANA OFFICINALIS ROOT WITH RHIZOME	1	(0,0)	0	(0,0)	1	(0,0)
ACOTIAMIDE HYDROCHLORIDE TRIHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
ALIZAPRIDE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
ALOE FEROX;CARUM CARVI;CICHORIUM INTYBUS;CUMINUM CYMINUM;FOENICULUM VULGARE;SENNA ALEXANDRINA;TARAXACUM OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
ALUMINIUM HYDROXIDE;HOMATROPINE METHYLBROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
ALVERINE CITRATE;SIMETICONE	4	(0,2)	2	(0,1)	6	(0,1)
ATRACTYLODES MACROCEPHALA, RHIZOMA;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;LEVOGLUTAMIDE;PANAX GINSENG ROOT;PORIA COCOS SCLEROTIUM	1	(0,0)	0	(0,0)	1	(0,0)
ATROPINE	18	(0,8)	16	(0,7)	34	(0,8)
ATROPINE SULFATE	9	(0,4)	4	(0,2)	13	(0,3)
BENDAZOL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CARPRONIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CHLORDIAZEPOXIDE HYDROCHLORIDE;CLIDINIUM BROMIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	**280**	**(13,0)**	**268**	**(12,5)**	**548**	**(12,7)**
CIMETROPIUM BROMIDE	3	(0,1)	2	(0,1)	5	(0,1)
CINITAPRIDE	1	(0,0)	0	(0,0)	1	(0,0)
CINITAPRIDE TARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
CITRUS AURANTIUM UNRIPE FRUIT;MAGNOLIA OFFICINALIS BARK;RHEUM PALMATUM RHIZOME;SAUSSUREA COSTUS ROOT	1	(0,0)	0	(0,0)	1	(0,0)
CLEBOPRIDE MALATE;SIMETICONE	1	(0,0)	1	(0,0)	2	(0,0)
CORYDALIS YANHUSUO TUBER;IPOMOEA NIL SEED	3	(0,1)	1	(0,0)	4	(0,1)
CROCUS SATIVUS	0	(0,0)	1	(0,0)	1	(0,0)
CURCUMA LONGA	3	(0,1)	1	(0,0)	4	(0,1)
DEXPANTHENOL	3	(0,1)	2	(0,1)	5	(0,1)
DICYCLOVERINE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
DIMETICONE	13	(0,6)	23	(1,1)	36	(0,8)
DIMETICONE;GUAIAZULENE	0	(0,0)	1	(0,0)	1	(0,0)
DOMPERIDONE	26	(1,2)	13	(0,6)	39	(0,9)
DROTAVERINE	5	(0,2)	1	(0,0)	6	(0,1)
DROTAVERINE HYDROCHLORIDE	8	(0,4)	6	(0,3)	14	(0,3)
FENPIVERINIUM BROMIDE;METAMIZOLE SODIUM;PITOFENONE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
FLOPROPIONE	1	(0,0)	0	(0,0)	1	(0,0)
GASTRODIA ELATA	0	(0,0)	2	(0,1)	2	(0,0)
GLYCOPYRRONIUM	2	(0,1)	3	(0,1)	5	(0,1)
GLYCOPYRRONIUM BROMIDE	7	(0,3)	13	(0,6)	20	(0,5)
GLYCYRRHIZA GLABRA	1	(0,0)	2	(0,1)	3	(0,1)
GLYCYRRHIZA URALENSIS	1	(0,0)	1	(0,0)	2	(0,0)
HYOSCINE	2	(0,1)	7	(0,3)	9	(0,2)
HYOSCINE BUTYLBROMIDE	26	(1,2)	36	(1,7)	62	(1,4)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	**280**	**(13,0)**	**268**	**(12,5)**	**548**	**(12,7)**
HYOSCINE BUTYLBROMIDE;MEDAZEPAM	1	(0,0)	0	(0,0)	1	(0,0)
HYOSCINE BUTYLBROMIDE;METAMIZOLE SODIUM	1	(0,0)	2	(0,1)	3	(0,1)
HYOSCINE BUTYLBROMIDE;PARACETAMOL	3	(0,1)	1	(0,0)	4	(0,1)
HYOSCINE HYDROBROMIDE	0	(0,0)	2	(0,1)	2	(0,0)
HYOSCINE METHOBROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
HYOSCYAMINE	1	(0,0)	0	(0,0)	1	(0,0)
ITOPRIDE	2	(0,1)	1	(0,0)	3	(0,1)
ITOPRIDE HYDROCHLORIDE	6	(0,3)	4	(0,2)	10	(0,2)
LEVOSULPIRIDE	1	(0,0)	2	(0,1)	3	(0,1)
MEBEVERINE HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
MENTHA X PIPERITA OIL	1	(0,0)	0	(0,0)	1	(0,0)
MEPENZOLATE BROMIDE	1	(0,0)	0	(0,0)	1	(0,0)
METAMIZOLE SODIUM;PITOFENONE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
METOCLOPRAMIDE	67	(3,1)	75	(3,5)	142	(3,3)
METOCLOPRAMIDE HYDROCHLORIDE	85	(3,9)	71	(3,3)	156	(3,6)
MOSAPRIDE	7	(0,3)	7	(0,3)	14	(0,3)
MOSAPRIDE CITRATE	20	(0,9)	26	(1,2)	46	(1,1)
OTILONIUM BROMIDE	2	(0,1)	0	(0,0)	2	(0,0)
PAPAVERINE HYDROCHLORIDE	4	(0,2)	6	(0,3)	10	(0,2)
PARGEVERINE	1	(0,0)	1	(0,0)	2	(0,0)
PARGEVERINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PHLOROGLUCINOL	0	(0,0)	5	(0,2)	5	(0,1)
PHLOROGLUCINOL;TRIMETHYLPHLOROGLUCINOL	1	(0,0)	0	(0,0)	1	(0,0)
PINAVERIUM BROMIDE	2	(0,1)	1	(0,0)	3	(0,1)
PIPOXOLAN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	**280**	**(13,0)**	**268**	**(12,5)**	**548**	**(12,7)**
PITOFENONE	0	(0,0)	1	(0,0)	1	(0,0)
RUSCOGENIN;TRIMEBUTINE	1	(0,0)	1	(0,0)	2	(0,0)
SILICON DIOXIDE	1	(0,0)	1	(0,0)	2	(0,0)
SILICON DIOXIDE, COLLOIDAL	1	(0,0)	0	(0,0)	1	(0,0)
SIMETICONE	17	(0,8)	13	(0,6)	30	(0,7)
TIQUIZIUM BROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
TIROPRAMIDE HYDROCHLORIDE	0	(0,0)	3	(0,1)	3	(0,1)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
TRIMEBUTINE	1	(0,0)	3	(0,1)	4	(0,1)
TRIMEBUTINE MALEATE	5	(0,2)	2	(0,1)	7	(0,2)
TRIMETHYLPHLOROGLUCINOL	0	(0,0)	1	(0,0)	1	(0,0)
TROSPIUM	1	(0,0)	0	(0,0)	1	(0,0)
TROSPIUM CHLORIDE	1	(0,0)	5	(0,2)	6	(0,1)
VALERIANA OFFICINALIS	2	(0,1)	1	(0,0)	3	(0,1)
ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
DRUGS USED IN DIABETES	**955**	**(44,4)**	**910**	**(42,3)**	**1.865**	**(43,3)**
ACARBOSE	40	(1,9)	29	(1,3)	69	(1,6)
ALOGLIPTIN	2	(0,1)	0	(0,0)	2	(0,0)
ALOGLIPTIN BENZOATE	4	(0,2)	6	(0,3)	10	(0,2)
ALOGLIPTIN BENZOATE;METFORMIN HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
ANAGLIPTIN	1	(0,0)	1	(0,0)	2	(0,0)
ASTRAGALUS MONGHOLICUS ROOT;DIOSCOREA OPPOSITIFOLIA RHIZOME;GLIBENCLAMIDE;PUERARIA LOBATA ROOT;REHMANNIA GLUTINOSA ROOT;SCHISANDRA SPHENANTHERA FRUIT;TRICHOSANTHES SPP. ROOT;ZEA MAYS STYLE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS USED IN DIABETES	**955**	**(44,4)**	**910**	**(42,3)**	**1.865**	**(43,3)**
ATORVASTATIN CALCIUM;METFORMIN HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CANAGLIFLOZIN	5	(0,2)	10	(0,5)	15	(0,3)
CANAGLIFLOZIN HEMIHYDRATE;TENELIGLIPTIN HYDROBROMIDE	2	(0,1)	3	(0,1)	5	(0,1)
CHLORPROPAMIDE;PHENFORMIN	1	(0,0)	0	(0,0)	1	(0,0)
CYAMOPSIS TETRAGONOLOBA GUM	0	(0,0)	1	(0,0)	1	(0,0)
DAPAGLIFLOZIN	10	(0,5)	8	(0,4)	18	(0,4)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	8	(0,4)	10	(0,5)	18	(0,4)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE;METFORMIN HYDROCHLORIDE	3	(0,1)	1	(0,0)	4	(0,1)
DULAGLUTIDE	12	(0,6)	6	(0,3)	18	(0,4)
EMPAGLIFLOZIN	65	(3,0)	74	(3,4)	139	(3,2)
EMPAGLIFLOZIN;LINAGLIPTIN	1	(0,0)	0	(0,0)	1	(0,0)
EMPAGLIFLOZIN;METFORMIN HYDROCHLORIDE	4	(0,2)	5	(0,2)	9	(0,2)
EPALRESTAT	1	(0,0)	1	(0,0)	2	(0,0)
ERTUGLIFLOZIN	1	(0,0)	0	(0,0)	1	(0,0)
EVOGLIPTIN TARTRATE	1	(0,0)	1	(0,0)	2	(0,0)
EXENATIDE	6	(0,3)	2	(0,1)	8	(0,2)
GEMIGLIPTIN TARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
GEMIGLIPTIN TARTRATE;METFORMIN HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
GLIBENCLAMIDE	19	(0,9)	15	(0,7)	34	(0,8)
GLIBENCLAMIDE;METFORMIN HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
GLICLAZIDE	101	(4,7)	94	(4,4)	195	(4,5)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS USED IN DIABETES	**955**	**(44,4)**	**910**	**(42,3)**	**1.865**	**(43,3)**
GLICLAZIDE;METFORMIN HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
GLIMEPIRIDE	61	(2,8)	65	(3,0)	126	(2,9)
GLIMEPIRIDE;METFORMIN HYDROCHLORIDE	3	(0,1)	2	(0,1)	5	(0,1)
GLIMEPIRIDE;PIOGLITAZONE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
GLIPIZIDE	38	(1,8)	23	(1,1)	61	(1,4)
GLIPIZIDE;METFORMIN HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
GLIQUIDONE	8	(0,4)	5	(0,2)	13	(0,3)
GLYCINE MAX SEED OIL	0	(0,0)	1	(0,0)	1	(0,0)
INSULIN	80	(3,7)	69	(3,2)	149	(3,5)
INSULIN ASPART	97	(4,5)	106	(4,9)	203	(4,7)
INSULIN ASPART PROTAMINE	0	(0,0)	1	(0,0)	1	(0,0)
INSULIN ASPART;INSULIN ASPART PROTAMINE	3	(0,1)	0	(0,0)	3	(0,1)
INSULIN ASPART;INSULIN ASPART PROTAMINE (CRYSTALLINE)	28	(1,3)	17	(0,8)	45	(1,0)
INSULIN ASPART;INSULIN DEGLUDEC	4	(0,2)	3	(0,1)	7	(0,2)
INSULIN BOVINE;INSULIN PORCINE	1	(0,0)	1	(0,0)	2	(0,0)
INSULIN DEGLUDEC	23	(1,1)	16	(0,7)	39	(0,9)
INSULIN DEGLUDEC;LIRAGLUTIDE	2	(0,1)	0	(0,0)	2	(0,0)
INSULIN DETEMIR	35	(1,6)	45	(2,1)	80	(1,9)
INSULIN GLARGINE	223	(10,4)	185	(8,6)	408	(9,5)
INSULIN GLARGINE BIOSIMILAR 1	4	(0,2)	3	(0,1)	7	(0,2)
INSULIN GLULISINE	44	(2,0)	52	(2,4)	96	(2,2)
INSULIN HUMAN	119	(5,5)	126	(5,9)	245	(5,7)
INSULIN HUMAN INJECTION, ISOPHANE	66	(3,1)	50	(2,3)	116	(2,7)
INSULIN HUMAN ZINC SUSPENSION (CRYSTALLINE)	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS USED IN DIABETES	**955**	**(44,4)**	**910**	**(42,3)**	**1.865**	**(43,3)**
INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE	56	(2,6)	46	(2,1)	102	(2,4)
INSULIN ISOPHANE PORCINE	6	(0,3)	3	(0,1)	9	(0,2)
INSULIN LISPRO	69	(3,2)	68	(3,2)	137	(3,2)
INSULIN LISPRO PROTAMINE SUSPENSION	0	(0,0)	1	(0,0)	1	(0,0)
INSULIN LISPRO;INSULIN LISPRO PROTAMINE SUSPENSION	9	(0,4)	8	(0,4)	17	(0,4)
INSULIN PORCINE	1	(0,0)	0	(0,0)	1	(0,0)
INSULIN ZINC PROTAMINE INJECTION	1	(0,0)	1	(0,0)	2	(0,0)
IPRAGLIFLOZIN	0	(0,0)	1	(0,0)	1	(0,0)
IPRAGLIFLOZIN L-PROLINE	5	(0,2)	4	(0,2)	9	(0,2)
IPRAGLIFLOZIN L-PROLINE;SITAGLIPTIN PHOSPHATE MONOHYDRATE	1	(0,0)	1	(0,0)	2	(0,0)
ISOPHANE INSULIN	3	(0,1)	3	(0,1)	6	(0,1)
LINAGLIPTIN	86	(4,0)	77	(3,6)	163	(3,8)
LINAGLIPTIN;METFORMIN HYDROCHLORIDE	6	(0,3)	7	(0,3)	13	(0,3)
LIRAGLUTIDE	18	(0,8)	17	(0,8)	35	(0,8)
LIXISENATIDE	0	(0,0)	1	(0,0)	1	(0,0)
LOBEGLITAZONE SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
LUSEOGLIFLOZIN	1	(0,0)	0	(0,0)	1	(0,0)
METFORMIN	300	(13,9)	287	(13,3)	587	(13,6)
METFORMIN EMBONATE	0	(0,0)	1	(0,0)	1	(0,0)
METFORMIN HYDROCHLORIDE	145	(6,7)	158	(7,3)	303	(7,0)
METFORMIN HYDROCHLORIDE;PIOGLITAZONE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
METFORMIN HYDROCHLORIDE;SITAGLIPTIN	3	(0,1)	4	(0,2)	7	(0,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
DRUGS USED IN DIABETES	**955**	**(44,4)**	**910**	**(42,3)**	**1.865**	**(43,3)**
METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE	2	(0,1)	1	(0,0)	3	(0,1)
METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE	13	(0,6)	10	(0,5)	23	(0,5)
METFORMIN HYDROCHLORIDE;VILDAGLIPTIN	12	(0,6)	9	(0,4)	21	(0,5)
MIGLITOL	2	(0,1)	3	(0,1)	5	(0,1)
MITIGLINIDE CALCIUM	3	(0,1)	3	(0,1)	6	(0,1)
MITIGLINIDE CALCIUM;VOGLIBOSE	1	(0,0)	0	(0,0)	1	(0,0)
NATEGLINIDE	1	(0,0)	1	(0,0)	2	(0,0)
PIOGLITAZONE	1	(0,0)	2	(0,1)	3	(0,1)
PIOGLITAZONE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
PLATYCODON GRANDIFLORUS	5	(0,2)	4	(0,2)	9	(0,2)
REPAGLINIDE	30	(1,4)	36	(1,7)	66	(1,5)
SAXAGLIPTIN	2	(0,1)	2	(0,1)	4	(0,1)
SAXAGLIPTIN HYDROCHLORIDE	5	(0,2)	6	(0,3)	11	(0,3)
SEMAGLUTIDE	3	(0,1)	1	(0,0)	4	(0,1)
SITAGLIPTIN	33	(1,5)	34	(1,6)	67	(1,6)
SITAGLIPTIN PHOSPHATE	43	(2,0)	42	(2,0)	85	(2,0)
SITAGLIPTIN PHOSPHATE MONOHYDRATE	2	(0,1)	2	(0,1)	4	(0,1)
TENELIGLIPTIN HYDROBROMIDE	16	(0,7)	11	(0,5)	27	(0,6)
TOFOGLIFLOZIN	3	(0,1)	2	(0,1)	5	(0,1)
TOLBUTAMIDE	2	(0,1)	1	(0,0)	3	(0,1)
TRIGONELLA FOENUM-GRAECUM	0	(0,0)	1	(0,0)	1	(0,0)
VILDAGLIPTIN	17	(0,8)	24	(1,1)	41	(1,0)
VOGLIBOSE	9	(0,4)	9	(0,4)	18	(0,4)
MINERAL SUPPLEMENTS	**886**	**(41,2)**	**876**	**(40,7)**	**1.762**	**(40,9)**
ASCORBIC ACID;ASPARTIC ACID;POTASSIUM	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;MAGNESIUM	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
MINERAL SUPPLEMENTS	**886**	**(41,2)**	**876**	**(40,7)**	**1.762**	**(40,9)**
ASCORBIC ACID;POTASSIUM BICARBONATE	7	(0,3)	1	(0,0)	8	(0,2)
ASPARTATE CALCIUM	1	(0,0)	1	(0,0)	2	(0,0)
BETAINE HYDROCHLORIDE;POTASSIUM BICARBONATE;POTASSIUM CHLORIDE	3	(0,1)	6	(0,3)	9	(0,2)
CALCIUM	24	(1,1)	27	(1,3)	51	(1,2)
CALCIUM ACETATE	7	(0,3)	7	(0,3)	14	(0,3)
CALCIUM CARBONATE	35	(1,6)	42	(2,0)	77	(1,8)
CALCIUM CARBONATE;CALCIUM GLUCONATE;CALCIUM LACTATE;ERGOCALCIFEROL	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM CARBONATE;CALCIUM LACTATE GLUCONATE	3	(0,1)	0	(0,0)	3	(0,1)
CALCIUM CARBONATE;COLECALCIFEROL	12	(0,6)	26	(1,2)	38	(0,9)
CALCIUM CARBONATE;ERGOCALCIFEROL	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM CARBONATE;MAGNESIUM CARBONATE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CARBONATE;MAGNESIUM CHLORIDE	1	(0,0)	3	(0,1)	4	(0,1)
CALCIUM CARBONATE;VITAMIN D NOS	2	(0,1)	2	(0,1)	4	(0,1)
CALCIUM CHLORIDE	8	(0,4)	12	(0,6)	20	(0,5)
CALCIUM CHLORIDE;GLUCOSE	3	(0,1)	4	(0,2)	7	(0,2)
CALCIUM CITRATE	0	(0,0)	2	(0,1)	2	(0,0)
CALCIUM CITRATE;COLECALCIFEROL	1	(0,0)	2	(0,1)	3	(0,1)
CALCIUM CITRATE;VITAMIN D NOS	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
MINERAL SUPPLEMENTS	**886**	**(41,2)**	**876**	**(40,7)**	**1.762**	**(40,9)**
CALCIUM GLUBIONATE;CALCIUM LACTOBIONATE	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM GLUCONATE	40	(1,9)	49	(2,3)	89	(2,1)
CALCIUM GLUCONATE;CALCIUM LAEVULINATE	2	(0,1)	2	(0,1)	4	(0,1)
CALCIUM GLUCONATE;CALCIUM SACCHARATE	1	(0,0)	1	(0,0)	2	(0,0)
CALCIUM GLUTAMATE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM HYDROGENCARBONATE	3	(0,1)	1	(0,0)	4	(0,1)
CALCIUM LACTATE	1	(0,0)	3	(0,1)	4	(0,1)
CALCIUM PHOSPHATE;COLECALCIFEROL	1	(0,0)	2	(0,1)	3	(0,1)
CALCIUM PHOSPHATE;FERROUS PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM;COLECALCIFEROL	6	(0,3)	4	(0,2)	10	(0,2)
CALCIUM;COLECALCIFEROL;MAGNESIUM;ZINC SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM;MAGNESIUM	2	(0,1)	1	(0,0)	3	(0,1)
CALCIUM;MAGNESIUM;ZINC	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM;SILICIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM;VITAMIN D NOS	4	(0,2)	1	(0,0)	5	(0,1)
CHROMIC CHLORIDE HEXAHYDRATE;COPPER CHLORIDE DIHYDRATE;FERRIC CHLORIDE HEXAHYDRATE;MANGANESE CHLORIDE TETRAHYDRATE;POTASSIUM IODIDE;SODIUM FLUORIDE;SODIUM MOLYBDATE DIHYDRATE;SODIUM SELENITE;ZINC CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
MINERAL SUPPLEMENTS	**886**	**(41,2)**	**876**	**(40,7)**	**1.762**	**(40,9)**
CHROMIC CHLORIDE;COPPER SULFATE;MANGANESE SULFATE;ZINC SULFATE	1	(0,0)	2	(0,1)	3	(0,1)
CITRIC ACID;POTASSIUM BICARBONATE	1	(0,0)	1	(0,0)	2	(0,0)
CITRIC ACID;POTASSIUM BICARBONATE;POTASSIUM CITRATE	9	(0,4)	12	(0,6)	21	(0,5)
COPPER SULFATE PENTAHYDRATE;FERRIC CHLORIDE HEXAHYDRATE;MANGANESE CHLORIDE TETRAHYDRATE;POTASSIUM IODIDE;ZINC SULFATE HEPTAHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
COPPER SULFATE;FERRIC CHLORIDE;MANGANESE CHLORIDE;POTASSIUM IODIDE;ZINC SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
MAGNESIUM	66	(3,1)	63	(2,9)	129	(3,0)
MAGNESIUM ASPARTATE	6	(0,3)	1	(0,0)	7	(0,2)
MAGNESIUM ASPARTATE DIHYDRATE	0	(0,0)	1	(0,0)	1	(0,0)
MAGNESIUM ASPARTATE HYDROCHLORIDE	4	(0,2)	5	(0,2)	9	(0,2)
MAGNESIUM ASPARTATE;POTASSIUM ASPARTATE	27	(1,3)	32	(1,5)	59	(1,4)
MAGNESIUM CARBONATE	4	(0,2)	6	(0,3)	10	(0,2)
MAGNESIUM CARBONATE;MAGNESIUM OXIDE	7	(0,3)	8	(0,4)	15	(0,3)
MAGNESIUM CHLORIDE	6	(0,3)	1	(0,0)	7	(0,2)
MAGNESIUM CITRATE	6	(0,3)	8	(0,4)	14	(0,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
MINERAL SUPPLEMENTS	**886**	**(41,2)**	**876**	**(40,7)**	**1.762**	**(40,9)**
MAGNESIUM CITRATE;MAGNESIUM GLUTAMATE	1	(0,0)	0	(0,0)	1	(0,0)
MAGNESIUM GLUCONATE	1	(0,0)	3	(0,1)	4	(0,1)
MAGNESIUM GLYCINATE;PYRIDOXINE HYDROCHLORIDE	1	(0,0)	4	(0,2)	5	(0,1)
MAGNESIUM HYDROXIDE	17	(0,8)	25	(1,2)	42	(1,0)
MAGNESIUM LACTATE	2	(0,1)	5	(0,2)	7	(0,2)
MAGNESIUM LACTATE;PYRIDOXINE HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
MAGNESIUM OROTATE	1	(0,0)	0	(0,0)	1	(0,0)
MAGNESIUM OXIDE	83	(3,9)	73	(3,4)	156	(3,6)
MAGNESIUM OXIDE;ZINC SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
MAGNESIUM PIDOLATE	1	(0,0)	1	(0,0)	2	(0,0)
MAGNESIUM SULFATE	87	(4,0)	92	(4,3)	179	(4,2)
MAGNESIUM;POTASSIUM	0	(0,0)	2	(0,1)	2	(0,0)
MINERALS NOS;VITAMINS NOS	4	(0,2)	10	(0,5)	14	(0,3)
POTASSIUM	75	(3,5)	78	(3,6)	153	(3,6)
POTASSIUM ASCORBATE	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM ASPARTATE	11	(0,5)	17	(0,8)	28	(0,7)
POTASSIUM BICARBONATE	3	(0,1)	2	(0,1)	5	(0,1)
POTASSIUM BICARBONATE;POTASSIUM CARBONATE;POTASSIUM CHLORIDE	6	(0,3)	2	(0,1)	8	(0,2)
POTASSIUM BICARBONATE;POTASSIUM CHLORIDE	1	(0,0)	3	(0,1)	4	(0,1)
POTASSIUM BICARBONATE;POTASSIUM CITRATE	12	(0,6)	8	(0,4)	20	(0,5)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
MINERAL SUPPLEMENTS	**886**	**(41,2)**	**876**	**(40,7)**	**1.762**	**(40,9)**
POTASSIUM BICARBONATE;POTASSIUM CITRATE MONOHYDRATE	1	(0,0)	3	(0,1)	4	(0,1)
POTASSIUM BICARBONATE;SODIUM BICARBONATE;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	0	(0,0)	1	(0,0)	1	(0,0)
POTASSIUM CHLORIDE	532	(24,7)	514	(23,9)	1.046	(24,3)
POTASSIUM CITRATE	15	(0,7)	14	(0,7)	29	(0,7)
POTASSIUM GLUCONATE	39	(1,8)	31	(1,4)	70	(1,6)
POTASSIUM PHOSPHATE DIBASIC	4	(0,2)	5	(0,2)	9	(0,2)
POTASSIUM PHOSPHATE DIBASIC;POTASSIUM PHOSPHATE MONOBASIC	1	(0,0)	1	(0,0)	2	(0,0)
POTASSIUM PHOSPHATE DIBASIC;POTASSIUM PHOSPHATE MONOBASIC;SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC	0	(0,0)	1	(0,0)	1	(0,0)
POTASSIUM PHOSPHATE MONOBASIC	5	(0,2)	6	(0,3)	11	(0,3)
POTASSIUM PHOSPHATE MONOBASIC;SODIUM PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
POTASSIUM PHOSPHATE MONOBASIC;SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	1	(0,0)	0	(0,0)	1	(0,0)
SELENIUM	1	(0,0)	2	(0,1)	3	(0,1)
SILICON DIOXIDE	1	(0,0)	1	(0,0)	2	(0,0)
SODIUM	3	(0,1)	1	(0,0)	4	(0,1)
SODIUM CHLORIDE	203	(9,4)	196	(9,1)	399	(9,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
MINERAL SUPPLEMENTS	**886**	**(41,2)**	**876**	**(40,7)**	**1.762**	**(40,9)**
SODIUM FLUORIDE	0	(0,0)	1	(0,0)	1	(0,0)
SODIUM PHOSPHATE DIBASIC	3	(0,1)	4	(0,2)	7	(0,2)
SODIUM PHOSPHATE DIBASIC DODECAHYDRATE;SODIUM PHOSPHATE MONOBASIC (DIHYDRATE)	4	(0,2)	2	(0,1)	6	(0,1)
SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC	5	(0,2)	5	(0,2)	10	(0,2)
SODIUM PHOSPHATE;SODIUM PHOSPHATE DIBASIC	3	(0,1)	2	(0,1)	5	(0,1)
ZINC	1	(0,0)	2	(0,1)	3	(0,1)
ZINC GLUCONATE	1	(0,0)	0	(0,0)	1	(0,0)
ZINC SULFATE	3	(0,1)	4	(0,2)	7	(0,2)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	**301**	**(14,0)**	**329**	**(15,3)**	**630**	**(14,6)**
ACETYLCYSTEINE	128	(5,9)	138	(6,4)	266	(6,2)
ADEMETIONINE	1	(0,0)	4	(0,2)	5	(0,1)
ADEMETIONINE 1,4-BUTANEDISULFONATE	0	(0,0)	4	(0,2)	4	(0,1)
ADENOSINE;COENZYME A;NADIDE	5	(0,2)	3	(0,1)	8	(0,2)
ALANYL GLUTAMINE	1	(0,0)	1	(0,0)	2	(0,0)
AMINO ACIDS NOS	3	(0,1)	6	(0,3)	9	(0,2)
ARCTIUM LAPPA	1	(0,0)	0	(0,0)	1	(0,0)
ASARUM HETEROTROPOIDES	1	(0,0)	0	(0,0)	1	(0,0)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	5	(0,2)	4	(0,2)	9	(0,2)
CARNITINE	1	(0,0)	0	(0,0)	1	(0,0)
CLOSTRIDIUM BUTYRICUM	15	(0,7)	12	(0,6)	27	(0,6)
CYSTEINE	1	(0,0)	0	(0,0)	1	(0,0)
ESCHERICHIA COLI	1	(0,0)	1	(0,0)	2	(0,0)
FIBRE, DIETARY	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	**301**	**(14,0)**	**329**	**(15,3)**	**630**	**(14,6)**
FRUCTOOLIGOSACCHARIDES;PROBIOTICS NOS	1	(0,0)	1	(0,0)	2	(0,0)
FUCOIDAN	4	(0,2)	1	(0,0)	5	(0,1)
GLUCUROLACTONE	1	(0,0)	0	(0,0)	1	(0,0)
GLYCINE	2	(0,1)	1	(0,0)	3	(0,1)
LEVOCARNITINE	3	(0,1)	7	(0,3)	10	(0,2)
LEVOCARNITINE PROPIONATE	1	(0,0)	0	(0,0)	1	(0,0)
LEVOGLUTAMIDE	2	(0,1)	0	(0,0)	2	(0,0)
ORNITHINE	1	(0,0)	0	(0,0)	1	(0,0)
ORYZANOL	0	(0,0)	1	(0,0)	1	(0,0)
OX BILE EXTRACT;PANCREATIN;RHAMNUS FRANGULA;RHEUM PALMATUM DRY EXTRACT;SODIUM BICARBONATE	1	(0,0)	0	(0,0)	1	(0,0)
OXIDIZED STARCH	1	(0,0)	1	(0,0)	2	(0,0)
POLAPREZINC	0	(0,0)	2	(0,1)	2	(0,0)
POTASSIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
PROBIOTICS NOS	8	(0,4)	10	(0,5)	18	(0,4)
QUERCETIN	0	(0,0)	2	(0,1)	2	(0,0)
SODIUM BICARBONATE	104	(4,8)	109	(5,1)	213	(5,0)
SUCRALFATE	22	(1,0)	24	(1,1)	46	(1,1)
THIOCTIC ACID	7	(0,3)	12	(0,6)	19	(0,4)
UBIDECARENONE	29	(1,3)	50	(2,3)	79	(1,8)
ULINASTATIN	3	(0,1)	2	(0,1)	5	(0,1)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	4	(0,2)	2	(0,1)	6	(0,1)
ZINC	1	(0,0)	2	(0,1)	3	(0,1)
STOMATOLOGICAL PREPARATIONS	**1.397**	**(64,9)**	**1.352**	**(62,9)**	**2.749**	**(63,9)**
ACETYLSALICYLIC ACID	1.060	(49,3)	1.015	(47,2)	2.075	(48,2)
ALTHAEA OFFICINALIS EXTRACT	1	(0,0)	3	(0,1)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
STOMATOLOGICAL PREPARATIONS	**1.397**	**(64,9)**	**1.352**	**(62,9)**	**2.749**	**(63,9)**
ALUMINIUM HYDROXIDE;DIPHENHYDRAMINE;LIDOCAINE;MAGNESIUM HYDROXIDE	1	(0,0)	0	(0,0)	1	(0,0)
AMPHOTERICIN B	2	(0,1)	1	(0,0)	3	(0,1)
BENZALKONIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
BENZOCAINE	3	(0,1)	0	(0,0)	3	(0,1)
BENZOCAINE;MENTHOL	0	(0,0)	5	(0,2)	5	(0,1)
BENZYDAMINE HYDROCHLORIDE	6	(0,3)	1	(0,0)	7	(0,2)
BENZYDAMINE HYDROCHLORIDE;CETYLPYRIDINIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
BENZYDAMINE HYDROCHLORIDE;CHLORHEXIDINE GLUCONATE	1	(0,0)	2	(0,1)	3	(0,1)
BORIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
BORIC ACID;BORNEOL;CITRULLUS LANATUS;COPTIS SPP.;FRITILLARIA THUNBERGII;GLYCYRRHIZA SPP.;INDIGO;IRIS DOMESTICA;MENTHOL;PHELLODENDRON CHINENSE;RHEUM SPP.;SAPINDUS MUKOROSSI;SCUTELLARIA BAICALENSIS;SODIUM SULFATE;SOPHORA TONKINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
CARBOMER	5	(0,2)	4	(0,2)	9	(0,2)
CARMELLOSE SODIUM;PECTIN	0	(0,0)	1	(0,0)	1	(0,0)
CETYLPYRIDINIUM CHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
CHLORAMPHENICOL	11	(0,5)	10	(0,5)	21	(0,5)
CHLORHEXIDINE	3	(0,1)	5	(0,2)	8	(0,2)
CHLORHEXIDINE DIACETATE	1	(0,0)	1	(0,0)	2	(0,0)

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All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
STOMATOLOGICAL PREPARATIONS	**1.397**	**(64,9)**	**1.352**	**(62,9)**	**2.749**	**(63,9)**
CHLORHEXIDINE GLUCONATE	6	(0,3)	14	(0,7)	20	(0,5)
CHLORHEXIDINE GLUCONATE;LIDOCAINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
CHLORHEXIDINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CHLORTETRACYCLINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
CHOLINE SALICYLATE	3	(0,1)	1	(0,0)	4	(0,1)
CLIOQUINOL;FLUMETASONE PIVALATE	2	(0,1)	0	(0,0)	2	(0,0)
CLOBETASOL PROPIONATE	13	(0,6)	16	(0,7)	29	(0,7)
CLOTRIMAZOLE	2	(0,1)	7	(0,3)	9	(0,2)
COCAINE	1	(0,0)	1	(0,0)	2	(0,0)
DEXAMETHASONE	37	(1,7)	37	(1,7)	74	(1,7)
DEXAMETHASONE DIPROPIONATE	3	(0,1)	0	(0,0)	3	(0,1)
DEXAMETHASONE SODIUM PHOSPHATE	17	(0,8)	16	(0,7)	33	(0,8)
DICLOFENAC	33	(1,5)	33	(1,5)	66	(1,5)
DICLOFENAC SODIUM	36	(1,7)	30	(1,4)	66	(1,5)
DIMETICONE	13	(0,6)	23	(1,1)	36	(0,8)
DOXYCYCLINE	36	(1,7)	37	(1,7)	73	(1,7)
DOXYCYCLINE HYCLATE	4	(0,2)	9	(0,4)	13	(0,3)
DOXYCYCLINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ELECTROLYTES NOS	26	(1,2)	30	(1,4)	56	(1,3)
EPINEPHRINE	52	(2,4)	53	(2,5)	105	(2,4)
EPINEPHRINE BITARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
EPINEPHRINE HYDROCHLORIDE	1	(0,0)	5	(0,2)	6	(0,1)
ERIOBOTRYA JAPONICA	0	(0,0)	2	(0,1)	2	(0,0)
FLURBIPROFEN	13	(0,6)	11	(0,5)	24	(0,6)
FLURBIPROFEN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
GLUCOSE OXIDASE;LACTOFERRIN;LACTOPEROXIDASE;LYSOZYME	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
STOMATOLOGICAL PREPARATIONS	**1.397**	**(64,9)**	**1.352**	**(62,9)**	**2.749**	**(63,9)**
GLYCEROL	21	(1,0)	20	(0,9)	41	(1,0)
GLYCYRRHIZIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
HYALURONATE SODIUM	23	(1,1)	17	(0,8)	40	(0,9)
HYDROCORTISONE	38	(1,8)	37	(1,7)	75	(1,7)
HYDROCORTISONE ACETATE	15	(0,7)	9	(0,4)	24	(0,6)
HYDROCORTISONE PROBUTAT	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE SODIUM SUCCINATE	5	(0,2)	13	(0,6)	18	(0,4)
KETOPROFEN	41	(1,9)	49	(2,3)	90	(2,1)
LACTOBACILLUS REUTERI	1	(0,0)	0	(0,0)	1	(0,0)
LIDOCAINE	61	(2,8)	62	(2,9)	123	(2,9)
LIDOCAINE HYDROCHLORIDE	43	(2,0)	40	(1,9)	83	(1,9)
LIDOCAINE HYDROCHLORIDE;TRIAMCINOLONE ACETONIDE	2	(0,1)	1	(0,0)	3	(0,1)
LYSOZYME HYDROCHLORIDE;PYRIDOXINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
MENTHA X PIPERITA OIL	1	(0,0)	0	(0,0)	1	(0,0)
METRONIDAZOLE	58	(2,7)	39	(1,8)	97	(2,3)
MICONAZOLE	6	(0,3)	4	(0,2)	10	(0,2)
MICONAZOLE NITRATE	6	(0,3)	3	(0,1)	9	(0,2)
MINOCYCLINE	1	(0,0)	3	(0,1)	4	(0,1)
MINOCYCLINE HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
NAPROXEN	10	(0,5)	16	(0,7)	26	(0,6)
NEOMYCIN	4	(0,2)	2	(0,1)	6	(0,1)
NIMESULIDE	3	(0,1)	9	(0,4)	12	(0,3)
NITROFURAL	2	(0,1)	1	(0,0)	3	(0,1)
NYSTATIN	17	(0,8)	15	(0,7)	32	(0,7)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	3	(0,1)	2	(0,1)	5	(0,1)
OXYGEN	55	(2,6)	58	(2,7)	113	(2,6)
PHENOL	0	(0,0)	3	(0,1)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
STOMATOLOGICAL PREPARATIONS	**1.397**	**(64,9)**	**1.352**	**(62,9)**	**2.749**	**(63,9)**
POLIHEXANIDE;UNDECYLENAMI DOPROPYL BETAINE	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM	75	(3,5)	78	(3,6)	153	(3,6)
POTASSIUM CHLORATE	3	(0,1)	2	(0,1)	5	(0,1)
POVIDONE	0	(0,0)	1	(0,0)	1	(0,0)
POVIDONE-IODINE	18	(0,8)	8	(0,4)	26	(0,6)
PREDNISOLONE	84	(3,9)	73	(3,4)	157	(3,6)
PREDNISOLONE ACETATE	3	(0,1)	3	(0,1)	6	(0,1)
PROPOLIS	1	(0,0)	1	(0,0)	2	(0,0)
RIFAMYCIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
SALICYLIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
SODIUM BICARBONATE	104	(4,8)	109	(5,1)	213	(5,0)
SODIUM CHLORIDE	203	(9,4)	196	(9,1)	399	(9,3)
SODIUM FLUORIDE	0	(0,0)	1	(0,0)	1	(0,0)
SUCRALFATE	22	(1,0)	24	(1,1)	46	(1,1)
TETRACYCLINE	2	(0,1)	3	(0,1)	5	(0,1)
TETRACYCLINE HYDROCHLORIDE	4	(0,2)	3	(0,1)	7	(0,2)
THYMOL	2	(0,1)	3	(0,1)	5	(0,1)
TINIDAZOLE	0	(0,0)	1	(0,0)	1	(0,0)
TRANEXAMIC ACID	25	(1,2)	24	(1,1)	49	(1,1)
TRIAMCINOLONE	3	(0,1)	9	(0,4)	12	(0,3)
TRIAMCINOLONE ACETONIDE	14	(0,7)	12	(0,6)	26	(0,6)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
UREA HYDROGEN PEROXIDE	0	(0,0)	1	(0,0)	1	(0,0)
ZINC	1	(0,0)	2	(0,1)	3	(0,1)
TONICS	**16**	**(0,7)**	**37**	**(1,7)**	**53**	**(1,2)**
ALLIUM SATIVUM	1	(0,0)	3	(0,1)	4	(0,1)
AMINO ACIDS NOS;MINERALS NOS;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)
AMINO ACIDS NOS;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
TONICS	**16**	**(0,7)**	**37**	**(1,7)**	**53**	**(1,2)**
ARGININE HYDROCHLORIDE;ASCORBIC ACID;CAFFEINE;ELEUTHEROCOCCUS SENTICOSUS;HERBAL NOS;NICOTINAMIDE;OXOAMIDINE; PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;VITAMIN B1 NOS;VITAMIN E NOS	1	(0,0)	0	(0,0)	1	(0,0)
ASTRAGALUS PROPINQUUS	1	(0,0)	4	(0,2)	5	(0,1)
ATRACTYLODES MACROCEPHALA	1	(0,0)	0	(0,0)	1	(0,0)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
CITRULLINE MALATE	1	(0,0)	0	(0,0)	1	(0,0)
CODONOPSIS PILOSULA	1	(0,0)	0	(0,0)	1	(0,0)
CURCUMA LONGA	3	(0,1)	1	(0,0)	4	(0,1)
DIETARY SUPPLEMENT	0	(0,0)	1	(0,0)	1	(0,0)
EUCOMMIA ULMOIDES	1	(0,0)	0	(0,0)	1	(0,0)
FALLOPIA MULTIFLORA	1	(0,0)	0	(0,0)	1	(0,0)
GASTRODIA ELATA	0	(0,0)	2	(0,1)	2	(0,0)
GLYCYRRHIZA URALENSIS	1	(0,0)	1	(0,0)	2	(0,0)
MINERALS NOS;VITAMINS NOS	4	(0,2)	10	(0,5)	14	(0,3)
OPHIOPOGON JAPONICUS ROOT TUBER;PANAX GINSENG ROOT;SCHISANDRA CHINENSIS FRUIT	1	(0,0)	7	(0,3)	8	(0,2)
TOCOPHEROL	3	(0,1)	8	(0,4)	11	(0,3)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
VITAMINS	**368**	**(17,1)**	**392**	**(18,2)**	**760**	**(17,7)**
ALFACALCIDOL	12	(0,6)	14	(0,7)	26	(0,6)
AMINO ACIDS NOS;MINERALS NOS;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)
AMINO ACIDS NOS;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**368**	**(17,1)**	**392**	**(18,2)**	**760**	**(17,7)**
AMINOBENZOIC ACID;ASCORBIC ACID;BIOTIN;CHOLINE;CYANOCOBALAMIN;FOLIC ACID;GLYCINE;INOSITOL;MAGNESIUM;NICOTINIC ACID;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1	(0,0)	1	(0,0)	2	(0,0)
ASCORBIC ACID	39	(1,8)	28	(1,3)	67	(1,6)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CHROMIC CHLORIDE;COLECALCIFEROL;COPPER SULFATE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;LYCOPENE;MAGNESIUM OXIDE;MANGANESE SULFATE;NICOTINAMIDE;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL ACETATE;RIBOFLAVIN;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**368**	**(17,1)**	**392**	**(18,2)**	**760**	**(17,7)**
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE DIBASIC;COLECALCIFEROL;CYANOCOBALAMIN;DL-ALPHA TOCOPHERYL ACETATE;FERROUS FUMARATE;FOLIC ACID;NICOTINAMIDE;PHYTOMENADIONE;PYRIDOXINE HYDROCHLORIDE;RETINOL ACETATE;RIBOFLAVIN;THIAMINE MONONITRATE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM PANTOTHENATE;CHROMIC CHLORIDE;CHROMIUM;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**368**	**(17,1)**	**392**	**(18,2)**	**760**	**(17,7)**
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM;CHROMIUM;COLECALCIFEROL;COPPER;FOLIC ACID;IODINE;IRON;LYCOPENE;MAGNESIUM;MANGANESE;NICOTINAMIDE;PANTOTHENIC ACID;PHOSPHORUS;PHYTOMENADIONE;POTASSIUM;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SELENIUM;VITAMIN B1 NOS;VITAMIN B12 NOS;VITAMIN E NOS;XANTOFYL;ZINC	0	(0,0)	2	(0,1)	2	(0,0)
ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;SODIUM SELENATE;TOCOPHERYL ACETATE;XANTOFYL;ZINC OXIDE	2	(0,1)	1	(0,0)	3	(0,1)
ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;TOCOPHERYL ACETATE;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**368**	**(17,1)**	**392**	**(18,2)**	**760**	**(17,7)**
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE;COPPER SULFATE;CYANOCOBALAMIN;DL-ALPHA TOCOPHERYL ACETATE;ERGOCALCIFEROL;IRON; MAGNESIUM OXIDE;MAGNESIUM PHOSPHATE;MAGNESIUM STEARATE;MANGANESE SULFATE;MOLYBDENUM;NICOTINAMIDE;PHOSPHORUS;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;ZINC SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FOLIC ACID;GLYCINE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**368**	**(17,1)**	**392**	**(18,2)**	**760**	**(17,7)**
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	3	(0,1)	1	(0,0)	4	(0,1)
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;BIOTIN;CALCIUM;CHROMIUM;COPPER;FOLIC ACID;IODINE;LYCOPENE;MAGNESIUM;MANGANESE;MENADIONE;MOLYBDENUM;NICOTINIC ACID;PANTOTHENIC ACID;PHOSPHORUS;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;SELENIUM;THIAMINE;TOCOPHEROL;VITAMIN B12 NOS;VITAMIN D NOS;XANTOFYL;ZEAXANTHIN;ZINC	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**368**	**(17,1)**	**392**	**(18,2)**	**760**	**(17,7)**
ASCORBIC ACID;BIOTIN;COCARBOXYLASE TETRAHYDRATE;COLECALCIFEROL;CYANOCOBALAMIN;DEXPANTHENOL;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL PALMITATE;RIBOFLAVIN SODIUM PHOSPHATE;TOCOPHEROL	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;BIOTIN;CYANOCOBALAMIN;ERGOCALCIFEROL;FOLIC ACID;NICOTINAMIDE;PANTHENOL;PHYTOMENADIONE;PYRIDOXINE HYDROCHLORIDE;RETINOL PALMITATE;RIBOFLAVIN SODIUM PHOSPHATE;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;BIOTIN;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;FURSULTIAMINE HYDROCHLORIDE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN TETRABUTYRATE;SELENIUM;TOCOPHERYL ACETATE;ZINC OXIDE	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;BIOTIN;CYANOCOBALAMIN;FOLIC ACID;NICOTINIC ACID;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**368**	**(17,1)**	**392**	**(18,2)**	**760**	**(17,7)**
ASCORBIC ACID;CALCIUM PANTOTHENATE	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;CALCIUM PANTOTHENATE;CHROMIUM;COLECALCIFEROL;COPPER;FOLIC ACID;IODINE;IRON;MAGNESIUM;MANGANESE;MOLYBDENUM;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SELENIUM;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE;ZINC	1	(0,0)	1	(0,0)	2	(0,0)
ASCORBIC ACID;CALCIUM PANTOTHENATE;COPPER;CYANOCOBALAMIN;ERGOCALCIFEROL;IODINE;IRON;MAGNESIUM;MANGANESE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;TOCOPHEROL;ZINC	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FERROUS SULFATE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**368**	**(17,1)**	**392**	**(18,2)**	**760**	**(17,7)**
ASCORBIC ACID;CUPRIC OXIDE;RETINOL;TOCOPHERYL ACETATE;ZINC OXIDE	3	(0,1)	1	(0,0)	4	(0,1)
ASCORBIC ACID;CUPRIC OXIDE;TOCOPHERYL ACID SUCCINATE;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;CYANOCOBALAMIN;FOLIC ACID;IRON;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;FERROUS SULFATE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	2	(0,1)	4	(0,2)	6	(0,1)
ASCORBIC ACID;FOLIC ACID;VITAMIN B COMPLEX	3	(0,1)	1	(0,0)	4	(0,1)
ASCORBIC ACID;GLUCOSE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;MAGNESIUM	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;NICOTINAMIDE;PANTHENOL;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN SODIUM PHOSPHATE;THIAMINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**368**	**(17,1)**	**392**	**(18,2)**	**760**	**(17,7)**
ASCORBIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;VITAMIN B COMPLEX	2	(0,1)	0	(0,0)	2	(0,0)
BENFOTIAMINE;CYANOCOBALAMIN	1	(0,0)	0	(0,0)	1	(0,0)
BENFOTIAMINE;CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE	0	(0,0)	4	(0,2)	4	(0,1)
BENFOTIAMINE;PYRIDOXINE HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
BENMETIAMINE;CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
BETACAROTENE	1	(0,0)	0	(0,0)	1	(0,0)
BIOTIN	5	(0,2)	2	(0,1)	7	(0,2)
CALCIFEDIOL	6	(0,3)	9	(0,4)	15	(0,3)
CALCITRIOL	31	(1,4)	33	(1,5)	64	(1,5)
CALCIUM ASCORBATE;INOSITOL;RUTOSIDE; VITAMIN B NOS	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CARBONATE;VITAMIN D NOS	2	(0,1)	2	(0,1)	4	(0,1)
CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE;SORBITOL	0	(0,0)	2	(0,1)	2	(0,0)
CALCIUM CITRATE;COLECALCIFEROL;CYANOCOBALAMIN;FOLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**368**	**(17,1)**	**392**	**(18,2)**	**760**	**(17,7)**
CALCIUM LEVOMEFOLATE;CYANOCOBALAMIN;MAGNESIUM;MAGNESIUM GLYCEROPHOSPHATE;PYRIDOXINE HYDROCHLORIDE;TAURINE	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM MEFOLINATE;PYRIDOXINE HYDROCHLORIDE;VITAMIN B12 NOS	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM PANTOTHENATE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
COD-LIVER OIL	0	(0,0)	1	(0,0)	1	(0,0)
COLECALCIFEROL	93	(4,3)	86	(4,0)	179	(4,2)
COLECALCIFEROL;DL-SELENOMETHIONINE;NICOTINAMIDE;POTASSIUM IODIDE;RETINOL PALMITATE;RIBOFLAVIN;ROSMARINUS OFFICINALIS LEAF;TOCOPHERYL ACID SUCCINATE;ZINC GLUCONATE	0	(0,0)	1	(0,0)	1	(0,0)
COLECALCIFEROL;FISH OIL	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
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All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**368**	**(17,1)**	**392**	**(18,2)**	**760**	**(17,7)**
CYANOCOBALAMIN;DEXPANTHENOL;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CYANOCOBALAMIN;NICOTINAMIDE;PHOSPHOLIPIDS;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE	2	(0,1)	1	(0,0)	3	(0,1)
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE DISULFIDE	7	(0,3)	7	(0,3)	14	(0,3)
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	14	(0,7)	15	(0,7)	29	(0,7)
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE;TOCOPHEROL	1	(0,0)	0	(0,0)	1	(0,0)
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE MONONITRATE	0	(0,0)	2	(0,1)	2	(0,0)
CYANOCOBALAMIN;PYRIDOXINE;THIAMINE	5	(0,2)	8	(0,4)	13	(0,3)
CYANOCOBALAMIN;THIAMINE	1	(0,0)	0	(0,0)	1	(0,0)
DEXPANTHENOL	3	(0,1)	2	(0,1)	5	(0,1)
DEXPANTHENOL;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN SODIUM PHOSPHATE;THIAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ELDECALCITOL	5	(0,2)	1	(0,0)	6	(0,1)
ERGOCALCIFEROL	6	(0,3)	12	(0,6)	18	(0,4)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**368**	**(17,1)**	**392**	**(18,2)**	**760**	**(17,7)**
ERGOCALCIFEROL;PHYTOMENADIONE;RETINOL PALMITATE;TOCOPHEROL	0	(0,0)	1	(0,0)	1	(0,0)
ERGOCALCIFEROL;PHYTOMENADIONE;RETINOL;TOCOPHEROL	1	(0,0)	2	(0,1)	3	(0,1)
FLAVINE ADENINE DINUCLEOTIDE	0	(0,0)	1	(0,0)	1	(0,0)
FOLIC ACID;PYRIDOXINE;VITAMIN B12 NOS	0	(0,0)	1	(0,0)	1	(0,0)
FOLIC ACID;VITAMIN B COMPLEX	1	(0,0)	0	(0,0)	1	(0,0)
FURSULTIAMINE	2	(0,1)	2	(0,1)	4	(0,1)
FURSULTIAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
FURSULTIAMINE;RIBOFLAVIN	2	(0,1)	1	(0,0)	3	(0,1)
HYDROXOCOBALAMIN ACETATE;PYRIDOXINE HYDROCHLORIDE;THIAMINE DISULFIDE	2	(0,1)	2	(0,1)	4	(0,1)
HYDROXOCOBALAMIN;LIDOCAINE HYDROCHLORIDE;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
MAGNESIUM GLYCINATE;PYRIDOXINE HYDROCHLORIDE	1	(0,0)	4	(0,2)	5	(0,1)
MAGNESIUM LACTATE;PYRIDOXINE HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
MINERALS NOS;VITAMINS NOS	4	(0,2)	10	(0,5)	14	(0,3)
MINERALS NOS;VITAMINS NOS;XANTOFYL	1	(0,0)	0	(0,0)	1	(0,0)
NICOTINAMIDE	0	(0,0)	3	(0,1)	3	(0,1)
NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	2	(0,1)	0	(0,0)	2	(0,0)
NICOTINIC ACID	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ALIMENTARY TRACT AND METABOLISM						
VITAMINS	**368**	**(17,1)**	**392**	**(18,2)**	**760**	**(17,7)**
PANTETHINE	4	(0,2)	0	(0,0)	4	(0,1)
PROBIOTICS NOS;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)
PROSULTIAMINE	1	(0,0)	0	(0,0)	1	(0,0)
PYRIDOXINE	11	(0,5)	16	(0,7)	27	(0,6)
PYRIDOXINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	3	(0,1)	1	(0,0)	4	(0,1)
PYRIDOXINE HYDROCHLORIDE;THIOCTIC ACID;VITAMIN B1 NOS;VITAMIN B12 NOS	1	(0,0)	0	(0,0)	1	(0,0)
PYRIDOXINE;THIAMINE	1	(0,0)	0	(0,0)	1	(0,0)
RETINOL	1	(0,0)	1	(0,0)	2	(0,0)
RIBOFLAVIN	1	(0,0)	2	(0,1)	3	(0,1)
SHARK-LIVER OIL	0	(0,0)	1	(0,0)	1	(0,0)
THIAMINE	44	(2,0)	48	(2,2)	92	(2,1)
THIAMINE HYDROCHLORIDE	5	(0,2)	6	(0,3)	11	(0,3)
THIAMINE MONONITRATE	1	(0,0)	2	(0,1)	3	(0,1)
TOCOPHEROL	3	(0,1)	8	(0,4)	11	(0,3)
TOCOPHERYL ACETATE	2	(0,1)	2	(0,1)	4	(0,1)
VITAMIN B COMPLEX	16	(0,7)	14	(0,7)	30	(0,7)
VITAMIN B NOS	6	(0,3)	5	(0,2)	11	(0,3)
VITAMIN D NOS	49	(2,3)	54	(2,5)	103	(2,4)
VITAMINS NOS	51	(2,4)	53	(2,5)	104	(2,4)
VITAMINS, OTHER COMBINATIONS	1	(0,0)	1	(0,0)	2	(0,0)
OTHER	**1**	**(0,0)**	**0**	**(0,0)**	**1**	**(0,0)**
ACORUS CALAMUS RHIZOME;MENTHA X PIPERITA LEAF;RHAMNUS FRANGULA BARK;URTICA DIOICA LEAF;VALERIANA OFFICINALIS ROOT WITH RHIZOME	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIBACTERIALS FOR SYSTEMIC USE	**838**	**(38,9)**	**846**	**(39,3)**	**1.684**	**(39,1)**
AKRITOIN	2	(0,1)	6	(0,3)	8	(0,2)
AKRITOIN POTASSIUM	0	(0,0)	2	(0,1)	2	(0,0)
ALLIUM SATIVUM	1	(0,0)	3	(0,1)	4	(0,1)
AMIKACIN	2	(0,1)	5	(0,2)	7	(0,2)
AMIKACIN SULFATE	1	(0,0)	3	(0,1)	4	(0,1)
AMOXICILLIN	87	(4,0)	97	(4,5)	184	(4,3)
AMOXICILLIN SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM	3	(0,1)	3	(0,1)	6	(0,1)
AMOXICILLIN SODIUM;SULBACTAM SODIUM	2	(0,1)	0	(0,0)	2	(0,0)
AMOXICILLIN TRIHYDRATE	12	(0,6)	5	(0,2)	17	(0,4)
AMOXICILLIN TRIHYDRATE;BROMHEXINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	41	(1,9)	45	(2,1)	86	(2,0)
AMOXICILLIN;CLAVULANATE POTASSIUM	140	(6,5)	124	(5,8)	264	(6,1)
AMOXICILLIN;CLAVULANIC ACID	7	(0,3)	5	(0,2)	12	(0,3)
AMPICILLIN	11	(0,5)	9	(0,4)	20	(0,5)
AMPICILLIN SODIUM	3	(0,1)	3	(0,1)	6	(0,1)
AMPICILLIN SODIUM;SULBACTAM SODIUM	46	(2,1)	47	(2,2)	93	(2,2)
AMPICILLIN;SULBACTAM	1	(0,0)	1	(0,0)	2	(0,0)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
ANIMAL HORN NOS;BEAR BILE;FORSYTHIA SUSPENSA FRUIT;LONICERA JAPONICA FLOWER;SCUTELLARIA BAICALENSIS ROOT	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIBACTERIALS FOR SYSTEMIC USE	**838**	**(38,9)**	**846**	**(39,3)**	**1.684**	**(39,1)**
ANTIBACTERIALS FOR SYSTEMIC USE	7	(0,3)	5	(0,2)	12	(0,3)
ARTEMISIA ARGYI LEAF	4	(0,2)	4	(0,2)	8	(0,2)
AZITHROMYCIN	76	(3,5)	76	(3,5)	152	(3,5)
AZTREONAM	2	(0,1)	5	(0,2)	7	(0,2)
BACITRACIN	2	(0,1)	5	(0,2)	7	(0,2)
BENZYLPENICILLIN	9	(0,4)	8	(0,4)	17	(0,4)
BENZYLPENICILLIN POTASSIUM	1	(0,0)	1	(0,0)	2	(0,0)
BENZYLPENICILLIN SODIUM	0	(0,0)	5	(0,2)	5	(0,1)
BIAPENEM	0	(0,0)	1	(0,0)	1	(0,0)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
CEFACLOR	7	(0,3)	9	(0,4)	16	(0,4)
CEFADROXIL	4	(0,2)	6	(0,3)	10	(0,2)
CEFALEXIN	53	(2,5)	42	(2,0)	95	(2,2)
CEFALEXIN MONOHYDRATE	8	(0,4)	4	(0,2)	12	(0,3)
CEFALOTIN SODIUM	2	(0,1)	0	(0,0)	2	(0,0)
CEFAMANDOLE NAFATE	0	(0,0)	1	(0,0)	1	(0,0)
CEFAZEDONE	0	(0,0)	1	(0,0)	1	(0,0)
CEFAZOLIN	57	(2,6)	62	(2,9)	119	(2,8)
CEFAZOLIN SODIUM	42	(2,0)	58	(2,7)	100	(2,3)
CEFAZOLIN SODIUM PENTAHYDRATE	1	(0,0)	2	(0,1)	3	(0,1)
CEFAZOLIN SODIUM;GLUCOSE	0	(0,0)	1	(0,0)	1	(0,0)
CEFBUPERAZONE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
CEFCAPENE PIVOXIL HYDROCHLORIDE	10	(0,5)	8	(0,4)	18	(0,4)
CEFDINIR	12	(0,6)	12	(0,6)	24	(0,6)
CEFDITOREN	0	(0,0)	1	(0,0)	1	(0,0)
CEFDITOREN PIVOXIL	5	(0,2)	9	(0,4)	14	(0,3)
CEFEPIME	11	(0,5)	13	(0,6)	24	(0,6)
CEFEPIME HYDROCHLORIDE	7	(0,3)	8	(0,4)	15	(0,3)
CEFETAMET PIVOXIL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIBACTERIALS FOR SYSTEMIC USE	**838**	**(38,9)**	**846**	**(39,3)**	**1.684**	**(39,1)**
CEFIXIME	8	(0,4)	20	(0,9)	28	(0,7)
CEFMENOXIME HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CEFMETAZOLE SODIUM	1	(0,0)	10	(0,5)	11	(0,3)
CEFMINOX SODIUM	4	(0,2)	1	(0,0)	5	(0,1)
CEFODIZIME DISODIUM	2	(0,1)	1	(0,0)	3	(0,1)
CEFONICID SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
CEFOPERAZONE	1	(0,0)	0	(0,0)	1	(0,0)
CEFOPERAZONE SODIUM	2	(0,1)	0	(0,0)	2	(0,0)
CEFOPERAZONE SODIUM;SULBACTAM SODIUM	7	(0,3)	9	(0,4)	16	(0,4)
CEFOTAXIME SODIUM	16	(0,7)	14	(0,7)	30	(0,7)
CEFOTAXIME SODIUM;SULBACTAM SODIUM	1	(0,0)	2	(0,1)	3	(0,1)
CEFOTIAM	1	(0,0)	0	(0,0)	1	(0,0)
CEFOTIAM HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CEFOXITIN	1	(0,0)	0	(0,0)	1	(0,0)
CEFOXITIN SODIUM	2	(0,1)	3	(0,1)	5	(0,1)
CEFPIROME	0	(0,0)	1	(0,0)	1	(0,0)
CEFPODOXIME PROXETIL	7	(0,3)	6	(0,3)	13	(0,3)
CEFPROZIL	2	(0,1)	3	(0,1)	5	(0,1)
CEFRADINE	2	(0,1)	1	(0,0)	3	(0,1)
CEFTAROLINE FOSAMIL ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
CEFTAZIDIME	8	(0,4)	19	(0,9)	27	(0,6)
CEFTAZIDIME PENTAHYDRATE	0	(0,0)	1	(0,0)	1	(0,0)
CEFTIBUTEN	1	(0,0)	0	(0,0)	1	(0,0)
CEFTIZOXIME SODIUM	7	(0,3)	3	(0,1)	10	(0,2)
CEFTOLOZANE SULFATE;TAZOBACTAM SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
CEFTRIAXONE	89	(4,1)	89	(4,1)	178	(4,1)
CEFTRIAXONE SODIUM	80	(3,7)	89	(4,1)	169	(3,9)
CEFTRIAXONE SODIUM SESQUATERHYDRATE	1	(0,0)	1	(0,0)	2	(0,0)

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(Incidence > 0% in One or More Treatment Groups)
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIBACTERIALS FOR SYSTEMIC USE	**838**	**(38,9)**	**846**	**(39,3)**	**1.684**	**(39,1)**
CEFTRIAXONE SODIUM SESQUATERHYDRATE;LIDOCAINE HYDROCHLORIDE	3	(0,1)	0	(0,0)	3	(0,1)
CEFTRIAXONE SODIUM;SULBACTAM SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
CEFUROXIME	43	(2,0)	42	(2,0)	85	(2,0)
CEFUROXIME AXETIL	27	(1,3)	28	(1,3)	55	(1,3)
CEFUROXIME SODIUM	19	(0,9)	14	(0,7)	33	(0,8)
CHLORAMPHENICOL	11	(0,5)	10	(0,5)	21	(0,5)
CHLORTETRACYCLINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
CILASTATIN SODIUM;IMIPENEM	7	(0,3)	6	(0,3)	13	(0,3)
CIPROFLOXACIN	79	(3,7)	92	(4,3)	171	(4,0)
CIPROFLOXACIN HYDROCHLORIDE	14	(0,7)	10	(0,5)	24	(0,6)
CIPROFLOXACIN LACTATE	0	(0,0)	3	(0,1)	3	(0,1)
CLARITHROMYCIN	43	(2,0)	46	(2,1)	89	(2,1)
CLARITHROMYCIN LACTOBIONATE	3	(0,1)	3	(0,1)	6	(0,1)
CLAVULANATE POTASSIUM	1	(0,0)	0	(0,0)	1	(0,0)
CLAVULANATE POTASSIUM;TICARCILLIN DISODIUM	0	(0,0)	1	(0,0)	1	(0,0)
CLAVULANIC ACID	20	(0,9)	23	(1,1)	43	(1,0)
CLINDAMYCIN	26	(1,2)	35	(1,6)	61	(1,4)
CLINDAMYCIN HYDROCHLORIDE	13	(0,6)	6	(0,3)	19	(0,4)
CLINDAMYCIN PHOSPHATE	2	(0,1)	4	(0,2)	6	(0,1)
CLOXACILLIN	14	(0,7)	10	(0,5)	24	(0,6)
CLOXACILLIN SODIUM	4	(0,2)	3	(0,1)	7	(0,2)
COLISTIMETHATE SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
COLISTIN	2	(0,1)	1	(0,0)	3	(0,1)
COLLAGEN;GENTAMICIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
DAPTOMYCIN	6	(0,3)	6	(0,3)	12	(0,3)
DICLOXACILLIN	4	(0,2)	5	(0,2)	9	(0,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIBACTERIALS FOR SYSTEMIC USE	**838**	**(38,9)**	**846**	**(39,3)**	**1.684**	**(39,1)**
DICLOXACILLIN SODIUM MONOHYDRATE	3	(0,1)	2	(0,1)	5	(0,1)
DIRITHROMYCIN	0	(0,0)	1	(0,0)	1	(0,0)
DORIPENEM	0	(0,0)	2	(0,1)	2	(0,0)
DOXYCYCLINE	36	(1,7)	37	(1,7)	73	(1,7)
DOXYCYCLINE HYCLATE	4	(0,2)	9	(0,4)	13	(0,3)
DOXYCYCLINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ERIOBOTRYA JAPONICA	0	(0,0)	2	(0,1)	2	(0,0)
ERTAPENEM SODIUM	8	(0,4)	13	(0,6)	21	(0,5)
ERYTHROMYCIN	4	(0,2)	5	(0,2)	9	(0,2)
ERYTHROMYCIN ETHYLSUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
ETIMICIN SULFATE	2	(0,1)	1	(0,0)	3	(0,1)
FAROPENEM SODIUM	3	(0,1)	0	(0,0)	3	(0,1)
FLOMOXEF	1	(0,0)	1	(0,0)	2	(0,0)
FLOMOXEF SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
FLUCLOXACILLIN	16	(0,7)	12	(0,6)	28	(0,7)
FLUCLOXACILLIN SODIUM	2	(0,1)	6	(0,3)	8	(0,2)
FOSFOMYCIN	3	(0,1)	5	(0,2)	8	(0,2)
FOSFOMYCIN CALCIUM	0	(0,0)	1	(0,0)	1	(0,0)
FOSFOMYCIN SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
FOSFOMYCIN TROMETAMOL	2	(0,1)	7	(0,3)	9	(0,2)
FUSIDATE SODIUM	3	(0,1)	5	(0,2)	8	(0,2)
FUSIDIC ACID	7	(0,3)	8	(0,4)	15	(0,3)
GARENOXACIN MESILATE	2	(0,1)	2	(0,1)	4	(0,1)
GATIFLOXACIN	2	(0,1)	2	(0,1)	4	(0,1)
GEMIFLOXACIN MESILATE	2	(0,1)	3	(0,1)	5	(0,1)
GENTAMICIN	17	(0,8)	15	(0,7)	32	(0,7)
GENTAMICIN SULFATE	10	(0,5)	12	(0,6)	22	(0,5)
GLUCOSE;LEVOFLOXACIN	0	(0,0)	1	(0,0)	1	(0,0)
HOUTTUYNIA CORDATA	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIBACTERIALS FOR SYSTEMIC USE	**838**	**(38,9)**	**846**	**(39,3)**	**1.684**	**(39,1)**
HYOSCYAMINE SULFATE;METHENAMINE;METHYL THIONINIUM CHLORIDE;PHENYL SALICYLATE;SODIUM PHOSPHATE MONOBASIC (DIHYDRATE)	0	(0,0)	1	(0,0)	1	(0,0)
IMIPENEM	5	(0,2)	1	(0,0)	6	(0,1)
ISEPAMICIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
LATAMOXEF SODIUM	2	(0,1)	2	(0,1)	4	(0,1)
LEVOFLOXACIN	95	(4,4)	99	(4,6)	194	(4,5)
LEVOFLOXACIN HEMIHYDRATE	8	(0,4)	2	(0,1)	10	(0,2)
LEVOFLOXACIN HYDROCHLORIDE	4	(0,2)	1	(0,0)	5	(0,1)
LEVOFLOXACIN HYDROCHLORIDE;SODIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
LEVOFLOXACIN LACTATE;SODIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
LEVOFLOXACIN;SODIUM CHLORIDE	3	(0,1)	2	(0,1)	5	(0,1)
LINEZOLID	16	(0,7)	9	(0,4)	25	(0,6)
LINUM USITATISSIMUM	1	(0,0)	0	(0,0)	1	(0,0)
LINUM USITATISSIMUM SEED	0	(0,0)	1	(0,0)	1	(0,0)
LOMEFLOXACIN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
LYMECYCLINE	1	(0,0)	0	(0,0)	1	(0,0)
MECILLINAM	0	(0,0)	1	(0,0)	1	(0,0)
MEROPENEM	28	(1,3)	44	(2,0)	72	(1,7)
MEROPENEM TRIHYDRATE	8	(0,4)	10	(0,5)	18	(0,4)
METHENAMINE ANHYDROMETHYLENECITRATE	0	(0,0)	1	(0,0)	1	(0,0)
METHENAMINE HIPPURATE	0	(0,0)	3	(0,1)	3	(0,1)
METRONIDAZOLE	58	(2,7)	39	(1,8)	97	(2,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIBACTERIALS FOR SYSTEMIC USE	**838**	**(38,9)**	**846**	**(39,3)**	**1.684**	**(39,1)**
MEZLOCILLIN SODIUM;SULBACTAM SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
MINOCYCLINE	1	(0,0)	3	(0,1)	4	(0,1)
MINOCYCLINE HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
MOXIFLOXACIN	17	(0,8)	10	(0,5)	27	(0,6)
MOXIFLOXACIN HYDROCHLORIDE	48	(2,2)	30	(1,4)	78	(1,8)
NEOMYCIN	4	(0,2)	2	(0,1)	6	(0,1)
NITROFURANTOIN	8	(0,4)	9	(0,4)	17	(0,4)
NITROXOLINE	1	(0,0)	0	(0,0)	1	(0,0)
NORFLOXACIN	4	(0,2)	3	(0,1)	7	(0,2)
OFLOXACIN	15	(0,7)	12	(0,6)	27	(0,6)
ORNIDAZOLE	0	(0,0)	2	(0,1)	2	(0,0)
ORNIDAZOLE;SODIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
OXACILLIN SODIUM	2	(0,1)	5	(0,2)	7	(0,2)
PAZUFLOXACIN MESILATE	0	(0,0)	1	(0,0)	1	(0,0)
PENICILLIN NOS	6	(0,3)	6	(0,3)	12	(0,3)
PHENOXYMETHYLPENICILLIN	4	(0,2)	4	(0,2)	8	(0,2)
PHENOXYMETHYLPENICILLIN POTASSIUM	4	(0,2)	4	(0,2)	8	(0,2)
PIPERACILLIN	17	(0,8)	20	(0,9)	37	(0,9)
PIPERACILLIN SODIUM	4	(0,2)	3	(0,1)	7	(0,2)
PIPERACILLIN SODIUM;SULBACTAM SODIUM	0	(0,0)	3	(0,1)	3	(0,1)
PIPERACILLIN SODIUM;TAZOBACTAM	1	(0,0)	2	(0,1)	3	(0,1)
PIPERACILLIN SODIUM;TAZOBACTAM SODIUM	102	(4,7)	100	(4,6)	202	(4,7)
PIVMECILLINAM	3	(0,1)	1	(0,0)	4	(0,1)
PLATYCODON GRANDIFLORUS	5	(0,2)	4	(0,2)	9	(0,2)
POLYMYXIN	0	(0,0)	2	(0,1)	2	(0,0)
POLYMYXIN B SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
PRISTINAMYCIN	1	(0,0)	1	(0,0)	2	(0,0)
PROCAINE BENZYLPENICILLIN	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIBACTERIALS FOR SYSTEMIC USE	**838**	**(38,9)**	**846**	**(39,3)**	**1.684**	**(39,1)**
PRULIFLOXACIN	1	(0,0)	0	(0,0)	1	(0,0)
ROXITHROMYCIN	17	(0,8)	18	(0,8)	35	(0,8)
SITAFLOXACIN	0	(0,0)	1	(0,0)	1	(0,0)
SODIUM CHLORIDE;VANCOMYCIN HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
SPIRAMYCIN ACETYLATE	0	(0,0)	1	(0,0)	1	(0,0)
SULBACTAM	2	(0,1)	4	(0,2)	6	(0,1)
SULBACTAM SODIUM	2	(0,1)	1	(0,0)	3	(0,1)
SULBENICILLIN SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
SULFADIAZINE SILVER	7	(0,3)	4	(0,2)	11	(0,3)
SULFAMETHOXAZOLE	9	(0,4)	10	(0,5)	19	(0,4)
SULFAMETHOXAZOLE SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
SULFAMETHOXAZOLE;TRIMETHOPRIM	23	(1,1)	22	(1,0)	45	(1,0)
SULFATHIAZOLE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
SULTAMICILLIN	4	(0,2)	4	(0,2)	8	(0,2)
SULTAMICILLIN TOSILATE	2	(0,1)	3	(0,1)	5	(0,1)
TAZOBACTAM	11	(0,5)	16	(0,7)	27	(0,6)
TAZOBACTAM SODIUM	2	(0,1)	1	(0,0)	3	(0,1)
TEICOPLANIN	10	(0,5)	6	(0,3)	16	(0,4)
TETRACYCLINE	2	(0,1)	3	(0,1)	5	(0,1)
TETRACYCLINE HYDROCHLORIDE	4	(0,2)	3	(0,1)	7	(0,2)
TIGECYCLINE	3	(0,1)	3	(0,1)	6	(0,1)
TINIDAZOLE	0	(0,0)	1	(0,0)	1	(0,0)
TOBRAMYCIN	6	(0,3)	3	(0,1)	9	(0,2)
TOBRAMYCIN SULFATE	0	(0,0)	2	(0,1)	2	(0,0)
TOSUFLOXACIN TOSILATE	1	(0,0)	0	(0,0)	1	(0,0)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
TRIMETHOPRIM	6	(0,3)	8	(0,4)	14	(0,3)
VACCINIUM MACROCARPON	0	(0,0)	2	(0,1)	2	(0,0)
VANCOMYCIN	58	(2,7)	60	(2,8)	118	(2,7)
VANCOMYCIN HYDROCHLORIDE	14	(0,7)	18	(0,8)	32	(0,7)
ANTIMYCOBACTERIALS	**8**	**(0,4)**	**8**	**(0,4)**	**16**	**(0,4)**

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIMYCOBACTERIALS	**8**	**(0,4)**	**8**	**(0,4)**	**16**	**(0,4)**
ETHAMBUTOL	1	(0,0)	0	(0,0)	1	(0,0)
ETHAMBUTOL DIHYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
ETHAMBUTOL DIHYDROCHLORIDE;ISONIAZID;PYRAZINAMIDE;RIFAMPICIN	0	(0,0)	1	(0,0)	1	(0,0)
ISONIAZID	3	(0,1)	0	(0,0)	3	(0,1)
ISONIAZID;RIFAMPICIN	0	(0,0)	1	(0,0)	1	(0,0)
PYRAZINAMIDE	3	(0,1)	0	(0,0)	3	(0,1)
RIFAMPICIN	6	(0,3)	6	(0,3)	12	(0,3)
RIFAMYCIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
ANTIMYCOTICS FOR SYSTEMIC USE	**49**	**(2,3)**	**44**	**(2,0)**	**93**	**(2,2)**
AMPHOTERICIN B	2	(0,1)	1	(0,0)	3	(0,1)
AMPHOTERICIN B, LIPOSOME	1	(0,0)	0	(0,0)	1	(0,0)
ANIDULAFUNGIN	2	(0,1)	2	(0,1)	4	(0,1)
CASPOFUNGIN ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
FLUCONAZOLE	14	(0,7)	15	(0,7)	29	(0,7)
FLUCONAZOLE;SODIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
FOSFLUCONAZOLE	1	(0,0)	0	(0,0)	1	(0,0)
ITRACONAZOLE	1	(0,0)	1	(0,0)	2	(0,0)
KETOCONAZOLE	5	(0,2)	4	(0,2)	9	(0,2)
MICAFUNGIN	1	(0,0)	2	(0,1)	3	(0,1)
MICAFUNGIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
MICONAZOLE	6	(0,3)	4	(0,2)	10	(0,2)
MICONAZOLE NITRATE	6	(0,3)	3	(0,1)	9	(0,2)
NYSTATIN	17	(0,8)	15	(0,7)	32	(0,7)
VORICONAZOLE	0	(0,0)	1	(0,0)	1	(0,0)
ANTIVIRALS FOR SYSTEMIC USE	**79**	**(3,7)**	**73**	**(3,4)**	**152**	**(3,5)**
ABACAVIR SULFATE;DOLUTEGRAVIR SODIUM;LAMIVUDINE	0	(0,0)	2	(0,1)	2	(0,0)
ACICLOVIR	9	(0,4)	8	(0,4)	17	(0,4)
AMANTADINE	1	(0,0)	0	(0,0)	1	(0,0)

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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIVIRALS FOR SYSTEMIC USE	**79**	**(3,7)**	**73**	**(3,4)**	**152**	**(3,5)**
AMANTADINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
AMENAMEVIR	2	(0,1)	0	(0,0)	2	(0,0)
ATAZANAVIR SULFATE;RITONAVIR	0	(0,0)	1	(0,0)	1	(0,0)
BALOXAVIR MARBOXIL	0	(0,0)	1	(0,0)	1	(0,0)
BICTEGRAVIR SODIUM;EMTRICITABINE;TENOFOVIR ALAFENAMIDE FUMARATE	0	(0,0)	1	(0,0)	1	(0,0)
BRIVUDINE	2	(0,1)	0	(0,0)	2	(0,0)
DARUNAVIR	0	(0,0)	1	(0,0)	1	(0,0)
DARUNAVIR ETHANOLATE	0	(0,0)	1	(0,0)	1	(0,0)
DEHYDROANDROGRAPHOLIDE SUCCINATE POTASSIUM SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
EFAVIRENZ	1	(0,0)	1	(0,0)	2	(0,0)
EFAVIRENZ;EMTRICITABINE;TENOFOVIR DISOPROXIL FUMARATE	3	(0,1)	6	(0,3)	9	(0,2)
EMTRICITABINE	0	(0,0)	2	(0,1)	2	(0,0)
EMTRICITABINE;RILPIVIRINE HYDROCHLORIDE;TENOFOVIR ALAFENAMIDE FUMARATE	0	(0,0)	1	(0,0)	1	(0,0)
ENISAMIUM IODIDE	0	(0,0)	1	(0,0)	1	(0,0)
ENTECAVIR	5	(0,2)	1	(0,0)	6	(0,1)
ERIOBOTRYA JAPONICA	0	(0,0)	2	(0,1)	2	(0,0)
FAMCICLOVIR	0	(0,0)	1	(0,0)	1	(0,0)
GANCICLOVIR	2	(0,1)	1	(0,0)	3	(0,1)
GANCICLOVIR SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
IMIDAZOLYL ETHANAMIDE PENTANDIOIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
INOSINE PRANOBEX	3	(0,1)	0	(0,0)	3	(0,1)
KAGOCEL	1	(0,0)	0	(0,0)	1	(0,0)
LAMIVUDINE	0	(0,0)	1	(0,0)	1	(0,0)
LANINAMIVIR OCTANOATE	1	(0,0)	1	(0,0)	2	(0,0)
LEDIPASVIR;SOFOSBUVIR	0	(0,0)	1	(0,0)	1	(0,0)
LOPINAVIR	0	(0,0)	1	(0,0)	1	(0,0)
LYSOZYME CHLORIDE	6	(0,3)	0	(0,0)	6	(0,1)

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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
ANTIVIRALS FOR SYSTEMIC USE	**79**	**(3,7)**	**73**	**(3,4)**	**152**	**(3,5)**
OSELTAMIVIR	7	(0,3)	10	(0,5)	17	(0,4)
OSELTAMIVIR PHOSPHATE	31	(1,4)	18	(0,8)	49	(1,1)
PERAMIVIR	0	(0,0)	1	(0,0)	1	(0,0)
RALTEGRAVIR	0	(0,0)	1	(0,0)	1	(0,0)
RITONAVIR	0	(0,0)	2	(0,1)	2	(0,0)
TENOFOVIR	0	(0,0)	2	(0,1)	2	(0,0)
TENOFOVIR DISOPROXIL FUMARATE	0	(0,0)	1	(0,0)	1	(0,0)
THYMALFASIN	0	(0,0)	2	(0,1)	2	(0,0)
TILORONE	1	(0,0)	0	(0,0)	1	(0,0)
VALACICLOVIR HYDROCHLORIDE	9	(0,4)	7	(0,3)	16	(0,4)
VALGANCICLOVIR HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
VIDARABINE	1	(0,0)	0	(0,0)	1	(0,0)
ZIDOVUDINE	1	(0,0)	0	(0,0)	1	(0,0)
IMMUNE SERA AND IMMUNOGLOBULINS	**2**	**(0,1)**	**5**	**(0,2)**	**7**	**(0,2)**
IMMUNOGLOBULIN G HUMAN	1	(0,0)	1	(0,0)	2	(0,0)
IMMUNOGLOBULIN HUMAN NORMAL	1	(0,0)	1	(0,0)	2	(0,0)
SNAKE VENOM ANTISERUM	0	(0,0)	1	(0,0)	1	(0,0)
TETANUS ANTITOXIN	0	(0,0)	2	(0,1)	2	(0,0)
VACCINES	**75**	**(3,5)**	**58**	**(2,7)**	**133**	**(3,1)**
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID	1	(0,0)	1	(0,0)	2	(0,0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIINFECTIVES FOR SYSTEMIC USE						
VACCINES	**75**	**(3,5)**	**58**	**(2,7)**	**133**	**(3,1)**
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE;TETANUS VACCINE TOXOID	0	(0,0)	1	(0,0)	1	(0,0)
DIPHTHERIA VACCINE TOXOID;TETANUS VACCINE TOXOID	2	(0,1)	0	(0,0)	2	(0,0)
HEPATITIS B VACCINE	1	(0,0)	0	(0,0)	1	(0,0)
HEPATITIS B VACCINE RHBSAG (YEAST)	2	(0,1)	2	(0,1)	4	(0,1)
INFLUENZA A(H1N1)PDM09 VACCINE INACT SPLIT VIRION	2	(0,1)	2	(0,1)	4	(0,1)
INFLUENZA VACCINE	34	(1,6)	21	(1,0)	55	(1,3)
INFLUENZA VACCINE INACT	6	(0,3)	5	(0,2)	11	(0,3)
INFLUENZA VACCINE INACT SAG 3V	1	(0,0)	1	(0,0)	2	(0,0)
INFLUENZA VACCINE INACT SAG 4V	3	(0,1)	2	(0,1)	5	(0,1)
INFLUENZA VACCINE INACT SPLIT VIRION 3V	3	(0,1)	5	(0,2)	8	(0,2)
INFLUENZA VACCINE INACT SPLIT VIRION 4V	15	(0,7)	10	(0,5)	25	(0,6)
PNEUMOCOCCAL VACCINE	6	(0,3)	4	(0,2)	10	(0,2)
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197)	8	(0,4)	5	(0,2)	13	(0,3)
PNEUMOCOCCAL VACCINE CONJ 7V (CRM197)	1	(0,0)	1	(0,0)	2	(0,0)
PNEUMOCOCCAL VACCINE POLYSACCH 23V	13	(0,6)	7	(0,3)	20	(0,5)
TETANUS VACCINE TOXOID	2	(0,1)	7	(0,3)	9	(0,2)
TICK-BORNE ENCEPHALITIS VACCINE INACT (K23)	1	(0,0)	0	(0,0)	1	(0,0)
OTHER	**1**	**(0,0)**	**0**	**(0,0)**	**1**	**(0,0)**
ANDROGRAPHOLIDE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS						
ANTINEOPLASTIC AGENTS	**88**	**(4,1)**	**103**	**(4,8)**	**191**	**(4,4)**
AFLIBERCEPT	2	(0,1)	1	(0,0)	3	(0,1)
BEVACIZUMAB	9	(0,4)	1	(0,0)	10	(0,2)
BORTEZOMIB	0	(0,0)	2	(0,1)	2	(0,0)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
CARBOPLATIN	1	(0,0)	3	(0,1)	4	(0,1)
CELECOXIB	15	(0,7)	18	(0,8)	33	(0,8)
CETUXIMAB	1	(0,0)	0	(0,0)	1	(0,0)
CHLORAMBUCIL	0	(0,0)	1	(0,0)	1	(0,0)
CISPLATIN	1	(0,0)	1	(0,0)	2	(0,0)
CLARITHROMYCIN	43	(2,0)	46	(2,1)	89	(2,1)
CLARITHROMYCIN LACTOBIONATE	3	(0,1)	3	(0,1)	6	(0,1)
CYCLOPHOSPHAMIDE	3	(0,1)	2	(0,1)	5	(0,1)
CYCLOPHOSPHAMIDE;DOXORUBICIN;PREDNISONE;RITUXIMAB;VINCRISTINE	0	(0,0)	1	(0,0)	1	(0,0)
DOCETAXEL	0	(0,0)	1	(0,0)	1	(0,0)
EPIRUBICIN	0	(0,0)	1	(0,0)	1	(0,0)
EPIRUBICIN HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ETOPOSIDE	0	(0,0)	1	(0,0)	1	(0,0)
EVEROLIMUS	1	(0,0)	1	(0,0)	2	(0,0)
FLUOROURACIL	1	(0,0)	1	(0,0)	2	(0,0)
FOLIC ACID ANALOGUES	1	(0,0)	0	(0,0)	1	(0,0)
GEMCITABINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
HYDRAZINE	1	(0,0)	0	(0,0)	1	(0,0)
HYDROXYCARBAMIDE	2	(0,1)	6	(0,3)	8	(0,2)
IMATINIB MESILATE	1	(0,0)	0	(0,0)	1	(0,0)
IRINOTECAN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
MELPHALAN	0	(0,0)	1	(0,0)	1	(0,0)
METHOTREXATE	2	(0,1)	7	(0,3)	9	(0,2)
METHOTREXATE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
MITOMYCIN	1	(0,0)	1	(0,0)	2	(0,0)
NIVOLUMAB	1	(0,0)	1	(0,0)	2	(0,0)
OXALIPLATIN	1	(0,0)	0	(0,0)	1	(0,0)
PACLITAXEL	1	(0,0)	3	(0,1)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS						
ANTINEOPLASTIC AGENTS	**88**	**(4,1)**	**103**	**(4,8)**	**191**	**(4,4)**
PACLITAXEL ALBUMIN	0	(0,0)	1	(0,0)	1	(0,0)
PEMBROLIZUMAB	0	(0,0)	1	(0,0)	1	(0,0)
PEMETREXED DISODIUM	0	(0,0)	1	(0,0)	1	(0,0)
PIRARUBICIN	1	(0,0)	0	(0,0)	1	(0,0)
POLYPEPTIDE	0	(0,0)	1	(0,0)	1	(0,0)
RITUXIMAB	0	(0,0)	1	(0,0)	1	(0,0)
RUXOLITINIB PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)
SENSITIZERS USED IN PHOTODYNAMIC/RADIATION THERAPY	0	(0,0)	1	(0,0)	1	(0,0)
TEGAFUR;URACIL	1	(0,0)	0	(0,0)	1	(0,0)
VISCUM ALBUM	1	(0,0)	0	(0,0)	1	(0,0)
VISCUM ALBUM EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
Z 100	1	(0,0)	0	(0,0)	1	(0,0)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
ENDOCRINE THERAPY	**23**	**(1,1)**	**31**	**(1,4)**	**54**	**(1,3)**
ANASTROZOLE	2	(0,1)	2	(0,1)	4	(0,1)
BICALUTAMIDE	5	(0,2)	6	(0,3)	11	(0,3)
DEGARELIX	0	(0,0)	1	(0,0)	1	(0,0)
ENZALUTAMIDE	0	(0,0)	1	(0,0)	1	(0,0)
ESTRADIOL	3	(0,1)	3	(0,1)	6	(0,1)
ESTROGENS CONJUGATED	1	(0,0)	3	(0,1)	4	(0,1)
EXEMESTANE	1	(0,0)	1	(0,0)	2	(0,0)
GOSERELIN	0	(0,0)	1	(0,0)	1	(0,0)
GOSERELIN ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
LETROZOLE	3	(0,1)	0	(0,0)	3	(0,1)
LEUPRORELIN	0	(0,0)	3	(0,1)	3	(0,1)
LEUPRORELIN ACETATE	0	(0,0)	2	(0,1)	2	(0,0)
MEDROXYPROGESTERONE ACETATE	0	(0,0)	3	(0,1)	3	(0,1)
MEGESTROL ACETATE	5	(0,2)	7	(0,3)	12	(0,3)
TAMOXIFEN	1	(0,0)	1	(0,0)	2	(0,0)
TAMOXIFEN CITRATE	1	(0,0)	0	(0,0)	1	(0,0)
TRIPTORELIN ACETATE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS						
IMMUNOSTIMULANTS	**29**	**(1,3)**	**32**	**(1,5)**	**61**	**(1,4)**
ANGELICA ACUTILOBA ROOT;ASTRAGALUS SPP. ROOT;ATRACTYLODES SPP. RHIZOME;BUPLEURUM FALCATUM ROOT;CIMICIFUGA SPP. RHIZOME;CITRUS RETICULATA PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;ZINGIBER OFFICINALE PROCESSED RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	2	(0,1)	2	(0,0)
ANGELICA SINENSIS ROOT;ASTRAGALUS PROPINQUUS ROOT;EPIMEDIUM BREVICORNU HERB;GELATIN;LESPEDEZA BUERGERI;SOPHORA FLAVESCENS ROOT;ZIZIPHUS JUJUBA FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
ASTRAGALUS PROPINQUUS	1	(0,0)	4	(0,2)	5	(0,1)
BCG VACCINE LIVE INTRAVESICAL (TOKYO 172)	1	(0,0)	0	(0,0)	1	(0,0)
FILGRASTIM	1	(0,0)	3	(0,1)	4	(0,1)
GANODERMA LUCIDUM	0	(0,0)	1	(0,0)	1	(0,0)
GLUTATHIONE	11	(0,5)	7	(0,3)	18	(0,4)
LENOGRASTIM	0	(0,0)	1	(0,0)	1	(0,0)
LEUCOGEN	3	(0,1)	3	(0,1)	6	(0,1)
OPHIOPOGON JAPONICUS ROOT TUBER;PANAX GINSENG	12	(0,6)	12	(0,6)	24	(0,6)
OPHIOPOGON JAPONICUS;PANAX GINSENG	1	(0,0)	1	(0,0)	2	(0,0)
OXIGLUTATIONE	2	(0,1)	0	(0,0)	2	(0,0)
PEGFILGRASTIM	0	(0,0)	1	(0,0)	1	(0,0)
POLYPEPTIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS						
IMMUNOSTIMULANTS	**29**	**(1,3)**	**32**	**(1,5)**	**61**	**(1,4)**
THYMALFASIN	0	(0,0)	2	(0,1)	2	(0,0)
THYMOPENTIN	1	(0,0)	0	(0,0)	1	(0,0)
IMMUNOSUPPRESSANTS	**15**	**(0,7)**	**26**	**(1,2)**	**41**	**(1,0)**
ABATACEPT	0	(0,0)	1	(0,0)	1	(0,0)
ADALIMUMAB	0	(0,0)	1	(0,0)	1	(0,0)
AZATHIOPRINE	5	(0,2)	2	(0,1)	7	(0,2)
BASILIXIMAB	1	(0,0)	1	(0,0)	2	(0,0)
CANAKINUMAB	0	(0,0)	1	(0,0)	1	(0,0)
CICLOSPORIN	1	(0,0)	4	(0,2)	5	(0,1)
EVEROLIMUS	1	(0,0)	1	(0,0)	2	(0,0)
HYDROXYCHLOROQUINE SULFATE	3	(0,1)	6	(0,3)	9	(0,2)
LEFLUNOMIDE	2	(0,1)	4	(0,2)	6	(0,1)
LENALIDOMIDE	1	(0,0)	0	(0,0)	1	(0,0)
METHOTREXATE	2	(0,1)	7	(0,3)	9	(0,2)
METHOTREXATE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
MYCOPHENOLATE MOFETIL	2	(0,1)	4	(0,2)	6	(0,1)
MYCOPHENOLATE SODIUM	2	(0,1)	1	(0,0)	3	(0,1)
SECUKINUMAB	1	(0,0)	0	(0,0)	1	(0,0)
SIROLIMUS	1	(0,0)	0	(0,0)	1	(0,0)
TACROLIMUS	2	(0,1)	5	(0,2)	7	(0,2)
USTEKINUMAB	0	(0,0)	1	(0,0)	1	(0,0)
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS						
ANTHELMINTICS	**2**	**(0,1)**	**8**	**(0,4)**	**10**	**(0,2)**
ALBENDAZOLE	0	(0,0)	2	(0,1)	2	(0,0)
IVERMECTIN	1	(0,0)	1	(0,0)	2	(0,0)
MEBENDAZOLE	0	(0,0)	1	(0,0)	1	(0,0)
PIPERAZINE FERULATE	0	(0,0)	2	(0,1)	2	(0,0)
PYRANTEL	1	(0,0)	0	(0,0)	1	(0,0)
PYRANTEL EMBONATE	0	(0,0)	1	(0,0)	1	(0,0)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
ANTIPROTOZOALS	**78**	**(3,6)**	**71**	**(3,3)**	**149**	**(3,5)**
CHLOROXINE	0	(0,0)	1	(0,0)	1	(0,0)
CLOTRIMAZOLE	2	(0,1)	7	(0,3)	9	(0,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS						
ANTIPROTOZOALS	**78**	**(3,6)**	**71**	**(3,3)**	**149**	**(3,5)**
HYDROXYCHLOROQUINE SULFATE	3	(0,1)	6	(0,3)	9	(0,2)
MEGLUMINE	0	(0,0)	1	(0,0)	1	(0,0)
METRONIDAZOLE	58	(2,7)	39	(1,8)	97	(2,3)
MICONAZOLE	6	(0,3)	4	(0,2)	10	(0,2)
MICONAZOLE NITRATE	6	(0,3)	3	(0,1)	9	(0,2)
NITAZOXANIDE	0	(0,0)	1	(0,0)	1	(0,0)
NITROFURAL	2	(0,1)	1	(0,0)	3	(0,1)
ORNIDAZOLE	0	(0,0)	2	(0,1)	2	(0,0)
QUINFAMIDE	0	(0,0)	1	(0,0)	1	(0,0)
QUININE	1	(0,0)	4	(0,2)	5	(0,1)
QUININE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
QUININE SULFATE	3	(0,1)	0	(0,0)	3	(0,1)
TECLOZAN	1	(0,0)	0	(0,0)	1	(0,0)
TINIDAZOLE	0	(0,0)	1	(0,0)	1	(0,0)
ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS	**21**	**(1,0)**	**31**	**(1,4)**	**52**	**(1,2)**
ACETIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
BENZYL BENZOATE	0	(0,0)	1	(0,0)	1	(0,0)
BUTYL PHTHALATE	0	(0,0)	1	(0,0)	1	(0,0)
CROTAMITON	6	(0,3)	6	(0,3)	12	(0,3)
DIMETHYL PHTHALATE	1	(0,0)	0	(0,0)	1	(0,0)
DIMETICONE	13	(0,6)	23	(1,1)	36	(0,8)
PELARGONIUM SIDOIDES	1	(0,0)	1	(0,0)	2	(0,0)
PERMETHRIN	2	(0,1)	0	(0,0)	2	(0,0)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
BLOOD AND BLOOD FORMING ORGANS						
ANTIANEMIC PREPARATIONS	**454**	**(21,1)**	**409**	**(19,0)**	**863**	**(20,1)**
ANIMAL FECES NOS;BOMBYX MORI	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
ANTIANEMIC PREPARATIONS	**454**	**(21,1)**	**409**	**(19,0)**	**863**	**(20,1)**
ASCORBIC ACID;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FERROUS SULFATE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;COPPER SULFATE;CYANOCOBALAMIN;FERROUS GLUCONATE;FOLIC ACID;MANGANESE SULFATE	1	(0,0)	1	(0,0)	2	(0,0)
ASCORBIC ACID;COPPER SULFATE;CYANOCOBALAMIN;FERROUS GLUCONATE;FOLIC ACID;MANGANESE SULFATE;SORBITOL	1	(0,0)	1	(0,0)	2	(0,0)
ASCORBIC ACID;CYANOCOBALAMIN;DOCUSATE SODIUM;FERROUS FUMARATE;FOLIC ACID;TOCOPHERYL ACID SUCCINATE	2	(0,1)	1	(0,0)	3	(0,1)
ASCORBIC ACID;CYANOCOBALAMIN;FERROUS BISGLYCINATE;FOLIC ACID	2	(0,1)	0	(0,0)	2	(0,0)
ASCORBIC ACID;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
ASCORBIC ACID;CYANOCOBALAMIN;FERROUS SULFATE;FOLIC ACID	2	(0,1)	2	(0,1)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
ANTIANEMIC PREPARATIONS	**454**	**(21,1)**	**409**	**(19,0)**	**863**	**(20,1)**
ASCORBIC ACID;CYANOCOBALAMIN;FERROUS SULFATE;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;CYANOCOBALAMIN;FOLIC ACID;IRON;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;FERRIC PYROPHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;FERROUS FUMARATE	2	(0,1)	1	(0,0)	3	(0,1)
ASCORBIC ACID;FERROUS GLUCONATE	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;FERROUS SULFATE	13	(0,6)	20	(0,9)	33	(0,8)
ASCORBIC ACID;FERROUS SULFATE;FOLIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
ASCORBIC ACID;FERROUS SULFATE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	2	(0,1)	4	(0,2)	6	(0,1)
CALCIUM FERROUS CITRATE	2	(0,1)	3	(0,1)	5	(0,1)
CALCIUM FOLINATE;IRON SUCCINYL-PROTEIN COMPLEX	0	(0,0)	1	(0,0)	1	(0,0)
CEPHARANTHINE	1	(0,0)	0	(0,0)	1	(0,0)
COBAMAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
CYANOCOBALAMIN	54	(2,5)	54	(2,5)	108	(2,5)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
ANTIANEMIC PREPARATIONS	**454**	**(21,1)**	**409**	**(19,0)**	**863**	**(20,1)**
CYANOCOBALAMIN;FERROUS GLYCINE SULFATE;FOLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
CYANOCOBALAMIN;FOLIC ACID;PYRIDOXINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
CYANOCOBALAMIN;NICOTINAMIDE;PHOSPHOLIPIDS;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE	2	(0,1)	1	(0,0)	3	(0,1)
DARBEPOETIN ALFA	26	(1,2)	18	(0,8)	44	(1,0)
DOXYLAMINE SUCCINATE;FOLIC ACID;PYRIDOXINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
EPOETIN ALFA	9	(0,4)	6	(0,3)	15	(0,3)
EPOETIN BETA	4	(0,2)	5	(0,2)	9	(0,2)
EPOETIN NOS	11	(0,5)	9	(0,4)	20	(0,5)
EPOETIN THETA	2	(0,1)	1	(0,0)	3	(0,1)
EPOETIN ZETA	3	(0,1)	1	(0,0)	4	(0,1)
FERRIC ACETYL TRANSFERRIN	0	(0,0)	1	(0,0)	1	(0,0)
FERRIC CARBOXYMALTOSE	43	(2,0)	36	(1,7)	79	(1,8)
FERRIC CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
FERRIC GLUCONATE TRIHYDRATE	0	(0,0)	1	(0,0)	1	(0,0)
FERRIC HYDROXIDE POLYMALTOSE	0	(0,0)	1	(0,0)	1	(0,0)
FERRIC HYDROXIDE POLYMALTOSE COMPLEX	8	(0,4)	12	(0,6)	20	(0,5)
FERRIC HYDROXIDE POLYMALTOSE COMPLEX;FOLIC ACID	3	(0,1)	2	(0,1)	5	(0,1)
FERRIC SODIUM GLUCONATE COMPLEX	5	(0,2)	5	(0,2)	10	(0,2)
FERRIC SULFATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
ANTIANEMIC PREPARATIONS	**454**	**(21,1)**	**409**	**(19,0)**	**863**	**(20,1)**
FERRIC SULFATE;MUCOPROTEOSE	1	(0,0)	1	(0,0)	2	(0,0)
FERRITIN	1	(0,0)	0	(0,0)	1	(0,0)
FERROUS BISGLYCINATE;FOLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
FERROUS CITRATE	0	(0,0)	1	(0,0)	1	(0,0)
FERROUS FUMARATE	27	(1,3)	12	(0,6)	39	(0,9)
FERROUS FUMARATE;FOLIC ACID	5	(0,2)	4	(0,2)	9	(0,2)
FERROUS GLUCONATE	15	(0,7)	8	(0,4)	23	(0,5)
FERROUS GLYCINE SULFATE	17	(0,8)	26	(1,2)	43	(1,0)
FERROUS GLYCINE SULFATE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN SODIUM PHOSPHATE;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
FERROUS SODIUM CITRATE	18	(0,8)	20	(0,9)	38	(0,9)
FERROUS SUCCINATE	4	(0,2)	3	(0,1)	7	(0,2)
FERROUS SULFATE	107	(5,0)	92	(4,3)	199	(4,6)
FERROUS SULFATE;FOLIC ACID	3	(0,1)	2	(0,1)	5	(0,1)
FERROUS SULFATE;FOLIC ACID;SERINE	1	(0,0)	0	(0,0)	1	(0,0)
FERROUS SULFATE;NICOTINAMIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
FERROUS SULFATE;SERINE	0	(0,0)	1	(0,0)	1	(0,0)
FLAVINE ADENINE DINUCLEOTIDE DISODIUM;LIVER EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
FOLIC ACID	93	(4,3)	93	(4,3)	186	(4,3)
FOLIC ACID;IRON	0	(0,0)	1	(0,0)	1	(0,0)
FOLIC ACID;SACCHARATED IRON OXIDE	0	(0,0)	3	(0,1)	3	(0,1)
HYDROXOCOBALAMIN	5	(0,2)	3	(0,1)	8	(0,2)
HYDROXOCOBALAMIN ACETATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
ANTIANEMIC PREPARATIONS	**454**	**(21,1)**	**409**	**(19,0)**	**863**	**(20,1)**
HYDROXOCOBALAMIN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
IRON	25	(1,2)	29	(1,3)	54	(1,3)
IRON DEXTRAN	1	(0,0)	3	(0,1)	4	(0,1)
IRON ISOMALTOSIDE 1000	5	(0,2)	2	(0,1)	7	(0,2)
IRON SUCCINYL-PROTEIN COMPLEX	1	(0,0)	2	(0,1)	3	(0,1)
LEVOGLUTAMIDE	2	(0,1)	0	(0,0)	2	(0,0)
LIVER HYDROLYSATE	0	(0,0)	1	(0,0)	1	(0,0)
MECOBALAMIN	23	(1,1)	11	(0,5)	34	(0,8)
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA	5	(0,2)	8	(0,4)	13	(0,3)
MINERALS NOS;VITAMINS NOS	4	(0,2)	10	(0,5)	14	(0,3)
POLYSACCHARIDE-IRON COMPLEX	4	(0,2)	4	(0,2)	8	(0,2)
RECOMBINANT HUMAN THROMBOPOIETIN	0	(0,0)	1	(0,0)	1	(0,0)
SACCHARATED IRON OXIDE	36	(1,7)	23	(1,1)	59	(1,4)
VITAMIN B NOS	6	(0,3)	5	(0,2)	11	(0,3)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
ANTIHEMORRHAGICS	**147**	**(6,8)**	**153**	**(7,1)**	**300**	**(7,0)**
AMINO ACIDS NOS	3	(0,1)	6	(0,3)	9	(0,2)
APROTININ;CALCIUM CHLORIDE;FACTOR I (FIBRINOGEN);THROMBIN	0	(0,0)	1	(0,0)	1	(0,0)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
CAMOSTAT MESILATE	2	(0,1)	1	(0,0)	3	(0,1)
CARBAZOCHROME SODIUM SULFONATE	4	(0,2)	12	(0,6)	16	(0,4)
COLLAGEN	2	(0,1)	2	(0,1)	4	(0,1)
CORDYCEPS SINENSIS	14	(0,7)	11	(0,5)	25	(0,6)
DESMOPRESSIN	2	(0,1)	3	(0,1)	5	(0,1)
DESMOPRESSIN ACETATE	4	(0,2)	2	(0,1)	6	(0,1)
EPINEPHRINE	52	(2,4)	53	(2,5)	105	(2,4)
EPINEPHRINE BITARTRATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
ANTIHEMORRHAGICS	**147**	**(6,8)**	**153**	**(7,1)**	**300**	**(7,0)**
EPINEPHRINE HYDROCHLORIDE	1	(0,0)	5	(0,2)	6	(0,1)
ERIOBOTRYA JAPONICA	0	(0,0)	2	(0,1)	2	(0,0)
ETAMSILATE	3	(0,1)	5	(0,2)	8	(0,2)
EUCOMMIA ULMOIDES	1	(0,0)	0	(0,0)	1	(0,0)
FACTOR I (FIBRINOGEN);THROMBIN	0	(0,0)	1	(0,0)	1	(0,0)
FACTOR II (PROTHROMBIN);FACTOR IX;FACTOR VII (PROCONVERTIN);FACTOR X (STUART PROWER FACTOR);PROTEIN C (COAGULATION INHIBITOR)	5	(0,2)	5	(0,2)	10	(0,2)
FACTOR II (PROTHROMBIN);FACTOR IX;FACTOR VII (PROCONVERTIN);FACTOR X (STUART PROWER FACTOR);PROTEIN C (COAGULATION INHIBITOR);PROTEIN S	1	(0,0)	3	(0,1)	4	(0,1)
GELATIN	2	(0,1)	0	(0,0)	2	(0,0)
HAEMOCOAGULASE	3	(0,1)	1	(0,0)	4	(0,1)
MENATETRENONE	3	(0,1)	4	(0,2)	7	(0,2)
METHYLETHYLPIRIDINOL	0	(0,0)	1	(0,0)	1	(0,0)
NAFAMOSTAT MESILATE	2	(0,1)	1	(0,0)	3	(0,1)
OXIDISED CELLULOSE	0	(0,0)	1	(0,0)	1	(0,0)
PANAX NOTOGINSENG	3	(0,1)	1	(0,0)	4	(0,1)
PHYTOMENADIONE	52	(2,4)	38	(1,8)	90	(2,1)
SODIUM CHLORIDE;TRANEXAMIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
THROMBIN	0	(0,0)	2	(0,1)	2	(0,0)
TRANEXAMIC ACID	25	(1,2)	24	(1,1)	49	(1,1)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
ULINASTATIN	3	(0,1)	2	(0,1)	5	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
ANTIHEMORRHAGICS	**147**	**(6,8)**	**153**	**(7,1)**	**300**	**(7,0)**
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
ANTITHROMBOTIC AGENTS	**1.940**	**(90,1)**	**1.945**	**(90,4)**	**3.885**	**(90,3)**
ACENOCOUMAROL	116	(5,4)	111	(5,2)	227	(5,3)
ACETYLSALICYLATE LYSINE	13	(0,6)	8	(0,4)	21	(0,5)
ACETYLSALICYLIC ACID	1.060	(49,3)	1.015	(47,2)	2.075	(48,2)
ACETYLSALICYLIC ACID;ALUMINIUM GLYCINATE;MAGNESIUM CARBONATE	2	(0,1)	2	(0,1)	4	(0,1)
ACETYLSALICYLIC ACID;CLOPIDOGREL BISULFATE	6	(0,3)	6	(0,3)	12	(0,3)
ACETYLSALICYLIC ACID;GLYCINE	18	(0,8)	15	(0,7)	33	(0,8)
ACETYLSALICYLIC ACID;LANSOPRAZOLE	3	(0,1)	7	(0,3)	10	(0,2)
ACETYLSALICYLIC ACID;MAGNESIUM HYDROXIDE	13	(0,6)	13	(0,6)	26	(0,6)
ACETYLSALICYLIC ACID;MAGNESIUM OXIDE	1	(0,0)	3	(0,1)	4	(0,1)
ALPROSTADIL	8	(0,4)	13	(0,6)	21	(0,5)
ALPROSTADIL ALFADEX	2	(0,1)	0	(0,0)	2	(0,0)
ALTEPLASE	1	(0,0)	5	(0,2)	6	(0,1)
ANTITHROMBIN III	0	(0,0)	2	(0,1)	2	(0,0)
APIXABAN	260	(12,1)	307	(14,3)	567	(13,2)
ARGATROBAN	1	(0,0)	2	(0,1)	3	(0,1)
BEMIPARIN SODIUM	0	(0,0)	2	(0,1)	2	(0,0)
BERAPROST SODIUM	3	(0,1)	5	(0,2)	8	(0,2)
BIVALIRUDIN	1	(0,0)	3	(0,1)	4	(0,1)
CARBASALATE CALCIUM	1	(0,0)	0	(0,0)	1	(0,0)
CERTOPARIN SODIUM	12	(0,6)	17	(0,8)	29	(0,7)
CILOSTAZOL	7	(0,3)	11	(0,5)	18	(0,4)
CLOPIDOGREL	280	(13,0)	274	(12,7)	554	(12,9)
CLOPIDOGREL BESYLATE	3	(0,1)	2	(0,1)	5	(0,1)
CLOPIDOGREL BISULFATE	192	(8,9)	178	(8,3)	370	(8,6)
CLOPIDOGREL CAMSILATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
ANTITHROMBOTIC AGENTS	**1.940**	**(90,1)**	**1.945**	**(90,4)**	**3.885**	**(90,3)**
CLOPIDOGREL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CLOPIDOGREL NAPADISILATE	1	(0,0)	0	(0,0)	1	(0,0)
CLOPIDOGREL RESINATE	3	(0,1)	4	(0,2)	7	(0,2)
DABIGATRAN	45	(2,1)	42	(2,0)	87	(2,0)
DABIGATRAN ETEXILATE	6	(0,3)	7	(0,3)	13	(0,3)
DABIGATRAN ETEXILATE MESILATE	52	(2,4)	47	(2,2)	99	(2,3)
DALTEPARIN SODIUM	20	(0,9)	24	(1,1)	44	(1,0)
DIPYRIDAMOLE	1	(0,0)	6	(0,3)	7	(0,2)
DIPYRIDAMOLE;GINKGO BILOBA	1	(0,0)	1	(0,0)	2	(0,0)
EDOXABAN	9	(0,4)	9	(0,4)	18	(0,4)
EDOXABAN TOSILATE	30	(1,4)	37	(1,7)	67	(1,6)
EDOXABAN TOSILATE MONOHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
ENOXAPARIN SODIUM	254	(11,8)	258	(12,0)	512	(11,9)
FLUINDIONE	7	(0,3)	12	(0,6)	19	(0,4)
FONDAPARINUX SODIUM	13	(0,6)	17	(0,8)	30	(0,7)
HEPARIN	86	(4,0)	111	(5,2)	197	(4,6)
HEPARIN CALCIUM	13	(0,6)	11	(0,5)	24	(0,6)
HEPARIN SODIUM	53	(2,5)	60	(2,8)	113	(2,6)
HEPARIN SODIUM;SODIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
HEPARINOID	19	(0,9)	9	(0,4)	28	(0,7)
HIRUDIN	1	(0,0)	2	(0,1)	3	(0,1)
ILOPROST	0	(0,0)	2	(0,1)	2	(0,0)
LIMAPROST ALFADEX	4	(0,2)	5	(0,2)	9	(0,2)
LOW MOLECULAR WEIGHT HEPARIN	4	(0,2)	2	(0,1)	6	(0,1)
LOW MOLECULAR WEIGHT HEPARIN, SODIUM SALT	1	(0,0)	5	(0,2)	6	(0,1)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	18	(0,8)	17	(0,8)	35	(0,8)
NADROPARIN CALCIUM	25	(1,2)	25	(1,2)	50	(1,2)
OTHER ANTITHROMBOTIC AGENTS	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
ANTITHROMBOTIC AGENTS	**1.940**	**(90,1)**	**1.945**	**(90,4)**	**3.885**	**(90,3)**
PARNAPARIN SODIUM	0	(0,0)	2	(0,1)	2	(0,0)
PHENPROCOUMON	35	(1,6)	40	(1,9)	75	(1,7)
PRASUGREL HYDROCHLORIDE	18	(0,8)	11	(0,5)	29	(0,7)
PROUROKINASE	0	(0,0)	1	(0,0)	1	(0,0)
RIVAROXABAN	223	(10,4)	239	(11,1)	462	(10,7)
SARPOGRELATE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
STREPTODORNASE;STREPTOKINASE	1	(0,0)	1	(0,0)	2	(0,0)
SULODEXIDE	1	(0,0)	2	(0,1)	3	(0,1)
TICAGRELOR	35	(1,6)	48	(2,2)	83	(1,9)
TICLOPIDINE	3	(0,1)	0	(0,0)	3	(0,1)
TICLOPIDINE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
TINZAPARIN SODIUM	7	(0,3)	9	(0,4)	16	(0,4)
TIROFIBAN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
TRIFLUSAL	0	(0,0)	1	(0,0)	1	(0,0)
WARFARIN	304	(14,1)	306	(14,2)	610	(14,2)
WARFARIN POTASSIUM	25	(1,2)	22	(1,0)	47	(1,1)
WARFARIN SODIUM	104	(4,8)	116	(5,4)	220	(5,1)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
ACETIC ACID	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
ALANINE;ARGININE GLUTAMATE;ASPARTIC ACID;CALCIUM CHLORIDE DIHYDRATE;GLUCOSE MONOHYDRATE;GLUTAMIC ACID;GLYCINE;HISTIDINE HYDROCHLORIDE;ISOLEUCINE;LEUCINE;LYSINE HYDROCHLORIDE;MAGNESIUM ACETATE TETRAHYDRATE;METHIONINE;PHENYLALANINE;POTASSIUM HYDROXIDE;POTASSIUM PHOSPHATE MONOBASIC;PROLINE;SERINE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE;SODIUM HYDROXIDE;THREONINE;TRYPTOPHAN, L-;VALINE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
ALANINE;ARGININE GLUTAMATE;ASPARTIC ACID;CALCIUM CHLORIDE DIHYDRATE;GLUCOSE MONOHYDRATE;GLUTAMIC ACID;GLYCINE;HISTIDINE HYDROCHLORIDE;ISOLEUCINE;LEUCINE;LYSINE HYDROCHLORIDE;MAGNESIUM ACETATE TETRAHYDRATE;METHIONINE;PHENYLALANINE;POTASSIUM HYDROXIDE;PROLINE;SERINE;SODIUM ACETATE TRIHYDRATE;SODIUM HYDROXIDE;SODIUM PHOSPHATE MONOBASIC (DIHYDRATE);THREONINE;TRYPTOPHAN, L-;VALINE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
ALANINE;ARGININE HYDROCHLORIDE;ASPARTIC ACID;CALCIUM GLUCONATE;CYSTEINE;GLUCOSE; GLUTAMIC ACID;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE HYDROCHLORIDE;MAGNESIUM SULFATE;METHIONINE;PHENYLALANINE;POTASSIUM PHOSPHATE DIBASIC;PROLINE;SERINE;SODIUM CHLORIDE;SODIUM LACTATE;THREONINE;TRYPTOPHAN, L-;TYROSINE;VALINE;ZINC SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
ALANINE;ARGININE HYDROCHLORIDE;ASPARTIC ACID;GLUTAMIC ACID;GLYCINE;HISTIDINE HYDROCHLORIDE;ISOLEUCINE;LEUCINE;LEVOGLUTAMIDE;LYSINE ACETATE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN, L-;TYROSINE;VALINE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
ALANINE;ARGININE;ASPARTIC ACID;CALCIUM CHLORIDE DIHYDRATE;GLUCOSE MONOHYDRATE;GLUTAMIC ACID;GLYCINE;GLYCINE MAX SEED OIL;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE HYDROCHLORIDE;MAGNESIUM SULFATE HEPTAHYDRATE;METHIONINE;PHENYLALANINE;POTASSIUM CHLORIDE;PROLINE;SERINE;SODIUM ACETATE TRIHYDRATE;SODIUM GLYCEROPHOSPHATE;THREONINE;TRYPTOPHAN, L-;TYROSINE;VALINE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
ALANINE;ARGININE;ASPARTIC ACID;CALCIUM CHLORIDE DIHYDRATE;GLUCOSE;GLUTAMIC ACID;GLYCINE;GLYCINE MAX OIL;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE ACETATE;MAGNESIUM CHLORIDE HEXAHYDRATE;METHIONINE;OLEA EUROPAEA OIL;PHENYLALANINE;POTASSIUM CHLORIDE;PROLINE;SERINE;SODIUM ACETATE TRIHYDRATE;SODIUM GLYCEROPHOSPHATE;THREONINE;TRYPTOPHAN, L-;TYROSINE;VALINE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
ALANINE;ARGININE;ASPARTIC ACID;CALCIUM CHLORIDE;GLUCOSE MONOHYDRATE;GLUTAMIC ACID;GLYCINE;GLYCINE MAX SEED OIL;HISTIDINE HYDROCHLORIDE;ISOLEUCINE;LEUCINE;LYSINE HYDROCHLORIDE;MAGNESIUM ACETATE TETRAHYDRATE;MEDIUM-CHAIN TRIGLYCERIDES;METHIONINE;PHENYLALANINE;POTASSIUM ACETATE;PROLINE;SERINE;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM HYDROXIDE;SODIUM PHOSPHATE MONOBASIC	0	(0,0)	1	(0,0)	1	(0,0)
ALANINE;ARGININE;ASPARTIC ACID;CALCIUM CHLORIDE;GLUCOSE;GLUTAMIC ACID;GLYCINE;GLYCINE MAX OIL;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE HYDROCHLORIDE;MAGNESIUM SULFATE;METHIONINE;PHENYLALANINE;POTASSIUM CHLORIDE;PROLINE;SERINE;SODIUM ACETATE;SODIUM GLYCEROPHOSPHATE;THREONINE;TRYPTOPHAN, L-;TYROSINE;VALINE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
ALANINE;ARGININE;ASPARTIC ACID;CYSTEINE HYDROCHLORIDE MONOHYDRATE;GLUTAMIC ACID;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE HYDROCHLORIDE;METHIONINE;ORNITHINE HYDROCHLORIDE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN, L-;TYROSINE;VALINE	1	(0,0)	0	(0,0)	1	(0,0)
ALANINE;ARGININE;ASPARTIC ACID;GLUTAMIC ACID;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE ACETATE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN, L-;TYROSINE;VALINE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
ALANINE;ARGININE;CALCIUM CHLORIDE DIHYDRATE;FISH OIL;GLUCOSE MONOHYDRATE;GLYCINE;GLYCINE MAX OIL;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE HYDROCHLORIDE;MAGNESIUM SULFATE HEPTAHYDRATE;MEDIUM-CHAIN TRIGLYCERIDES;METHIONINE;OLEA EUROPAEA OIL;PHENYLALANINE;POTASSIUM CHLORIDE;PROLINE;SERINE;SODIUM ACETATE TRIHYDRATE;SODIUM GLYCEROPHOSPHATE;THREONINE;TRYPTOPHAN, L-;TYROSINE;VALINE;ZINC SULFATE	2	(0,1)	1	(0,0)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
ALANINE;ARGININE;CALCIUM CHLORIDE;CYSTEINE HYDROCHLORIDE;GLUCOSE;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE ACETATE;MAGNESIUM CHLORIDE;METHIONINE;PHENYLALANINE;POTASSIUM CHLORIDE;POTASSIUM PHOSPHATE MONOBASIC;PROLINE;SERINE;SODIUM ACETATE;SODIUM CHLORIDE;THREONINE;TRYPTOPHAN, L-;VALINE	1	(0,0)	1	(0,0)	2	(0,0)
ALANINE;ARGININE;CALCIUM CHLORIDE;FISH OIL;GLUCOSE MONOHYDRATE;GLYCINE;GLYCINE MAX SEED OIL;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE ACETATE;MAGNESIUM SULFATE;MEDIUM-CHAIN TRIGLYCERIDES;METHIONINE;OLEA EUROPAEA OIL;PHENYLALANINE;POTASSIUM CHLORIDE;PROLINE;SERINE;SODIUM ACETATE;SODIUM GLYCEROPHOSPHATE;TAURINE;THREONINE;TRYPTOPHAN, L-;TYROSINE;VALINE;ZINC SULFATE	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
ALANINE;ARGININE;CYSTEINE HYDROCHLORIDE;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE ACETATE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN, L-;VALINE	0	(0,0)	1	(0,0)	1	(0,0)
ALANYL GLUTAMINE	1	(0,0)	1	(0,0)	2	(0,0)
ALBUMIN HUMAN	43	(2,0)	58	(2,7)	101	(2,3)
AMINO ACIDS NOS	3	(0,1)	6	(0,3)	9	(0,2)
AMINO ACIDS NOS;ASPARTIC ACID;GLYCINE;XYLITOL	0	(0,0)	1	(0,0)	1	(0,0)
AMINO ACIDS NOS;CARBOHYDRATES NOS;ELECTROLYTES NOS;LIPIDS NOS	0	(0,0)	1	(0,0)	1	(0,0)
AMINO ACIDS NOS;ELECTROLYTES NOS	0	(0,0)	1	(0,0)	1	(0,0)
AMINO ACIDS NOS;ELECTROLYTES NOS;GLUCOSE	0	(0,0)	3	(0,1)	3	(0,1)
AMINO ACIDS NOS;ELECTROLYTES NOS;GLUCOSE;THIAMINE HYDROCHLORIDE	5	(0,2)	5	(0,2)	10	(0,2)
AMINO ACIDS NOS;FATS NOS;GLUCOSE	1	(0,0)	0	(0,0)	1	(0,0)
AMINO ACIDS NOS;GLUCOSE	1	(0,0)	0	(0,0)	1	(0,0)
AMINO ACIDS NOS;MINERALS NOS;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)
AMINO ACIDS NOS;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)
AMMONIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
ARGININE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FOLIC ACID;GLYCINE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	3	(0,1)	1	(0,0)	4	(0,1)
ASCORBIC ACID;BIOTIN;COCARBOXYLASE TETRAHYDRATE;COLECALCIFEROL;CYANOCOBALAMIN;DEXPANTHENOL;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL PALMITATE;RIBOFLAVIN SODIUM PHOSPHATE;TOCOPHEROL	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
ASCORBIC ACID;GLUCOSE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
BLOOD PLASMA	13	(0,6)	12	(0,6)	25	(0,6)
BLOOD, CALF, DEPROT., LMW PORTION	3	(0,1)	1	(0,0)	4	(0,1)
BLOOD, WHOLE	7	(0,3)	2	(0,1)	9	(0,2)
CALCIUM ACETATE;MAGNESIUM ACETATE;POTASSIUM ACETATE;SODIUM ACETATE;SODIUM CHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
CALCIUM CHLORIDE	8	(0,4)	12	(0,6)	20	(0,5)
CALCIUM CHLORIDE DIHYDRATE;FRUCTOSE;GLUCOSE; MAGNESIUM CHLORIDE;POTASSIUM PHOSPHATE DIBASIC;SODIUM ACETATE;SODIUM CHLORIDE;XYLITOL;ZINC SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
CALCIUM CHLORIDE DIHYDRATE;GELATINE POLYSUCCINATE;SODIUM CHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
CALCIUM CHLORIDE DIHYDRATE;GLUCOSE MONOHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;SODIUM CHLORIDE;SODIUM LACTATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
CALCIUM CHLORIDE DIHYDRATE;GLUCOSE;POTASSIUM CHLORIDE;SODIUM ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CHLORIDE DIHYDRATE;GLUCOSE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
CALCIUM CHLORIDE DIHYDRATE;GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	1	(0,0)	3	(0,1)	4	(0,1)
CALCIUM CHLORIDE DIHYDRATE;HETASTARCH;MAGNESIUM CHLORIDE HEXAHYDRATE;MALIC ACID;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	1	(0,0)	9	(0,4)	10	(0,2)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE;SODIUM CITRATE DIHYDRATE	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE;SUCCINYLATED GELATIN	0	(0,0)	2	(0,1)	2	(0,0)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM CITRATE DIHYDRATE	2	(0,1)	2	(0,1)	4	(0,1)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	2	(0,1)	4	(0,2)	6	(0,1)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM CHLORIDE DIHYDRATE;MALTOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	0	(0,0)	2	(0,1)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	11	(0,5)	8	(0,4)	19	(0,4)
CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	8	(0,4)	7	(0,3)	15	(0,3)
CALCIUM CHLORIDE;GLUCONATE SODIUM;MAGNESIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
CALCIUM CHLORIDE;GLUCOSE	3	(0,1)	4	(0,2)	7	(0,2)
CALCIUM CHLORIDE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;MALIC ACID;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE DIHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE;XYLITOL	1	(0,0)	1	(0,0)	2	(0,0)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE;SORBITOL	4	(0,2)	6	(0,3)	10	(0,2)
CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE;SORBITOL	0	(0,0)	2	(0,1)	2	(0,0)
CALCIUM GLUCONATE	40	(1,9)	49	(2,3)	89	(2,1)
CALCIUM GLUCONATE MONOHYDRATE;GLUCOSE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE DIHYDRATE	3	(0,1)	4	(0,2)	7	(0,2)
CALCIUM GLUCONATE;CALCIUM SACCHARATE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
CALCIUM GLUCONATE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;POTASSIUM PHOSPHATE MONOBASIC;SODIUM ACETATE;SODIUM CHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
CALCIUM GLUCONATE;SODIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CARBOHYDRATES NOS;ELECTROLYTES NOS	1	(0,0)	0	(0,0)	1	(0,0)
CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;PROTEIN;VITAMINS NOS	0	(0,0)	3	(0,1)	3	(0,1)
CARBOHYDRATES NOS;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	13	(0,6)	11	(0,5)	24	(0,6)
CETYLPYRIDINIUM CHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
CHLORHEXIDINE	3	(0,1)	5	(0,2)	8	(0,2)
CHLORHEXIDINE DIACETATE	1	(0,0)	1	(0,0)	2	(0,0)
CHLORHEXIDINE GLUCONATE	6	(0,3)	14	(0,7)	20	(0,5)
CHLORHEXIDINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CHROMIC CHLORIDE HEXAHYDRATE;COPPER CHLORIDE DIHYDRATE;FERRIC CHLORIDE HEXAHYDRATE;MANGANESE CHLORIDE TETRAHYDRATE;POTASSIUM IODIDE;SODIUM FLUORIDE;SODIUM MOLYBDATE DIHYDRATE;SODIUM SELENITE;ZINC CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
CHROMIC CHLORIDE;COPPER CHLORIDE;FERRIC CHLORIDE;MANGANESE CHLORIDE;POTASSIUM IODIDE;SODIUM FLUORIDE;SODIUM MOLYBDATE;SODIUM SELENITE;SORBITOL;ZINC CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CHROMIC CHLORIDE;COPPER GLUCONATE;FERROUS GLUCONATE;MANGANESE GLUCONATE;POTASSIUM IODIDE;SODIUM FLUORIDE;SODIUM MOLYBDATE;SODIUM SELENITE;ZINC GLUCONATE	0	(0,0)	2	(0,1)	2	(0,0)
CHROMIC CHLORIDE;COPPER SULFATE;MANGANESE SULFATE;ZINC SULFATE	1	(0,0)	2	(0,1)	3	(0,1)
CITRIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
COPPER SULFATE PENTAHYDRATE;FERRIC CHLORIDE HEXAHYDRATE;MANGANESE CHLORIDE TETRAHYDRATE;POTASSIUM IODIDE;ZINC SULFATE HEPTAHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
COPPER SULFATE;FERRIC CHLORIDE;MANGANESE CHLORIDE;POTASSIUM IODIDE;ZINC SULFATE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
CYSTEINE HYDROCHLORIDE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE ACETATE;METHIONINE;PHENYLALANINE;THREONINE;TRYPTOPHAN, L-;VALINE	2	(0,1)	1	(0,0)	3	(0,1)
CYSTEINE;GLYCINE;GLYCYRRHIZIC ACID	2	(0,1)	0	(0,0)	2	(0,0)
ELECTROLYTE SOLUTIONS [UMBRELLA TERM]	1	(0,0)	1	(0,0)	2	(0,0)
ELECTROLYTES NOS	26	(1,2)	30	(1,4)	56	(1,3)
ELECTROLYTES NOS;GELATIN	1	(0,0)	0	(0,0)	1	(0,0)
ELECTROLYTES NOS;GLUCOSE	4	(0,2)	5	(0,2)	9	(0,2)
ELECTROLYTES NOS;SODIUM LACTATE	25	(1,2)	21	(1,0)	46	(1,1)
ERGOCALCIFEROL;PHYTOMENADIONE;RETINOL PALMITATE;TOCOPHEROL	0	(0,0)	1	(0,0)	1	(0,0)
ERGOCALCIFEROL;PHYTOMENADIONE;RETINOL;TOCOPHEROL	1	(0,0)	2	(0,1)	3	(0,1)
ETHACRIDINE LACTATE	0	(0,0)	2	(0,1)	2	(0,0)
FATS NOS	1	(0,0)	3	(0,1)	4	(0,1)
FISH OIL;GLYCINE MAX SEED OIL;OLEA EUROPAEA OIL;TRIGLYCERIDES	3	(0,1)	0	(0,0)	3	(0,1)
FOSFRUCTOSE TRISODIUM	0	(0,0)	3	(0,1)	3	(0,1)
FRUCTOSE	1	(0,0)	1	(0,0)	2	(0,0)
FRUCTOSE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE;SODIUM PHOSPHATE	0	(0,0)	1	(0,0)	1	(0,0)
FRUCTOSE;GLYCEROL	1	(0,0)	0	(0,0)	1	(0,0)
GELATIN	2	(0,1)	0	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
GLUCONATE SODIUM;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
GLUCOSE	102	(4,7)	94	(4,4)	196	(4,6)
GLUCOSE 1-PHOSPHATE DISODIUM	0	(0,0)	2	(0,1)	2	(0,0)
GLUCOSE MONOHYDRATE;POTASSIUM CHLORIDE;POTASSIUM PHOSPHATE DIBASIC;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
GLUCOSE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM ACETATE;POTASSIUM PHOSPHATE MONOBASIC;SODIUM ACETATE;SODIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;POTASSIUM PHOSPHATE MONOBASIC;SODIUM ACETATE;SODIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
GLUCOSE;MAGNESIUM SULFATE	1	(0,0)	2	(0,1)	3	(0,1)
GLUCOSE;POTASSIUM CHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	0	(0,0)	3	(0,1)	3	(0,1)
GLUCOSE;POTASSIUM;SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
GLUCOSE;SODIUM BICARBONATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
GLUCOSE;SODIUM CHLORIDE	13	(0,6)	13	(0,6)	26	(0,6)
GLUCOSE;SODIUM CHLORIDE;SODIUM LACTATE	19	(0,9)	18	(0,8)	37	(0,9)
GLYCEROL	21	(1,0)	20	(0,9)	41	(1,0)
GLYCEROL;GLYCINE MAX OIL;LECITHIN;MEDIUM-CHAIN TRIGLYCERIDES	2	(0,1)	0	(0,0)	2	(0,0)
GLYCINE	2	(0,1)	1	(0,0)	3	(0,1)
GLYCINE MAX SEED OIL	0	(0,0)	1	(0,0)	1	(0,0)
HEMOGLOBIN	1	(0,0)	0	(0,0)	1	(0,0)
HETASTARCH	2	(0,1)	3	(0,1)	5	(0,1)
HETASTARCH;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
HETASTARCH;SODIUM CHLORIDE	1	(0,0)	4	(0,2)	5	(0,1)
HISTIDINE;ISOLEUCINE;LEUCINE; LYSINE ACETATE;METHIONINE;PHENYLALANINE;THREONINE;TRYPTOPHAN, L-;VALINE	1	(0,0)	0	(0,0)	1	(0,0)
ICODEXTRIN	1	(0,0)	0	(0,0)	1	(0,0)
ISOLEUCINE;LEUCINE;VALINE	0	(0,0)	1	(0,0)	1	(0,0)
ISOSORBIDE	15	(0,7)	5	(0,2)	20	(0,5)
MAGNESIUM ASPARTATE;POTASSIUM ASPARTATE;POTASSIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
MAGNESIUM CHLORIDE	6	(0,3)	1	(0,0)	7	(0,2)
MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
MAGNESIUM CITRATE	6	(0,3)	8	(0,4)	14	(0,3)
MAGNESIUM SULFATE	87	(4,0)	92	(4,3)	179	(4,2)
MAGNESIUM SULFATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
MAGNESIUM;POTASSIUM	0	(0,0)	2	(0,1)	2	(0,0)
MANNITOL	17	(0,8)	12	(0,6)	29	(0,7)
MANNITOL;SORBITOL	0	(0,0)	1	(0,0)	1	(0,0)
MINERALS NOS;VITAMINS NOS	4	(0,2)	10	(0,5)	14	(0,3)
NEOMYCIN	4	(0,2)	2	(0,1)	6	(0,1)
NITROFURAL	2	(0,1)	1	(0,0)	3	(0,1)
NUTRIENTS NOS	11	(0,5)	5	(0,2)	16	(0,4)
OTHER BLOOD PRODUCTS	0	(0,0)	1	(0,0)	1	(0,0)
PHOSPHATIDYL CHOLINE	0	(0,0)	1	(0,0)	1	(0,0)
PHOSPHOLIPIDS	2	(0,1)	2	(0,1)	4	(0,1)
PLASMA	0	(0,0)	2	(0,1)	2	(0,0)
PLATELETS	1	(0,0)	1	(0,0)	2	(0,0)
PLATELETS, CONCENTRATED	2	(0,1)	1	(0,0)	3	(0,1)
POLYGELINE	0	(0,0)	1	(0,0)	1	(0,0)
POTASSIUM	75	(3,5)	78	(3,6)	153	(3,6)
POTASSIUM CHLORIDE	532	(24,7)	514	(23,9)	1.046	(24,3)
POTASSIUM CHLORIDE;SODIUM CHLORIDE	5	(0,2)	5	(0,2)	10	(0,2)
POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	1	(0,0)	1	(0,0)	2	(0,0)
POTASSIUM PHOSPHATE DIBASIC	4	(0,2)	5	(0,2)	9	(0,2)
POTASSIUM PHOSPHATE DIBASIC;POTASSIUM PHOSPHATE MONOBASIC	1	(0,0)	1	(0,0)	2	(0,0)
POTASSIUM PHOSPHATE MONOBASIC	5	(0,2)	6	(0,3)	11	(0,3)
POTASSIUM;SODIUM CHLORIDE	1	(0,0)	3	(0,1)	4	(0,1)
POVIDONE	0	(0,0)	1	(0,0)	1	(0,0)
PROTEIN HYDROLYSATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
RED BLOOD CELLS	63	(2,9)	43	(2,0)	106	(2,5)
RED BLOOD CELLS, CONCENTRATED	1	(0,0)	3	(0,1)	4	(0,1)
SODIUM ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
SODIUM BICARBONATE	104	(4,8)	109	(5,1)	213	(5,0)
SODIUM CHLORIDE	203	(9,4)	196	(9,1)	399	(9,3)
SODIUM CHLORIDE;SUCCINYLATED GELATIN	4	(0,2)	6	(0,3)	10	(0,2)
SODIUM CITRATE	1	(0,0)	2	(0,1)	3	(0,1)
SODIUM GLYCEROPHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
SODIUM LACTATE	1	(0,0)	1	(0,0)	2	(0,0)
SODIUM PHOSPHATE DIBASIC	3	(0,1)	4	(0,2)	7	(0,2)
SODIUM PHOSPHATE DIBASIC DODECAHYDRATE;SODIUM PHOSPHATE MONOBASIC (DIHYDRATE)	4	(0,2)	2	(0,1)	6	(0,1)
SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC	5	(0,2)	5	(0,2)	10	(0,2)
SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	0	(0,0)	1	(0,0)	1	(0,0)
SODIUM PHOSPHATE;SODIUM PHOSPHATE DIBASIC	3	(0,1)	2	(0,1)	5	(0,1)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	1	(0,0)	2	(0,1)	3	(0,1)
SOLUTIONS FOR PARENTERAL NUTRITION	5	(0,2)	4	(0,2)	9	(0,2)
SORBITOL	1	(0,0)	0	(0,0)	1	(0,0)
STEM CELLS NOS	1	(0,0)	0	(0,0)	1	(0,0)
UREA	17	(0,8)	10	(0,5)	27	(0,6)
VITAMINS NOS	51	(2,4)	53	(2,5)	104	(2,4)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
BLOOD AND BLOOD FORMING ORGANS						
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	**903**	**(42,0)**	**843**	**(39,2)**	**1.746**	**(40,6)**
ZINC	1	(0,0)	2	(0,1)	3	(0,1)
ZINC SULFATE	3	(0,1)	4	(0,2)	7	(0,2)
OTHER HEMATOLOGICAL AGENTS	**109**	**(5,1)**	**115**	**(5,3)**	**224**	**(5,2)**
BROMELAINS	0	(0,0)	1	(0,0)	1	(0,0)
BROMELAINS;CYSTEINE	2	(0,1)	1	(0,0)	3	(0,1)
CHYMOTRYPSIN	0	(0,0)	1	(0,0)	1	(0,0)
ENZYMES NOS	5	(0,2)	3	(0,1)	8	(0,2)
PRONASE	2	(0,1)	6	(0,3)	8	(0,2)
SODIUM BICARBONATE	104	(4,8)	109	(5,1)	213	(5,0)
STREPTODORNASE;STREPTOKINASE	1	(0,0)	1	(0,0)	2	(0,0)
CARDIOVASCULAR SYSTEM						
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	**1.964**	**(91,3)**	**1.977**	**(91,9)**	**3.941**	**(91,6)**
ALLISARTAN ISOPROXIL	1	(0,0)	2	(0,1)	3	(0,1)
AMLODIPINE ADIPATE;VALSARTAN	0	(0,0)	1	(0,0)	1	(0,0)
AMLODIPINE BESILATE;AZILSARTAN	1	(0,0)	0	(0,0)	1	(0,0)
AMLODIPINE BESILATE;HYDROCHLOROTHIAZIDE;OLMESARTAN MEDOXOMIL	0	(0,0)	1	(0,0)	1	(0,0)
AMLODIPINE BESILATE;HYDROCHLOROTHIAZIDE;VALSARTAN	0	(0,0)	1	(0,0)	1	(0,0)
AMLODIPINE BESILATE;INDAPAMIDE;PERINDOPRIL ARGININE	1	(0,0)	1	(0,0)	2	(0,0)
AMLODIPINE BESILATE;IRBESARTAN	1	(0,0)	0	(0,0)	1	(0,0)
AMLODIPINE BESILATE;OLMESARTAN MEDOXOMIL	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	**1.964**	**(91,3)**	**1.977**	**(91,9)**	**3.941**	**(91,6)**
AMLODIPINE BESILATE;PERINDOPRIL ARGININE	3	(0,1)	3	(0,1)	6	(0,1)
AMLODIPINE BESILATE;RAMIPRIL	1	(0,0)	2	(0,1)	3	(0,1)
AMLODIPINE BESILATE;TELMISARTAN	1	(0,0)	1	(0,0)	2	(0,0)
AMLODIPINE BESILATE;VALSARTAN	1	(0,0)	6	(0,3)	7	(0,2)
AZILSARTAN	3	(0,1)	7	(0,3)	10	(0,2)
AZILSARTAN KAMEDOXOMIL	1	(0,0)	0	(0,0)	1	(0,0)
BENAZEPRIL HYDROCHLORIDE	21	(1,0)	21	(1,0)	42	(1,0)
BISOPROLOL FUMARATE;PERINDOPRIL ARGININE	1	(0,0)	2	(0,1)	3	(0,1)
CANDESARTAN	66	(3,1)	71	(3,3)	137	(3,2)
CANDESARTAN CILEXETIL	58	(2,7)	45	(2,1)	103	(2,4)
CANDESARTAN CILEXETIL;HYDROCHLOROTHIAZIDE	5	(0,2)	0	(0,0)	5	(0,1)
CAPTOPRIL	35	(1,6)	35	(1,6)	70	(1,6)
CILAZAPRIL	17	(0,8)	14	(0,7)	31	(0,7)
ENALAPRIL	296	(13,8)	303	(14,1)	599	(13,9)
ENALAPRIL MALEATE	87	(4,0)	75	(3,5)	162	(3,8)
ENALAPRIL MALEATE;HYDROCHLOROTHIAZIDE	2	(0,1)	2	(0,1)	4	(0,1)
ENALAPRIL MALEATE;LERCANIDIPINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ENALAPRILAT	2	(0,1)	0	(0,0)	2	(0,0)
EPROSARTAN MESILATE	0	(0,0)	1	(0,0)	1	(0,0)
FIMASARTAN POTASSIUM TRIHYDRATE	2	(0,1)	0	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	**1.964**	**(91,3)**	**1.977**	**(91,9)**	**3.941**	**(91,6)**
FOSINOPRIL SODIUM	26	(1,2)	18	(0,8)	44	(1,0)
FOSINOPRIL SODIUM;HYDROCHLOROTHIAZIDE	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCHLOROTHIAZIDE;IRBESARTAN	2	(0,1)	4	(0,2)	6	(0,1)
HYDROCHLOROTHIAZIDE;LISINOPRIL DIHYDRATE	2	(0,1)	0	(0,0)	2	(0,0)
HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM	13	(0,6)	7	(0,3)	20	(0,5)
HYDROCHLOROTHIAZIDE;OLMESARTAN MEDOXOMIL	0	(0,0)	1	(0,0)	1	(0,0)
HYDROCHLOROTHIAZIDE;QUINAPRIL HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCHLOROTHIAZIDE;RAMIPRIL	3	(0,1)	1	(0,0)	4	(0,1)
HYDROCHLOROTHIAZIDE;TELMISARTAN	1	(0,0)	1	(0,0)	2	(0,0)
HYDROCHLOROTHIAZIDE;VALSARTAN	7	(0,3)	4	(0,2)	11	(0,3)
IMIDAPRIL	1	(0,0)	2	(0,1)	3	(0,1)
IMIDAPRIL HYDROCHLORIDE	11	(0,5)	7	(0,3)	18	(0,4)
INDAPAMIDE;PERINDOPRIL	0	(0,0)	1	(0,0)	1	(0,0)
INDAPAMIDE;PERINDOPRIL ARGININE	1	(0,0)	4	(0,2)	5	(0,1)
INDAPAMIDE;PERINDOPRIL ERBUMINE	0	(0,0)	4	(0,2)	4	(0,1)
IRBESARTAN	36	(1,7)	38	(1,8)	74	(1,7)
LISINOPRIL	115	(5,3)	118	(5,5)	233	(5,4)
LISINOPRIL DIHYDRATE	1	(0,0)	1	(0,0)	2	(0,0)
LOSARTAN	234	(10,9)	237	(11,0)	471	(10,9)
LOSARTAN POTASSIUM	100	(4,6)	82	(3,8)	182	(4,2)
OLMESARTAN	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	**1.964**	**(91,3)**	**1.977**	**(91,9)**	**3.941**	**(91,6)**
OLMESARTAN MEDOXOMIL	14	(0,7)	12	(0,6)	26	(0,6)
PERINDOPRIL	99	(4,6)	118	(5,5)	217	(5,0)
PERINDOPRIL ARGININE	46	(2,1)	42	(2,0)	88	(2,0)
PERINDOPRIL ERBUMINE	31	(1,4)	44	(2,0)	75	(1,7)
QUINAPRIL HYDROCHLORIDE	4	(0,2)	8	(0,4)	12	(0,3)
RAMIPRIL	388	(18,0)	383	(17,8)	771	(17,9)
SACUBITRIL VALSARTAN SODIUM HYDRATE	370	(17,2)	424	(19,7)	794	(18,5)
SACUBITRIL;VALSARTAN	138	(6,4)	120	(5,6)	258	(6,0)
TELMISARTAN	24	(1,1)	46	(2,1)	70	(1,6)
TRANDOLAPRIL	11	(0,5)	12	(0,6)	23	(0,5)
VALSARTAN	182	(8,5)	173	(8,0)	355	(8,3)
ZOFENOPRIL CALCIUM	6	(0,3)	12	(0,6)	18	(0,4)
ANTIHYPERTENSIVES	**229**	**(10,6)**	**246**	**(11,4)**	**475**	**(11,0)**
ASARUM HETEROTROPOIDES	1	(0,0)	0	(0,0)	1	(0,0)
CLONIDINE	4	(0,2)	9	(0,4)	13	(0,3)
CLONIDINE HYDROCHLORIDE	0	(0,0)	6	(0,3)	6	(0,1)
DIHYDRALAZINE SULFATE	6	(0,3)	12	(0,6)	18	(0,4)
DOXAZOSIN	17	(0,8)	21	(1,0)	38	(0,9)
DOXAZOSIN MESILATE	22	(1,0)	17	(0,8)	39	(0,9)
EUCOMMIA ULMOIDES	1	(0,0)	0	(0,0)	1	(0,0)
HYDRALAZINE	55	(2,6)	61	(2,8)	116	(2,7)
HYDRALAZINE HYDROCHLORIDE	15	(0,7)	12	(0,6)	27	(0,6)
MACITENTAN	1	(0,0)	0	(0,0)	1	(0,0)
MAGNESIUM SULFATE	87	(4,0)	92	(4,3)	179	(4,2)
METHYLDOPA	1	(0,0)	1	(0,0)	2	(0,0)
MINOXIDIL	1	(0,0)	1	(0,0)	2	(0,0)
MOXONIDINE	6	(0,3)	18	(0,8)	24	(0,6)
NAFTOPIDIL	2	(0,1)	1	(0,0)	3	(0,1)
NITROPRUSSIDE SODIUM	9	(0,4)	12	(0,6)	21	(0,5)
PRAZOSIN	7	(0,3)	5	(0,2)	12	(0,3)
RILMENIDINE PHOSPHATE	2	(0,1)	3	(0,1)	5	(0,1)
SILDENAFIL CITRATE	12	(0,6)	14	(0,7)	26	(0,6)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
ANTIHYPERTENSIVES	**229**	**(10,6)**	**246**	**(11,4)**	**475**	**(11,0)**
TADALAFIL	2	(0,1)	0	(0,0)	2	(0,0)
TERAZOSIN	2	(0,1)	2	(0,1)	4	(0,1)
TERAZOSIN HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
URAPIDIL	9	(0,4)	8	(0,4)	17	(0,4)
VISCUM ALBUM	1	(0,0)	0	(0,0)	1	(0,0)
VISCUM ALBUM EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
BETA BLOCKING AGENTS	**2.043**	**(94,9)**	**2.054**	**(95,5)**	**4.097**	**(95,2)**
ATENOLOL	14	(0,7)	18	(0,8)	32	(0,7)
ATENOLOL;CHLORTALIDONE;NIFEDIPINE	0	(0,0)	1	(0,0)	1	(0,0)
BETA BLOCKING AGENTS, SELECTIVE	1	(0,0)	0	(0,0)	1	(0,0)
BETAXOLOL HYDROCHLORIDE	4	(0,2)	4	(0,2)	8	(0,2)
BISOPROLOL	468	(21,7)	485	(22,5)	953	(22,1)
BISOPROLOL FUMARATE	374	(17,4)	351	(16,3)	725	(16,8)
CARTEOLOL HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CARVEDILOL	834	(38,8)	860	(40,0)	1.694	(39,4)
CARVEDILOL;IVABRADINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CELIPROLOL HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ESMOLOL HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
LABETALOL	2	(0,1)	3	(0,1)	5	(0,1)
LABETALOL HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
LANDIOLOL HYDROCHLORIDE	2	(0,1)	5	(0,2)	7	(0,2)
METOPROLOL	198	(9,2)	224	(10,4)	422	(9,8)
METOPROLOL SUCCINATE	248	(11,5)	229	(10,6)	477	(11,1)
METOPROLOL TARTRATE	98	(4,6)	88	(4,1)	186	(4,3)
NADOLOL	0	(0,0)	1	(0,0)	1	(0,0)
NEBIVOLOL	41	(1,9)	50	(2,3)	91	(2,1)
NEBIVOLOL HYDROCHLORIDE	21	(1,0)	24	(1,1)	45	(1,0)
NIPRADOLOL	0	(0,0)	1	(0,0)	1	(0,0)
PROPRANOLOL	3	(0,1)	2	(0,1)	5	(0,1)
PROPRANOLOL HYDROCHLORIDE	2	(0,1)	5	(0,2)	7	(0,2)
SOTALOL	9	(0,4)	13	(0,6)	22	(0,5)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
BETA BLOCKING AGENTS	**2.043**	**(94,9)**	**2.054**	**(95,5)**	**4.097**	**(95,2)**
SOTALOL HYDROCHLORIDE	6	(0,3)	4	(0,2)	10	(0,2)
TIMOLOL	4	(0,2)	3	(0,1)	7	(0,2)
TIMOLOL MALEATE	2	(0,1)	0	(0,0)	2	(0,0)
CALCIUM CHANNEL BLOCKERS	**282**	**(13,1)**	**310**	**(14,4)**	**592**	**(13,8)**
AMLODIPINE	139	(6,5)	144	(6,7)	283	(6,6)
AMLODIPINE BESILATE	57	(2,6)	70	(3,3)	127	(3,0)
AMLODIPINE CAMSILATE	0	(0,0)	1	(0,0)	1	(0,0)
AMLODIPINE MALEATE	2	(0,1)	3	(0,1)	5	(0,1)
AMLODIPINE MESILATE	1	(0,0)	0	(0,0)	1	(0,0)
AZELNIDIPINE	2	(0,1)	2	(0,1)	4	(0,1)
BARNIDIPINE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
BENIDIPINE	1	(0,0)	0	(0,0)	1	(0,0)
BENIDIPINE HYDROCHLORIDE	7	(0,3)	3	(0,1)	10	(0,2)
BEPRIDIL HYDROCHLORIDE MONOHYDRATE	5	(0,2)	1	(0,0)	6	(0,1)
CILNIDIPINE	7	(0,3)	3	(0,1)	10	(0,2)
DILTIAZEM	5	(0,2)	11	(0,5)	16	(0,4)
DILTIAZEM HYDROCHLORIDE	14	(0,7)	14	(0,7)	28	(0,7)
EFONIDIPINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
FELODIPINE	4	(0,2)	6	(0,3)	10	(0,2)
LACIDIPINE	1	(0,0)	0	(0,0)	1	(0,0)
LERCANIDIPINE	5	(0,2)	11	(0,5)	16	(0,4)
LERCANIDIPINE HYDROCHLORIDE	16	(0,7)	19	(0,9)	35	(0,8)
LEVAMLODIPINE	0	(0,0)	1	(0,0)	1	(0,0)
LEVAMLODIPINE BESILATE	4	(0,2)	2	(0,1)	6	(0,1)
LEVAMLODIPINE MALEATE	0	(0,0)	1	(0,0)	1	(0,0)
NICARDIPINE HYDROCHLORIDE	8	(0,4)	7	(0,3)	15	(0,3)
NIFEDIPINE	18	(0,8)	31	(1,4)	49	(1,1)
NIMODIPINE	1	(0,0)	2	(0,1)	3	(0,1)
NITRENDIPINE	5	(0,2)	1	(0,0)	6	(0,1)
PERHEXILINE MALEATE	1	(0,0)	3	(0,1)	4	(0,1)
S AMLODIPINE NICOTINATE	1	(0,0)	0	(0,0)	1	(0,0)
VERAPAMIL	6	(0,3)	4	(0,2)	10	(0,2)
VERAPAMIL HYDROCHLORIDE	2	(0,1)	11	(0,5)	13	(0,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
CARDIAC THERAPY	**1.416**	**(65,8)**	**1.425**	**(66,2)**	**2.841**	**(66,0)**
ACETYLDIGOXIN	1	(0,0)	0	(0,0)	1	(0,0)
ACONITUM CARMICHAELII	1	(0,0)	0	(0,0)	1	(0,0)
ADENOSINE	3	(0,1)	6	(0,3)	9	(0,2)
ADENOSINE TRIPHOSPHATE, DISODIUM SALT	4	(0,2)	2	(0,1)	6	(0,1)
ADRENERGIC AND DOPAMINERGIC AGENTS	1	(0,0)	0	(0,0)	1	(0,0)
ALGINIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
ALLIUM MACROSTEMON BULB;BUXUS SPP.;GINKGO BILOBA LEAF;LITSEA LANCILIMBA;SALVIA MILTIORRHIZA ROOT WITH RHIZOME	1	(0,0)	0	(0,0)	1	(0,0)
ALPROSTADIL	8	(0,4)	13	(0,6)	21	(0,5)
ALPROSTADIL ALFADEX	2	(0,1)	0	(0,0)	2	(0,0)
AMBER;CODONOPSIS PILOSULA ROOT;NARDOSTACHYS JATAMANSI ROOT WITH RHIZOME;PANAX NOTOGINSENG ROOT;POLYGONATUM SIBIRICUM ROOT	5	(0,2)	0	(0,0)	5	(0,1)
AMEZINIUM METILSULFATE	0	(0,0)	1	(0,0)	1	(0,0)
AMIODARONE	263	(12,2)	282	(13,1)	545	(12,7)
AMIODARONE HYDROCHLORIDE	205	(9,5)	243	(11,3)	448	(10,4)
AMRINONE	0	(0,0)	1	(0,0)	1	(0,0)
APRINDINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
ASTRAGALUS MONGHOLICUS ROOT	0	(0,0)	1	(0,0)	1	(0,0)
ASTRAGALUS MONGHOLICUS ROOT;DALBERGIA ODORIFERA OIL;PANAX NOTOGINSENG ROOT;SALVIA MILTIORRHIZA ROOT	3	(0,1)	5	(0,2)	8	(0,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
CARDIAC THERAPY	**1.416**	**(65,8)**	**1.425**	**(66,2)**	**2.841**	**(66,0)**
ATROPINE	18	(0,8)	16	(0,7)	34	(0,8)
ATROPINE SULFATE	9	(0,4)	4	(0,2)	13	(0,3)
BETA-ACETYLDIGOXIN	0	(0,0)	1	(0,0)	1	(0,0)
BORNEOL;BOSWELLIA SACRA RESIN;CENTIPEDE;CICADA SLOUGH;DALBERGIA ODORIFERA;EUPOLYPHAGA STELEOPHAGA;LEECH EXTRACT;MESOBUTHUS MARTENSII;PAEONIA SPP. ROOT;PANAX GINSENG ROOT;SANTALUM ALBUM HEARTWOOD;ZIZIPHUS JUJUBA VAR. SPINOSA SEED	0	(0,0)	1	(0,0)	1	(0,0)
BORNEOL;CINNAMOMUM CASSIA BARK;COW BEZOAR;LIQUIDAMBAR ORIENTALIS RESIN;MUSK;PANAX GINSENG EXTRACT;TOAD VENOM	3	(0,1)	10	(0,5)	13	(0,3)
BORNEOL;PANAX NOTOGINSENG ROOT;SALVIA MILTIORRHIZA ROOT	3	(0,1)	2	(0,1)	5	(0,1)
BUCLADESINE CALCIUM	3	(0,1)	7	(0,3)	10	(0,2)
CAFEDRINE HYDROCHLORIDE;THEODRENALINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CAFFEINE	1	(0,0)	1	(0,0)	2	(0,0)
CAFFEINE CITRATE;GLYCERYL TRINITRATE	0	(0,0)	2	(0,1)	2	(0,0)
CAMPHOR	2	(0,1)	1	(0,0)	3	(0,1)
CAMPHOR;MENTHOL	1	(0,0)	0	(0,0)	1	(0,0)
CARNITINE	1	(0,0)	0	(0,0)	1	(0,0)
CARPERITIDE	23	(1,1)	15	(0,7)	38	(0,9)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
CARDIAC THERAPY	**1.416**	**(65,8)**	**1.425**	**(66,2)**	**2.841**	**(66,0)**
CARTHAMUS TINCTORIUS FLOWER;SALVIA MILTIORRHIZA ROOT	1	(0,0)	3	(0,1)	4	(0,1)
CONVALLATOXIN	2	(0,1)	1	(0,0)	3	(0,1)
CRATAEGUS LAEVIGATA	1	(0,0)	1	(0,0)	2	(0,0)
CRATAEGUS SPP. EXTRACT	1	(0,0)	2	(0,1)	3	(0,1)
CYCLIC AMP	1	(0,0)	3	(0,1)	4	(0,1)
DENOPAMINE	2	(0,1)	0	(0,0)	2	(0,0)
DESLANOSIDE	23	(1,1)	21	(1,0)	44	(1,0)
DIGITOXIN	32	(1,5)	22	(1,0)	54	(1,3)
DIGOXIN	508	(23,6)	499	(23,2)	1.007	(23,4)
DIOSPYROS KAKI LEAF	0	(0,0)	1	(0,0)	1	(0,0)
DOBUTAMINE	70	(3,3)	83	(3,9)	153	(3,6)
DOBUTAMINE HYDROCHLORIDE	56	(2,6)	64	(3,0)	120	(2,8)
DOBUTAMINE HYDROCHLORIDE;GLUCOSE	3	(0,1)	2	(0,1)	5	(0,1)
DOBUTAMINE;GLUCOSE	1	(0,0)	0	(0,0)	1	(0,0)
DOCARPAMINE	1	(0,0)	1	(0,0)	2	(0,0)
DOFETILIDE	5	(0,2)	2	(0,1)	7	(0,2)
DOPAMINE	48	(2,2)	66	(3,1)	114	(2,6)
DOPAMINE HYDROCHLORIDE	52	(2,4)	43	(2,0)	95	(2,2)
DOPAMINE HYDROCHLORIDE;GLUCOSE	1	(0,0)	1	(0,0)	2	(0,0)
ENOXIMONE	1	(0,0)	0	(0,0)	1	(0,0)
EPHEDRINE	5	(0,2)	9	(0,4)	14	(0,3)
EPHEDRINE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
EPHEDRINE SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
EPINEPHRINE	52	(2,4)	53	(2,5)	105	(2,4)
EPINEPHRINE BITARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
EPINEPHRINE HYDROCHLORIDE	1	(0,0)	5	(0,2)	6	(0,1)
ETHACIZINE	0	(0,0)	1	(0,0)	1	(0,0)
ETHANOL	0	(0,0)	2	(0,1)	2	(0,0)
ETILEFRINE	0	(0,0)	1	(0,0)	1	(0,0)
ETILEFRINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)

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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
CARDIAC THERAPY	**1.416**	**(65,8)**	**1.425**	**(66,2)**	**2.841**	**(66,0)**
FLECAINIDE ACETATE	0	(0,0)	6	(0,3)	6	(0,1)
FOSFRUCTOSE TRISODIUM	0	(0,0)	3	(0,1)	3	(0,1)
GINKGO BILOBA EXTRACT;LIGUSTRAZINE	0	(0,0)	1	(0,0)	1	(0,0)
GLYCERYL TRINITRATE	246	(11,4)	268	(12,5)	514	(11,9)
HYDRALAZINE HYDROCHLORIDE;ISOSORBIDE DINITRATE	0	(0,0)	1	(0,0)	1	(0,0)
IBUPROFEN	49	(2,3)	33	(1,5)	82	(1,9)
IBUTILIDE FUMARATE	0	(0,0)	1	(0,0)	1	(0,0)
INDOMETACIN	14	(0,7)	10	(0,5)	24	(0,6)
INOSINE	0	(0,0)	1	(0,0)	1	(0,0)
IPRATROPIUM BROMIDE	161	(7,5)	183	(8,5)	344	(8,0)
ISOPRENALINE HYDROCHLORIDE	5	(0,2)	3	(0,1)	8	(0,2)
ISOPRENALINE SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
ISOSORBIDE DINITRATE	84	(3,9)	78	(3,6)	162	(3,8)
ISOSORBIDE MONONITRATE	44	(2,0)	70	(3,3)	114	(2,6)
IVABRADINE	118	(5,5)	112	(5,2)	230	(5,3)
IVABRADINE HYDROCHLORIDE	77	(3,6)	92	(4,3)	169	(3,9)
LANATOSIDE C	1	(0,0)	0	(0,0)	1	(0,0)
LAPPACONITINE HYDROBROMIDE	0	(0,0)	2	(0,1)	2	(0,0)
LEVOCARNITINE	3	(0,1)	7	(0,3)	10	(0,2)
LEVOSIMENDAN	62	(2,9)	66	(3,1)	128	(3,0)
LIDOCAINE	61	(2,8)	62	(2,9)	123	(2,9)
LIDOCAINE HYDROCHLORIDE	43	(2,0)	40	(1,9)	83	(1,9)
LIGUSTRAZINE HYDROCHLORIDE;SALVIA MILTIORRHIZA	5	(0,2)	5	(0,2)	10	(0,2)
LIMAPROST ALFADEX	4	(0,2)	5	(0,2)	9	(0,2)
MAGNESIUM ASPARTATE;POTASSIUM ASPARTATE	27	(1,3)	32	(1,5)	59	(1,4)
MAGNESIUM TANSHINOATE B	3	(0,1)	4	(0,2)	7	(0,2)
MAGNESIUM;POTASSIUM	0	(0,0)	2	(0,1)	2	(0,0)

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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
CARDIAC THERAPY	**1.416**	**(65,8)**	**1.425**	**(66,2)**	**2.841**	**(66,0)**
MEGLUMINE ADENOSINE CYCLOPHOSPHATE	4	(0,2)	2	(0,1)	6	(0,1)
MELDONIUM	3	(0,1)	2	(0,1)	5	(0,1)
MELDONIUM DIHYDRATE	1	(0,0)	1	(0,0)	2	(0,0)
METARAMINOL	1	(0,0)	1	(0,0)	2	(0,0)
METARAMINOL TARTRATE	0	(0,0)	1	(0,0)	1	(0,0)
METILDIGOXIN	19	(0,9)	29	(1,3)	48	(1,1)
MEXILETINE	7	(0,3)	5	(0,2)	12	(0,3)
MEXILETINE HYDROCHLORIDE	5	(0,2)	3	(0,1)	8	(0,2)
MIDODRINE HYDROCHLORIDE	7	(0,3)	9	(0,4)	16	(0,4)
MILRINONE	34	(1,6)	47	(2,2)	81	(1,9)
MILRINONE LACTATE	6	(0,3)	8	(0,4)	14	(0,3)
MOLSIDOMINE	4	(0,2)	5	(0,2)	9	(0,2)
NESIRITIDE	19	(0,9)	12	(0,6)	31	(0,7)
NICORANDIL	9	(0,4)	20	(0,9)	29	(0,7)
NICOTINAMIDE	0	(0,0)	3	(0,1)	3	(0,1)
NIFEKALANT HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
NOREPINEPHRINE	64	(3,0)	69	(3,2)	133	(3,1)
NOREPINEPHRINE BITARTRATE	17	(0,8)	37	(1,7)	54	(1,3)
NOREPINEPHRINE HYDROCHLORIDE	3	(0,1)	3	(0,1)	6	(0,1)
OPHIOPOGON JAPONICUS ROOT TUBER;PANAX GINSENG	12	(0,6)	12	(0,6)	24	(0,6)
OPHIOPOGON JAPONICUS ROOT TUBER;PANAX GINSENG ROOT;SCHISANDRA CHINENSIS FRUIT	1	(0,0)	7	(0,3)	8	(0,2)
OPHIOPOGON JAPONICUS;PANAX GINSENG	1	(0,0)	1	(0,0)	2	(0,0)
PACLITAXEL	1	(0,0)	3	(0,1)	4	(0,1)
PANAX NOTOGINSENG	3	(0,1)	1	(0,0)	4	(0,1)
PENTAERITHRITYL TETRANITRATE	1	(0,0)	0	(0,0)	1	(0,0)
PHENYLEPHRINE	11	(0,5)	16	(0,7)	27	(0,6)
PHENYLEPHRINE HYDROCHLORIDE	9	(0,4)	10	(0,5)	19	(0,4)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
CARDIAC THERAPY	**1.416**	**(65,8)**	**1.425**	**(66,2)**	**2.841**	**(66,0)**
PHOSPHOCREATINE SODIUM	5	(0,2)	13	(0,6)	18	(0,4)
PILSICAINIDE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
PIMOBENDAN	26	(1,2)	28	(1,3)	54	(1,3)
PROPAFENONE HYDROCHLORIDE	0	(0,0)	4	(0,2)	4	(0,1)
RANOLAZINE	15	(0,7)	15	(0,7)	30	(0,7)
RANOLAZINE HYDROCHLORIDE	8	(0,4)	13	(0,6)	21	(0,5)
REGADENOSON	1	(0,0)	2	(0,1)	3	(0,1)
RELAXIN	0	(0,0)	1	(0,0)	1	(0,0)
SALVIA MILTIORRHIZA	1	(0,0)	0	(0,0)	1	(0,0)
SALVIA MILTIORRHIZA ROOT	0	(0,0)	1	(0,0)	1	(0,0)
SODIUM ALGINATE	5	(0,2)	4	(0,2)	9	(0,2)
STROPHANTHIN-K	3	(0,1)	1	(0,0)	4	(0,1)
TANSHINONE IIA SODIUM SULFONATE	0	(0,0)	3	(0,1)	3	(0,1)
THIOTRIAZOLINE	2	(0,1)	3	(0,1)	5	(0,1)
TRIMETAZIDINE	67	(3,1)	44	(2,0)	111	(2,6)
TRIMETAZIDINE HYDROCHLORIDE	105	(4,9)	105	(4,9)	210	(4,9)
UBIDECARENONE	29	(1,3)	50	(2,3)	79	(1,8)
XINMAILONG	4	(0,2)	3	(0,1)	7	(0,2)
ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
DIURETICS	**2.129**	**(98,9)**	**2.135**	**(99,3)**	**4.264**	**(99,1)**
ABIES ALBA OIL;DAUCUS CAROTA;HUMULUS LUPULUS;MENTHA X PIPERITA OIL;ORIGANUM VULGARE;PICEA ABIES OIL;RICINUS COMMUNIS OIL	1	(0,0)	0	(0,0)	1	(0,0)
ACETAZOLAMIDE	23	(1,1)	16	(0,7)	39	(0,9)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
DIURETICS	**2.129**	**(98,9)**	**2.135**	**(99,3)**	**4.264**	**(99,1)**
ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;ATRACTYLODES LANCEA RHIZOME;CINNAMOMUM CASSIA BARK;POLYPORUS UMBELLATUS SCLEROTIUM;PORIA COCOS SCLEROTIUM	0	(0,0)	1	(0,0)	1	(0,0)
AMILORIDE	3	(0,1)	5	(0,2)	8	(0,2)
AMILORIDE HYDROCHLORIDE;HYDROCHLOROTHIAZIDE	6	(0,3)	3	(0,1)	9	(0,2)
ARCTIUM LAPPA	1	(0,0)	0	(0,0)	1	(0,0)
ASARUM HETEROTROPOIDES	1	(0,0)	0	(0,0)	1	(0,0)
ASTRAGALUS MONGHOLICUS ROOT	0	(0,0)	1	(0,0)	1	(0,0)
ASTRAGALUS PROPINQUUS	1	(0,0)	4	(0,2)	5	(0,1)
ATRACTYLODES MACROCEPHALA	1	(0,0)	0	(0,0)	1	(0,0)
AZOSEMIDE	57	(2,6)	55	(2,6)	112	(2,6)
BENDROFLUMETHIAZIDE	5	(0,2)	2	(0,1)	7	(0,2)
BENDROFLUMETHIAZIDE;POTASSIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
BIDENS TRIPARTITA HERB;HYPERICUM PERFORATUM HERB;ROSA SPP. FRUIT;VACCINIUM VITIS-IDAEA LEAF	1	(0,0)	0	(0,0)	1	(0,0)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
BUMETANIDE	156	(7,2)	141	(6,6)	297	(6,9)
BUTIZIDE;SPIRONOLACTONE	1	(0,0)	0	(0,0)	1	(0,0)
CANRENONE	14	(0,7)	17	(0,8)	31	(0,7)
CENTAURIUM ERYTHRAEA;LEVISTICUM OFFICINALE;ROSMARINUS OFFICINALIS	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
DIURETICS	**2.129**	**(98,9)**	**2.135**	**(99,3)**	**4.264**	**(99,1)**
CHLOROTHIAZIDE	3	(0,1)	5	(0,2)	8	(0,2)
CHLORTALIDONE	44	(2,0)	30	(1,4)	74	(1,7)
CHLORTALIDONE;SPIRONOLACTONE	0	(0,0)	1	(0,0)	1	(0,0)
CLOPAMIDE	1	(0,0)	2	(0,1)	3	(0,1)
CYNARA CARDUNCULUS	0	(0,0)	1	(0,0)	1	(0,0)
DIURETICS	4	(0,2)	2	(0,1)	6	(0,1)
EPLERENONE	334	(15,5)	363	(16,9)	697	(16,2)
ERIOBOTRYA JAPONICA	0	(0,0)	2	(0,1)	2	(0,0)
ETACRYNIC ACID	2	(0,1)	3	(0,1)	5	(0,1)
EUCOMMIA ULMOIDES	1	(0,0)	0	(0,0)	1	(0,0)
FUROSEMIDE	1.789	(83,1)	1.804	(83,9)	3.593	(83,5)
FUROSEMIDE SODIUM	138	(6,4)	148	(6,9)	286	(6,6)
FUROSEMIDE;POTASSIUM CHLORIDE	0	(0,0)	3	(0,1)	3	(0,1)
FUROSEMIDE;SPIRONOLACTONE	1	(0,0)	2	(0,1)	3	(0,1)
HYDROCHLOROTHIAZIDE	131	(6,1)	156	(7,3)	287	(6,7)
HYDROCHLOROTHIAZIDE;SPIRONOLACTONE	18	(0,8)	19	(0,9)	37	(0,9)
HYDROCHLOROTHIAZIDE;TRIAMTERENE	0	(0,0)	1	(0,0)	1	(0,0)
INDAPAMIDE	22	(1,0)	31	(1,4)	53	(1,2)
ISOSORBIDE	15	(0,7)	5	(0,2)	20	(0,5)
LESPEDEZA CAPITATA	0	(0,0)	1	(0,0)	1	(0,0)
MANNITOL	17	(0,8)	12	(0,6)	29	(0,7)
METOLAZONE	140	(6,5)	131	(6,1)	271	(6,3)
POTASSIUM CANRENOATE	23	(1,1)	23	(1,1)	46	(1,1)
POTASSIUM CANRENOATE;TROMETAMOL	1	(0,0)	1	(0,0)	2	(0,0)
SPIRONOLACTONE	1.404	(65,2)	1.421	(66,1)	2.825	(65,7)
THEOBROMINE	0	(0,0)	2	(0,1)	2	(0,0)
TOLVAPTAN	90	(4,2)	75	(3,5)	165	(3,8)
TORASEMIDE	383	(17,8)	435	(20,2)	818	(19,0)
TRIAMTERENE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
DIURETICS	**2.129**	**(98,9)**	**2.135**	**(99,3)**	**4.264**	**(99,1)**
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
TRICHLORMETHIAZIDE	25	(1,2)	24	(1,1)	49	(1,1)
XIPAMIDE	34	(1,6)	30	(1,4)	64	(1,5)
LIPID MODIFYING AGENTS	**1.512**	**(70,3)**	**1.504**	**(69,9)**	**3.016**	**(70,1)**
ACETYLSALICYLIC ACID;ATORVASTATIN CALCIUM;RAMIPRIL	1	(0,0)	0	(0,0)	1	(0,0)
ALIROCUMAB	1	(0,0)	0	(0,0)	1	(0,0)
ALLIUM SATIVUM	1	(0,0)	3	(0,1)	4	(0,1)
AMLODIPINE BESILATE;ATORVASTATIN CALCIUM	2	(0,1)	3	(0,1)	5	(0,1)
AMLODIPINE BESILATE;ATORVASTATIN CALCIUM TRIHYDRATE	0	(0,0)	1	(0,0)	1	(0,0)
AMLODIPINE BESILATE;ATORVASTATIN CALCIUM TRIHYDRATE;PERINDOPRIL ARGININE	0	(0,0)	1	(0,0)	1	(0,0)
ATORVASTATIN	665	(30,9)	667	(31,0)	1.332	(31,0)
ATORVASTATIN CALCIUM	320	(14,9)	321	(14,9)	641	(14,9)
ATORVASTATIN CALCIUM TRIHYDRATE	2	(0,1)	0	(0,0)	2	(0,0)
ATORVASTATIN CALCIUM TRIHYDRATE;EZETIMIBE	0	(0,0)	1	(0,0)	1	(0,0)
ATORVASTATIN CALCIUM;EZETIMIBE	11	(0,5)	12	(0,6)	23	(0,5)
ATORVASTATIN CALCIUM;IRBESARTAN	1	(0,0)	0	(0,0)	1	(0,0)
BERBERINE	0	(0,0)	1	(0,0)	1	(0,0)
BEZAFIBRATE	4	(0,2)	8	(0,4)	12	(0,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
LIPID MODIFYING AGENTS	**1.512**	**(70,3)**	**1.504**	**(69,9)**	**3.016**	**(70,1)**
BORAGO OFFICINALIS;DL-ALPHA TOCOPHEROL;FISH OIL;LINUM USITATISSIMUM	0	(0,0)	1	(0,0)	1	(0,0)
CARNITINE	1	(0,0)	0	(0,0)	1	(0,0)
CERIVASTATIN SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
CHOLINE FENOFIBRATE	1	(0,0)	0	(0,0)	1	(0,0)
CIPROFIBRATE	0	(0,0)	1	(0,0)	1	(0,0)
COLECALCIFEROL;FISH OIL	0	(0,0)	1	(0,0)	1	(0,0)
COLESEVELAM HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
COLESTIPOL HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
COLESTYRAMINE	4	(0,2)	2	(0,1)	6	(0,1)
CYAMOPSIS TETRAGONOLOBA GUM	0	(0,0)	1	(0,0)	1	(0,0)
CYNARA CARDUNCULUS	0	(0,0)	1	(0,0)	1	(0,0)
EICOSAPENTAENOIC ACID ETHYL ESTER	5	(0,2)	6	(0,3)	11	(0,3)
EUCOMMIA ULMOIDES	1	(0,0)	0	(0,0)	1	(0,0)
EVOLOCUMAB	2	(0,1)	3	(0,1)	5	(0,1)
EZETIMIBE	81	(3,8)	71	(3,3)	152	(3,5)
EZETIMIBE;ROSUVASTATIN CALCIUM	4	(0,2)	3	(0,1)	7	(0,2)
EZETIMIBE;ROSUVASTATIN ZINC	1	(0,0)	1	(0,0)	2	(0,0)
EZETIMIBE;SIMVASTATIN	10	(0,5)	12	(0,6)	22	(0,5)
FALLOPIA MULTIFLORA	1	(0,0)	0	(0,0)	1	(0,0)
FENOFIBRATE	25	(1,2)	18	(0,8)	43	(1,0)
FENOFIBRATE;SIMVASTATIN	0	(0,0)	1	(0,0)	1	(0,0)
FIBRATES	1	(0,0)	2	(0,1)	3	(0,1)
FISH OIL	1	(0,0)	0	(0,0)	1	(0,0)
FLUVASTATIN SODIUM	9	(0,4)	9	(0,4)	18	(0,4)
GEMFIBROZIL	5	(0,2)	2	(0,1)	7	(0,2)
GLYCINE MAX SEED OIL	0	(0,0)	1	(0,0)	1	(0,0)
LECITHIN	1	(0,0)	1	(0,0)	2	(0,0)
LINUM USITATISSIMUM	1	(0,0)	0	(0,0)	1	(0,0)
LINUM USITATISSIMUM SEED	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
LIPID MODIFYING AGENTS	**1.512**	**(70,3)**	**1.504**	**(69,9)**	**3.016**	**(70,1)**
LOVASTATIN	3	(0,1)	8	(0,4)	11	(0,3)
LOVASTATIN;NICOTINIC ACID	0	(0,0)	3	(0,1)	3	(0,1)
MONASCUS PURPUREUS	1	(0,0)	0	(0,0)	1	(0,0)
NICERITROL	1	(0,0)	0	(0,0)	1	(0,0)
NICOTINIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
OMEGA-3 MARINE TRIGLYCERIDES	26	(1,2)	15	(0,7)	41	(1,0)
OMEGA-3 TRIGLYCERIDES	1	(0,0)	0	(0,0)	1	(0,0)
OMEGA-3-ACID ETHYL ESTER	6	(0,3)	7	(0,3)	13	(0,3)
OTHER LIPID MODIFYING AGENTS	1	(0,0)	0	(0,0)	1	(0,0)
PHOSPHOLIPIDS	2	(0,1)	2	(0,1)	4	(0,1)
PITAVASTATIN CALCIUM	31	(1,4)	24	(1,1)	55	(1,3)
POLYENE PHOSPHATIDYLCHOLINE	8	(0,4)	12	(0,6)	20	(0,5)
PRAVASTATIN	34	(1,6)	20	(0,9)	54	(1,3)
PRAVASTATIN SODIUM	17	(0,8)	13	(0,6)	30	(0,7)
PROBUCOL	0	(0,0)	1	(0,0)	1	(0,0)
ROSUVASTATIN	133	(6,2)	128	(6,0)	261	(6,1)
ROSUVASTATIN CALCIUM	150	(7,0)	146	(6,8)	296	(6,9)
ROSUVASTATIN CALCIUM;TELMISARTAN	1	(0,0)	0	(0,0)	1	(0,0)
ROSUVASTATIN ZINC	1	(0,0)	1	(0,0)	2	(0,0)
SIMVASTATIN	220	(10,2)	224	(10,4)	444	(10,3)
TOCOPHERYL NICOTINATE	2	(0,1)	1	(0,0)	3	(0,1)
PERIPHERAL VASODILATORS	**51**	**(2,4)**	**78**	**(3,6)**	**129**	**(3,0)**
ACONITUM CARMICHAELII	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
PERIPHERAL VASODILATORS	**51**	**(2,4)**	**78**	**(3,6)**	**129**	**(3,0)**
ACONITUM SPP. PROCESSED ROOT;ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;CINNAMOMUM CASSIA BARK;CORNUS OFFICINALIS FRUIT;DIOSCOREA SPP. RHIZOME;PAEONIA X SUFFRUTICOSA ROOT BARK;PORIA COCOS SCLEROTIUM;REHMANNIA GLUTINOSA ROOT	0	(0,0)	2	(0,1)	2	(0,0)
AKEBIA SPP. STEM;ANGELICA ACUTILOBA ROOT;ASARUM SPP. ROOT;CINNAMOMUM CASSIA BARK;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;TETRADIUM RUTICARPUM FRUIT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
ASTRAGALUS MONGHOLICUS ROOT	0	(0,0)	1	(0,0)	1	(0,0)
BENCYCLANE FUMARATE	2	(0,1)	3	(0,1)	5	(0,1)
BENDAZOL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
BUTYL PHTHALATE	0	(0,0)	1	(0,0)	1	(0,0)
CILOSTAZOL	7	(0,3)	11	(0,5)	18	(0,4)
CINEPAZIDE	0	(0,0)	2	(0,1)	2	(0,0)
CINEPAZIDE MALEATE	1	(0,0)	2	(0,1)	3	(0,1)
DIHYDROERGOTOXINE MESILATE	0	(0,0)	1	(0,0)	1	(0,0)
DIISOPROPYLAMINE DICHLOROACETATE	1	(0,0)	0	(0,0)	1	(0,0)
ENZYMES NOS	5	(0,2)	3	(0,1)	8	(0,2)
EUCOMMIA ULMOIDES	1	(0,0)	0	(0,0)	1	(0,0)
GASTRODIA ELATA	0	(0,0)	2	(0,1)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
PERIPHERAL VASODILATORS	**51**	**(2,4)**	**78**	**(3,6)**	**129**	**(3,0)**
GINKGO BILOBA	6	(0,3)	3	(0,1)	9	(0,2)
GINKGO BILOBA EXTRACT	1	(0,0)	4	(0,2)	5	(0,1)
GINKGO BILOBA LEAF EXTRACT	1	(0,0)	1	(0,0)	2	(0,0)
IFENPRODIL TARTRATE	1	(0,0)	1	(0,0)	2	(0,0)
ILOPROST	0	(0,0)	2	(0,1)	2	(0,0)
KALLIDINOGENASE	0	(0,0)	2	(0,1)	2	(0,0)
METHYLETHYLPIRIDINOL	0	(0,0)	1	(0,0)	1	(0,0)
METHYLETHYLPIRIDINOL SUCCINATE	1	(0,0)	2	(0,1)	3	(0,1)
NAFTIDROFURYL OXALATE	2	(0,1)	3	(0,1)	5	(0,1)
NICERGOLINE	3	(0,1)	1	(0,0)	4	(0,1)
NICOTINIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
PAPAVERINE HYDROCHLORIDE	4	(0,2)	6	(0,3)	10	(0,2)
PENTOXIFYLLINE	17	(0,8)	26	(1,2)	43	(1,0)
PHENOXYBENZAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PHENTOLAMINE MESILATE	1	(0,0)	0	(0,0)	1	(0,0)
PIRIBEDIL	0	(0,0)	1	(0,0)	1	(0,0)
VASOPROTECTIVES	**651**	**(30,3)**	**677**	**(31,5)**	**1.328**	**(30,9)**
AESCULUS HIPPOCASTANUM;HAMAMELIS VIRGINIANA;RUSCUS ACULEATUS;VITIS VINIFERA	0	(0,0)	1	(0,0)	1	(0,0)
ALLANTOIN;CHLORHEXIDINE HYDROCHLORIDE;CHLORPHENAMINE MALEATE;HYDROCORTISONE ACETATE;LIDOCAINE;TETRYZOLINE HYDROCHLORIDE;TOCOPHERYL ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
ALOE VERA;GERANIUM THUNBERGII;POGOSTEMON CABLIN LEAF	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
VASOPROTECTIVES	**651**	**(30,3)**	**677**	**(31,5)**	**1.328**	**(30,9)**
ALUMINIUM ACETOTARTRATE	2	(0,1)	0	(0,0)	2	(0,0)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
ANISODAMINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
ARNICA MONTANA	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;RUTOSIDE	1	(0,0)	0	(0,0)	1	(0,0)
BECLOMETASONE DIPROPIONATE	42	(2,0)	26	(1,2)	68	(1,6)
BENZOCAINE	3	(0,1)	0	(0,0)	3	(0,1)
BENZOCAINE;BISMUTH OXYCHLORIDE;MENTHOL;THYMOL IODIDE;ZINC OXIDE	1	(0,0)	1	(0,0)	2	(0,0)
BENZOCAINE;BISMUTH SUBGALLATE;DIPHENHYDRAMINE HYDROCHLORIDE;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE	6	(0,3)	9	(0,4)	15	(0,3)
BETAMETHASONE ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE BUTYRATE PROPIONATE	9	(0,4)	7	(0,3)	16	(0,4)
BETAMETHASONE DIPROPIONATE	4	(0,2)	2	(0,1)	6	(0,1)
BETAMETHASONE SODIUM PHOSPHATE	5	(0,2)	6	(0,3)	11	(0,3)
BETAMETHASONE VALERATE	11	(0,5)	9	(0,4)	20	(0,5)
BIOFLAVONOIDS	0	(0,0)	1	(0,0)	1	(0,0)
BISMUTH	0	(0,0)	1	(0,0)	1	(0,0)
BISMUTH OXIDE;BISMUTH SUBGALLATE;MYROXYLON BALSAMUM VAR. PEREIRAE BALSAM;ZINC OXIDE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM DOBESILATE	5	(0,2)	5	(0,2)	10	(0,2)
CHONDRUS CRISPUS;TITANIUM DIOXIDE;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
CINCHOCAINE HYDROCHLORIDE;ESCULOSIDE;FRAMYCETIN SULFATE;HYDROCORTISONE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
VASOPROTECTIVES	**651**	**(30,3)**	**677**	**(31,5)**	**1.328**	**(30,9)**
CINCHOCAINE HYDROCHLORIDE;ESCULOSIDE;HYDROCORTISONE;NEOMYCIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
CINCHOCAINE HYDROCHLORIDE;PREDNISOLONE CAPROATE	1	(0,0)	1	(0,0)	2	(0,0)
CINNAMOMUM CASSIA BARK;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;NUPHAR JAPONICA RHIZOME;QUERCUS SPP. BARK;RHEUM SPP. RHIZOME;SYZYGIUM AROMATICUM FLOWER BUD	0	(0,0)	1	(0,0)	1	(0,0)
CROTAMITON;HYDROCORTISONE	2	(0,1)	2	(0,1)	4	(0,1)
DEXAMETHASONE	37	(1,7)	37	(1,7)	74	(1,7)
DEXAMETHASONE DIPROPIONATE	3	(0,1)	0	(0,0)	3	(0,1)
DEXAMETHASONE SODIUM PHOSPHATE	17	(0,8)	16	(0,7)	33	(0,8)
DIFLUCORTOLONE VALERATE;LIDOCAINE	2	(0,1)	2	(0,1)	4	(0,1)
DILTIAZEM	5	(0,2)	11	(0,5)	16	(0,4)
DILTIAZEM HYDROCHLORIDE	14	(0,7)	14	(0,7)	28	(0,7)
DIOSMIN	5	(0,2)	5	(0,2)	10	(0,2)
DIOSMIN;HESPERIDIN	7	(0,3)	8	(0,4)	15	(0,3)
ERIGERON BREVISCAPUS	0	(0,0)	1	(0,0)	1	(0,0)
ESCHERICHIA COLI	1	(0,0)	1	(0,0)	2	(0,0)
ESCHERICHIA COLI;HYDROCORTISONE	3	(0,1)	0	(0,0)	3	(0,1)
FALLOPIA MULTIFLORA	1	(0,0)	0	(0,0)	1	(0,0)
FLUOCINOLONE ACETONIDE	4	(0,2)	7	(0,3)	11	(0,3)
FLUOCINONIDE	4	(0,2)	1	(0,0)	5	(0,1)
FLUOROMETHOLONE	13	(0,6)	7	(0,3)	20	(0,5)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
VASOPROTECTIVES	**651**	**(30,3)**	**677**	**(31,5)**	**1.328**	**(30,9)**
GLUCOSE;SODIUM CHLORIDE	13	(0,6)	13	(0,6)	26	(0,6)
GLYCERYL TRINITRATE	246	(11,4)	268	(12,5)	514	(11,9)
HAMAMELIS VIRGINIANA EXTRACT	1	(0,0)	2	(0,1)	3	(0,1)
HEPARIN	86	(4,0)	111	(5,2)	197	(4,6)
HEPARIN CALCIUM	13	(0,6)	11	(0,5)	24	(0,6)
HEPARIN SODIUM	53	(2,5)	60	(2,8)	113	(2,6)
HEPARIN SODIUM;POLIDOCANOL;PREDNISOLONE	0	(0,0)	1	(0,0)	1	(0,0)
HEPARINOID	19	(0,9)	9	(0,4)	28	(0,7)
HESPERIDIN	1	(0,0)	1	(0,0)	2	(0,0)
HIDROSMIN	1	(0,0)	0	(0,0)	1	(0,0)
HIRUDIN	1	(0,0)	2	(0,1)	3	(0,1)
HYALURONATE SODIUM	23	(1,1)	17	(0,8)	40	(0,9)
HYDROCORTISONE	38	(1,8)	37	(1,7)	75	(1,7)
HYDROCORTISONE ACETATE	15	(0,7)	9	(0,4)	24	(0,6)
HYDROCORTISONE ACETATE;PRAMOCAINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
HYDROCORTISONE PROBUTAT	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE SODIUM PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
HYDROCORTISONE SODIUM SUCCINATE	5	(0,2)	13	(0,6)	18	(0,4)
HYDROCORTISONE;LIDOCAINE	0	(0,0)	2	(0,1)	2	(0,0)
IODINE	1	(0,0)	1	(0,0)	2	(0,0)
ISOSORBIDE DINITRATE	84	(3,9)	78	(3,6)	162	(3,8)
LIDOCAINE	61	(2,8)	62	(2,9)	123	(2,9)
LIDOCAINE HYDROCHLORIDE	43	(2,0)	40	(1,9)	83	(1,9)
LIDOCAINE HYDROCHLORIDE;TRIAMCINOLONE ACETONIDE	2	(0,1)	1	(0,0)	3	(0,1)
LIDOCAINE;TRIBENOSIDE	2	(0,1)	1	(0,0)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
CARDIOVASCULAR SYSTEM						
VASOPROTECTIVES	**651**	**(30,3)**	**677**	**(31,5)**	**1.328**	**(30,9)**
LOCAL ANESTHETICS	0	(0,0)	1	(0,0)	1	(0,0)
LYSINE AESCINAT	1	(0,0)	0	(0,0)	1	(0,0)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	18	(0,8)	17	(0,8)	35	(0,8)
NIFEDIPINE	18	(0,8)	31	(1,4)	49	(1,1)
OXETACAINE	3	(0,1)	2	(0,1)	5	(0,1)
PHENOL	0	(0,0)	3	(0,1)	3	(0,1)
PHENYLEPHRINE	11	(0,5)	16	(0,7)	27	(0,6)
PHENYLEPHRINE HYDROCHLORIDE	9	(0,4)	10	(0,5)	19	(0,4)
PRAMOCAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PREDNISOLONE	84	(3,9)	73	(3,4)	157	(3,6)
PREDNISOLONE ACETATE	3	(0,1)	3	(0,1)	6	(0,1)
PREDNISOLONE HEMISUCCINATE	0	(0,0)	2	(0,1)	2	(0,0)
PREDNISOLONE SODIUM SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE VALEROACETATE	6	(0,3)	0	(0,0)	6	(0,1)
QUERCETIN	0	(0,0)	2	(0,1)	2	(0,0)
RUSCOGENIN;TRIMEBUTINE	1	(0,0)	1	(0,0)	2	(0,0)
RUTOSIDE	0	(0,0)	1	(0,0)	1	(0,0)
SCUTELLAREIN GLUCURONIDE	0	(0,0)	1	(0,0)	1	(0,0)
THIOTRIAZOLINE	2	(0,1)	3	(0,1)	5	(0,1)
TRIAMCINOLONE	3	(0,1)	9	(0,4)	12	(0,3)
TRIAMCINOLONE ACETONIDE	14	(0,7)	12	(0,6)	26	(0,6)
TROXERUTIN	1	(0,0)	0	(0,0)	1	(0,0)
VITIS VINIFERA EXTRACT	4	(0,2)	3	(0,1)	7	(0,2)
ZINC	1	(0,0)	2	(0,1)	3	(0,1)
ZINC SULFATE	3	(0,1)	4	(0,2)	7	(0,2)
OTHER	**1**	**(0,0)**	**3**	**(0,1)**	**4**	**(0,1)**
ALLIUM SATIVUM	1	(0,0)	3	(0,1)	4	(0,1)
DERMATOLOGICALS						
ANTI-ACNE PREPARATIONS	**279**	**(13,0)**	**276**	**(12,8)**	**555**	**(12,9)**
ADAPALENE	1	(0,0)	0	(0,0)	1	(0,0)
AZELAIC ACID	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
ANTI-ACNE PREPARATIONS	**279**	**(13,0)**	**276**	**(12,8)**	**555**	**(12,9)**
AZITHROMYCIN	76	(3,5)	76	(3,5)	152	(3,5)
CHLORAMPHENICOL	11	(0,5)	10	(0,5)	21	(0,5)
CHLORHEXIDINE	3	(0,1)	5	(0,2)	8	(0,2)
CHLORHEXIDINE GLUCONATE	6	(0,3)	14	(0,7)	20	(0,5)
CLINDAMYCIN	26	(1,2)	35	(1,6)	61	(1,4)
CLINDAMYCIN HYDROCHLORIDE	13	(0,6)	6	(0,3)	19	(0,4)
CLINDAMYCIN PHOSPHATE	2	(0,1)	4	(0,2)	6	(0,1)
DEXAMETHASONE	37	(1,7)	37	(1,7)	74	(1,7)
DEXAMETHASONE DIPROPIONATE	3	(0,1)	0	(0,0)	3	(0,1)
DEXAMETHASONE SODIUM PHOSPHATE	17	(0,8)	16	(0,7)	33	(0,8)
DIMETICONE	13	(0,6)	23	(1,1)	36	(0,8)
DOXYCYCLINE	36	(1,7)	37	(1,7)	73	(1,7)
ERYTHROMYCIN	4	(0,2)	5	(0,2)	9	(0,2)
ERYTHROMYCIN ETHYLSUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
FLUOROMETHOLONE	13	(0,6)	7	(0,3)	20	(0,5)
FLUOROMETHOLONE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
MATRICARIA RECUTITA;MELALEUCA ALTERNIFOLIA	0	(0,0)	1	(0,0)	1	(0,0)
METHYLPREDNISOLONE	46	(2,1)	41	(1,9)	87	(2,0)
METHYLPREDNISOLONE ACETATE	2	(0,1)	3	(0,1)	5	(0,1)
METHYLPREDNISOLONE HEMISUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
METHYLPREDNISOLONE SODIUM SUCCINATE	33	(1,5)	21	(1,0)	54	(1,3)
METRONIDAZOLE;PYRIDOXINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
NADIFLOXACIN	2	(0,1)	0	(0,0)	2	(0,0)
NICOTINAMIDE	0	(0,0)	3	(0,1)	3	(0,1)
POLYPEPTIDE	0	(0,0)	1	(0,0)	1	(0,0)
RETINOL	1	(0,0)	1	(0,0)	2	(0,0)
SALICYLIC ACID	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
ANTI-ACNE PREPARATIONS	**279**	**(13,0)**	**276**	**(12,8)**	**555**	**(12,9)**
SULFACETAMIDE	0	(0,0)	1	(0,0)	1	(0,0)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	**276**	**(12,8)**	**293**	**(13,6)**	**569**	**(13,2)**
ACICLOVIR	9	(0,4)	8	(0,4)	17	(0,4)
AMIKACIN	2	(0,1)	5	(0,2)	7	(0,2)
AMIKACIN SULFATE	1	(0,0)	3	(0,1)	4	(0,1)
BACITRACIN	2	(0,1)	5	(0,2)	7	(0,2)
BACITRACIN ZINC;NEOMYCIN SULFATE	0	(0,0)	2	(0,1)	2	(0,0)
BACITRACIN ZINC;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
BACITRACIN;LIDOCAINE HYDROCHLORIDE;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	0	(0,0)	2	(0,1)	2	(0,0)
BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	4	(0,2)	3	(0,1)	7	(0,2)
BENZYLPENICILLIN	9	(0,4)	8	(0,4)	17	(0,4)
CHLORAMPHENICOL	11	(0,5)	10	(0,5)	21	(0,5)
CHLORAMPHENICOL;METHYLURACIL	1	(0,0)	0	(0,0)	1	(0,0)
CHLORTETRACYCLINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
CIPROFLOXACIN	79	(3,7)	92	(4,3)	171	(4,0)
CIPROFLOXACIN HYDROCHLORIDE	14	(0,7)	10	(0,5)	24	(0,6)
CLARITHROMYCIN	43	(2,0)	46	(2,1)	89	(2,1)
COLLAGEN;GENTAMICIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
DOXYCYCLINE	36	(1,7)	37	(1,7)	73	(1,7)
DOXYCYCLINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ERYTHROMYCIN	4	(0,2)	5	(0,2)	9	(0,2)
FRAMYCETIN	0	(0,0)	1	(0,0)	1	(0,0)
FUSIDATE SODIUM	3	(0,1)	5	(0,2)	8	(0,2)
FUSIDIC ACID	7	(0,3)	8	(0,4)	15	(0,3)
GANCICLOVIR	2	(0,1)	1	(0,0)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	**276**	**(12,8)**	**293**	**(13,6)**	**569**	**(13,2)**
GANCICLOVIR SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
GENTAMICIN	17	(0,8)	15	(0,7)	32	(0,7)
GENTAMICIN SULFATE	10	(0,5)	12	(0,6)	22	(0,5)
GLYCYRRHIZIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
HYALURONATE SODIUM;SULFADIAZINE SILVER	0	(0,0)	1	(0,0)	1	(0,0)
IMIQUIMOD	0	(0,0)	1	(0,0)	1	(0,0)
INOSINE	0	(0,0)	1	(0,0)	1	(0,0)
LOMEFLOXACIN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
LYSOZYME CHLORIDE	6	(0,3)	0	(0,0)	6	(0,1)
METRONIDAZOLE	58	(2,7)	39	(1,8)	97	(2,3)
MUPIROCIN	14	(0,7)	18	(0,8)	32	(0,7)
MUPIROCIN CALCIUM	3	(0,1)	1	(0,0)	4	(0,1)
NEOMYCIN	4	(0,2)	2	(0,1)	6	(0,1)
NORFLOXACIN	4	(0,2)	3	(0,1)	7	(0,2)
POLYMYXIN B SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
PROCAINE BENZYLPENICILLIN	0	(0,0)	1	(0,0)	1	(0,0)
RIFAMPICIN	6	(0,3)	6	(0,3)	12	(0,3)
RIFAMYCIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
RIFAXIMIN	5	(0,2)	7	(0,3)	12	(0,3)
SULFADIAZINE SILVER	7	(0,3)	4	(0,2)	11	(0,3)
TETRACYCLINE	2	(0,1)	3	(0,1)	5	(0,1)
TETRACYCLINE HYDROCHLORIDE	4	(0,2)	3	(0,1)	7	(0,2)
VIDARABINE	1	(0,0)	0	(0,0)	1	(0,0)
ANTIFUNGALS FOR DERMATOLOGICAL USE	**71**	**(3,3)**	**65**	**(3,0)**	**136**	**(3,2)**
AMOROLFINE	0	(0,0)	1	(0,0)	1	(0,0)
AMOROLFINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
AMPHOTERICIN B	2	(0,1)	1	(0,0)	3	(0,1)
BETAMETHASONE DIPROPIONATE;CLOTRIMAZOLE	3	(0,1)	1	(0,0)	4	(0,1)
BIFONAZOLE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
ANTIFUNGALS FOR DERMATOLOGICAL USE	**71**	**(3,3)**	**65**	**(3,0)**	**136**	**(3,2)**
BUTENAFINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CICLOPIROX	2	(0,1)	2	(0,1)	4	(0,1)
CICLOPIROX OLAMINE;KELUAMID;PYRITHIONE ZINC	1	(0,0)	0	(0,0)	1	(0,0)
CLOBETASOL PROPIONATE;KETOCONAZOLE	2	(0,1)	0	(0,0)	2	(0,0)
CLOTRIMAZOLE	2	(0,1)	7	(0,3)	9	(0,2)
DIFLUCORTOLONE VALERATE;ISOCONAZOLE NITRATE	1	(0,0)	0	(0,0)	1	(0,0)
ECONAZOLE	0	(0,0)	2	(0,1)	2	(0,0)
ECONAZOLE NITRATE	1	(0,0)	4	(0,2)	5	(0,1)
ECONAZOLE NITRATE;TRIAMCINOLONE ACETONIDE	1	(0,0)	1	(0,0)	2	(0,0)
EFINACONAZOLE	2	(0,1)	0	(0,0)	2	(0,0)
FLUCONAZOLE	14	(0,7)	15	(0,7)	29	(0,7)
GRISEOFULVIN	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE;MICONAZOLE NITRATE	1	(0,0)	1	(0,0)	2	(0,0)
ISOCONAZOLE NITRATE	2	(0,1)	0	(0,0)	2	(0,0)
KETOCONAZOLE	5	(0,2)	4	(0,2)	9	(0,2)
LANOCONAZOLE	0	(0,0)	1	(0,0)	1	(0,0)
LULICONAZOLE	3	(0,1)	2	(0,1)	5	(0,1)
METHYL SALICYLATE;TOLNAFTATE	0	(0,0)	1	(0,0)	1	(0,0)
MICONAZOLE	6	(0,3)	4	(0,2)	10	(0,2)
MICONAZOLE NITRATE	6	(0,3)	3	(0,1)	9	(0,2)
NAFTIFINE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
NYSTATIN	17	(0,8)	15	(0,7)	32	(0,7)
NYSTATIN;ZINC OXIDE	1	(0,0)	0	(0,0)	1	(0,0)
SALICYLIC ACID	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
ANTIFUNGALS FOR DERMATOLOGICAL USE	**71**	**(3,3)**	**65**	**(3,0)**	**136**	**(3,2)**
SERTACONAZOLE	1	(0,0)	1	(0,0)	2	(0,0)
SERTACONAZOLE NITRATE	1	(0,0)	1	(0,0)	2	(0,0)
SULCONAZOLE NITRATE	0	(0,0)	1	(0,0)	1	(0,0)
TERBINAFINE	0	(0,0)	1	(0,0)	1	(0,0)
TERBINAFINE HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
TIOCONAZOLE	0	(0,0)	2	(0,1)	2	(0,0)
TOLNAFTATE	1	(0,0)	0	(0,0)	1	(0,0)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	**214**	**(9,9)**	**181**	**(8,4)**	**395**	**(9,2)**
ANTIHISTAMINES FOR TOPICAL USE	6	(0,3)	6	(0,3)	12	(0,3)
ARNICA MONTANA	0	(0,0)	1	(0,0)	1	(0,0)
BENZOCAINE	3	(0,1)	0	(0,0)	3	(0,1)
BENZOCAINE;BUTYL AMINOBENZOATE;TETRACAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
BENZOCAINE;MENTHOL	0	(0,0)	5	(0,2)	5	(0,1)
CALAMINE	1	(0,0)	1	(0,0)	2	(0,0)
CALAMINE;PRAMOCAINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CALAMINE;ZINC OXIDE	8	(0,4)	4	(0,2)	12	(0,3)
CAMPHOR	2	(0,1)	1	(0,0)	3	(0,1)
CAMPHOR;CHLORPHENAMINE MALEATE;HEXACHLOROPHENE;LIDOCAINE HYDROCHLORIDE;MENTHOL;METHYL SALICYLATE	2	(0,1)	4	(0,2)	6	(0,1)
CAMPHOR;MENTHOL	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	**214**	**(9,9)**	**181**	**(8,4)**	**395**	**(9,2)**
CERAMIDE;CETYL ALCOHOL;CYCLOMETHICONE 5;ETHYLHEXYLGLYCERIN;GLYCEROL;GLYCERYL MONOSTEARATE;HYDROXYETHYL UREA;ISOPROPYL MYRISTATE;ISOSTEARYL ALCOHOL;LAUROYL GLUTAMIC ACID;MENTHOL;OCTYLDODECANOL;PHYTOSTEROLS NOS;PROPYLENE GLYCOL	1	(0,0)	0	(0,0)	1	(0,0)
CHLORHEXIDINE GLUCONATE;LIDOCAINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
CHLOROPYRAMINE HYDROCHLORIDE	3	(0,1)	1	(0,0)	4	(0,1)
CINCHOCAINE HYDROCHLORIDE;DIPHENHYDRAMINE;ZINC OXIDE	1	(0,0)	1	(0,0)	2	(0,0)
CLEMASTINE	4	(0,2)	2	(0,1)	6	(0,1)
CLEMASTINE FUMARATE	2	(0,1)	1	(0,0)	3	(0,1)
CROTAMITON	6	(0,3)	6	(0,3)	12	(0,3)
CYSTEINE;GLYCINE;GLYCYRRHIZIC ACID	2	(0,1)	0	(0,0)	2	(0,0)
DEXCHLORPHENIRAMINE MALEATE	2	(0,1)	3	(0,1)	5	(0,1)
DIMETINDENE MALEATE	3	(0,1)	1	(0,0)	4	(0,1)
DIPHENHYDRAMINE	20	(0,9)	18	(0,8)	38	(0,9)
DIPHENHYDRAMINE HYDROCHLORIDE	16	(0,7)	21	(1,0)	37	(0,9)
DIPHENHYDRAMINE HYDROCHLORIDE;ZINC ACETATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	**214**	**(9,9)**	**181**	**(8,4)**	**395**	**(9,2)**
DOXEPIN HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
FALLOPIA MULTIFLORA	1	(0,0)	0	(0,0)	1	(0,0)
HYDROXYZINE	21	(1,0)	21	(1,0)	42	(1,0)
KETOTIFEN FUMARATE	6	(0,3)	4	(0,2)	10	(0,2)
LEVOMENTHOL	1	(0,0)	1	(0,0)	2	(0,0)
LIDOCAINE	61	(2,8)	62	(2,9)	123	(2,9)
LIDOCAINE HYDROCHLORIDE	43	(2,0)	40	(1,9)	83	(1,9)
MENTHA X PIPERITA OIL	1	(0,0)	0	(0,0)	1	(0,0)
MENTHOL	1	(0,0)	1	(0,0)	2	(0,0)
MENTHOL;METHYL SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)
OTHER ANTIPRURITICS	1	(0,0)	0	(0,0)	1	(0,0)
OXATOMIDE	1	(0,0)	0	(0,0)	1	(0,0)
OXYBUPROCAINE HYDROCHLORIDE	3	(0,1)	1	(0,0)	4	(0,1)
PHENIRAMINE MALEATE	6	(0,3)	3	(0,1)	9	(0,2)
PRAMOCAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PROMETHAZINE	16	(0,7)	14	(0,7)	30	(0,7)
PROMETHAZINE HYDROCHLORIDE	20	(0,9)	7	(0,3)	27	(0,6)
ANTIPSORIATICS	**38**	**(1,8)**	**44**	**(2,0)**	**82**	**(1,9)**
ACITRETIN	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
ARCTIUM LAPPA	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE BUTYRATE PROPIONATE;MAXACALCITOL	1	(0,0)	1	(0,0)	2	(0,0)
BETAMETHASONE DIPROPIONATE;CALCIPOTRIOL	0	(0,0)	5	(0,2)	5	(0,1)
BETAMETHASONE DIPROPIONATE;CALCIPOTRIOL MONOHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIPOTRIOL	2	(0,1)	0	(0,0)	2	(0,0)
CALCITRIOL	31	(1,4)	33	(1,5)	64	(1,5)
COAL TAR	0	(0,0)	2	(0,1)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
ANTIPSORIATICS	**38**	**(1,8)**	**44**	**(2,0)**	**82**	**(1,9)**
COAL TAR;SALICYLIC ACID;SULFUR	0	(0,0)	1	(0,0)	1	(0,0)
DISODIUM FUMARATE	0	(0,0)	1	(0,0)	1	(0,0)
HAMAMELIS VIRGINIANA;ICHTHAMMOL;TITANIUM DIOXIDE;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
MAXACALCITOL	1	(0,0)	1	(0,0)	2	(0,0)
MENTHOL;METHYL SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
ANTISEPTICS AND DISINFECTANTS	**53**	**(2,5)**	**48**	**(2,2)**	**101**	**(2,3)**
ACRIFLAVINE	1	(0,0)	0	(0,0)	1	(0,0)
ALUMINIUM ACETOTARTRATE	2	(0,1)	0	(0,0)	2	(0,0)
BENZALKONIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
BENZETHONIUM CHLORIDE	3	(0,1)	0	(0,0)	3	(0,1)
BISMUTH	0	(0,0)	1	(0,0)	1	(0,0)
BORIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
CETYLPYRIDINIUM CHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
CHLORHEXIDINE	3	(0,1)	5	(0,2)	8	(0,2)
CHLORHEXIDINE DIACETATE	1	(0,0)	1	(0,0)	2	(0,0)
CHLORHEXIDINE GLUCONATE	6	(0,3)	14	(0,7)	20	(0,5)
CHLORHEXIDINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CHLOROXINE	0	(0,0)	1	(0,0)	1	(0,0)
DECAMETHOXINE	0	(0,0)	1	(0,0)	1	(0,0)
DEQUALINIUM CHLORIDE	7	(0,3)	5	(0,2)	12	(0,3)
ETHACRIDINE LACTATE	0	(0,0)	2	(0,1)	2	(0,0)
ETHANOL	0	(0,0)	2	(0,1)	2	(0,0)
ETHANOL;POVIDONE-IODINE	1	(0,0)	0	(0,0)	1	(0,0)
HEXAMIDINE ISETIONATE	1	(0,0)	0	(0,0)	1	(0,0)
HYPOCHLOROUS ACID;SODIUM HYPOCHLORITE	1	(0,0)	0	(0,0)	1	(0,0)
IODINE	1	(0,0)	1	(0,0)	2	(0,0)
IODINE PRODUCTS	0	(0,0)	1	(0,0)	1	(0,0)
MIRAMISTIN	2	(0,1)	0	(0,0)	2	(0,0)
NITROFURAL	2	(0,1)	1	(0,0)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
ANTISEPTICS AND DISINFECTANTS	**53**	**(2,5)**	**48**	**(2,2)**	**101**	**(2,3)**
OCTENIDINE HYDROCHLORIDE;PHENOXYETHANOL	1	(0,0)	1	(0,0)	2	(0,0)
PHENOL	0	(0,0)	3	(0,1)	3	(0,1)
POLIHEXANIDE;UNDECYLENAMIDOPROPYL BETAINE	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM PERMANGANATE	3	(0,1)	0	(0,0)	3	(0,1)
POVIDONE	0	(0,0)	1	(0,0)	1	(0,0)
POVIDONE-IODINE	18	(0,8)	8	(0,4)	26	(0,6)
SILVER NITRATE	0	(0,0)	1	(0,0)	1	(0,0)
SILVER OXIDE	1	(0,0)	0	(0,0)	1	(0,0)
THYMOL	2	(0,1)	3	(0,1)	5	(0,1)
TOSYLCHLORAMIDE SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	**429**	**(19,9)**	**406**	**(18,9)**	**835**	**(19,4)**
ALCLOMETASONE DIPROPIONATE	3	(0,1)	1	(0,0)	4	(0,1)
AMCINONIDE	1	(0,0)	0	(0,0)	1	(0,0)
BACTERIA NOS;HYDROCORTISONE	0	(0,0)	1	(0,0)	1	(0,0)
BECLOMETASONE DIPROPIONATE	42	(2,0)	26	(1,2)	68	(1,6)
BETAMETHASONE	6	(0,3)	9	(0,4)	15	(0,3)
BETAMETHASONE ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE ACETATE;BETAMETHASONE SODIUM PHOSPHATE	2	(0,1)	0	(0,0)	2	(0,0)
BETAMETHASONE BUTYRATE PROPIONATE	9	(0,4)	7	(0,3)	16	(0,4)
BETAMETHASONE DIPROPIONATE	4	(0,2)	2	(0,1)	6	(0,1)
BETAMETHASONE DIPROPIONATE;BETAMETHASONE SODIUM PHOSPHATE	4	(0,2)	0	(0,0)	4	(0,1)
BETAMETHASONE DIPROPIONATE;CLOTRIMAZOLE;GENTAMICIN SULFATE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	**429**	**(19,9)**	**406**	**(18,9)**	**835**	**(19,4)**
BETAMETHASONE DIPROPIONATE;GENTAMICIN SULFATE	1	(0,0)	2	(0,1)	3	(0,1)
BETAMETHASONE DIPROPIONATE;SALICYLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE SODIUM PHOSPHATE	5	(0,2)	6	(0,3)	11	(0,3)
BETAMETHASONE SODIUM PHOSPHATE;NEOMYCIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE VALERATE	11	(0,5)	9	(0,4)	20	(0,5)
BETAMETHASONE VALERATE;CLIOQUINOL	2	(0,1)	1	(0,0)	3	(0,1)
BETAMETHASONE VALERATE;CLIOQUINOL;GENTAMICIN SULFATE;TOLNAFTATE	1	(0,0)	1	(0,0)	2	(0,0)
BETAMETHASONE VALERATE;FUSIDIC ACID	3	(0,1)	3	(0,1)	6	(0,1)
BETAMETHASONE VALERATE;GENTAMICIN SULFATE	5	(0,2)	10	(0,5)	15	(0,3)
BETAMETHASONE VALERATE;NEOMYCIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE VALERATE;SALICYLIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
BUDESONIDE	71	(3,3)	80	(3,7)	151	(3,5)
CHLORQUINALDOL;HYDROCORTISONE BUTYRATE	0	(0,0)	1	(0,0)	1	(0,0)
CIPROFLOXACIN HYDROCHLORIDE;FLUOCINOLONE ACETONIDE	0	(0,0)	1	(0,0)	1	(0,0)
CLIOQUINOL;FLUMETASONE PIVALATE	2	(0,1)	0	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	**429**	**(19,9)**	**406**	**(18,9)**	**835**	**(19,4)**
CLOBETASOL PROPIONATE	13	(0,6)	16	(0,7)	29	(0,7)
CLOBETASONE BUTYRATE	1	(0,0)	2	(0,1)	3	(0,1)
CLOCORTOLONE PIVALATE	1	(0,0)	0	(0,0)	1	(0,0)
CORTICOSTEROIDS, WEAK, COMBINATIONS WITH ANTISEPTICS	1	(0,0)	0	(0,0)	1	(0,0)
CROTAMITON;HYDROCORTISONE	2	(0,1)	2	(0,1)	4	(0,1)
DESONIDE	1	(0,0)	3	(0,1)	4	(0,1)
DESOXIMETASONE	1	(0,0)	1	(0,0)	2	(0,0)
DEXAMETHASONE	37	(1,7)	37	(1,7)	74	(1,7)
DEXAMETHASONE DIPROPIONATE	3	(0,1)	0	(0,0)	3	(0,1)
DEXAMETHASONE PROPIONATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM PHOSPHATE	17	(0,8)	16	(0,7)	33	(0,8)
DEXAMETHASONE;GENTAMICIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
DEXAMETHASONE;NEOMYCIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
DIFLORASONE DIACETATE	2	(0,1)	0	(0,0)	2	(0,0)
DIFLUCORTOLONE VALERATE	1	(0,0)	4	(0,2)	5	(0,1)
DIFLUPREDNATE	3	(0,1)	3	(0,1)	6	(0,1)
FLUDROXYCORTIDE	0	(0,0)	1	(0,0)	1	(0,0)
FLUOCINOLONE ACETONIDE	4	(0,2)	7	(0,3)	11	(0,3)
FLUOCINOLONE ACETONIDE;NEOMYCIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
FLUOCINONIDE	4	(0,2)	1	(0,0)	5	(0,1)
FLUOROMETHOLONE	13	(0,6)	7	(0,3)	20	(0,5)
FLUOROMETHOLONE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
FLUTICASONE	29	(1,3)	24	(1,1)	53	(1,2)
FLUTICASONE PROPIONATE	30	(1,4)	38	(1,8)	68	(1,6)
GENTAMICIN SULFATE;PREDNISOLONE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	**429**	**(19,9)**	**406**	**(18,9)**	**835**	**(19,4)**
GRAMICIDIN;NEOMYCIN;NYSTATIN;TRIAMCINOLONE ACETONIDE	0	(0,0)	2	(0,1)	2	(0,0)
HALOMETASONE	0	(0,0)	1	(0,0)	1	(0,0)
HYDROCORTISONE	38	(1,8)	37	(1,7)	75	(1,7)
HYDROCORTISONE ACETATE	15	(0,7)	9	(0,4)	24	(0,6)
HYDROCORTISONE ACETATE;NEOMYCIN SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
HYDROCORTISONE ACETATE;PRAMOCAINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
HYDROCORTISONE ACETATE;UREA	1	(0,0)	2	(0,1)	3	(0,1)
HYDROCORTISONE BUTYRATE	5	(0,2)	8	(0,4)	13	(0,3)
HYDROCORTISONE PROBUTAT	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE SODIUM PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
HYDROCORTISONE SODIUM SUCCINATE	5	(0,2)	13	(0,6)	18	(0,4)
HYDROCORTISONE;LIDOCAINE	0	(0,0)	2	(0,1)	2	(0,0)
HYDROCORTISONE;NATAMYCIN; NEOMYCIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
METHYLPREDNISOLONE	46	(2,1)	41	(1,9)	87	(2,0)
METHYLPREDNISOLONE ACEPONATE	2	(0,1)	2	(0,1)	4	(0,1)
METHYLPREDNISOLONE ACETATE	2	(0,1)	3	(0,1)	5	(0,1)
METHYLPREDNISOLONE HEMISUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
METHYLPREDNISOLONE SODIUM SUCCINATE	33	(1,5)	21	(1,0)	54	(1,3)
METHYLPREDNISOLONE;NEOMYCIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
MOMETASONE FUROATE	18	(0,8)	14	(0,7)	32	(0,7)
PREDNICARBATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	**429**	**(19,9)**	**406**	**(18,9)**	**835**	**(19,4)**
PREDNISOLONE	84	(3,9)	73	(3,4)	157	(3,6)
PREDNISOLONE ACETATE	3	(0,1)	3	(0,1)	6	(0,1)
PREDNISOLONE HEMISUCCINATE	0	(0,0)	2	(0,1)	2	(0,0)
PREDNISOLONE SODIUM SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE VALEROACETATE	6	(0,3)	0	(0,0)	6	(0,1)
TRIAMCINOLONE	3	(0,1)	9	(0,4)	12	(0,3)
TRIAMCINOLONE ACETONIDE	14	(0,7)	12	(0,6)	26	(0,6)
ULOBETASOL PROPIONATE	1	(0,0)	0	(0,0)	1	(0,0)
EMOLLIENTS AND PROTECTIVES	**141**	**(6,6)**	**148**	**(6,9)**	**289**	**(6,7)**
AMMONIUM LACTATE	2	(0,1)	0	(0,0)	2	(0,0)
BETACAROTENE	1	(0,0)	0	(0,0)	1	(0,0)
BORIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
BUTYROSPERMUM PARKII;DIMETHICONOL;DIMETICONE;GLYCEROL;GLYCERYL MONOSTEARATE;NICOTINAMIDE;PARAFFIN, LIQUID	0	(0,0)	1	(0,0)	1	(0,0)
CALAMINE;ZINC OXIDE	8	(0,4)	4	(0,2)	12	(0,3)
CALCIUM PANTOTHENATE;NICOTINAMIDE;RETINOL ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM;MAGNESIUM;PYRIDOXINE HYDROCHLORIDE;RETINOL;ZINC	1	(0,0)	0	(0,0)	1	(0,0)
CAMPHOR;CAPSICUM SPP.;METHYL SALICYLATE	0	(0,0)	2	(0,1)	2	(0,0)
CAMPHOR;LEVOMENTHOL;METHYL SALICYLATE	1	(0,0)	2	(0,1)	3	(0,1)
CAMPHOR;MENTHOL	1	(0,0)	0	(0,0)	1	(0,0)
CAMPHOR;MENTHOL;METHYL SALICYLATE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
EMOLLIENTS AND PROTECTIVES	**141**	**(6,6)**	**148**	**(6,9)**	**289**	**(6,7)**
CETOMACROGOL	0	(0,0)	1	(0,0)	1	(0,0)
CETOMACROGOL;CETOSTEARYL ALCOHOL;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	2	(0,1)	0	(0,0)	2	(0,0)
CETOMACROGOL;PARAFFIN, LIQUID;PROPYLENE GLYCOL;WHITE SOFT PARAFFIN	0	(0,0)	1	(0,0)	1	(0,0)
CETOSTEARYL ALCOHOL;ISOPROPYL MYRISTATE;PARAFFIN	0	(0,0)	1	(0,0)	1	(0,0)
CETOSTEARYL ALCOHOL;SODIUM LAURYL SULFATE	16	(0,7)	11	(0,5)	27	(0,6)
CETYL ALCOHOL;PROPYLENE GLYCOL;SODIUM LAURYL SULFATE;STEARYL ALCOHOL	1	(0,0)	0	(0,0)	1	(0,0)
COAL TAR;SALICYLIC ACID;SULFUR	0	(0,0)	1	(0,0)	1	(0,0)
DIMETICONE	13	(0,6)	23	(1,1)	36	(0,8)
EMOLLIENTS AND PROTECTIVES	1	(0,0)	0	(0,0)	1	(0,0)
EMULSIFYING WAX;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	5	(0,2)	2	(0,1)	7	(0,2)
FATS NOS	1	(0,0)	3	(0,1)	4	(0,1)
GLYCEROL	21	(1,0)	20	(0,9)	41	(1,0)
GLYCEROL;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	6	(0,3)	3	(0,1)	9	(0,2)
GLYCERYL MONOSTEARATE	0	(0,0)	1	(0,0)	1	(0,0)
GLYCINE MAX SEED OIL	0	(0,0)	1	(0,0)	1	(0,0)
HEPARINOID	19	(0,9)	9	(0,4)	28	(0,7)
LIGHT LIQUID PARAFFIN;WHITE SOFT PARAFFIN	1	(0,0)	0	(0,0)	1	(0,0)
LINOLEIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
LINUM USITATISSIMUM	1	(0,0)	0	(0,0)	1	(0,0)
LINUM USITATISSIMUM SEED	0	(0,0)	1	(0,0)	1	(0,0)
MENTHOL;METHYL SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
EMOLLIENTS AND PROTECTIVES	**141**	**(6,6)**	**148**	**(6,9)**	**289**	**(6,7)**
METHYL SALICYLATE	4	(0,2)	5	(0,2)	9	(0,2)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	18	(0,8)	17	(0,8)	35	(0,8)
OLEA EUROPAEA OIL	3	(0,1)	2	(0,1)	5	(0,1)
OTHER EMOLLIENTS AND PROTECTIVES	2	(0,1)	3	(0,1)	5	(0,1)
PARAFFIN	3	(0,1)	2	(0,1)	5	(0,1)
PARAFFIN SOFT	2	(0,1)	0	(0,0)	2	(0,0)
PARAFFIN, LIQUID	2	(0,1)	4	(0,2)	6	(0,1)
PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	3	(0,1)	1	(0,0)	4	(0,1)
PARAFFIN, LIQUID;WHITE SOFT PARAFFIN;WOOL FAT	2	(0,1)	2	(0,1)	4	(0,1)
PETROLATUM	0	(0,0)	1	(0,0)	1	(0,0)
PETROLATUM;WOOL FAT	0	(0,0)	1	(0,0)	1	(0,0)
PRUNUS ARMENIACA SEED EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
RICINUS COMMUNIS OIL	1	(0,0)	1	(0,0)	2	(0,0)
SALICYLIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
SESAMUM INDICUM SEED OIL	1	(0,0)	0	(0,0)	1	(0,0)
SILICON	0	(0,0)	1	(0,0)	1	(0,0)
THIOCTIC ACID	7	(0,3)	12	(0,6)	19	(0,4)
TOCOPHEROL	3	(0,1)	8	(0,4)	11	(0,3)
TOCOPHEROL;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
TOCOPHERYL ACETATE	2	(0,1)	2	(0,1)	4	(0,1)
TRIGONELLA FOENUM-GRAECUM	0	(0,0)	1	(0,0)	1	(0,0)
UREA	17	(0,8)	10	(0,5)	27	(0,6)
WHITE SOFT PARAFFIN	12	(0,6)	10	(0,5)	22	(0,5)
ZINC	1	(0,0)	2	(0,1)	3	(0,1)
ZINC OXIDE	6	(0,3)	5	(0,2)	11	(0,3)
ZINC SULFATE	3	(0,1)	4	(0,2)	7	(0,2)
MEDICATED DRESSINGS	**255**	**(11,8)**	**238**	**(11,1)**	**493**	**(11,5)**
ALGINIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
BENZALKONIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
MEDICATED DRESSINGS	**255**	**(11,8)**	**238**	**(11,1)**	**493**	**(11,5)**
CALAMINE;ZINC OXIDE	8	(0,4)	4	(0,2)	12	(0,3)
CALCIUM ALGINATE;CARMELLOSE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM ALGINATE;GLUCOSE OXIDASE;LACTOPEROXIDASE;SODIUM ALGINATE	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM;MAGNESIUM;PYRIDOXINE HYDROCHLORIDE;RETINOL;ZINC	1	(0,0)	0	(0,0)	1	(0,0)
CARMELLOSE	1	(0,0)	0	(0,0)	1	(0,0)
CARMELLOSE SODIUM	6	(0,3)	1	(0,0)	7	(0,2)
CETYLPYRIDINIUM CHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
CHLORHEXIDINE	3	(0,1)	5	(0,2)	8	(0,2)
CHLORHEXIDINE DIACETATE	1	(0,0)	1	(0,0)	2	(0,0)
CHLORHEXIDINE GLUCONATE	6	(0,3)	14	(0,7)	20	(0,5)
CHLORHEXIDINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
FRAMYCETIN	0	(0,0)	1	(0,0)	1	(0,0)
FUSIDATE SODIUM	3	(0,1)	5	(0,2)	8	(0,2)
FUSIDIC ACID	7	(0,3)	8	(0,4)	15	(0,3)
NITROFURAL	2	(0,1)	1	(0,0)	3	(0,1)
PARAFFIN	3	(0,1)	2	(0,1)	5	(0,1)
PARAFFIN SOFT	2	(0,1)	0	(0,0)	2	(0,0)
POVIDONE-IODINE	18	(0,8)	8	(0,4)	26	(0,6)
POVIDONE-IODINE;SUCROSE	2	(0,1)	0	(0,0)	2	(0,0)
SODIUM ALGINATE	5	(0,2)	4	(0,2)	9	(0,2)
SODIUM CHLORIDE	203	(9,4)	196	(9,1)	399	(9,3)
ZINC	1	(0,0)	2	(0,1)	3	(0,1)
ZINC OXIDE	6	(0,3)	5	(0,2)	11	(0,3)
OTHER DERMATOLOGICAL PREPARATIONS	**489**	**(22,7)**	**495**	**(23,0)**	**984**	**(22,9)**
ALDIOXA	1	(0,0)	1	(0,0)	2	(0,0)
ALUMINIUM SILICATE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
OTHER DERMATOLOGICAL PREPARATIONS	**489**	**(22,7)**	**495**	**(23,0)**	**984**	**(22,9)**
ANGELICA DAHURICA;ANGELICA SINENSIS;ASTRAGALUS PROPINQUUS;ATRACTYLODES LANCEA RHIZOME;CARTHAMUS TINCTORIUS;PAEONIA LACTIFLORA;PAEONIA X SUFFRUTICOSA BARK;PANAX NOTOGINSENG;PORTULACA OLERACEA;PRUNUS PERSICA SEED;SAPOSHNIKOVIA DIVARICATA	1	(0,0)	0	(0,0)	1	(0,0)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
ARCTIUM LAPPA	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID	39	(1,8)	28	(1,3)	67	(1,6)
ASTRAGALUS MONGHOLICUS ROOT	0	(0,0)	1	(0,0)	1	(0,0)
BIMATOPROST	2	(0,1)	1	(0,0)	3	(0,1)
BOTULINUM TOXIN TYPE A	1	(0,0)	0	(0,0)	1	(0,0)
BRIMONIDINE TARTRATE	7	(0,3)	6	(0,3)	13	(0,3)
CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
CALCIUM GLUCONATE	40	(1,9)	49	(2,3)	89	(2,1)
CARPRONIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;PUERARIA LOBATA ROOT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	1	(0,0)	4	(0,2)	5	(0,1)
COAL TAR;SALICYLIC ACID;SULFUR	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
OTHER DERMATOLOGICAL PREPARATIONS	**489**	**(22,7)**	**495**	**(23,0)**	**984**	**(22,9)**
COLLAGEN	2	(0,1)	2	(0,1)	4	(0,1)
CROMOGLICATE SODIUM	3	(0,1)	0	(0,0)	3	(0,1)
DICLOFENAC	33	(1,5)	33	(1,5)	66	(1,5)
DICLOFENAC SODIUM	36	(1,7)	30	(1,4)	66	(1,5)
ESTRADIOL	3	(0,1)	3	(0,1)	6	(0,1)
ETOFESALAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
FATTY ACIDS NOS	1	(0,0)	1	(0,0)	2	(0,0)
FINASTERIDE	38	(1,8)	48	(2,2)	86	(2,0)
GLYCEROL	21	(1,0)	20	(0,9)	41	(1,0)
GLYCOPYRRONIUM	2	(0,1)	3	(0,1)	5	(0,1)
GLYCOPYRRONIUM BROMIDE	7	(0,3)	13	(0,6)	20	(0,5)
GUAIAZULENE	10	(0,5)	4	(0,2)	14	(0,3)
HYALURONATE SODIUM	23	(1,1)	17	(0,8)	40	(0,9)
IVERMECTIN	1	(0,0)	1	(0,0)	2	(0,0)
MAGNESIUM SULFATE	87	(4,0)	92	(4,3)	179	(4,2)
MENTHOL;METHYL SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)
MINOXIDIL	1	(0,0)	1	(0,0)	2	(0,0)
NITRIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
OTHER DERMATOLOGICALS	2	(0,1)	1	(0,0)	3	(0,1)
OXYGEN	55	(2,6)	58	(2,7)	113	(2,6)
OXYMETAZOLINE HYDROCHLORIDE	10	(0,5)	4	(0,2)	14	(0,3)
PHYTOMENADIONE	52	(2,4)	38	(1,8)	90	(2,1)
POLYPEPTIDE	0	(0,0)	1	(0,0)	1	(0,0)
POVIDONE-IODINE	18	(0,8)	8	(0,4)	26	(0,6)
PROPOLIS	1	(0,0)	1	(0,0)	2	(0,0)
PYRIDOXINE	11	(0,5)	16	(0,7)	27	(0,6)
PYRIDOXINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
SALICYLIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
SELENIUM	1	(0,0)	2	(0,1)	3	(0,1)
SILDENAFIL CITRATE	12	(0,6)	14	(0,7)	26	(0,6)
SILICON DIOXIDE	1	(0,0)	1	(0,0)	2	(0,0)
SIROLIMUS	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
OTHER DERMATOLOGICAL PREPARATIONS	**489**	**(22,7)**	**495**	**(23,0)**	**984**	**(22,9)**
SODIUM BICARBONATE	104	(4,8)	109	(5,1)	213	(5,0)
SUCRALFATE	22	(1,0)	24	(1,1)	46	(1,1)
SULFACETAMIDE	0	(0,0)	1	(0,0)	1	(0,0)
TACROLIMUS	2	(0,1)	5	(0,2)	7	(0,2)
THIOTRIAZOLINE	2	(0,1)	3	(0,1)	5	(0,1)
UBIDECARENONE	29	(1,3)	50	(2,3)	79	(1,8)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	**254**	**(11,8)**	**251**	**(11,7)**	**505**	**(11,7)**
ARNICA MONTANA	0	(0,0)	1	(0,0)	1	(0,0)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
BROMELAINS	0	(0,0)	1	(0,0)	1	(0,0)
CADEXOMER IODINE	1	(0,0)	1	(0,0)	2	(0,0)
CALCIUM ALGINATE;CARMELLOSE	1	(0,0)	0	(0,0)	1	(0,0)
CAMPHOR;CHLORPHENAMINE MALEATE;HEXACHLOROPHENE;LIDOCAINE HYDROCHLORIDE;MENTHOL;METHYL SALICYLATE	2	(0,1)	4	(0,2)	6	(0,1)
CARMELLOSE	1	(0,0)	0	(0,0)	1	(0,0)
CARMELLOSE SODIUM	6	(0,3)	1	(0,0)	7	(0,2)
CARMELLOSE SODIUM;PECTIN	0	(0,0)	1	(0,0)	1	(0,0)
CHLORHEXIDINE HYDROCHLORIDE;DEXPANTHENOL	1	(0,0)	0	(0,0)	1	(0,0)
COD-LIVER OIL	0	(0,0)	1	(0,0)	1	(0,0)
COLLAGENASE	1	(0,0)	3	(0,1)	4	(0,1)
CRILANOMER	1	(0,0)	1	(0,0)	2	(0,0)
DEXPANTHENOL	3	(0,1)	2	(0,1)	5	(0,1)
DIMETICONE	13	(0,6)	23	(1,1)	36	(0,8)
FALLOPIA MULTIFLORA	1	(0,0)	0	(0,0)	1	(0,0)
FIBRONECTIN	0	(0,0)	3	(0,1)	3	(0,1)
FISH OIL	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
DERMATOLOGICALS						
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	**254**	**(11,8)**	**251**	**(11,7)**	**505**	**(11,7)**
HAMAMELIS VIRGINIANA EXTRACT	1	(0,0)	2	(0,1)	3	(0,1)
HEMOGLOBIN	1	(0,0)	0	(0,0)	1	(0,0)
HONEY	0	(0,0)	1	(0,0)	1	(0,0)
HOUTTUYNIA CORDATA	0	(0,0)	1	(0,0)	1	(0,0)
HYALURONATE SODIUM	23	(1,1)	17	(0,8)	40	(0,9)
HYPOCHLOROUS ACID;SODIUM HYPOCHLORITE	1	(0,0)	0	(0,0)	1	(0,0)
MANUKA HONEY	1	(0,0)	0	(0,0)	1	(0,0)
NEPIDERMIN	0	(0,0)	1	(0,0)	1	(0,0)
OTHER CICATRIZANTS	0	(0,0)	1	(0,0)	1	(0,0)
PERIPLANETA AMERICANA	1	(0,0)	1	(0,0)	2	(0,0)
PHENOXYETHANOL;TRITICUM AESTIVUM	1	(0,0)	2	(0,1)	3	(0,1)
POLIDERIBOTIDE	0	(0,0)	1	(0,0)	1	(0,0)
POVIDONE-IODINE;SUCROSE	2	(0,1)	0	(0,0)	2	(0,0)
SODIUM CHLORIDE	203	(9,4)	196	(9,1)	399	(9,3)
STREPTODORNASE;STREPTOKINASE	1	(0,0)	1	(0,0)	2	(0,0)
TANNIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
TOCOPHEROL	3	(0,1)	8	(0,4)	11	(0,3)
TOCOPHERYL ACETATE	2	(0,1)	2	(0,1)	4	(0,1)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
OTHER	**17**	**(0,8)**	**27**	**(1,3)**	**44**	**(1,0)**
DIOSMECTITE	17	(0,8)	27	(1,3)	44	(1,0)
GENITO URINARY SYSTEM AND SEX HORMONES						
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	**321**	**(14,9)**	**308**	**(14,3)**	**629**	**(14,6)**
ACETIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
AMPHOTERICIN B	2	(0,1)	1	(0,0)	3	(0,1)
ASCORBIC ACID	39	(1,8)	28	(1,3)	67	(1,6)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
GENITO URINARY SYSTEM AND SEX HORMONES						
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	**321**	**(14,9)**	**308**	**(14,3)**	**629**	**(14,6)**
BENZALKONIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
BORIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
CHLORAMPHENICOL	11	(0,5)	10	(0,5)	21	(0,5)
CHLORHEXIDINE	3	(0,1)	5	(0,2)	8	(0,2)
CHLORHEXIDINE GLUCONATE	6	(0,3)	14	(0,7)	20	(0,5)
CICLOPIROX	2	(0,1)	2	(0,1)	4	(0,1)
CIPROFLOXACIN	79	(3,7)	92	(4,3)	171	(4,0)
CIPROFLOXACIN LACTATE	0	(0,0)	3	(0,1)	3	(0,1)
CLINDAMYCIN	26	(1,2)	35	(1,6)	61	(1,4)
CLINDAMYCIN HYDROCHLORIDE	13	(0,6)	6	(0,3)	19	(0,4)
CLINDAMYCIN PHOSPHATE	2	(0,1)	4	(0,2)	6	(0,1)
CLOTRIMAZOLE	2	(0,1)	7	(0,3)	9	(0,2)
DEQUALINIUM CHLORIDE	7	(0,3)	5	(0,2)	12	(0,3)
ECONAZOLE	0	(0,0)	2	(0,1)	2	(0,0)
ECONAZOLE NITRATE	1	(0,0)	4	(0,2)	5	(0,1)
FLUCONAZOLE	14	(0,7)	15	(0,7)	29	(0,7)
HYDROCORTISONE ACETATE;NEOMYCIN SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
INOSINE	0	(0,0)	1	(0,0)	1	(0,0)
ISOCONAZOLE NITRATE	2	(0,1)	0	(0,0)	2	(0,0)
KETOCONAZOLE	5	(0,2)	4	(0,2)	9	(0,2)
LACTOBACILLUS RHAMNOSUS	6	(0,3)	5	(0,2)	11	(0,3)
METRONIDAZOLE	58	(2,7)	39	(1,8)	97	(2,3)
MICONAZOLE	6	(0,3)	4	(0,2)	10	(0,2)
MICONAZOLE NITRATE	6	(0,3)	3	(0,1)	9	(0,2)
NITROFURAL	2	(0,1)	1	(0,0)	3	(0,1)
NYSTATIN	17	(0,8)	15	(0,7)	32	(0,7)
OCTENIDINE HYDROCHLORIDE;PHENOXYETHANOL	1	(0,0)	1	(0,0)	2	(0,0)
ORNIDAZOLE	0	(0,0)	2	(0,1)	2	(0,0)
POTASSIUM	75	(3,5)	78	(3,6)	153	(3,6)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
GENITO URINARY SYSTEM AND SEX HORMONES						
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	**321**	**(14,9)**	**308**	**(14,3)**	**629**	**(14,6)**
POVIDONE-IODINE	18	(0,8)	8	(0,4)	26	(0,6)
SERTACONAZOLE	1	(0,0)	1	(0,0)	2	(0,0)
SERTACONAZOLE NITRATE	1	(0,0)	1	(0,0)	2	(0,0)
TINIDAZOLE	0	(0,0)	1	(0,0)	1	(0,0)
TIOCONAZOLE	0	(0,0)	2	(0,1)	2	(0,0)
OTHER GYNECOLOGICALS	**264**	**(12,3)**	**278**	**(12,9)**	**542**	**(12,6)**
AKEBIA SPP. STEM;ANGELICA ACUTILOBA ROOT;ASARUM SPP. ROOT;CINNAMOMUM CASSIA BARK;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;TETRADIUM RUTICARPUM FRUIT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
ARTEMISIA ARGYI LEAF	4	(0,2)	4	(0,2)	8	(0,2)
ASTRAGALUS MONGHOLICUS ROOT	0	(0,0)	1	(0,0)	1	(0,0)
BENZALKONIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
BENZYDAMINE HYDROCHLORIDE	6	(0,3)	1	(0,0)	7	(0,2)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
CABERGOLINE	1	(0,0)	1	(0,0)	2	(0,0)
CARBOMER	5	(0,2)	4	(0,2)	9	(0,2)
CROCUS SATIVUS	0	(0,0)	1	(0,0)	1	(0,0)
ETHACRIDINE LACTATE	0	(0,0)	2	(0,1)	2	(0,0)
FENOTEROL	9	(0,4)	12	(0,6)	21	(0,5)
FENOTEROL HYDROBROMIDE	5	(0,2)	8	(0,4)	13	(0,3)
GLUCOSE;MAGNESIUM SULFATE	1	(0,0)	2	(0,1)	3	(0,1)
GLYCEROL	21	(1,0)	20	(0,9)	41	(1,0)
HYALURONATE SODIUM	23	(1,1)	17	(0,8)	40	(0,9)
IBUPROFEN	49	(2,3)	33	(1,5)	82	(1,9)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
GENITO URINARY SYSTEM AND SEX HORMONES						
OTHER GYNECOLOGICALS	**264**	**(12,3)**	**278**	**(12,9)**	**542**	**(12,6)**
LACTOBACILLUS ACIDOPHILUS	9	(0,4)	14	(0,7)	23	(0,5)
LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS CASEI;LACTOBACILLUS RHAMNOSUS	2	(0,1)	1	(0,0)	3	(0,1)
LACTOBACILLUS NOS	1	(0,0)	0	(0,0)	1	(0,0)
LEVONORGESTREL	1	(0,0)	0	(0,0)	1	(0,0)
METHOTREXATE	2	(0,1)	7	(0,3)	9	(0,2)
MISOPROSTOL	1	(0,0)	0	(0,0)	1	(0,0)
NAPROXEN	10	(0,5)	16	(0,7)	26	(0,6)
NAPROXEN SODIUM	2	(0,1)	4	(0,2)	6	(0,1)
NIFEDIPINE	18	(0,8)	31	(1,4)	49	(1,1)
PAROXETINE	6	(0,3)	4	(0,2)	10	(0,2)
PHENOXYETHANOL;TRITICUM AESTIVUM	1	(0,0)	2	(0,1)	3	(0,1)
PROGESTERONE	1	(0,0)	0	(0,0)	1	(0,0)
SALVIA MILTIORRHIZA	1	(0,0)	0	(0,0)	1	(0,0)
SALVIA MILTIORRHIZA ROOT	0	(0,0)	1	(0,0)	1	(0,0)
SODIUM BICARBONATE	104	(4,8)	109	(5,1)	213	(5,0)
STREPTODORNASE;STREPTOKINASE	1	(0,0)	1	(0,0)	2	(0,0)
TERBUTALINE SULFATE	14	(0,7)	13	(0,6)	27	(0,6)
THIOTRIAZOLINE	2	(0,1)	3	(0,1)	5	(0,1)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
TRICHOSANTHES KIRILOWII	0	(0,0)	1	(0,0)	1	(0,0)
TRIGONELLA FOENUM-GRAECUM	0	(0,0)	1	(0,0)	1	(0,0)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	**22**	**(1,0)**	**27**	**(1,3)**	**49**	**(1,1)**
CYPROTERONE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
DESOGESTREL;ETHINYLESTRADIOL	1	(0,0)	0	(0,0)	1	(0,0)
ESTRADIOL	3	(0,1)	3	(0,1)	6	(0,1)
ESTRIOL	3	(0,1)	2	(0,1)	5	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
GENITO URINARY SYSTEM AND SEX HORMONES						
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	**22**	**(1,0)**	**27**	**(1,3)**	**49**	**(1,1)**
ESTROGENS CONJUGATED	1	(0,0)	3	(0,1)	4	(0,1)
ETHINYLESTRADIOL;GESTODENE	0	(0,0)	1	(0,0)	1	(0,0)
ETHINYLESTRADIOL;LEVONORGESTREL	1	(0,0)	0	(0,0)	1	(0,0)
GLYCINE MAX SEED OIL	0	(0,0)	1	(0,0)	1	(0,0)
LEVONORGESTREL	1	(0,0)	0	(0,0)	1	(0,0)
MEDROXYPROGESTERONE ACETATE	0	(0,0)	3	(0,1)	3	(0,1)
MEGESTROL ACETATE	5	(0,2)	7	(0,3)	12	(0,3)
NORETHISTERONE ENANTATE	2	(0,1)	2	(0,1)	4	(0,1)
PROGESTERONE	1	(0,0)	0	(0,0)	1	(0,0)
RALOXIFENE	0	(0,0)	1	(0,0)	1	(0,0)
TESTOSTERONE	1	(0,0)	2	(0,1)	3	(0,1)
TESTOSTERONE CIPIONATE	1	(0,0)	1	(0,0)	2	(0,0)
TESTOSTERONE ENANTHATE	1	(0,0)	0	(0,0)	1	(0,0)
TESTOSTERONE PROPIONATE	1	(0,0)	0	(0,0)	1	(0,0)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
UROLOGICALS	**495**	**(23,0)**	**499**	**(23,2)**	**994**	**(23,1)**
ABELMOSCHUS MANIHOT FLOWER	0	(0,0)	1	(0,0)	1	(0,0)
ACHYRANTHES BIDENTATA;CARTHAMUS TINCTORIUS;CITRUS RETICULATA;COPTIS CHINENSIS;GLYCYRRHIZA URALENSIS;PINELLIA TERNATA;PORIA COCOS;PSEUDOSTELLARIA HETEROPHYLLA;RHEUM PALMATUM;SALVIA MILTIORRHIZA	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
GENITO URINARY SYSTEM AND SEX HORMONES						
UROLOGICALS	**495**	**(23,0)**	**499**	**(23,2)**	**994**	**(23,1)**
ACONITUM SPP. PROCESSED ROOT;ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;CINNAMOMUM CASSIA BARK;CORNUS OFFICINALIS FRUIT;DIOSCOREA SPP. RHIZOME;PAEONIA X SUFFRUTICOSA ROOT BARK;PORIA COCOS SCLEROTIUM;REHMANNIA GLUTINOSA ROOT	0	(0,0)	2	(0,1)	2	(0,0)
AESCULUS HIPPOCASTANUM SEED;SERENOA REPENS;SOLIDAGO VIRGAUREA	0	(0,0)	1	(0,0)	1	(0,0)
ALFUZOSIN HYDROCHLORIDE	16	(0,7)	27	(1,3)	43	(1,0)
ALPROSTADIL	8	(0,4)	13	(0,6)	21	(0,5)
ALPROSTADIL ALFADEX	2	(0,1)	0	(0,0)	2	(0,0)
AMMONIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
ANETHOLE;BORNEOL;CAMPHENE ;CINEOLE;FENCHONE;PINENE	1	(0,0)	0	(0,0)	1	(0,0)
ASTRAGALUS MONGHOLICUS ROOT	0	(0,0)	1	(0,0)	1	(0,0)
BENZOCAINE	3	(0,1)	0	(0,0)	3	(0,1)
BIDENS TRIPARTITA HERB;HYPERICUM PERFORATUM HERB;ROSA SPP. FRUIT;VACCINIUM VITIS-IDAEA LEAF	1	(0,0)	0	(0,0)	1	(0,0)
BORON;CHROMIUM;COPPER;GERMANIUM;IODINE;MANGANESE;MOLYBDENUM;SELENIUM;SILICON;SITOSTEROL;VANADIUM;VITAMIN D NOS;ZINC	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CHLORIDE	8	(0,4)	12	(0,6)	20	(0,5)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
GENITO URINARY SYSTEM AND SEX HORMONES						
UROLOGICALS	**495**	**(23,0)**	**499**	**(23,2)**	**994**	**(23,1)**
CENTAURIUM ERYTHRAEA;LEVISTICUM OFFICINALE;ROSMARINUS OFFICINALIS	1	(0,0)	0	(0,0)	1	(0,0)
CHONDROITIN SULFATE SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
CITRIC ACID;POTASSIUM CITRATE	1	(0,0)	0	(0,0)	1	(0,0)
CITRIC ACID;SODIUM BICARBONATE;SODIUM CITRATE;TARTARIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
CITRIC ACID;SODIUM CITRATE ACID	1	(0,0)	0	(0,0)	1	(0,0)
COLLAGEN	2	(0,1)	2	(0,1)	4	(0,1)
CORDYCEPS SINENSIS	14	(0,7)	11	(0,5)	25	(0,6)
CROCUS SATIVUS	0	(0,0)	1	(0,0)	1	(0,0)
CUCURBITA PEPO SEED;CUCURBITA PEPO SEED OIL;SERENOA REPENS FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
CUCURBITA PEPO SEED;GLYCINE MAX	0	(0,0)	1	(0,0)	1	(0,0)
DOXAZOSIN	17	(0,8)	21	(1,0)	38	(0,9)
DOXAZOSIN MESILATE	22	(1,0)	17	(0,8)	39	(0,9)
DULOXETINE HYDROCHLORIDE	15	(0,7)	18	(0,8)	33	(0,8)
DUTASTERIDE	25	(1,2)	29	(1,3)	54	(1,3)
DUTASTERIDE;TAMSULOSIN HYDROCHLORIDE	8	(0,4)	11	(0,5)	19	(0,4)
ESCHERICHIA COLI	1	(0,0)	1	(0,0)	2	(0,0)
EUCOMMIA ULMOIDES	1	(0,0)	0	(0,0)	1	(0,0)
FESOTERODINE FUMARATE	1	(0,0)	1	(0,0)	2	(0,0)
FINASTERIDE	38	(1,8)	48	(2,2)	86	(2,0)
GASTRODIA ELATA	0	(0,0)	2	(0,1)	2	(0,0)
HYALURONATE SODIUM	23	(1,1)	17	(0,8)	40	(0,9)
ILLICIUM VERUM;LESPEDEZA CAPITATA	0	(0,0)	1	(0,0)	1	(0,0)
LIDOCAINE	61	(2,8)	62	(2,9)	123	(2,9)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
GENITO URINARY SYSTEM AND SEX HORMONES						
UROLOGICALS	**495**	**(23,0)**	**499**	**(23,2)**	**994**	**(23,1)**
LIDOCAINE HYDROCHLORIDE	43	(2,0)	40	(1,9)	83	(1,9)
MAGNESIUM CITRATE	6	(0,3)	8	(0,4)	14	(0,3)
MAGNESIUM HYDROXIDE	17	(0,8)	25	(1,2)	42	(1,0)
MIRABEGRON	8	(0,4)	15	(0,7)	23	(0,5)
NAFTOPIDIL	2	(0,1)	1	(0,0)	3	(0,1)
OXYBUTYNIN	4	(0,2)	4	(0,2)	8	(0,2)
OXYBUTYNIN HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
PAPAVERINE HYDROCHLORIDE	4	(0,2)	6	(0,3)	10	(0,2)
PHENAZOPYRIDINE HYDROCHLORIDE	6	(0,3)	9	(0,4)	15	(0,3)
PHENTOLAMINE MESILATE	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM CITRATE	15	(0,7)	14	(0,7)	29	(0,7)
POTASSIUM CITRATE;SODIUM CITRATE DIHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM PHOSPHATE MONOBASIC	5	(0,2)	6	(0,3)	11	(0,3)
POTASSIUM PHOSPHATE MONOBASIC;SODIUM PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
POTASSIUM PHOSPHATE MONOBASIC;SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	1	(0,0)	0	(0,0)	1	(0,0)
SERENOA REPENS	6	(0,3)	1	(0,0)	7	(0,2)
SERENOA REPENS EXTRACT	4	(0,2)	4	(0,2)	8	(0,2)
SERENOA REPENS EXTRACT;URTICA DIOICA EXTRACT	1	(0,0)	1	(0,0)	2	(0,0)
SILDENAFIL CITRATE	12	(0,6)	14	(0,7)	26	(0,6)
SILODOSIN	18	(0,8)	31	(1,4)	49	(1,1)
SODIUM BICARBONATE	104	(4,8)	109	(5,1)	213	(5,0)
SODIUM CITRATE	1	(0,0)	2	(0,1)	3	(0,1)
SOLIFENACIN SUCCINATE	4	(0,2)	7	(0,3)	11	(0,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
GENITO URINARY SYSTEM AND SEX HORMONES						
UROLOGICALS	**495**	**(23,0)**	**499**	**(23,2)**	**994**	**(23,1)**
TADALAFIL	2	(0,1)	0	(0,0)	2	(0,0)
TAMSULOSIN HYDROCHLORIDE	135	(6,3)	138	(6,4)	273	(6,3)
TERAZOSIN	2	(0,1)	2	(0,1)	4	(0,1)
TERAZOSIN HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
TOLTERODINE	0	(0,0)	2	(0,1)	2	(0,0)
TOLTERODINE L-TARTRATE	2	(0,1)	4	(0,2)	6	(0,1)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
TROSPIUM	1	(0,0)	0	(0,0)	1	(0,0)
TROSPIUM CHLORIDE	1	(0,0)	5	(0,2)	6	(0,1)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
OTHER	**2**	**(0,1)**	**2**	**(0,1)**	**4**	**(0,1)**
ARGININE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
MUSCULO-SKELETAL SYSTEM						
ANTIGOUT PREPARATIONS	**653**	**(30,3)**	**639**	**(29,7)**	**1.292**	**(30,0)**
ALLOPURINOL	449	(20,9)	440	(20,5)	889	(20,7)
BENZBROMARONE	31	(1,4)	33	(1,5)	64	(1,5)
COLCHICINE	122	(5,7)	111	(5,2)	233	(5,4)
COLCHICINE;DICYCLOVERINE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
COLCHICINE;PAPAVER SOMNIFERUM POWDER;TIEMONIUM METHYLSULPHATE	0	(0,0)	1	(0,0)	1	(0,0)
COLCHICINE;PROBENECID	1	(0,0)	0	(0,0)	1	(0,0)
COLCHICUM AUTUMNALE	0	(0,0)	1	(0,0)	1	(0,0)
COLCHICUM AUTUMNALE TINCTURE	0	(0,0)	1	(0,0)	1	(0,0)
FEBUXOSTAT	158	(7,3)	152	(7,1)	310	(7,2)
PROBENECID	1	(0,0)	0	(0,0)	1	(0,0)
SULFINPYRAZONE	2	(0,1)	1	(0,0)	3	(0,1)
TOPIROXOSTAT	4	(0,2)	1	(0,0)	5	(0,1)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	**323**	**(15,0)**	**312**	**(14,5)**	**635**	**(14,8)**
ACECLOFENAC	4	(0,2)	1	(0,0)	5	(0,1)
ACEMETACIN	1	(0,0)	2	(0,1)	3	(0,1)
ACONITUM CARMICHAELII	1	(0,0)	0	(0,0)	1	(0,0)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
ANIMAL HORN NOS;BEAR BILE;FORSYTHIA SUSPENSA FRUIT;LONICERA JAPONICA FLOWER;SCUTELLARIA BAICALENSIS ROOT	1	(0,0)	0	(0,0)	1	(0,0)
APRONAL;CAFFEINE;IBUPROFEN	0	(0,0)	1	(0,0)	1	(0,0)
ARGININE HYDROCHLORIDE;IBUPROFEN	2	(0,1)	2	(0,1)	4	(0,1)
ARNICA MONTANA	0	(0,0)	1	(0,0)	1	(0,0)
ASARUM HETEROTROPOIDES	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;CHONDROITIN SULFATE;GLUCOSAMINE SULFATE;MANGANESE SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
AZULENE	2	(0,1)	0	(0,0)	2	(0,0)
BAICALIN;BUFFALO HORN;CHOLIC ACID;CONCHA MARGARITIFERA;GARDENIA JASMINOIDES FRUIT;HYODEOXYCHOLIC ACID;ISATIS INDIGOTICA ROOT;LONICERA JAPONICA FLOWER	1	(0,0)	0	(0,0)	1	(0,0)
BENZYDAMINE HYDROCHLORIDE	6	(0,3)	1	(0,0)	7	(0,2)
BOSWELLIA SACRA;COMMIPHORA MYRRHA RESIN;COW BEZOAR;MUSK	0	(0,0)	1	(0,0)	1	(0,0)
BOSWELLIA SERRATA;CURCUMA LONGA	1	(0,0)	0	(0,0)	1	(0,0)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	**323**	**(15,0)**	**312**	**(14,5)**	**635**	**(14,8)**
BROMFENAC SODIUM	10	(0,5)	9	(0,4)	19	(0,4)
BUCILLAMINE	0	(0,0)	1	(0,0)	1	(0,0)
BUCOLOME	0	(0,0)	1	(0,0)	1	(0,0)
CELECOXIB	15	(0,7)	18	(0,8)	33	(0,8)
CHONDROITIN SULFATE SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
CHONDROITIN SULFATE SODIUM;GLUCOSAMINE HYDROCHLORIDE;HYALURONIC ACID;METHYLSULFONYLMETHANE	1	(0,0)	0	(0,0)	1	(0,0)
CHONDROITIN SULFATE SODIUM;GLUCOSAMINE SULFATE;METHYLSULFONYLMETHANE	1	(0,0)	0	(0,0)	1	(0,0)
CHONDROITIN;GLUCOSAMINE	3	(0,1)	3	(0,1)	6	(0,1)
CINNAMOMUM CASSIA BARK;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;NUPHAR JAPONICA RHIZOME;QUERCUS SPP. BARK;RHEUM SPP. RHIZOME;SYZYGIUM AROMATICUM FLOWER BUD	0	(0,0)	1	(0,0)	1	(0,0)
CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PRUNUS SPP. SEED	0	(0,0)	1	(0,0)	1	(0,0)
COLLAGEN	2	(0,1)	2	(0,1)	4	(0,1)
CORYDALIS BUNGEANA HERB;ISATIS INDIGOTICA ROOT;SCUTELLARIA BAICALENSIS ROOT;TARAXACUM MONGOLICUM HERB	5	(0,2)	2	(0,1)	7	(0,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	**323**	**(15,0)**	**312**	**(14,5)**	**635**	**(14,8)**
CURCUMA LONGA	3	(0,1)	1	(0,0)	4	(0,1)
DEXIBUPROFEN	1	(0,0)	0	(0,0)	1	(0,0)
DEXKETOPROFEN	2	(0,1)	1	(0,0)	3	(0,1)
DEXKETOPROFEN TROMETAMOL	7	(0,3)	4	(0,2)	11	(0,3)
DIACEREIN;MELOXICAM	0	(0,0)	1	(0,0)	1	(0,0)
DICLOFENAC	33	(1,5)	33	(1,5)	66	(1,5)
DICLOFENAC DIETHYLAMINE	12	(0,6)	15	(0,7)	27	(0,6)
DICLOFENAC EPOLAMINE	1	(0,0)	0	(0,0)	1	(0,0)
DICLOFENAC POTASSIUM	5	(0,2)	6	(0,3)	11	(0,3)
DICLOFENAC SODIUM	36	(1,7)	30	(1,4)	66	(1,5)
EDETIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
ETODOLAC	12	(0,6)	0	(0,0)	12	(0,3)
ETOFENAMATE	3	(0,1)	2	(0,1)	5	(0,1)
ETORICOXIB	6	(0,3)	7	(0,3)	13	(0,3)
FLURBIPROFEN	13	(0,6)	11	(0,5)	24	(0,6)
FLURBIPROFEN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
GLUCOSAMINE	0	(0,0)	3	(0,1)	3	(0,1)
GLUCOSAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
GLUCOSAMINE SULFATE	2	(0,1)	1	(0,0)	3	(0,1)
GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT	3	(0,1)	10	(0,5)	13	(0,3)
GUAIAZULENE	10	(0,5)	4	(0,2)	14	(0,3)
HEPARINOID	19	(0,9)	9	(0,4)	28	(0,7)
HYDROXYCHLOROQUINE SULFATE	3	(0,1)	6	(0,3)	9	(0,2)
IBUPROFEN	49	(2,3)	33	(1,5)	82	(1,9)
IBUPROFEN;PSEUDOEPHEDRINE	1	(0,0)	0	(0,0)	1	(0,0)
INDOMETACIN	14	(0,7)	10	(0,5)	24	(0,6)
KETOPROFEN	41	(1,9)	49	(2,3)	90	(2,1)
KETOROLAC TROMETHAMINE	21	(1,0)	24	(1,1)	45	(1,0)
LINUM USITATISSIMUM	1	(0,0)	0	(0,0)	1	(0,0)
LORNOXICAM	1	(0,0)	4	(0,2)	5	(0,1)
LOXOPROFEN	3	(0,1)	2	(0,1)	5	(0,1)
LOXOPROFEN SODIUM	42	(2,0)	31	(1,4)	73	(1,7)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	**323**	**(15,0)**	**312**	**(14,5)**	**635**	**(14,8)**
LOXOPROFEN SODIUM DIHYDRATE	0	(0,0)	1	(0,0)	1	(0,0)
MEFENAMIC ACID	4	(0,2)	4	(0,2)	8	(0,2)
MELOXICAM	8	(0,4)	9	(0,4)	17	(0,4)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	18	(0,8)	17	(0,8)	35	(0,8)
NABUMETONE	0	(0,0)	1	(0,0)	1	(0,0)
NAPROXEN	10	(0,5)	16	(0,7)	26	(0,6)
NAPROXEN SODIUM	2	(0,1)	4	(0,2)	6	(0,1)
NIFLUMIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
NIMESULIDE	3	(0,1)	9	(0,4)	12	(0,3)
PELUBIPROFEN	1	(0,0)	0	(0,0)	1	(0,0)
PHENYLBUTAZONE	0	(0,0)	1	(0,0)	1	(0,0)
PIROXICAM	1	(0,0)	2	(0,1)	3	(0,1)
PIROXICAM BETADEX	0	(0,0)	1	(0,0)	1	(0,0)
POLIDERIBOTIDE	0	(0,0)	1	(0,0)	1	(0,0)
PRANOPROFEN	4	(0,2)	3	(0,1)	7	(0,2)
RABBIT VACCINIA EXTRACT	3	(0,1)	2	(0,1)	5	(0,1)
SULFASALAZINE	2	(0,1)	7	(0,3)	9	(0,2)
SUPROFEN	1	(0,0)	0	(0,0)	1	(0,0)
TALNIFLUMATE	1	(0,0)	0	(0,0)	1	(0,0)
TENOXICAM	1	(0,0)	0	(0,0)	1	(0,0)
TIARAMIDE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
TRICHOSANTHES KIRILOWII	0	(0,0)	1	(0,0)	1	(0,0)
VACCINIUM MACROCARPON	0	(0,0)	2	(0,1)	2	(0,0)
ZALTOPROFEN	1	(0,0)	2	(0,1)	3	(0,1)
ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
DRUGS FOR TREATMENT OF BONE DISEASES	**21**	**(1,0)**	**23**	**(1,1)**	**44**	**(1,0)**
ALENDRONATE SODIUM	6	(0,3)	10	(0,5)	16	(0,4)
ALENDRONIC ACID	1	(0,0)	3	(0,1)	4	(0,1)
COLECALCIFEROL;IBANDRONATE SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
DENOSUMAB	7	(0,3)	6	(0,3)	13	(0,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
DRUGS FOR TREATMENT OF BONE DISEASES	**21**	**(1,0)**	**23**	**(1,1)**	**44**	**(1,0)**
IBANDRONATE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
IBANDRONIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
PAMIDRONATE DISODIUM	1	(0,0)	0	(0,0)	1	(0,0)
PAMIDRONIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
RISEDRONATE SODIUM	4	(0,2)	2	(0,1)	6	(0,1)
ZOLEDRONIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
MUSCLE RELAXANTS	**103**	**(4,8)**	**126**	**(5,9)**	**229**	**(5,3)**
ATRACURIUM BESILATE	3	(0,1)	0	(0,0)	3	(0,1)
BACLOFEN	6	(0,3)	5	(0,2)	11	(0,3)
BOTULINUM TOXIN TYPE A	1	(0,0)	0	(0,0)	1	(0,0)
CHLORZOXAZONE	2	(0,1)	8	(0,4)	10	(0,2)
CHLORZOXAZONE;PARACETAMOL	0	(0,0)	1	(0,0)	1	(0,0)
CISATRACURIUM BESILATE	0	(0,0)	6	(0,3)	6	(0,1)
CYCLOBENZAPRINE HYDROCHLORIDE	7	(0,3)	21	(1,0)	28	(0,7)
DIAZEPAM	34	(1,6)	37	(1,7)	71	(1,7)
DICLOFENAC SODIUM;ORPHENADRINE CITRATE	2	(0,1)	1	(0,0)	3	(0,1)
EPERISONE	2	(0,1)	0	(0,0)	2	(0,0)
EPERISONE HYDROCHLORIDE	3	(0,1)	5	(0,2)	8	(0,2)
MEPHENOXALONE	0	(0,0)	4	(0,2)	4	(0,1)
METHOCARBAMOL	3	(0,1)	6	(0,3)	9	(0,2)
ORPHENADRINE	1	(0,0)	0	(0,0)	1	(0,0)
ORPHENADRINE CITRATE	1	(0,0)	1	(0,0)	2	(0,0)
ORPHENADRINE CITRATE;PARACETAMOL	8	(0,4)	6	(0,3)	14	(0,3)
PANCURONIUM BROMIDE	1	(0,0)	0	(0,0)	1	(0,0)
PIPECURONIUM BROMIDE	2	(0,1)	0	(0,0)	2	(0,0)
ROCURONIUM BROMIDE	14	(0,7)	17	(0,8)	31	(0,7)
SUXAMETHONIUM CHLORIDE	9	(0,4)	6	(0,3)	15	(0,3)
THIOCOLCHICOSIDE	2	(0,1)	1	(0,0)	3	(0,1)
TIZANIDINE HYDROCHLORIDE	5	(0,2)	10	(0,5)	15	(0,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
MUSCLE RELAXANTS	**103**	**(4,8)**	**126**	**(5,9)**	**229**	**(5,3)**
TOLPERISONE	3	(0,1)	2	(0,1)	5	(0,1)
TOLPERISONE HYDROCHLORIDE	1	(0,0)	5	(0,2)	6	(0,1)
VECURONIUM BROMIDE	5	(0,2)	7	(0,3)	12	(0,3)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	**71**	**(3,3)**	**56**	**(2,6)**	**127**	**(3,0)**
AMINOPHYLLINE;QUININE SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
BROMELAINS	0	(0,0)	1	(0,0)	1	(0,0)
CHYMOTRYPSIN	0	(0,0)	1	(0,0)	1	(0,0)
ENZYMES NOS	5	(0,2)	3	(0,1)	8	(0,2)
GELATIN	2	(0,1)	0	(0,0)	2	(0,0)
HEPARINOID	19	(0,9)	9	(0,4)	28	(0,7)
HYALURONATE SODIUM	23	(1,1)	17	(0,8)	40	(0,9)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	18	(0,8)	17	(0,8)	35	(0,8)
PAPAIN	1	(0,0)	0	(0,0)	1	(0,0)
PERNA CALICULATA EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
PRONASE	2	(0,1)	6	(0,3)	8	(0,2)
QUININE	1	(0,0)	4	(0,2)	5	(0,1)
QUININE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
QUININE SULFATE	3	(0,1)	0	(0,0)	3	(0,1)
SERRAPEPTASE	0	(0,0)	1	(0,0)	1	(0,0)
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	**1.221**	**(56,7)**	**1.178**	**(54,8)**	**2.399**	**(55,8)**
ACECLOFENAC	4	(0,2)	1	(0,0)	5	(0,1)
ACETYLSALICYLIC ACID	1.060	(49,3)	1.015	(47,2)	2.075	(48,2)
ALUMINIUM ACETOTARTRATE	2	(0,1)	0	(0,0)	2	(0,0)
ARNICA MONTANA	0	(0,0)	1	(0,0)	1	(0,0)
BENZYDAMINE HYDROCHLORIDE	6	(0,3)	1	(0,0)	7	(0,2)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
CAMPHOR	2	(0,1)	1	(0,0)	3	(0,1)
CAMPHOR;CAPSICUM SPP.;METHYL SALICYLATE	0	(0,0)	2	(0,1)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	**1.221**	**(56,7)**	**1.178**	**(54,8)**	**2.399**	**(55,8)**
CAMPHOR;CHLORPHENAMINE MALEATE;HEXACHLOROPHENE;LIDOCAINE HYDROCHLORIDE;MENTHOL;METHYL SALICYLATE	2	(0,1)	4	(0,2)	6	(0,1)
CAMPHOR;ENOXOLONE;LEVOMENTHOL;METHYL SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)
CAMPHOR;LEVOMENTHOL;METHYL SALICYLATE	1	(0,0)	2	(0,1)	3	(0,1)
CAMPHOR;MENTHOL	1	(0,0)	0	(0,0)	1	(0,0)
CAMPHOR;MENTHOL;METHYL SALICYLATE	1	(0,0)	1	(0,0)	2	(0,0)
CAPSAICIN	3	(0,1)	2	(0,1)	5	(0,1)
CHONDROITIN SULFATE SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
CHONDROITIN SULFATE SODIUM;GLUCOSAMINE SULFATE;METHYLSULFONYLMETHANE	1	(0,0)	0	(0,0)	1	(0,0)
CHONDROITIN;GLUCOSAMINE	3	(0,1)	3	(0,1)	6	(0,1)
CINEOLE;MELALEUCA LEUCADENDRA OIL;MENTHOL;METHYL SALICYLATE	1	(0,0)	2	(0,1)	3	(0,1)
DEXIBUPROFEN	1	(0,0)	0	(0,0)	1	(0,0)
DEXKETOPROFEN	2	(0,1)	1	(0,0)	3	(0,1)
DEXKETOPROFEN TROMETAMOL	7	(0,3)	4	(0,2)	11	(0,3)
DICLOFENAC	33	(1,5)	33	(1,5)	66	(1,5)
DICLOFENAC DIETHYLAMINE	12	(0,6)	15	(0,7)	27	(0,6)
DICLOFENAC EPOLAMINE	1	(0,0)	0	(0,0)	1	(0,0)
DICLOFENAC SODIUM	36	(1,7)	30	(1,4)	66	(1,5)
ESFLURBIPROFEN;MENTHA SPP. OIL	3	(0,1)	2	(0,1)	5	(0,1)
ETOFENAMATE	3	(0,1)	2	(0,1)	5	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	**1.221**	**(56,7)**	**1.178**	**(54,8)**	**2.399**	**(55,8)**
FELBINAC	9	(0,4)	14	(0,7)	23	(0,5)
FLURBIPROFEN	13	(0,6)	11	(0,5)	24	(0,6)
FLURBIPROFEN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
FOLIC ACID	93	(4,3)	93	(4,3)	186	(4,3)
GLUCOSAMINE	0	(0,0)	3	(0,1)	3	(0,1)
GLUCOSAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
GLUCOSAMINE SULFATE	2	(0,1)	1	(0,0)	3	(0,1)
HEPARINOID	19	(0,9)	9	(0,4)	28	(0,7)
HEPARINOID;SALICYLIC ACID;SUPRARENAL EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
IBUPROFEN	49	(2,3)	33	(1,5)	82	(1,9)
INDOMETACIN	14	(0,7)	10	(0,5)	24	(0,6)
KETOPROFEN	41	(1,9)	49	(2,3)	90	(2,1)
LINUM USITATISSIMUM	1	(0,0)	0	(0,0)	1	(0,0)
LOXOPROFEN	3	(0,1)	2	(0,1)	5	(0,1)
LOXOPROFEN SODIUM	42	(2,0)	31	(1,4)	73	(1,7)
LOXOPROFEN SODIUM DIHYDRATE	0	(0,0)	1	(0,0)	1	(0,0)
MAGNESIUM CHLORIDE	6	(0,3)	1	(0,0)	7	(0,2)
MELOXICAM	8	(0,4)	9	(0,4)	17	(0,4)
MENTHOL	1	(0,0)	1	(0,0)	2	(0,0)
MENTHOL;METHYL SALICYLATE	0	(0,0)	1	(0,0)	1	(0,0)
METHYL SALICYLATE	4	(0,2)	5	(0,2)	9	(0,2)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	18	(0,8)	17	(0,8)	35	(0,8)
NAPROXEN	10	(0,5)	16	(0,7)	26	(0,6)
NAPROXEN SODIUM	2	(0,1)	4	(0,2)	6	(0,1)
NICOTINIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
NIFLUMIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
NIMESULIDE	3	(0,1)	9	(0,4)	12	(0,3)
PHENYLBUTAZONE	0	(0,0)	1	(0,0)	1	(0,0)
PHOSPHOLIPIDS	2	(0,1)	2	(0,1)	4	(0,1)
PIROXICAM	1	(0,0)	2	(0,1)	3	(0,1)
PIROXICAM BETADEX	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
MUSCULO-SKELETAL SYSTEM						
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	**1.221**	**(56,7)**	**1.178**	**(54,8)**	**2.399**	**(55,8)**
SALICYLIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
SUPROFEN	1	(0,0)	0	(0,0)	1	(0,0)
TOLPERISONE	3	(0,1)	2	(0,1)	5	(0,1)
TOLPERISONE HYDROCHLORIDE	1	(0,0)	5	(0,2)	6	(0,1)
TROLAMINE SALICYLATE	1	(0,0)	0	(0,0)	1	(0,0)
VACCINIUM MACROCARPON	0	(0,0)	2	(0,1)	2	(0,0)
ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
OTHER	**1**	**(0,0)**	**0**	**(0,0)**	**1**	**(0,0)**
FOSFOCREATININE	1	(0,0)	0	(0,0)	1	(0,0)
NERVOUS SYSTEM						
ANALGESICS	**1.618**	**(75,2)**	**1.611**	**(74,9)**	**3.229**	**(75,0)**
ACETYLSALICYLATE LYSINE	13	(0,6)	8	(0,4)	21	(0,5)
ACETYLSALICYLIC ACID	1.060	(49,3)	1.015	(47,2)	2.075	(48,2)
ACETYLSALICYLIC ACID;ALUMINIUM GLYCINATE;MAGNESIUM CARBONATE	2	(0,1)	2	(0,1)	4	(0,1)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	1	(0,0)	1	(0,0)	2	(0,0)
ACETYLSALICYLIC ACID;CALCIUM CARBONATE	0	(0,0)	1	(0,0)	1	(0,0)
ACETYLSALICYLIC ACID;GLYCINE	18	(0,8)	15	(0,7)	33	(0,8)
ACETYLSALICYLIC ACID;MAGNESIUM HYDROXIDE	13	(0,6)	13	(0,6)	26	(0,6)
ACETYLSALICYLIC ACID;MAGNESIUM OXIDE	1	(0,0)	3	(0,1)	4	(0,1)
ACONITUM CARMICHAELII	1	(0,0)	0	(0,0)	1	(0,0)
AMANTADINE HYDROCHLORIDE;CAFFEINE;CHLORPHENAMINE MALEATE;COW BEZOAR;PARACETAMOL	5	(0,2)	0	(0,0)	5	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANALGESICS	**1.618**	**(75,2)**	**1.611**	**(74,9)**	**3.229**	**(75,0)**
AMANTADINE HYDROCHLORIDE;PARACETAMOL	1	(0,0)	0	(0,0)	1	(0,0)
AMINOPHENAZONE;CAFFEINE;CHLORPHENAMINE MALEATE;PARACETAMOL	0	(0,0)	1	(0,0)	1	(0,0)
AMINOPHENAZONE;PHENAZONE;PHENOBARBITAL	1	(0,0)	1	(0,0)	2	(0,0)
AMITRIPTYLINE HYDROCHLORIDE	33	(1,5)	25	(1,2)	58	(1,3)
ANALGESICS	1	(0,0)	4	(0,2)	5	(0,1)
ARTEMISIA ARGYI LEAF	4	(0,2)	4	(0,2)	8	(0,2)
ASARUM HETEROTROPOIDES	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;ATROPINE SULFATE;CAFFEINE;CHLORPHENAMINE MALEATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;CAFFEINE;CHLORPHENAMINE MALEATE;PARACETAMOL	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;CAFFEINE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE;TERPIN	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;PARACETAMOL;PHENIRAMINE MALEATE	1	(0,0)	1	(0,0)	2	(0,0)
ASCORBIC ACID;PARACETAMOL;PHENIRAMINE MALEATE;PHENYLEPHRINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;RUTOSIDE;SALICYLAMIDE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
NERVOUS SYSTEM						
ANALGESICS	**1.618**	**(75,2)**	**1.611**	**(74,9)**	**3.229**	**(75,0)**
BAPHICACANTHUS CUSIA;CAFFEINE;CHLORPHENAMINE MALEATE;CHRYSANTHEMUM INDICUM;CITRUS MEDICA VAR. SARCODACTYLIS;EVODIA LEPTA;ILEX ASPRELLA;LONICERA JAPONICA;PARACETAMOL	1	(0,0)	0	(0,0)	1	(0,0)
BIDENS BITERNATA;CAFFEINE;CHLORPHENAMINE MALEATE;CHRYSANTHEMUM INDICUM FLOWER;ILEX ASPRELLA ROOT;MELICOPE PTELEIFOLIA;MENTHA CANADENSIS OIL;PARACETAMOL	1	(0,0)	1	(0,0)	2	(0,0)
BORNEOL;CALCIUM SULFATE;COW BEZOAR;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;PLATYCODON GRANDIFLORUS ROOT;REALGAR;RHEUM SPP. ROOT WITH RHIZOME;SCUTELLARIA BAICALENSIS ROOT	1	(0,0)	1	(0,0)	2	(0,0)
BOTULINUM TOXIN TYPE A	1	(0,0)	0	(0,0)	1	(0,0)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
BROMHEXINE HYDROCHLORIDE;CHLORPHENAMINE MALEATE;NOSCAPINE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANALGESICS	**1.618**	**(75,2)**	**1.611**	**(74,9)**	**3.229**	**(75,0)**
BROMISOVAL;DIHYDROCODEINE PHOSPHATE;DIPHENHYDRAMINE SALICYLATE;DIPROPHYLLINE;METHYLEPHEDRINE HYDROCHLORIDE-DL;PARACETAMOL	1	(0,0)	0	(0,0)	1	(0,0)
BUPRENORPHINE	2	(0,1)	6	(0,3)	8	(0,2)
BUPRENORPHINE HYDROCHLORIDE	1	(0,0)	3	(0,1)	4	(0,1)
BUPRENORPHINE HYDROCHLORIDE;NALOXONE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
BUTALBITAL;CAFFEINE;PARACETAMOL	1	(0,0)	2	(0,1)	3	(0,1)
CAFFEINE;CARBINOXAMINE MALEATE;DIHYDROCODEINE PHOSPHATE;GUAIFENESIN;LYSOZYME CHLORIDE;METHYLEPHEDRINE HYDROCHLORIDE-DL;PARACETAMOL;RIBOFLAVIN;SULBUTIAMINE	1	(0,0)	0	(0,0)	1	(0,0)
CAFFEINE;CHLORPHENAMINE MALEATE;COW BEZOAR;PARACETAMOL	1	(0,0)	1	(0,0)	2	(0,0)
CAFFEINE;CHLORPHENAMINE MALEATE;DIHYDROCODEINE PHOSPHATE;GLYCYRRHIZA GLABRA EXTRACT;METHYLEPHEDRINE HYDROCHLORIDE-DL;PARACETAMOL	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANALGESICS	**1.618**	**(75,2)**	**1.611**	**(74,9)**	**3.229**	**(75,0)**
CAFFEINE;CHLORPHENAMINE MALEATE;PARACETAMOL;SALICYLAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
CAFFEINE;CODEINE PHOSPHATE;MEPROBAMATE;PARACETAMOL	0	(0,0)	2	(0,1)	2	(0,0)
CAFFEINE;CODEINE PHOSPHATE;METAMIZOLE SODIUM;PARACETAMOL;PHENOBARBITAL	0	(0,0)	1	(0,0)	1	(0,0)
CAFFEINE;CODEINE PHOSPHATE;PARACETAMOL	5	(0,2)	6	(0,3)	11	(0,3)
CAFFEINE;ETHENZAMIDE;PARACETAMOL	1	(0,0)	0	(0,0)	1	(0,0)
CAFFEINE;GUAIFENESIN;PARACETAMOL	0	(0,0)	1	(0,0)	1	(0,0)
CAFFEINE;PARACETAMOL	1	(0,0)	0	(0,0)	1	(0,0)
CAFFEINE;PARACETAMOL;PROMETHAZINE METHYLENE DISALICYLATE;SALICYLAMIDE	16	(0,7)	15	(0,7)	31	(0,7)
CAFFEINE;PARACETAMOL;PROPYPHENAZONE	3	(0,1)	2	(0,1)	5	(0,1)
CALCIUM BROMIDE;CINCHOCAINE HYDROCHLORIDE;SALICYLATE SODIUM	2	(0,1)	1	(0,0)	3	(0,1)
CARBAMAZEPINE	8	(0,4)	5	(0,2)	13	(0,3)
CARBASALATE CALCIUM	1	(0,0)	0	(0,0)	1	(0,0)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANALGESICS	**1.618**	**(75,2)**	**1.611**	**(74,9)**	**3.229**	**(75,0)**
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROCHLORIDE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
CHLORPHENAMINE MALEATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
CHLORPHENAMINE MALEATE;PARACETAMOL;PHENYLPROPANOLAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CHOLINE SALICYLATE	3	(0,1)	1	(0,0)	4	(0,1)
CINNAMOMUM CASSIA BARK;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;NUPHAR JAPONICA RHIZOME;QUERCUS SPP. BARK;RHEUM SPP. RHIZOME;SYZYGIUM AROMATICUM FLOWER BUD	0	(0,0)	1	(0,0)	1	(0,0)
CLONIDINE	4	(0,2)	9	(0,4)	13	(0,3)
CLONIDINE HYDROCHLORIDE	0	(0,0)	6	(0,3)	6	(0,1)
CLONIXIN LYSINATE	0	(0,0)	1	(0,0)	1	(0,0)
CODEINE	21	(1,0)	13	(0,6)	34	(0,8)
CODEINE PHOSPHATE	14	(0,7)	14	(0,7)	28	(0,7)
CODEINE PHOSPHATE;IBUPROFEN	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANALGESICS	**1.618**	**(75,2)**	**1.611**	**(74,9)**	**3.229**	**(75,0)**
CODEINE PHOSPHATE;IBUPROFEN;PARACETAMOL	1	(0,0)	1	(0,0)	2	(0,0)
CODEINE PHOSPHATE;PARACETAMOL	12	(0,6)	17	(0,8)	29	(0,7)
CODEINE;PARACETAMOL	3	(0,1)	6	(0,3)	9	(0,2)
CROCUS SATIVUS	0	(0,0)	1	(0,0)	1	(0,0)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	0	(0,0)	1	(0,0)	1	(0,0)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
DEZOCINE	2	(0,1)	2	(0,1)	4	(0,1)
DIHYDROCODEINE	3	(0,1)	5	(0,2)	8	(0,2)
DIHYDROCODEINE BITARTRATE	3	(0,1)	4	(0,2)	7	(0,2)
DIHYDROCODEINE BITARTRATE;PARACETAMOL	1	(0,0)	0	(0,0)	1	(0,0)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1	(0,0)	1	(0,0)	2	(0,0)
DULOXETINE HYDROCHLORIDE	15	(0,7)	18	(0,8)	33	(0,8)
ERIOBOTRYA JAPONICA	0	(0,0)	2	(0,1)	2	(0,0)
EUCOMMIA ULMOIDES	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANALGESICS	**1.618**	**(75,2)**	**1.611**	**(74,9)**	**3.229**	**(75,0)**
FENPIVERINIUM BROMIDE;METAMIZOLE SODIUM;PITOFENONE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
FENTANYL	80	(3,7)	71	(3,3)	151	(3,5)
FENTANYL CITRATE	12	(0,6)	20	(0,9)	32	(0,7)
FLUNARIZINE	3	(0,1)	0	(0,0)	3	(0,1)
FLUNARIZINE DIHYDROCHLORIDE	1	(0,0)	4	(0,2)	5	(0,1)
FLUPIRTINE MALEATE	0	(0,0)	1	(0,0)	1	(0,0)
GABAPENTIN	67	(3,1)	79	(3,7)	146	(3,4)
GASTRODIA ELATA	0	(0,0)	2	(0,1)	2	(0,0)
GLUCUROLACTONE	1	(0,0)	0	(0,0)	1	(0,0)
GUAIFENESIN;NOSCAPINE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
HYDROCODONE	8	(0,4)	10	(0,5)	18	(0,4)
HYDROCODONE BITARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCODONE BITARTRATE;PARACETAMOL	20	(0,9)	22	(1,0)	42	(1,0)
HYDROMORPHONE	20	(0,9)	28	(1,3)	48	(1,1)
HYDROMORPHONE HYDROCHLORIDE	11	(0,5)	16	(0,7)	27	(0,6)
HYOSCINE BUTYLBROMIDE;METAMIZOLE SODIUM	1	(0,0)	2	(0,1)	3	(0,1)
IBUPROFEN;PARACETAMOL	1	(0,0)	1	(0,0)	2	(0,0)
IPRAZOCHROME	0	(0,0)	1	(0,0)	1	(0,0)
LORATADINE;PARACETAMOL;PHENYLEPHRINE	0	(0,0)	1	(0,0)	1	(0,0)
METAMIZOLE MAGNESIUM	5	(0,2)	4	(0,2)	9	(0,2)
METAMIZOLE SODIUM	124	(5,8)	131	(6,1)	255	(5,9)
METAMIZOLE SODIUM MONOHYDRATE	1	(0,0)	1	(0,0)	2	(0,0)
METHADONE HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANALGESICS	**1.618**	**(75,2)**	**1.611**	**(74,9)**	**3.229**	**(75,0)**
METOPROLOL	198	(9,2)	224	(10,4)	422	(9,8)
METOPROLOL SUCCINATE	248	(11,5)	229	(10,6)	477	(11,1)
METOPROLOL TARTRATE	98	(4,6)	88	(4,1)	186	(4,3)
MILNACIPRAN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
MORPHINE	88	(4,1)	98	(4,6)	186	(4,3)
MORPHINE HYDROCHLORIDE	22	(1,0)	21	(1,0)	43	(1,0)
MORPHINE SULFATE	14	(0,7)	19	(0,9)	33	(0,8)
MORPHINE SULFATE PENTAHYDRATE	0	(0,0)	1	(0,0)	1	(0,0)
NALBUPHINE HYDROCHLORIDE	3	(0,1)	1	(0,0)	4	(0,1)
NALOXONE HYDROCHLORIDE;OXYCODONE HYDROCHLORIDE	8	(0,4)	7	(0,3)	15	(0,3)
NALOXONE HYDROCHLORIDE;TILIDINE HYDROCHLORIDE	6	(0,3)	5	(0,2)	11	(0,3)
NEFOPAM	2	(0,1)	1	(0,0)	3	(0,1)
NEFOPAM HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
OXCARBAZEPINE	2	(0,1)	0	(0,0)	2	(0,0)
OXYCODONE	26	(1,2)	32	(1,5)	58	(1,3)
OXYCODONE HYDROCHLORIDE	18	(0,8)	26	(1,2)	44	(1,0)
OXYCODONE HYDROCHLORIDE;PARACETAMOL	18	(0,8)	17	(0,8)	35	(0,8)
OXYMORPHONE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
PARACETAMOL	475	(22,1)	484	(22,5)	959	(22,3)
PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
PARACETAMOL;TRAMADOL HYDROCHLORIDE	42	(2,0)	25	(1,2)	67	(1,6)
PENTAZOCINE	11	(0,5)	8	(0,4)	19	(0,4)
PENTAZOCINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
PETHIDINE HYDROCHLORIDE	12	(0,6)	12	(0,6)	24	(0,6)
PIRITRAMIDE	1	(0,0)	4	(0,2)	5	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANALGESICS	**1.618**	**(75,2)**	**1.611**	**(74,9)**	**3.229**	**(75,0)**
PLATYCODON GRANDIFLORUS	5	(0,2)	4	(0,2)	9	(0,2)
PREGABALIN	54	(2,5)	58	(2,7)	112	(2,6)
PRONILIDE	0	(0,0)	1	(0,0)	1	(0,0)
PROPACETAMOL	0	(0,0)	2	(0,1)	2	(0,0)
PROPACETAMOL HYDROCHLORIDE	4	(0,2)	2	(0,1)	6	(0,1)
PROPRANOLOL	3	(0,1)	2	(0,1)	5	(0,1)
PROPRANOLOL HYDROCHLORIDE	2	(0,1)	5	(0,2)	7	(0,2)
SALICYLIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
SUFENTANIL	3	(0,1)	5	(0,2)	8	(0,2)
SUFENTANIL CITRATE	2	(0,1)	2	(0,1)	4	(0,1)
SUMATRIPTAN	1	(0,0)	0	(0,0)	1	(0,0)
TAPENTADOL	1	(0,0)	0	(0,0)	1	(0,0)
TAPENTADOL HYDROCHLORIDE	4	(0,2)	3	(0,1)	7	(0,2)
TETRAHYDROPALMATINE	0	(0,0)	1	(0,0)	1	(0,0)
TOPIRAMATE	3	(0,1)	2	(0,1)	5	(0,1)
TRAMADOL HYDROCHLORIDE	158	(7,3)	166	(7,7)	324	(7,5)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
TRIMEPERIDINE	1	(0,0)	0	(0,0)	1	(0,0)
VALPROATE SEMISODIUM	1	(0,0)	2	(0,1)	3	(0,1)
VALPROIC ACID	2	(0,1)	3	(0,1)	5	(0,1)
VENLAFAXINE HYDROCHLORIDE	13	(0,6)	13	(0,6)	26	(0,6)
VERAPAMIL	6	(0,3)	4	(0,2)	10	(0,2)
VERAPAMIL HYDROCHLORIDE	2	(0,1)	11	(0,5)	13	(0,3)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
ANESTHETICS	**210**	**(9,8)**	**197**	**(9,2)**	**407**	**(9,5)**
ACONITUM CARMICHAELII	1	(0,0)	0	(0,0)	1	(0,0)
ALFENTANIL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
AMIDES	0	(0,0)	1	(0,0)	1	(0,0)
ANAESTHETICS	2	(0,1)	1	(0,0)	3	(0,1)
BENZOCAINE	3	(0,1)	0	(0,0)	3	(0,1)
BENZOCAINE;BUTYL AMINOBENZOATE;TETRACAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
BENZOCAINE;MENTHOL	0	(0,0)	5	(0,2)	5	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANESTHETICS	**210**	**(9,8)**	**197**	**(9,2)**	**407**	**(9,5)**
BUPIVACAINE	9	(0,4)	6	(0,3)	15	(0,3)
BUPIVACAINE HYDROCHLORIDE	8	(0,4)	2	(0,1)	10	(0,2)
BUPIVACAINE HYDROCHLORIDE;EPINEPHRINE BITARTRATE	1	(0,0)	2	(0,1)	3	(0,1)
BUPIVACAINE HYDROCHLORIDE;LIDOCAINE	1	(0,0)	0	(0,0)	1	(0,0)
CAMPHORSULFONIC ACID;PROCAINE	0	(0,0)	1	(0,0)	1	(0,0)
CAPSAICIN	3	(0,1)	2	(0,1)	5	(0,1)
CHLORHEXIDINE GLUCONATE;LIDOCAINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
COCAINE	1	(0,0)	1	(0,0)	2	(0,0)
DESFLURANE	3	(0,1)	0	(0,0)	3	(0,1)
EPINEPHRINE BITARTRATE;LIDOCAINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
EPINEPHRINE HYDROCHLORIDE;LIDOCAINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
EPINEPHRINE;LIDOCAINE HYDROCHLORIDE	5	(0,2)	5	(0,2)	10	(0,2)
EPINEPHRINE;LIDOCAINE;TETRACAINE	1	(0,0)	0	(0,0)	1	(0,0)
ESKETAMINE	0	(0,0)	1	(0,0)	1	(0,0)
ETOMIDATE	10	(0,5)	7	(0,3)	17	(0,4)
FELYPRESSIN;PRILOCAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
FENTANYL	80	(3,7)	71	(3,3)	151	(3,5)
FENTANYL CITRATE	12	(0,6)	20	(0,9)	32	(0,7)
KETAMINE	5	(0,2)	8	(0,4)	13	(0,3)
KETAMINE HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
KETAMINE;PROPOFOL	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANESTHETICS	**210**	**(9,8)**	**197**	**(9,2)**	**407**	**(9,5)**
LEVOBUPIVACAINE	2	(0,1)	0	(0,0)	2	(0,0)
LIDOCAINE	61	(2,8)	62	(2,9)	123	(2,9)
LIDOCAINE HYDROCHLORIDE	43	(2,0)	40	(1,9)	83	(1,9)
LIDOCAINE;SODIUM BICARBONATE	0	(0,0)	1	(0,0)	1	(0,0)
MEPIVACAINE HYDROCHLORIDE	4	(0,2)	6	(0,3)	10	(0,2)
OTHER GENERAL ANESTHETICS	1	(0,0)	0	(0,0)	1	(0,0)
OTHER LOCAL ANESTHETICS	1	(0,0)	0	(0,0)	1	(0,0)
OXETACAINE	3	(0,1)	2	(0,1)	5	(0,1)
PHENOL	0	(0,0)	3	(0,1)	3	(0,1)
PRILOCAINE	1	(0,0)	0	(0,0)	1	(0,0)
PRILOCAINE HYDROCHLORIDE	4	(0,2)	1	(0,0)	5	(0,1)
PROPOFOL	45	(2,1)	64	(3,0)	109	(2,5)
REMIFENTANIL HYDROCHLORIDE	10	(0,5)	7	(0,3)	17	(0,4)
ROPIVACAINE	2	(0,1)	4	(0,2)	6	(0,1)
ROPIVACAINE HYDROCHLORIDE	3	(0,1)	1	(0,0)	4	(0,1)
SEVOFLURANE	0	(0,0)	3	(0,1)	3	(0,1)
SUFENTANIL	3	(0,1)	5	(0,2)	8	(0,2)
SUFENTANIL CITRATE	2	(0,1)	2	(0,1)	4	(0,1)
THIAMYLAL SODIUM	4	(0,2)	3	(0,1)	7	(0,2)
THIOPENTAL SODIUM	4	(0,2)	3	(0,1)	7	(0,2)
TRIMECAINE HYDROCHLORIDE	6	(0,3)	7	(0,3)	13	(0,3)
ANTI-PARKINSON DRUGS	**54**	**(2,5)**	**58**	**(2,7)**	**112**	**(2,6)**
AMANTADINE	1	(0,0)	0	(0,0)	1	(0,0)
AMANTADINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ANISODAMINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
BENSERAZIDE	0	(0,0)	2	(0,1)	2	(0,0)
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	6	(0,3)	3	(0,1)	9	(0,2)
BENZATROPINE MESILATE	0	(0,0)	1	(0,0)	1	(0,0)
CABERGOLINE	1	(0,0)	1	(0,0)	2	(0,0)
CARBIDOPA	2	(0,1)	1	(0,0)	3	(0,1)
CARBIDOPA;LEVODOPA	1	(0,0)	3	(0,1)	4	(0,1)
DIPHENHYDRAMINE	20	(0,9)	18	(0,8)	38	(0,9)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANTI-PARKINSON DRUGS	**54**	**(2,5)**	**58**	**(2,7)**	**112**	**(2,6)**
DIPHENHYDRAMINE HYDROCHLORIDE	16	(0,7)	21	(1,0)	37	(0,9)
LEVODOPA	3	(0,1)	4	(0,2)	7	(0,2)
ORPHENADRINE	1	(0,0)	0	(0,0)	1	(0,0)
PIRIBEDIL	0	(0,0)	1	(0,0)	1	(0,0)
PRAMIPEXOLE	4	(0,2)	4	(0,2)	8	(0,2)
PRAMIPEXOLE DIHYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
ROPINIROLE	2	(0,1)	2	(0,1)	4	(0,1)
ROPINIROLE HYDROCHLORIDE	1	(0,0)	3	(0,1)	4	(0,1)
ROTIGOTINE	1	(0,0)	1	(0,0)	2	(0,0)
SELEGILINE	1	(0,0)	0	(0,0)	1	(0,0)
SELEGILINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ANTIEPILEPTICS	**341**	**(15,8)**	**377**	**(17,5)**	**718**	**(16,7)**
ACETAZOLAMIDE	23	(1,1)	16	(0,7)	39	(0,9)
CARBAMAZEPINE	8	(0,4)	5	(0,2)	13	(0,3)
CLOBAZAM	3	(0,1)	1	(0,0)	4	(0,1)
CLONAZEPAM	36	(1,7)	48	(2,2)	84	(2,0)
DIAZEPAM	34	(1,6)	37	(1,7)	71	(1,7)
GABAPENTIN	67	(3,1)	79	(3,7)	146	(3,4)
GASTRODIA ELATA	0	(0,0)	2	(0,1)	2	(0,0)
LACOSAMIDE	1	(0,0)	2	(0,1)	3	(0,1)
LAMOTRIGINE	4	(0,2)	4	(0,2)	8	(0,2)
LEVETIRACETAM	12	(0,6)	24	(1,1)	36	(0,8)
LORAZEPAM	61	(2,8)	75	(3,5)	136	(3,2)
MAGNESIUM SULFATE	87	(4,0)	92	(4,3)	179	(4,2)
OXCARBAZEPINE	2	(0,1)	0	(0,0)	2	(0,0)
PHENOBARBITAL SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
PHENYTOIN	0	(0,0)	4	(0,2)	4	(0,1)
PHENYTOIN SODIUM	2	(0,1)	0	(0,0)	2	(0,0)
PREGABALIN	54	(2,5)	58	(2,7)	112	(2,6)
PRIMIDONE	4	(0,2)	5	(0,2)	9	(0,2)
TIAGABINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
TOPIRAMATE	3	(0,1)	2	(0,1)	5	(0,1)
VALPROATE SEMISODIUM	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
ANTIEPILEPTICS	**341**	**(15,8)**	**377**	**(17,5)**	**718**	**(16,7)**
VALPROATE SODIUM	9	(0,4)	9	(0,4)	18	(0,4)
VALPROATE SODIUM;VALPROIC ACID	2	(0,1)	1	(0,0)	3	(0,1)
VALPROIC ACID	2	(0,1)	3	(0,1)	5	(0,1)
VALPROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
ZONISAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
OTHER NERVOUS SYSTEM DRUGS	**347**	**(16,1)**	**336**	**(15,6)**	**683**	**(15,9)**
ANTIVERTIGO PREPARATIONS	1	(0,0)	0	(0,0)	1	(0,0)
BETAHISTINE	10	(0,5)	8	(0,4)	18	(0,4)
BETAHISTINE HYDROCHLORIDE	7	(0,3)	4	(0,2)	11	(0,3)
BETAHISTINE MESILATE	9	(0,4)	10	(0,5)	19	(0,4)
BETHANECHOL CHLORIDE	2	(0,1)	6	(0,3)	8	(0,2)
BORNEOL;BUFFALO HORN;COPTIS SPP. RHIZOME;COW BEZOAR;CURCUMA SPP. ROOT TUBER;GARDENIA JASMINOIDES FRUIT;MERCURY SULFIDE;MUSK;PEARL;REALGAR;SCUTELLARIA BAICALENSIS ROOT	1	(0,0)	0	(0,0)	1	(0,0)
BORNEOL;CURCUMA SPP. TUBER;GARDENIA JASMINOIDES FRUIT;MUSK	2	(0,1)	1	(0,0)	3	(0,1)
BUPRENORPHINE	2	(0,1)	6	(0,3)	8	(0,2)
BUPRENORPHINE HYDROCHLORIDE	1	(0,0)	3	(0,1)	4	(0,1)
BUPRENORPHINE HYDROCHLORIDE;NALOXONE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
BUPROPION	5	(0,2)	1	(0,0)	6	(0,1)
BUPROPION HYDROCHLORIDE	6	(0,3)	6	(0,3)	12	(0,3)
BUTYLPHTHALIDE	1	(0,0)	1	(0,0)	2	(0,0)
CEREBROPROTEIN HYDROLYSATE	1	(0,0)	1	(0,0)	2	(0,0)
CHOLINE ALFOSCERATE	1	(0,0)	3	(0,1)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
OTHER NERVOUS SYSTEM DRUGS	**347**	**(16,1)**	**336**	**(15,6)**	**683**	**(15,9)**
CINNARIZINE	3	(0,1)	3	(0,1)	6	(0,1)
DIMENHYDRINATE	7	(0,3)	7	(0,3)	14	(0,3)
DISTIGMINE BROMIDE	2	(0,1)	2	(0,1)	4	(0,1)
EDARAVONE	2	(0,1)	0	(0,0)	2	(0,0)
ERIGERON BREVISCAPUS HERB;OPHIOPOGON JAPONICUS;PANAX GINSENG ROOT;SCHISANDRA CHINENSIS FRUIT	3	(0,1)	0	(0,0)	3	(0,1)
FLUNARIZINE	3	(0,1)	0	(0,0)	3	(0,1)
FLUNARIZINE DIHYDROCHLORIDE	1	(0,0)	4	(0,2)	5	(0,1)
FLUOXETINE	13	(0,6)	13	(0,6)	26	(0,6)
FLUOXETINE HYDROCHLORIDE	4	(0,2)	5	(0,2)	9	(0,2)
GABAPENTIN	67	(3,1)	79	(3,7)	146	(3,4)
GANGLIOSIDE : GM1 SODIUM	0	(0,0)	2	(0,1)	2	(0,0)
GASTRODIN	3	(0,1)	0	(0,0)	3	(0,1)
GINKGO BILOBA	6	(0,3)	3	(0,1)	9	(0,2)
GINKGO BILOBA LEAF EXTRACT	1	(0,0)	1	(0,0)	2	(0,0)
ISOPRENALINE HYDROCHLORIDE	5	(0,2)	3	(0,1)	8	(0,2)
MECLOZINE	3	(0,1)	6	(0,3)	9	(0,2)
MECLOZINE HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
MELDONIUM	3	(0,1)	2	(0,1)	5	(0,1)
METHADONE HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
METHYLETHYLPIRIDINOL	0	(0,0)	1	(0,0)	1	(0,0)
METHYLETHYLPIRIDINOL SUCCINATE	1	(0,0)	2	(0,1)	3	(0,1)
NALOXONE HYDROCHLORIDE	12	(0,6)	10	(0,5)	22	(0,5)
NALOXONE HYDROCHLORIDE;OXYCODONE HYDROCHLORIDE	8	(0,4)	7	(0,3)	15	(0,3)
NALTREXONE	1	(0,0)	0	(0,0)	1	(0,0)
NEOSTIGMINE BROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
NEOSTIGMINE METILSULFATE	7	(0,3)	5	(0,2)	12	(0,3)
NERVE GROWTH FACTOR, MOUSE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
OTHER NERVOUS SYSTEM DRUGS	**347**	**(16,1)**	**336**	**(15,6)**	**683**	**(15,9)**
NICOTINE	5	(0,2)	9	(0,4)	14	(0,3)
NICOTINE POLACRILEX	0	(0,0)	2	(0,1)	2	(0,0)
PARASYMPATHOMIMETICS	1	(0,0)	0	(0,0)	1	(0,0)
PHOSPHOLIPIDS	2	(0,1)	2	(0,1)	4	(0,1)
PILOCARPINE HYDROCHLORIDE	3	(0,1)	0	(0,0)	3	(0,1)
PYRIDOSTIGMINE BROMIDE	0	(0,0)	2	(0,1)	2	(0,0)
SILVER NITRATE	0	(0,0)	1	(0,0)	1	(0,0)
THIOCTIC ACID	7	(0,3)	12	(0,6)	19	(0,4)
TRIMETAZIDINE	67	(3,1)	44	(2,0)	111	(2,6)
TRIMETAZIDINE HYDROCHLORIDE	105	(4,9)	105	(4,9)	210	(4,9)
VARENICLINE TARTRATE	1	(0,0)	1	(0,0)	2	(0,0)
PSYCHOANALEPTICS	**330**	**(15,3)**	**340**	**(15,8)**	**670**	**(15,6)**
ACETYLCARNITINE	1	(0,0)	0	(0,0)	1	(0,0)
ACETYLCARNITINE HYDROCHLORIDE	3	(0,1)	0	(0,0)	3	(0,1)
ACONITUM CARMICHAELII ROOT;PANAX GINSENG ROOT	5	(0,2)	1	(0,0)	6	(0,1)
ADEMETIONINE	1	(0,0)	4	(0,2)	5	(0,1)
ADEMETIONINE 1,4-BUTANEDISULFONATE	0	(0,0)	4	(0,2)	4	(0,1)
AGOMELATINE	0	(0,0)	1	(0,0)	1	(0,0)
AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
AMITRIPTYLINE HYDROCHLORIDE	33	(1,5)	25	(1,2)	58	(1,3)
AMITRIPTYLINE HYDROCHLORIDE;PERPHENAZINE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
PSYCHOANALEPTICS	**330**	**(15,3)**	**340**	**(15,8)**	**670**	**(15,6)**
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CITRUS RETICULATA PEEL;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	1	(0,0)	0	(0,0)	1	(0,0)
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	1	(0,0)	0	(0,0)	1	(0,0)
ATRACTYLODES MACROCEPHALA	1	(0,0)	0	(0,0)	1	(0,0)
BUPROPION	5	(0,2)	1	(0,0)	6	(0,1)
BUPROPION HYDROCHLORIDE	6	(0,3)	6	(0,3)	12	(0,3)
CAFFEINE	1	(0,0)	1	(0,0)	2	(0,0)
CITALOPRAM	13	(0,6)	16	(0,7)	29	(0,7)
CITALOPRAM HYDROBROMIDE	12	(0,6)	10	(0,5)	22	(0,5)
CITICOLINE	2	(0,1)	2	(0,1)	4	(0,1)
CITICOLINE SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
CITRULLINE MALATE	1	(0,0)	0	(0,0)	1	(0,0)
CLOMIPRAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CLONIDINE	4	(0,2)	9	(0,4)	13	(0,3)
CLONIDINE HYDROCHLORIDE	0	(0,0)	6	(0,3)	6	(0,1)
CORDYCEPS SINENSIS	14	(0,7)	11	(0,5)	25	(0,6)
DESVENLAFAXINE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
PSYCHOANALEPTICS	**330**	**(15,3)**	**340**	**(15,8)**	**670**	**(15,6)**
DONEPEZIL	4	(0,2)	2	(0,1)	6	(0,1)
DONEPEZIL HYDROCHLORIDE	2	(0,1)	9	(0,4)	11	(0,3)
DOSULEPIN HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
DOXEPIN HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
DULOXETINE HYDROCHLORIDE	15	(0,7)	18	(0,8)	33	(0,8)
ENZYMES NOS	5	(0,2)	3	(0,1)	8	(0,2)
ESCITALOPRAM	19	(0,9)	14	(0,7)	33	(0,8)
ESCITALOPRAM OXALATE	18	(0,8)	22	(1,0)	40	(0,9)
FLUOXETINE	13	(0,6)	13	(0,6)	26	(0,6)
FLUOXETINE HYDROCHLORIDE	4	(0,2)	5	(0,2)	9	(0,2)
FLUPENTIXOL DIHYDROCHLORIDE;MELITRACEN HYDROCHLORIDE	4	(0,2)	0	(0,0)	4	(0,1)
FLUVOXAMINE MALEATE	0	(0,0)	1	(0,0)	1	(0,0)
GALANTAMINE	2	(0,1)	0	(0,0)	2	(0,0)
GALANTAMINE HYDROBROMIDE	1	(0,0)	1	(0,0)	2	(0,0)
GINKGO BILOBA	6	(0,3)	3	(0,1)	9	(0,2)
GINKGO BILOBA EXTRACT	1	(0,0)	4	(0,2)	5	(0,1)
GINKGO BILOBA LEAF EXTRACT	1	(0,0)	1	(0,0)	2	(0,0)
HOPANTENATE CALCIUM	1	(0,0)	0	(0,0)	1	(0,0)
IMIPRAMINE	1	(0,0)	2	(0,1)	3	(0,1)
IMIPRAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
LAMOTRIGINE	4	(0,2)	4	(0,2)	8	(0,2)
MEMANTINE	1	(0,0)	5	(0,2)	6	(0,1)
MEMANTINE HYDROCHLORIDE	2	(0,1)	4	(0,2)	6	(0,1)
METHYLETHYLPIRIDINOL	0	(0,0)	1	(0,0)	1	(0,0)
METHYLETHYLPIRIDINOL SUCCINATE	1	(0,0)	2	(0,1)	3	(0,1)
METHYLPHENIDATE	0	(0,0)	1	(0,0)	1	(0,0)
MIANSERIN HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
MILNACIPRAN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
MIRTAZAPINE	29	(1,3)	20	(0,9)	49	(1,1)
NIMODIPINE	1	(0,0)	2	(0,1)	3	(0,1)
NORTRIPTYLINE	2	(0,1)	0	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
PSYCHOANALEPTICS	**330**	**(15,3)**	**340**	**(15,8)**	**670**	**(15,6)**
NORTRIPTYLINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
OPIPRAMOL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
OTHER ANTIDEPRESSANTS	1	(0,0)	0	(0,0)	1	(0,0)
OXIRACETAM	1	(0,0)	1	(0,0)	2	(0,0)
PANAX GINSENG	1	(0,0)	0	(0,0)	1	(0,0)
PANAX GINSENG TOTAL GINSENOSIDE EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
PAROXETINE	6	(0,3)	4	(0,2)	10	(0,2)
PAROXETINE HYDROCHLORIDE	7	(0,3)	6	(0,3)	13	(0,3)
PEMOLINE	1	(0,0)	0	(0,0)	1	(0,0)
PHENIBUT	0	(0,0)	1	(0,0)	1	(0,0)
PIRACETAM	13	(0,6)	12	(0,6)	25	(0,6)
POLYPEPTIDE	0	(0,0)	1	(0,0)	1	(0,0)
RIVASTIGMINE	3	(0,1)	0	(0,0)	3	(0,1)
SELEGILINE	1	(0,0)	0	(0,0)	1	(0,0)
SERTRALINE HYDROCHLORIDE	56	(2,6)	61	(2,8)	117	(2,7)
TIANEPTINE	1	(0,0)	0	(0,0)	1	(0,0)
TIANEPTINE SODIUM	0	(0,0)	2	(0,1)	2	(0,0)
TRAZODONE HYDROCHLORIDE	49	(2,3)	66	(3,1)	115	(2,7)
TRIMIPRAMINE	0	(0,0)	1	(0,0)	1	(0,0)
VENLAFAXINE HYDROCHLORIDE	13	(0,6)	13	(0,6)	26	(0,6)
VINPOCETINE	7	(0,3)	4	(0,2)	11	(0,3)
PSYCHOLEPTICS	**657**	**(30,5)**	**669**	**(31,1)**	**1.326**	**(30,8)**
ALPHA-CASOZEPINE;MAGNESIUM;MELISSA OFFICINALIS;PYRIDOXINE HYDROCHLORIDE;ZINC	1	(0,0)	0	(0,0)	1	(0,0)
ALPRAZOLAM	71	(3,3)	95	(4,4)	166	(3,9)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
PSYCHOLEPTICS	**657**	**(30,5)**	**669**	**(31,1)**	**1.326**	**(30,8)**
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CITRUS RETICULATA PEEL;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	1	(0,0)	0	(0,0)	1	(0,0)
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	1	(0,0)	0	(0,0)	1	(0,0)
ARIPIPRAZOLE	0	(0,0)	4	(0,2)	4	(0,1)
BROMAZEPAM	12	(0,6)	12	(0,6)	24	(0,6)
BROTIZOLAM	41	(1,9)	43	(2,0)	84	(2,0)
BUSPIRONE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
CARBAMAZEPINE	8	(0,4)	5	(0,2)	13	(0,3)
CHLORDIAZEPOXIDE	1	(0,0)	1	(0,0)	2	(0,0)
CHLORDIAZEPOXIDE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
CHLORPROMAZINE	1	(0,0)	1	(0,0)	2	(0,0)
CHLORPROTHIXENE	1	(0,0)	0	(0,0)	1	(0,0)
CINNAMOMUM VERUM;CITRUS AURANTIUM;MELISSA OFFICINALIS;PASSIFLORA ALATA	3	(0,1)	3	(0,1)	6	(0,1)
CLOBAZAM	3	(0,1)	1	(0,0)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
PSYCHOLEPTICS	**657**	**(30,5)**	**669**	**(31,1)**	**1.326**	**(30,8)**
CLONAZEPAM	36	(1,7)	48	(2,2)	84	(2,0)
CLORAZEPATE DIPOTASSIUM	1	(0,0)	3	(0,1)	4	(0,1)
CLOTIAPINE	0	(0,0)	2	(0,1)	2	(0,0)
CLOTIAZEPAM	2	(0,1)	1	(0,0)	3	(0,1)
CROCUS SATIVUS	0	(0,0)	1	(0,0)	1	(0,0)
DELORAZEPAM	2	(0,1)	1	(0,0)	3	(0,1)
DEXMEDETOMIDINE	1	(0,0)	4	(0,2)	5	(0,1)
DEXMEDETOMIDINE HYDROCHLORIDE	13	(0,6)	9	(0,4)	22	(0,5)
DIAZEPAM	34	(1,6)	37	(1,7)	71	(1,7)
DIPHENHYDRAMINE	20	(0,9)	18	(0,8)	38	(0,9)
DIPHENHYDRAMINE HYDROCHLORIDE	16	(0,7)	21	(1,0)	37	(0,9)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1	(0,0)	1	(0,0)	2	(0,0)
DOXEPIN HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
DOXYLAMINE SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
DROPERIDOL	0	(0,0)	2	(0,1)	2	(0,0)
DULOXETINE HYDROCHLORIDE	15	(0,7)	18	(0,8)	33	(0,8)
ERIOBOTRYA JAPONICA	0	(0,0)	2	(0,1)	2	(0,0)
ESCITALOPRAM	19	(0,9)	14	(0,7)	33	(0,8)
ESCITALOPRAM OXALATE	18	(0,8)	22	(1,0)	40	(0,9)
ESTAZOLAM	17	(0,8)	25	(1,2)	42	(1,0)
ESZOPICLONE	10	(0,5)	5	(0,2)	15	(0,3)
ETHYL LOFLAZEPATE	1	(0,0)	0	(0,0)	1	(0,0)
ETIFOXINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ETIZOLAM	11	(0,5)	6	(0,3)	17	(0,4)
EUCOMMIA ULMOIDES	1	(0,0)	0	(0,0)	1	(0,0)
FABOMOTIZOLE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
FLUDIAZEPAM	0	(0,0)	1	(0,0)	1	(0,0)
FLUNITRAZEPAM	8	(0,4)	1	(0,0)	9	(0,2)
FLUOXETINE	13	(0,6)	13	(0,6)	26	(0,6)
FLUOXETINE HYDROCHLORIDE	4	(0,2)	5	(0,2)	9	(0,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
PSYCHOLEPTICS	**657**	**(30,5)**	**669**	**(31,1)**	**1.326**	**(30,8)**
FLURAZEPAM	0	(0,0)	1	(0,0)	1	(0,0)
GASTRODIA ELATA	0	(0,0)	2	(0,1)	2	(0,0)
GIDAZEPAM	0	(0,0)	1	(0,0)	1	(0,0)
GLYCINE	2	(0,1)	1	(0,0)	3	(0,1)
GLYCYRRHIZA GLABRA;HUMULUS LUPULUS;LEONURUS SPP.;MENTHA X PIPERITA;VALERIANA OFFICINALIS	0	(0,0)	1	(0,0)	1	(0,0)
HALOPERIDOL	31	(1,4)	22	(1,0)	53	(1,2)
HALOPERIDOL DECANOATE	1	(0,0)	0	(0,0)	1	(0,0)
HUMULUS LUPULUS EXTRACT;PASSIFLORA INCARNATA EXTRACT;VALERIANA OFFICINALIS EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
HYDROXYZINE	21	(1,0)	21	(1,0)	42	(1,0)
HYDROXYZINE EMBONATE	2	(0,1)	3	(0,1)	5	(0,1)
HYDROXYZINE HYDROCHLORIDE	21	(1,0)	24	(1,1)	45	(1,0)
HYOSCINE	2	(0,1)	7	(0,3)	9	(0,2)
HYOSCINE HYDROBROMIDE	0	(0,0)	2	(0,1)	2	(0,0)
LEVOMEPROMAZINE	1	(0,0)	2	(0,1)	3	(0,1)
LEVOSULPIRIDE	1	(0,0)	2	(0,1)	3	(0,1)
LORAZEPAM	61	(2,8)	75	(3,5)	136	(3,2)
LORMETAZEPAM	5	(0,2)	5	(0,2)	10	(0,2)
MEDAZEPAM	1	(0,0)	0	(0,0)	1	(0,0)
MELATONIN	17	(0,8)	19	(0,9)	36	(0,8)
MELATONIN;PYRIDOXINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
MELISSA OFFICINALIS;MENTHA X PIPERITA;VALERIANA OFFICINALIS	1	(0,0)	0	(0,0)	1	(0,0)
MELPERONE	0	(0,0)	2	(0,1)	2	(0,0)
MEPHENOXALONE	0	(0,0)	4	(0,2)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
PSYCHOLEPTICS	**657**	**(30,5)**	**669**	**(31,1)**	**1.326**	**(30,8)**
MEXAZOLAM	0	(0,0)	1	(0,0)	1	(0,0)
MIDAZOLAM	82	(3,8)	79	(3,7)	161	(3,7)
MIDAZOLAM HYDROCHLORIDE	14	(0,7)	22	(1,0)	36	(0,8)
NITRAZEPAM	3	(0,1)	5	(0,2)	8	(0,2)
OLANZAPINE	8	(0,4)	4	(0,2)	12	(0,3)
OTHER HYPNOTICS AND SEDATIVES	1	(0,0)	1	(0,0)	2	(0,0)
OXAZEPAM	27	(1,3)	27	(1,3)	54	(1,3)
PANAX NOTOGINSENG	3	(0,1)	1	(0,0)	4	(0,1)
PAROXETINE	6	(0,3)	4	(0,2)	10	(0,2)
PAROXETINE HYDROCHLORIDE	7	(0,3)	6	(0,3)	13	(0,3)
PERAZINE	1	(0,0)	0	(0,0)	1	(0,0)
PEROSPIRONE	2	(0,1)	0	(0,0)	2	(0,0)
PEROSPIRONE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PERPHENAZINE	0	(0,0)	1	(0,0)	1	(0,0)
PHENAZEPAM	2	(0,1)	4	(0,2)	6	(0,1)
PHENIBUT	0	(0,0)	1	(0,0)	1	(0,0)
PIPAMPERONE	0	(0,0)	2	(0,1)	2	(0,0)
PLATYCODON GRANDIFLORUS	5	(0,2)	4	(0,2)	9	(0,2)
PRAZEPAM	1	(0,0)	0	(0,0)	1	(0,0)
PREGABALIN	54	(2,5)	58	(2,7)	112	(2,6)
PROCHLORPERAZINE	11	(0,5)	2	(0,1)	13	(0,3)
PROCHLORPERAZINE EDISYLATE	1	(0,0)	0	(0,0)	1	(0,0)
PROCHLORPERAZINE MALEATE	3	(0,1)	10	(0,5)	13	(0,3)
PROCHLORPERAZINE MESILATE	1	(0,0)	3	(0,1)	4	(0,1)
PROMAZINE HYDROCHLORIDE	3	(0,1)	3	(0,1)	6	(0,1)
PROMETHAZINE	16	(0,7)	14	(0,7)	30	(0,7)
PROMETHAZINE HYDROCHLORIDE	20	(0,9)	7	(0,3)	27	(0,6)
PROPIOMAZINE MALEATE	0	(0,0)	2	(0,1)	2	(0,0)
PROTHIPENDYL HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
PRUNUS SEROTINA BARK	0	(0,0)	1	(0,0)	1	(0,0)
QUETIAPINE	2	(0,1)	0	(0,0)	2	(0,0)
QUETIAPINE FUMARATE	21	(1,0)	34	(1,6)	55	(1,3)
RAMELTEON	7	(0,3)	6	(0,3)	13	(0,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
NERVOUS SYSTEM						
PSYCHOLEPTICS	**657**	**(30,5)**	**669**	**(31,1)**	**1.326**	**(30,8)**
RILMAZAFONE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
RISPERIDONE	4	(0,2)	9	(0,4)	13	(0,3)
SERTRALINE HYDROCHLORIDE	56	(2,6)	61	(2,8)	117	(2,7)
SODIUM BROMIDE	1	(0,0)	0	(0,0)	1	(0,0)
SULPIRIDE	0	(0,0)	2	(0,1)	2	(0,0)
SUVOREXANT	13	(0,6)	12	(0,6)	25	(0,6)
TANDOSPIRONE CITRATE	0	(0,0)	1	(0,0)	1	(0,0)
TEMAZEPAM	9	(0,4)	13	(0,6)	22	(0,5)
THIOPENTAL SODIUM	4	(0,2)	3	(0,1)	7	(0,2)
THIORIDAZINE	3	(0,1)	1	(0,0)	4	(0,1)
THIORIDAZINE HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
TIAPRIDE	0	(0,0)	1	(0,0)	1	(0,0)
TIAPRIDE HYDROCHLORIDE	2	(0,1)	5	(0,2)	7	(0,2)
TRIAZOLAM	10	(0,5)	17	(0,8)	27	(0,6)
VALERIANA OFFICINALIS	2	(0,1)	1	(0,0)	3	(0,1)
VALPROATE SEMISODIUM	1	(0,0)	2	(0,1)	3	(0,1)
VALPROIC ACID	2	(0,1)	3	(0,1)	5	(0,1)
VENLAFAXINE HYDROCHLORIDE	13	(0,6)	13	(0,6)	26	(0,6)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
ZOLPIDEM	30	(1,4)	21	(1,0)	51	(1,2)
ZOLPIDEM TARTRATE	36	(1,7)	56	(2,6)	92	(2,1)
ZOPICLONE	56	(2,6)	52	(2,4)	108	(2,5)
ZUCLOPENTHIXOL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
RESPIRATORY SYSTEM						
ANTIHISTAMINES FOR SYSTEMIC USE	**288**	**(13,4)**	**267**	**(12,4)**	**555**	**(12,9)**
ALIMEMAZINE TARTRATE	1	(0,0)	3	(0,1)	4	(0,1)
ANTAZOLINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
AZELASTINE HYDROCHLORIDE	3	(0,1)	3	(0,1)	6	(0,1)
BEPOTASTINE BESILATE	2	(0,1)	1	(0,0)	3	(0,1)
BEPOTASTINE SALICYLATE	1	(0,0)	0	(0,0)	1	(0,0)
BILASTINE	3	(0,1)	6	(0,3)	9	(0,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
ANTIHISTAMINES FOR SYSTEMIC USE	**288**	**(13,4)**	**267**	**(12,4)**	**555**	**(12,9)**
BISULEPIN HYDROCHLORIDE	4	(0,2)	2	(0,1)	6	(0,1)
BUCLIZINE HYDROCHLORIDE	0	(0,0)	3	(0,1)	3	(0,1)
CARBINOXAMINE MALEATE;PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CETIRIZINE HYDROCHLORIDE	30	(1,4)	37	(1,7)	67	(1,6)
CHLOROPYRAMINE HYDROCHLORIDE	3	(0,1)	1	(0,0)	4	(0,1)
CHLORPHENAMINE	11	(0,5)	7	(0,3)	18	(0,4)
CHLORPHENAMINE MALEATE	25	(1,2)	21	(1,0)	46	(1,1)
CLEMASTINE	4	(0,2)	2	(0,1)	6	(0,1)
CLEMASTINE FUMARATE	2	(0,1)	1	(0,0)	3	(0,1)
CYCLIZINE	3	(0,1)	3	(0,1)	6	(0,1)
CYPROHEPTADINE HYDROCHLORIDE	2	(0,1)	3	(0,1)	5	(0,1)
DESLORATADINE	12	(0,6)	8	(0,4)	20	(0,5)
DESLORATADINE CITRATE DISODIUM	0	(0,0)	1	(0,0)	1	(0,0)
DEXCHLORPHENIRAMINE MALEATE	2	(0,1)	3	(0,1)	5	(0,1)
DIMENHYDRINATE	7	(0,3)	7	(0,3)	14	(0,3)
DIMETINDENE MALEATE	3	(0,1)	1	(0,0)	4	(0,1)
DIPHENHYDRAMINE	20	(0,9)	18	(0,8)	38	(0,9)
DIPHENHYDRAMINE HYDROCHLORIDE	16	(0,7)	21	(1,0)	37	(0,9)
DOXYLAMINE SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
DOXYLAMINE SUCCINATE;FOLIC ACID;PYRIDOXINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
EBASTINE	5	(0,2)	4	(0,2)	9	(0,2)
EPINASTINE HYDROCHLORIDE	7	(0,3)	5	(0,2)	12	(0,3)
FEXOFENADINE HYDROCHLORIDE	25	(1,2)	30	(1,4)	55	(1,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
ANTIHISTAMINES FOR SYSTEMIC USE	**288**	**(13,4)**	**267**	**(12,4)**	**555**	**(12,9)**
FEXOFENADINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	3	(0,1)	4	(0,2)	7	(0,2)
HYDROXYZINE	21	(1,0)	21	(1,0)	42	(1,0)
HYDROXYZINE EMBONATE	2	(0,1)	3	(0,1)	5	(0,1)
HYDROXYZINE HYDROCHLORIDE	21	(1,0)	24	(1,1)	45	(1,0)
KETOTIFEN FUMARATE	6	(0,3)	4	(0,2)	10	(0,2)
LEVOCETIRIZINE	6	(0,3)	8	(0,4)	14	(0,3)
LEVOCETIRIZINE DIHYDROCHLORIDE	11	(0,5)	16	(0,7)	27	(0,6)
LORATADINE	46	(2,1)	38	(1,8)	84	(2,0)
MEBHYDROLIN	1	(0,0)	0	(0,0)	1	(0,0)
MECLOZINE	3	(0,1)	6	(0,3)	9	(0,2)
MECLOZINE HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
MEQUITAZINE	2	(0,1)	2	(0,1)	4	(0,1)
OLOPATADINE HYDROCHLORIDE	10	(0,5)	4	(0,2)	14	(0,3)
OXATOMIDE	1	(0,0)	0	(0,0)	1	(0,0)
OXOMEMAZINE;SODIUM BENZOATE;SULFOGAIACOL	1	(0,0)	0	(0,0)	1	(0,0)
PHENIRAMINE MALEATE	6	(0,3)	3	(0,1)	9	(0,2)
PIPRINHYDRINATE	0	(0,0)	1	(0,0)	1	(0,0)
PROMETHAZINE	16	(0,7)	14	(0,7)	30	(0,7)
PROMETHAZINE HYDROCHLORIDE	20	(0,9)	7	(0,3)	27	(0,6)
QUERCETIN	0	(0,0)	2	(0,1)	2	(0,0)
RUPATADINE FUMARATE	5	(0,2)	2	(0,1)	7	(0,2)
THIETHYLPERAZINE	0	(0,0)	1	(0,0)	1	(0,0)
THIETHYLPERAZINE MALEATE	0	(0,0)	1	(0,0)	1	(0,0)
TRIMETHOBENZAMIDE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
COUGH AND COLD PREPARATIONS	**510**	**(23,7)**	**503**	**(23,4)**	**1.013**	**(23,5)**
ACETYLCYSTEINE	128	(5,9)	138	(6,4)	266	(6,2)
ACETYLCYSTEINE;ASCORBIC ACID	2	(0,1)	3	(0,1)	5	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**510**	**(23,7)**	**503**	**(23,4)**	**1.013**	**(23,5)**
ACONITUM SPP. PROCESSED ROOT;ASARUM SPP. ROOT;EPHEDRA SPP. HERB	0	(0,0)	1	(0,0)	1	(0,0)
ADENOPHORA SPP. ROOT;ANDROGRAPHIS PANICULATA HERB;ELAEAGNUS PUNGENS;EPHEDRA SPP. HERB;PAPAVER SOMNIFERUM;PLATYCODON GRANDIFLORUS ROOT;PSEUDOSTELLARIA HETEROPHYLLA ROOT;STEMONA SPP. ROOT;VITEX NEGUNDO FRUIT	1	(0,0)	0	(0,0)	1	(0,0)
ADIANTUM CAPILLUS-VENERIS;APIUM GRAVEOLENS SEED;CYMBOPOGON DISTANS;FOENICULUM VULGARE DRY FRUIT;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;HYSSOPUS OFFICINALIS;ROSA RUGOSA BUD;TRIGONELLA FOENUM-GRAECUM SEED;URTICA SPP.	0	(0,0)	1	(0,0)	1	(0,0)
ALTHAEA OFFICINALIS EXTRACT	1	(0,0)	3	(0,1)	4	(0,1)
AMBROXOL	23	(1,1)	25	(1,2)	48	(1,1)
AMBROXOL ACEFYLLINATE	3	(0,1)	2	(0,1)	5	(0,1)
AMBROXOL HYDROCHLORIDE	44	(2,0)	46	(2,1)	90	(2,1)
AMBROXOL HYDROCHLORIDE;LORATADINE	0	(0,0)	1	(0,0)	1	(0,0)
AMMONIA;CAMPHOR;GLYCEROL; GLYCYRRHIZA GLABRA;GUAIFENESIN	8	(0,4)	6	(0,3)	14	(0,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**510**	**(23,7)**	**503**	**(23,4)**	**1.013**	**(23,5)**
AMMONIUM BICARBONATE;AMMONIUM CHLORIDE;DRIMIA MARITIMA;GLYCYRRHIZA GLABRA;POLYGALA SENEGA;SODIUM CITRATE	0	(0,0)	1	(0,0)	1	(0,0)
AMMONIUM BICARBONATE;CEPHAELIS SPP.	4	(0,2)	3	(0,1)	7	(0,2)
AMMONIUM CARBONATE;CEPHAELIS SPP.;GLYCYRRHIZA GLABRA	0	(0,0)	1	(0,0)	1	(0,0)
AMMONIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
AMMONIUM CHLORIDE;CHLORPHENAMINE MALEATE;DIHYDROCODEINE BITARTRATE;METHYLEPHEDRINE HYDROCHLORIDE-DL	6	(0,3)	8	(0,4)	14	(0,3)
AMMONIUM CHLORIDE;DIPHENHYDRAMINE HYDROCHLORIDE	5	(0,2)	2	(0,1)	7	(0,2)
AMMONIUM CHLORIDE;DIPHENHYDRAMINE HYDROCHLORIDE;MENTHOL;SODIUM CITRATE	2	(0,1)	0	(0,0)	2	(0,0)
AMMONIUM CHLORIDE;DIPHENHYDRAMINE HYDROCHLORIDE;SODIUM CITRATE	1	(0,0)	3	(0,1)	4	(0,1)
ANTIMONY POTASSIUM TARTRATE;GLYCEROL;GLYCYRRHIZA GLABRA LIQUID EXTRACT;NITROUS ETHER SPIRIT;PAPAVER SOMNIFERUM TINCTURE	3	(0,1)	3	(0,1)	6	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**510**	**(23,7)**	**503**	**(23,4)**	**1.013**	**(23,5)**
ANTIMONY POTASSIUM TARTRATE;GLYCYRRHIZA SPP.;NITROUS ETHER SPIRIT;PAPAVER SOMNIFERUM TINCTURE	1	(0,0)	0	(0,0)	1	(0,0)
ANTIMONY POTASSIUM TARTRATE;GLYCYRRHIZA SPP.;PAPAVER SOMNIFERUM TINCTURE	4	(0,2)	3	(0,1)	7	(0,2)
ARCTIUM LAPPA	1	(0,0)	0	(0,0)	1	(0,0)
ARCTIUM LAPPA FRUIT;CICADA SLOUGH;EPHEDRA SPP. HERB;ERIOBOTRYA JAPONICA LEAF;PERILLA FRUTESCENS FRUIT;PERILLA FRUTESCENS LEAF;PEUCEDANUM PRAERUPTORUM ROOT;PHERETIMA SPP.;SCHISANDRA CHINENSIS FRUIT	3	(0,1)	3	(0,1)	6	(0,1)
ASARUM HETEROTROPOIDES	1	(0,0)	0	(0,0)	1	(0,0)
ASARUM SPP. ROOT;CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;PINELLIA TERNATA TUBER;SCHISANDRA CHINENSIS FRUIT;ZINGIBER OFFICINALE RHIZOME	2	(0,1)	2	(0,1)	4	(0,1)
BENPROPERINE PHOSPHATE	3	(0,1)	4	(0,2)	7	(0,2)
BENZONATATE	15	(0,7)	17	(0,8)	32	(0,7)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
BROMHEXINE HYDROCHLORIDE	24	(1,1)	30	(1,4)	54	(1,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**510**	**(23,7)**	**503**	**(23,4)**	**1.013**	**(23,5)**
BROMHEXINE HYDROCHLORIDE;CHLORPHENAMINE MALEATE;NOSCAPINE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
BROMHEXINE HYDROCHLORIDE;GLUCOSE	0	(0,0)	1	(0,0)	1	(0,0)
BUTAMIRATE CITRATE	4	(0,2)	4	(0,2)	8	(0,2)
BUTAMIRATE CITRATE;GUAIFENESIN	1	(0,0)	0	(0,0)	1	(0,0)
CAFFEINE;CHLORPHENAMINE MALEATE;PARACETAMOL;SALICYLAMIDE	1	(0,0)	0	(0,0)	1	(0,0)
CAMPHOR	2	(0,1)	1	(0,0)	3	(0,1)
CAMPHOR;GLYCYRRHIZA GLABRA;ILLICIUM VERUM OIL;PAPAVER SOMNIFERUM;SODIUM BENZOATE	2	(0,1)	3	(0,1)	5	(0,1)
CAMPHOR;MENTHOL	1	(0,0)	0	(0,0)	1	(0,0)
CARBOCISTEINE	19	(0,9)	19	(0,9)	38	(0,9)
CHLORPHENAMINE MALEATE;CODEINE PHOSPHATE;GLYCYRRHIZIC ACID;METHYLEPHEDRINE HYDROCHLORIDE-DL	0	(0,0)	1	(0,0)	1	(0,0)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**510**	**(23,7)**	**503**	**(23,4)**	**1.013**	**(23,5)**
CHLORPHENAMINE MALEATE;DIHYDROCODEINE BITARTRATE;GUAIFENESIN;METHYLEPHEDRINE HYDROCHLORIDE-DL	0	(0,0)	1	(0,0)	1	(0,0)
CHLORPHENAMINE MALEATE;DIHYDROCODEINE PHOSPHATE;METHYLEPHEDRINE HYDROCHLORIDE-DL	3	(0,1)	5	(0,2)	8	(0,2)
CHLORPHENAMINE MALEATE;HYDROCODONE BITARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
CHLORPHENAMINE MALEATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
CHLORPHENIRAMINE POLISTIREX;HYDROCODONE POLISTIREX	1	(0,0)	0	(0,0)	1	(0,0)
CINEOLE;DIPENTEN;PINENE	1	(0,0)	1	(0,0)	2	(0,0)
CINEOLE;LIMONENE, (+)-;PINENE	5	(0,2)	7	(0,3)	12	(0,3)
CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;PUERARIA LOBATA ROOT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	1	(0,0)	4	(0,2)	5	(0,1)
CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PRUNUS SPP. SEED	0	(0,0)	1	(0,0)	1	(0,0)
CITRIC ACID	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**510**	**(23,7)**	**503**	**(23,4)**	**1.013**	**(23,5)**
CITRUS MAXIMA;CYNANCHUM STAUNTONII;DELPHINIUM GRANDIFLORUM;GLYCYRRHIZA SPP.;PINELLIA TERNATA;PORIA COCOS;PRUNUS SPP.;SCHISANDRA CHINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
CLOFEDANOL HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CLOPERASTINE	1	(0,0)	1	(0,0)	2	(0,0)
CLOPERASTINE FENDIZOATE	0	(0,0)	1	(0,0)	1	(0,0)
CLOPERASTINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CODEINE	21	(1,0)	13	(0,6)	34	(0,8)
CODEINE PHOSPHATE	14	(0,7)	14	(0,7)	28	(0,7)
CODEINE PHOSPHATE;EPHEDRINE HYDROCHLORIDE;PROMETHAZINE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
CODEINE PHOSPHATE;EPHEDRINE HYDROCHLORIDE;SULFOGAIACOL; TRIPROLIDINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CODEINE PHOSPHATE;GUAIFENESIN	3	(0,1)	0	(0,0)	3	(0,1)
CODEINE PHOSPHATE;PLATYCODON GRANDIFLORUS	4	(0,2)	0	(0,0)	4	(0,1)
CODEINE PHOSPHATE;PROMETHAZINE HYDROCHLORIDE	9	(0,4)	2	(0,1)	11	(0,3)
CODEINE PHOSPHATE;PSEUDOEPHEDRINE HYDROCHLORIDE;TRIPROLIDINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
CODEINE PHOSPHATE;SULFOGAIACOL	2	(0,1)	2	(0,1)	4	(0,1)
CODEINE;GUAIFENESIN	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**510**	**(23,7)**	**503**	**(23,4)**	**1.013**	**(23,5)**
CODEINE;PHENYLTOLOXAMINE	0	(0,0)	1	(0,0)	1	(0,0)
COPTIS SPP. RHIZOME;HEDERA HELIX LEAF	0	(0,0)	2	(0,1)	2	(0,0)
COUGH AND COLD PREPARATIONS	6	(0,3)	3	(0,1)	9	(0,2)
CROCUS SATIVUS	0	(0,0)	1	(0,0)	1	(0,0)
CYSTEINE;GLYCINE;GLYCYRRHIZIC ACID	2	(0,1)	0	(0,0)	2	(0,0)
DEXTROMETHORPHAN	14	(0,7)	8	(0,4)	22	(0,5)
DEXTROMETHORPHAN HYDROBROMIDE	22	(1,0)	18	(0,8)	40	(0,9)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	0	(0,0)	1	(0,0)	1	(0,0)
DEXTROMETHORPHAN HYDROBROMIDE;EPHEDRINE HYDROCHLORIDE;PROMETHAZINE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN	4	(0,2)	5	(0,2)	9	(0,2)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PHENYLEPHRINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PSEUDOEPHEDRINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
DEXTROMETHORPHAN HYDROBROMIDE;LYSOZYME CHLORIDE;POTASSIUM CRESOLSULFONATE	2	(0,1)	1	(0,0)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**510**	**(23,7)**	**503**	**(23,4)**	**1.013**	**(23,5)**
DEXTROMETHORPHAN HYDROBROMIDE;LYSOZYME HYDROCHLORIDE;POTASSIUM CRESOLSULFONATE	11	(0,5)	10	(0,5)	21	(0,5)
DIHYDROCODEINE	3	(0,1)	5	(0,2)	8	(0,2)
DIHYDROCODEINE THIOCYANATE	2	(0,1)	3	(0,1)	5	(0,1)
DIMEMORFAN PHOSPHATE	2	(0,1)	4	(0,2)	6	(0,1)
DRIMIA MARITIMA;MORPHINE	0	(0,0)	1	(0,0)	1	(0,0)
ELECTROLYTES NOS	26	(1,2)	30	(1,4)	56	(1,3)
EPRAZINONE HYDROCHLORIDE	3	(0,1)	0	(0,0)	3	(0,1)
ERDOSTEINE	12	(0,6)	16	(0,7)	28	(0,7)
ERIOBOTRYA JAPONICA	0	(0,0)	2	(0,1)	2	(0,0)
ETHYLMORPHINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ETHYLMORPHINE HYDROCHLORIDE;GUAREA GUIDONIA;POLYGALA SENEGA	1	(0,0)	2	(0,1)	3	(0,1)
ETHYLMORPHINE HYDROCHLORIDE;MENTHOL;RHAMNUS PURSHIANA	0	(0,0)	1	(0,0)	1	(0,0)
FALLOPIA MULTIFLORA	1	(0,0)	0	(0,0)	1	(0,0)
FUDOSTEINE	0	(0,0)	4	(0,2)	4	(0,1)
GENTIANA LUTEA ROOT;PRIMULA SPP. FLOWER;RUMEX SPP. HERB;SAMBUCUS NIGRA FLOWER;VERBENA OFFICINALIS HERB	2	(0,1)	0	(0,0)	2	(0,0)
GENTIANA LUTEA ROOT;PRIMULA SPP.;RUMEX SPP.;SAMBUCUS NIGRA FLOWER;VERBENA OFFICINALIS	0	(0,0)	1	(0,0)	1	(0,0)
GLYCEROL	21	(1,0)	20	(0,9)	41	(1,0)
GLYCYRRHIZA GLABRA	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**510**	**(23,7)**	**503**	**(23,4)**	**1.013**	**(23,5)**
GLYCYRRHIZA GLABRA;PANAX GINSENG;PLATYCODON GRANDIFLORUS;POLYGALA SENEGA;PRUNUS ARMENIACA;UNCARIA GAMBIR	0	(0,0)	1	(0,0)	1	(0,0)
GLYCYRRHIZA GLABRA;PLATYCODON GRANDIFLORUS;POLYGALA SENEGA;PRUNUS ARMENIACA SEED	0	(0,0)	1	(0,0)	1	(0,0)
GLYCYRRHIZA SPP. ROOT;OPHIOPOGON JAPONICUS TUBER;ORYZA SATIVA FRUIT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	1	(0,0)	1	(0,0)	2	(0,0)
GLYCYRRHIZA URALENSIS	1	(0,0)	1	(0,0)	2	(0,0)
GLYCYRRHIZIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
GUAIFENESIN	15	(0,7)	14	(0,7)	29	(0,7)
GUAIFENESIN;PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
GUAIFENESIN;TERBUTALINE SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
GUAREA GUIDONIA	1	(0,0)	1	(0,0)	2	(0,0)
HEDERA HELIX	1	(0,0)	1	(0,0)	2	(0,0)
HEDERA HELIX EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
HOUTTUYNIA CORDATA	0	(0,0)	1	(0,0)	1	(0,0)
HYDROCODONE	8	(0,4)	10	(0,5)	18	(0,4)
HYDROCODONE BITARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
IODINATED GLYCEROL	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**510**	**(23,7)**	**503**	**(23,4)**	**1.013**	**(23,5)**
IODINE	1	(0,0)	1	(0,0)	2	(0,0)
LEVOCLOPERASTINE FENDIZOATE	0	(0,0)	1	(0,0)	1	(0,0)
LEVODROPROPIZINE	4	(0,2)	4	(0,2)	8	(0,2)
LEVOMENTHOL	1	(0,0)	1	(0,0)	2	(0,0)
LINUM USITATISSIMUM	1	(0,0)	0	(0,0)	1	(0,0)
LINUM USITATISSIMUM SEED	0	(0,0)	1	(0,0)	1	(0,0)
MANNITOL	17	(0,8)	12	(0,6)	29	(0,7)
MECYSTEINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
MENTHOL	1	(0,0)	1	(0,0)	2	(0,0)
MESNA	1	(0,0)	3	(0,1)	4	(0,1)
MYROXYLON BALSAMUM SYRUP;PAPAVER SOMNIFERUM TINCTURE;SQUILL OXYMEL	1	(0,0)	0	(0,0)	1	(0,0)
NOSCAPINE	0	(0,0)	1	(0,0)	1	(0,0)
OPIUM ALKALOIDS AND DERIVATIVES	1	(0,0)	0	(0,0)	1	(0,0)
OPIUM DERIVATIVES AND EXPECTORANTS	0	(0,0)	1	(0,0)	1	(0,0)
OXOLAMINE PHOSPHATE	0	(0,0)	1	(0,0)	1	(0,0)
PELARGONIUM SIDOIDES	1	(0,0)	1	(0,0)	2	(0,0)
PENTOXYVERINE CITRATE	0	(0,0)	1	(0,0)	1	(0,0)
PHENYLTOLOXAMINE;PHOLCODINE	0	(0,0)	1	(0,0)	1	(0,0)
PHOLCODINE	4	(0,2)	2	(0,1)	6	(0,1)
PLATYCODON GRANDIFLORUS	5	(0,2)	4	(0,2)	9	(0,2)
POLYGALA SENEGA	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM IODIDE	0	(0,0)	3	(0,1)	3	(0,1)
PRONASE;SODIUM BICARBONATE	0	(0,0)	1	(0,0)	1	(0,0)
PRUNUS SEROTINA BARK	0	(0,0)	1	(0,0)	1	(0,0)
QUININE	1	(0,0)	4	(0,2)	5	(0,1)
QUININE SULFATE	3	(0,1)	0	(0,0)	3	(0,1)
SODIUM CHLORIDE	203	(9,4)	196	(9,1)	399	(9,3)
SODIUM CITRATE	1	(0,0)	2	(0,1)	3	(0,1)
TERPIN HYDRATE	0	(0,0)	2	(0,1)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
COUGH AND COLD PREPARATIONS	**510**	**(23,7)**	**503**	**(23,4)**	**1.013**	**(23,5)**
TIPEPIDINE HIBENZATE	2	(0,1)	2	(0,1)	4	(0,1)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
TRICHOSANTHES KIRILOWII	0	(0,0)	1	(0,0)	1	(0,0)
TRIGONELLA FOENUM-GRAECUM	0	(0,0)	1	(0,0)	1	(0,0)
ZINC	1	(0,0)	2	(0,1)	3	(0,1)
ZINC GLUCONATE	1	(0,0)	0	(0,0)	1	(0,0)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	**612**	**(28,4)**	**639**	**(29,7)**	**1.251**	**(29,1)**
ACLIDINIUM BROMIDE	11	(0,5)	6	(0,3)	17	(0,4)
ACLIDINIUM BROMIDE;FORMOTEROL FUMARATE	4	(0,2)	1	(0,0)	5	(0,1)
ACONITUM SPP. PROCESSED ROOT;ASARUM SPP. ROOT;EPHEDRA SPP. HERB	0	(0,0)	1	(0,0)	1	(0,0)
AMINOPHYLLINE	14	(0,7)	20	(0,9)	34	(0,8)
AMINOPHYLLINE;CHLORPHENAMINE MALEATE;METHOXYPHENAMINE HYDROCHLORIDE;NOSCAPINE	6	(0,3)	7	(0,3)	13	(0,3)
AMMONIUM CHLORIDE;DIPHENHYDRAMINE HYDROCHLORIDE;ETOFYLLINE;SODIUM CITRATE;THEOPHYLLINE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	**612**	**(28,4)**	**639**	**(29,7)**	**1.251**	**(29,1)**
ARCTIUM LAPPA FRUIT;CICADA SLOUGH;EPHEDRA SPP. HERB;ERIOBOTRYA JAPONICA LEAF;PERILLA FRUTESCENS FRUIT;PERILLA FRUTESCENS LEAF;PEUCEDANUM PRAERUPTORUM ROOT;PHERETIMA SPP.;SCHISANDRA CHINENSIS FRUIT	3	(0,1)	3	(0,1)	6	(0,1)
ARTEMISIA ARGYI LEAF	4	(0,2)	4	(0,2)	8	(0,2)
ASARUM SPP. ROOT;CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;PINELLIA TERNATA TUBER;SCHISANDRA CHINENSIS FRUIT;ZINGIBER OFFICINALE RHIZOME	2	(0,1)	2	(0,1)	4	(0,1)
BAMBUTEROL	0	(0,0)	2	(0,1)	2	(0,0)
BECLOMETASONE DIPROPIONATE	42	(2,0)	26	(1,2)	68	(1,6)
BECLOMETASONE DIPROPIONATE;FORMOTEROL FUMARATE	16	(0,7)	7	(0,3)	23	(0,5)
BECLOMETASONE DIPROPIONATE;FORMOTEROL FUMARATE;GLYCOPYRRONIUM BROMIDE	0	(0,0)	2	(0,1)	2	(0,0)
BECLOMETASONE DIPROPIONATE;SALBUTAMOL	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE	6	(0,3)	9	(0,4)	15	(0,3)
BETAMETHASONE DIPROPIONATE	4	(0,2)	2	(0,1)	6	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	**612**	**(28,4)**	**639**	**(29,7)**	**1.251**	**(29,1)**
BETAMETHASONE SODIUM PHOSPHATE	5	(0,2)	6	(0,3)	11	(0,3)
BETAMETHASONE VALERATE	11	(0,5)	9	(0,4)	20	(0,5)
BUDESONIDE	71	(3,3)	80	(3,7)	151	(3,5)
BUDESONIDE;FORMOTEROL FUMARATE	40	(1,9)	37	(1,7)	77	(1,8)
CHLORPHENAMINE MALEATE;DIPROPHYLLINE;METHOXYPHENAMINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CICLESONIDE	5	(0,2)	4	(0,2)	9	(0,2)
CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PRUNUS SPP. SEED	0	(0,0)	1	(0,0)	1	(0,0)
CORDYCEPS SINENSIS	14	(0,7)	11	(0,5)	25	(0,6)
CROCUS SATIVUS	0	(0,0)	1	(0,0)	1	(0,0)
CROMOGLICATE SODIUM	3	(0,1)	0	(0,0)	3	(0,1)
DESLORATADINE;MONTELUKAST SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
DEXAMETHASONE	37	(1,7)	37	(1,7)	74	(1,7)
DIPHENHYDRAMINE HYDROCHLORIDE;DIPROPHYLLINE;EPHEDRINE HYDROCHLORIDE;NOSCAPINE;PAPAVERINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
DIPROPHYLLINE	3	(0,1)	9	(0,4)	12	(0,3)
DOXOFYLLINE	8	(0,4)	6	(0,3)	14	(0,3)
DOXOFYLLINE;GLUCOSE	0	(0,0)	1	(0,0)	1	(0,0)
EPHEDRINE	5	(0,2)	9	(0,4)	14	(0,3)
EPHEDRINE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
EPHEDRINE SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
EPINEPHRINE	52	(2,4)	53	(2,5)	105	(2,4)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	**612**	**(28,4)**	**639**	**(29,7)**	**1.251**	**(29,1)**
EPINEPHRINE BITARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
EPINEPHRINE HYDROCHLORIDE	1	(0,0)	5	(0,2)	6	(0,1)
ERIOBOTRYA JAPONICA	0	(0,0)	2	(0,1)	2	(0,0)
FENOTEROL	9	(0,4)	12	(0,6)	21	(0,5)
FENOTEROL HYDROBROMIDE	5	(0,2)	8	(0,4)	13	(0,3)
FENOTEROL HYDROBROMIDE;IPRATROPIUM BROMIDE	37	(1,7)	24	(1,1)	61	(1,4)
FENOTEROL;IPRATROPIUM BROMIDE	4	(0,2)	5	(0,2)	9	(0,2)
FENSPIRIDE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
FLUTICASONE	29	(1,3)	24	(1,1)	53	(1,2)
FLUTICASONE FUROATE	3	(0,1)	11	(0,5)	14	(0,3)
FLUTICASONE FUROATE;VILANTEROL TRIFENATATE	10	(0,5)	15	(0,7)	25	(0,6)
FLUTICASONE PROPIONATE	30	(1,4)	38	(1,8)	68	(1,6)
FLUTICASONE PROPIONATE;FORMOTEROL FUMARATE	1	(0,0)	3	(0,1)	4	(0,1)
FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE	48	(2,2)	41	(1,9)	89	(2,1)
FORMOTEROL FUMARATE	29	(1,3)	32	(1,5)	61	(1,4)
FORMOTEROL FUMARATE;MOMETASONE FUROATE	2	(0,1)	3	(0,1)	5	(0,1)
GLYCOPYRRONIUM	2	(0,1)	3	(0,1)	5	(0,1)
GLYCOPYRRONIUM BROMIDE	7	(0,3)	13	(0,6)	20	(0,5)
GLYCOPYRRONIUM BROMIDE;INDACATEROL MALEATE	12	(0,6)	11	(0,5)	23	(0,5)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	**612**	**(28,4)**	**639**	**(29,7)**	**1.251**	**(29,1)**
GLYCYRRHIZA SPP. ROOT;OPHIOPOGON JAPONICUS TUBER;ORYZA SATIVA FRUIT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	1	(0,0)	1	(0,0)	2	(0,0)
INDACATEROL	2	(0,1)	2	(0,1)	4	(0,1)
INDACATEROL MALEATE	3	(0,1)	2	(0,1)	5	(0,1)
IPRATROPIUM BROMIDE	161	(7,5)	183	(8,5)	344	(8,0)
IPRATROPIUM BROMIDE MONOHYDRATE	2	(0,1)	1	(0,0)	3	(0,1)
IPRATROPIUM BROMIDE MONOHYDRATE;SALBUTAMOL SULFATE	0	(0,0)	3	(0,1)	3	(0,1)
IPRATROPIUM BROMIDE;SALBUTAMOL	16	(0,7)	16	(0,7)	32	(0,7)
IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE	50	(2,3)	50	(2,3)	100	(2,3)
ISOPRENALINE HYDROCHLORIDE	5	(0,2)	3	(0,1)	8	(0,2)
ISOPRENALINE SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
LEVOCETIRIZINE DIHYDROCHLORIDE;MONTELUKAST SODIUM	2	(0,1)	2	(0,1)	4	(0,1)
LEVOSALBUTAMOL	1	(0,0)	1	(0,0)	2	(0,0)
LEVOSALBUTAMOL HYDROCHLORIDE	3	(0,1)	0	(0,0)	3	(0,1)
LOBELINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
METHYLEPHEDRINE HYDROCHLORIDE-DL	2	(0,1)	0	(0,0)	2	(0,0)
MOMETASONE FUROATE	18	(0,8)	14	(0,7)	32	(0,7)
MONTELUKAST	10	(0,5)	12	(0,6)	22	(0,5)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	**612**	**(28,4)**	**639**	**(29,7)**	**1.251**	**(29,1)**
MONTELUKAST SODIUM	22	(1,0)	23	(1,1)	45	(1,0)
OLODATEROL	4	(0,2)	3	(0,1)	7	(0,2)
OLODATEROL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
OLODATEROL HYDROCHLORIDE;TIOTROPIUM BROMIDE	0	(0,0)	2	(0,1)	2	(0,0)
OLODATEROL HYDROCHLORIDE;TIOTROPIUM BROMIDE MONOHYDRATE	13	(0,6)	5	(0,2)	18	(0,4)
OMALIZUMAB	1	(0,0)	0	(0,0)	1	(0,0)
OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS	0	(0,0)	1	(0,0)	1	(0,0)
PELARGONIUM SIDOIDES	1	(0,0)	1	(0,0)	2	(0,0)
PRANLUKAST	3	(0,1)	1	(0,0)	4	(0,1)
PROCATEROL HYDROCHLORIDE	6	(0,3)	5	(0,2)	11	(0,3)
REPROTEROL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ROFLUMILAST	0	(0,0)	1	(0,0)	1	(0,0)
SALBUTAMOL	153	(7,1)	150	(7,0)	303	(7,0)
SALBUTAMOL SULFATE	44	(2,0)	50	(2,3)	94	(2,2)
SALMETEROL	10	(0,5)	6	(0,3)	16	(0,4)
SALMETEROL XINAFOATE	4	(0,2)	3	(0,1)	7	(0,2)
TERBUTALINE SULFATE	14	(0,7)	13	(0,6)	27	(0,6)
THEOBROMINE	0	(0,0)	2	(0,1)	2	(0,0)
THEOPHYLLINE	37	(1,7)	35	(1,6)	72	(1,7)
TIOTROPIUM BROMIDE	75	(3,5)	79	(3,7)	154	(3,6)
TRANILAST	1	(0,0)	0	(0,0)	1	(0,0)
TRETOQUINOL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
TRIAMCINOLONE	3	(0,1)	9	(0,4)	12	(0,3)
TRIAMCINOLONE ACETONIDE	14	(0,7)	12	(0,6)	26	(0,6)
TULOBUTEROL	0	(0,0)	2	(0,1)	2	(0,0)
TULOBUTEROL HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
UMECLIDINIUM	4	(0,2)	0	(0,0)	4	(0,1)
UMECLIDINIUM BROMIDE	3	(0,1)	5	(0,2)	8	(0,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	**612**	**(28,4)**	**639**	**(29,7)**	**1.251**	**(29,1)**
UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	6	(0,3)	7	(0,3)	13	(0,3)
VILANTEROL	3	(0,1)	1	(0,0)	4	(0,1)
VILANTEROL TRIFENATATE	0	(0,0)	1	(0,0)	1	(0,0)
NASAL PREPARATIONS	**676**	**(31,4)**	**684**	**(31,8)**	**1.360**	**(31,6)**
ACETYLCYSTEINE	128	(5,9)	138	(6,4)	266	(6,2)
ANGELICA DAHURICA;ASTRAGALUS PROPINQUUS;CHRYSANTHEMUM INDICUM;GLYCYRRHIZA SPP.;LIGUSTICUM CHUANXIONG;MAGNOLIA SPP.;PLATYCARYA STROBILACEA;PRUNELLA VULGARIS;SAPOSHNIKOVIA DIVARICATA	0	(0,0)	1	(0,0)	1	(0,0)
ANTAZOLINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ATROPA BELLADONNA;CHLORPHENAMINE MALEATE;PHENYLPROPANOLAMIN E HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
AZELASTINE HYDROCHLORIDE	3	(0,1)	3	(0,1)	6	(0,1)
AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE	0	(0,0)	2	(0,1)	2	(0,0)
BECLOMETASONE DIPROPIONATE	42	(2,0)	26	(1,2)	68	(1,6)
BENZALKONIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
BENZODODECINIUM BROMIDE;POLYSORBATE 80	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE	6	(0,3)	9	(0,4)	15	(0,3)
BETAMETHASONE DIPROPIONATE	4	(0,2)	2	(0,1)	6	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
NASAL PREPARATIONS	**676**	**(31,4)**	**684**	**(31,8)**	**1.360**	**(31,6)**
BETAMETHASONE SODIUM PHOSPHATE	5	(0,2)	6	(0,3)	11	(0,3)
BETAMETHASONE VALERATE	11	(0,5)	9	(0,4)	20	(0,5)
BROMPHENIRAMINE MALEATE;PHENYLPROPANOLAMINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
BUDESONIDE	71	(3,3)	80	(3,7)	151	(3,5)
CAFFEINE;CHLORPHENAMINE MALEATE;PHENYLEPHRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
CAMPHOR;LEVOMENTHOL;METHYL SALICYLATE	1	(0,0)	2	(0,1)	3	(0,1)
CAMPHOR;MENTHOL;METHYL SALICYLATE	1	(0,0)	1	(0,0)	2	(0,0)
CARBINOXAMINE MALEATE;PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CETIRIZINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CHLORPHENAMINE MALEATE;DATURA STRAMONIUM;PHENYLEPHRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CICLESONIDE	5	(0,2)	4	(0,2)	9	(0,2)
CROMOGLICATE SODIUM	3	(0,1)	0	(0,0)	3	(0,1)
DEXAMETHASONE	37	(1,7)	37	(1,7)	74	(1,7)
DEXAMETHASONE DIPROPIONATE	3	(0,1)	0	(0,0)	3	(0,1)
DEXAMETHASONE ISONICOTINATE;NEOMYCIN SULFATE;TRAMAZOLINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
NASAL PREPARATIONS	**676**	**(31,4)**	**684**	**(31,8)**	**1.360**	**(31,6)**
DEXAMETHASONE ISONICOTINATE;TRAMAZOLINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM METASULFOBENZOATE;NEOMYCIN SULFATE;PHENYLEPHRINE HYDROCHLORIDE;POLYMYXIN B SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM PHOSPHATE	17	(0,8)	16	(0,7)	33	(0,8)
DEXPANTHENOL	3	(0,1)	2	(0,1)	5	(0,1)
DEXPANTHENOL;RETINOL	1	(0,0)	1	(0,0)	2	(0,0)
EBASTINE;PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
EPHEDRINE	5	(0,2)	9	(0,4)	14	(0,3)
EPHEDRINE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
EPHEDRINE SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
EPINEPHRINE	52	(2,4)	53	(2,5)	105	(2,4)
EPINEPHRINE BITARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
EPINEPHRINE HYDROCHLORIDE	1	(0,0)	5	(0,2)	6	(0,1)
ETHANOL	0	(0,0)	2	(0,1)	2	(0,0)
FEXOFENADINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	3	(0,1)	4	(0,2)	7	(0,2)
FLUTICASONE	29	(1,3)	24	(1,1)	53	(1,2)
FLUTICASONE FUROATE	3	(0,1)	11	(0,5)	14	(0,3)
FLUTICASONE PROPIONATE	30	(1,4)	38	(1,8)	68	(1,6)
FRAMYCETIN	0	(0,0)	1	(0,0)	1	(0,0)
FRAMYCETIN SULFATE;NAPHAZOLINE NITRATE;PREDNISOLONE ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
HEXAMIDINE ISETIONATE	1	(0,0)	0	(0,0)	1	(0,0)
HYALURONATE SODIUM	23	(1,1)	17	(0,8)	40	(0,9)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
NASAL PREPARATIONS	**676**	**(31,4)**	**684**	**(31,8)**	**1.360**	**(31,6)**
IPRATROPIUM BROMIDE	161	(7,5)	183	(8,5)	344	(8,0)
KETOTIFEN FUMARATE	6	(0,3)	4	(0,2)	10	(0,2)
LEVOCABASTINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
LEVOCETIRIZINE DIHYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
LORATADINE;PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
LORATADINE;PSEUDOEPHEDRINE SULFATE	1	(0,0)	1	(0,0)	2	(0,0)
MOMETASONE FUROATE	18	(0,8)	14	(0,7)	32	(0,7)
MUPIROCIN	14	(0,7)	18	(0,8)	32	(0,7)
MUPIROCIN CALCIUM	3	(0,1)	1	(0,0)	4	(0,1)
NAPHAZOLINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
NAPHAZOLINE NITRATE	0	(0,0)	1	(0,0)	1	(0,0)
OLOPATADINE HYDROCHLORIDE	10	(0,5)	4	(0,2)	14	(0,3)
OXYMETAZOLINE HYDROCHLORIDE	10	(0,5)	4	(0,2)	14	(0,3)
PHENYLEPHRINE	11	(0,5)	16	(0,7)	27	(0,6)
PHENYLEPHRINE HYDROCHLORIDE	9	(0,4)	10	(0,5)	19	(0,4)
POTASSIUM CHLORIDE;SODIUM CHLORIDE	5	(0,2)	5	(0,2)	10	(0,2)
POTASSIUM;SODIUM CHLORIDE	1	(0,0)	3	(0,1)	4	(0,1)
PREDNISOLONE	84	(3,9)	73	(3,4)	157	(3,6)
PREDNISOLONE HEMISUCCINATE	0	(0,0)	2	(0,1)	2	(0,0)
PSEUDOEPHEDRINE	2	(0,1)	5	(0,2)	7	(0,2)
PSEUDOEPHEDRINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
PSEUDOEPHEDRINE HYDROCHLORIDE;TRIPROLIDINE HYDROCHLORIDE	0	(0,0)	3	(0,1)	3	(0,1)
RETINOL	1	(0,0)	1	(0,0)	2	(0,0)
SEA WATER	0	(0,0)	2	(0,1)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
NASAL PREPARATIONS	**676**	**(31,4)**	**684**	**(31,8)**	**1.360**	**(31,6)**
SODIUM BICARBONATE	104	(4,8)	109	(5,1)	213	(5,0)
SODIUM CHLORIDE	203	(9,4)	196	(9,1)	399	(9,3)
TETRYZOLINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
TRAMAZOLINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
TRIAMCINOLONE	3	(0,1)	9	(0,4)	12	(0,3)
TRIAMCINOLONE ACETONIDE	14	(0,7)	12	(0,6)	26	(0,6)
XYLOMETAZOLINE HYDROCHLORIDE	5	(0,2)	4	(0,2)	9	(0,2)
ZINC	1	(0,0)	2	(0,1)	3	(0,1)
ZINC GLUCONATE	1	(0,0)	0	(0,0)	1	(0,0)
OTHER RESPIRATORY SYSTEM PRODUCTS	**164**	**(7,6)**	**166**	**(7,7)**	**330**	**(7,7)**
AMBROXOL	23	(1,1)	25	(1,2)	48	(1,1)
AMBROXOL HYDROCHLORIDE	44	(2,0)	46	(2,1)	90	(2,1)
ASARUM SPP. ROOT;CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;PINELLIA TERNATA TUBER;SCHISANDRA CHINENSIS FRUIT;ZINGIBER OFFICINALE RHIZOME	2	(0,1)	2	(0,1)	4	(0,1)
ASCORBIC ACID;ATROPINE SULFATE;CAFFEINE;CHLORPHENAMINE MALEATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE	6	(0,3)	9	(0,4)	15	(0,3)
CAFFEINE	1	(0,0)	1	(0,0)	2	(0,0)
DEXAMETHASONE	37	(1,7)	37	(1,7)	74	(1,7)
FALLOPIA MULTIFLORA	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
OTHER RESPIRATORY SYSTEM PRODUCTS	**164**	**(7,6)**	**166**	**(7,7)**	**330**	**(7,7)**
GLYCYRRHIZA SPP. ROOT;OPHIOPOGON JAPONICUS TUBER;ORYZA SATIVA FRUIT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	1	(0,0)	1	(0,0)	2	(0,0)
LOBELINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
NIKETHAMIDE	2	(0,1)	1	(0,0)	3	(0,1)
OXYGEN	55	(2,6)	58	(2,7)	113	(2,6)
PELARGONIUM SIDOIDES	1	(0,0)	1	(0,0)	2	(0,0)
PHOSPHOLIPIDS	2	(0,1)	2	(0,1)	4	(0,1)
SIVELESTAT SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
THROAT PREPARATIONS	**304**	**(14,1)**	**303**	**(14,1)**	**607**	**(14,1)**
ACRIFLAVINE	1	(0,0)	0	(0,0)	1	(0,0)
AMBROXOL	23	(1,1)	25	(1,2)	48	(1,1)
AMBROXOL HYDROCHLORIDE	44	(2,0)	46	(2,1)	90	(2,1)
AMYLMETACRESOL;DICHLOROBENZYL ALCOHOL	3	(0,1)	2	(0,1)	5	(0,1)
AZULENE	2	(0,1)	0	(0,0)	2	(0,0)
BACITRACIN	2	(0,1)	5	(0,2)	7	(0,2)
BACITRACIN ZINC;NEOMYCIN SULFATE	0	(0,0)	2	(0,1)	2	(0,0)
BENZALKONIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
BENZETHONIUM CHLORIDE	3	(0,1)	0	(0,0)	3	(0,1)
BENZOCAINE	3	(0,1)	0	(0,0)	3	(0,1)
BENZOCAINE;BUTYL AMINOBENZOATE;TETRACAINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
BENZOCAINE;MENTHOL	0	(0,0)	5	(0,2)	5	(0,1)
BENZYDAMINE HYDROCHLORIDE	6	(0,3)	1	(0,0)	7	(0,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
THROAT PREPARATIONS	**304**	**(14,1)**	**303**	**(14,1)**	**607**	**(14,1)**
BENZYDAMINE HYDROCHLORIDE;CETYLPYRIDINIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
BENZYDAMINE HYDROCHLORIDE;CHLORHEXIDINE GLUCONATE	1	(0,0)	2	(0,1)	3	(0,1)
BORIC ACID;BORNEOL;CITRULLUS LANATUS;COPTIS SPP.;FRITILLARIA THUNBERGII;GLYCYRRHIZA SPP.;INDIGO;IRIS DOMESTICA;MENTHOL;PHELLODENDRON CHINENSE;RHEUM SPP.;SAPINDUS MUKOROSSI;SCUTELLARIA BAICALENSIS;SODIUM SULFATE;SOPHORA TONKINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
CETYLPYRIDINIUM CHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
CHLORHEXIDINE	3	(0,1)	5	(0,2)	8	(0,2)
CHLORHEXIDINE DIACETATE	1	(0,0)	1	(0,0)	2	(0,0)
CHLORHEXIDINE GLUCONATE	6	(0,3)	14	(0,7)	20	(0,5)
CHLORHEXIDINE GLUCONATE;LIDOCAINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
CHLORHEXIDINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
COCAINE	1	(0,0)	1	(0,0)	2	(0,0)
DECAMETHOXINE	0	(0,0)	1	(0,0)	1	(0,0)
DEQUALINIUM CHLORIDE	7	(0,3)	5	(0,2)	12	(0,3)
DICLOFENAC	33	(1,5)	33	(1,5)	66	(1,5)
DICLOFENAC SODIUM	36	(1,7)	30	(1,4)	66	(1,5)
FLURBIPROFEN	13	(0,6)	11	(0,5)	24	(0,6)
FRAMYCETIN	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
RESPIRATORY SYSTEM						
THROAT PREPARATIONS	**304**	**(14,1)**	**303**	**(14,1)**	**607**	**(14,1)**
GARDENIA JASMINOIDES FRUIT;ISATIS INDIGOTICA ROOT;PHELLODENDRON CHINENSE BARK;SCUTELLARIA BAICALENSIS ROOT;STERCULIA LYCHNOPHORA SEED	0	(0,0)	1	(0,0)	1	(0,0)
GLYCEROL;MENTHOL;METHYL SALICYLATE;SALICYLATE SODIUM;SODIUM BORATE DECAHYDRATE;THYMOL	1	(0,0)	1	(0,0)	2	(0,0)
HEXAMIDINE ISETIONATE	1	(0,0)	0	(0,0)	1	(0,0)
IBUPROFEN	49	(2,3)	33	(1,5)	82	(1,9)
IODINE	1	(0,0)	1	(0,0)	2	(0,0)
KETOPROFEN	41	(1,9)	49	(2,3)	90	(2,1)
LIDOCAINE	61	(2,8)	62	(2,9)	123	(2,9)
LIDOCAINE HYDROCHLORIDE	43	(2,0)	40	(1,9)	83	(1,9)
NEOMYCIN	4	(0,2)	2	(0,1)	6	(0,1)
PECTIN	1	(0,0)	0	(0,0)	1	(0,0)
PHENOL	0	(0,0)	3	(0,1)	3	(0,1)
POVIDONE-IODINE	18	(0,8)	8	(0,4)	26	(0,6)
PROPOLIS	1	(0,0)	1	(0,0)	2	(0,0)
TETRACYCLINE	2	(0,1)	3	(0,1)	5	(0,1)
TETRACYCLINE HYDROCHLORIDE	4	(0,2)	3	(0,1)	7	(0,2)
SENSORY ORGANS						
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	**349**	**(16,2)**	**346**	**(16,1)**	**695**	**(16,2)**
AZULENE	2	(0,1)	0	(0,0)	2	(0,0)
BACITRACIN ZINC;NEOMYCIN SULFATE	0	(0,0)	2	(0,1)	2	(0,0)
BETAMETHASONE	6	(0,3)	9	(0,4)	15	(0,3)
BETAMETHASONE DIPROPIONATE;GENTAMICIN SULFATE	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	**349**	**(16,2)**	**346**	**(16,1)**	**695**	**(16,2)**
BETAMETHASONE SODIUM PHOSPHATE	5	(0,2)	6	(0,3)	11	(0,3)
BETAMETHASONE SODIUM PHOSPHATE;NEOMYCIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE VALERATE;GENTAMICIN SULFATE	5	(0,2)	10	(0,5)	15	(0,3)
BETAMETHASONE VALERATE;NEOMYCIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
CHLORAMPHENICOL	11	(0,5)	10	(0,5)	21	(0,5)
CHLORHEXIDINE	3	(0,1)	5	(0,2)	8	(0,2)
CHLORHEXIDINE DIACETATE	1	(0,0)	1	(0,0)	2	(0,0)
CHLORHEXIDINE GLUCONATE	6	(0,3)	14	(0,7)	20	(0,5)
CHLORHEXIDINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CIPROFLOXACIN	79	(3,7)	92	(4,3)	171	(4,0)
CIPROFLOXACIN HYDROCHLORIDE	14	(0,7)	10	(0,5)	24	(0,6)
CIPROFLOXACIN HYDROCHLORIDE;HYDROCORTISONE	1	(0,0)	0	(0,0)	1	(0,0)
CIPROFLOXACIN LACTATE	0	(0,0)	3	(0,1)	3	(0,1)
DEXAMETHASONE	37	(1,7)	37	(1,7)	74	(1,7)
DEXAMETHASONE DIPROPIONATE	3	(0,1)	0	(0,0)	3	(0,1)
DEXAMETHASONE SODIUM PHOSPHATE	17	(0,8)	16	(0,7)	33	(0,8)
DEXAMETHASONE SODIUM PHOSPHATE;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE;GENTAMICIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
DEXAMETHASONE;NEOMYCIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	3	(0,1)	3	(0,1)	6	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	**349**	**(16,2)**	**346**	**(16,1)**	**695**	**(16,2)**
DEXAMETHASONE;TOBRAMYCIN	7	(0,3)	6	(0,3)	13	(0,3)
GATIFLOXACIN	2	(0,1)	2	(0,1)	4	(0,1)
GENTAMICIN	17	(0,8)	15	(0,7)	32	(0,7)
GENTAMICIN SULFATE	10	(0,5)	12	(0,6)	22	(0,5)
GENTAMICIN SULFATE;PREDNISOLONE	1	(0,0)	0	(0,0)	1	(0,0)
HEXAMIDINE ISETIONATE	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE ACETATE;NEOMYCIN SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
LEVOFLOXACIN	95	(4,4)	99	(4,6)	194	(4,5)
LEVOFLOXACIN HEMIHYDRATE	8	(0,4)	2	(0,1)	10	(0,2)
LOMEFLOXACIN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
METHYLPREDNISOLONE;NEOMYCIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
NEOMYCIN	4	(0,2)	2	(0,1)	6	(0,1)
OFLOXACIN	15	(0,7)	12	(0,6)	27	(0,6)
POLYMYXIN B SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE	84	(3,9)	73	(3,4)	157	(3,6)
PREDNISOLONE ACETATE	3	(0,1)	3	(0,1)	6	(0,1)
PREDNISOLONE SODIUM SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE VALEROACETATE	6	(0,3)	0	(0,0)	6	(0,1)
TETRACYCLINE	2	(0,1)	3	(0,1)	5	(0,1)
TETRACYCLINE HYDROCHLORIDE	4	(0,2)	3	(0,1)	7	(0,2)
OPHTHALMOLOGICALS	**1.220**	**(56,7)**	**1.207**	**(56,1)**	**2.427**	**(56,4)**
ACETAZOLAMIDE	23	(1,1)	16	(0,7)	39	(0,9)
ACETYLCYSTEINE	128	(5,9)	138	(6,4)	266	(6,2)
ACICLOVIR	9	(0,4)	8	(0,4)	17	(0,4)
ADENOSINE	3	(0,1)	6	(0,3)	9	(0,2)
AFLIBERCEPT	2	(0,1)	1	(0,0)	3	(0,1)
ALBUMIN HUMAN	43	(2,0)	58	(2,7)	101	(2,3)
ALCLOMETASONE DIPROPIONATE	3	(0,1)	1	(0,0)	4	(0,1)
ALGINIC ACID	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**1.220**	**(56,7)**	**1.207**	**(56,1)**	**2.427**	**(56,4)**
ALTEPLASE	1	(0,0)	5	(0,2)	6	(0,1)
AMIKACIN	2	(0,1)	5	(0,2)	7	(0,2)
AMIKACIN SULFATE	1	(0,0)	3	(0,1)	4	(0,1)
AMINO ACIDS NOS	3	(0,1)	6	(0,3)	9	(0,2)
AMPICILLIN	11	(0,5)	9	(0,4)	20	(0,5)
AMPICILLIN SODIUM	3	(0,1)	3	(0,1)	6	(0,1)
ANTAZOLINE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
ANTAZOLINE PHOSPHATE;CHLORHEXIDINE GLUCONATE;TETRYZOLINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
ANTIINFLAMMATORY AGENTS, NON-STEROIDS	1	(0,0)	1	(0,0)	2	(0,0)
ASCORBIC ACID	39	(1,8)	28	(1,3)	67	(1,6)
ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;SODIUM SELENATE;TOCOPHERYL ACETATE;XANTOFYL;ZINC OXIDE	2	(0,1)	1	(0,0)	3	(0,1)
ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;TOCOPHERYL ACETATE;ZINC OXIDE	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID;COPPER CITRATE;TOCOPHERYL ACETATE;XANTOFYL;ZEAXANTHIN;ZINC OXIDE	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;COPPER;OMEGA-3 FATTY ACIDS;VITAMIN E NOS;XANTOFYL;ZEAXANTHIN;ZINC	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;CUPRIC OXIDE;RETINOL;TOCOPHERYL ACETATE;ZINC OXIDE	3	(0,1)	1	(0,0)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**1.220**	**(56,7)**	**1.207**	**(56,1)**	**2.427**	**(56,4)**
ATROPINE	18	(0,8)	16	(0,7)	34	(0,8)
ATROPINE SULFATE	9	(0,4)	4	(0,2)	13	(0,3)
AZELASTINE HYDROCHLORIDE	3	(0,1)	3	(0,1)	6	(0,1)
AZITHROMYCIN	76	(3,5)	76	(3,5)	152	(3,5)
BACITRACIN	2	(0,1)	5	(0,2)	7	(0,2)
BACITRACIN ZINC;NEOMYCIN SULFATE	0	(0,0)	2	(0,1)	2	(0,0)
BACITRACIN ZINC;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	4	(0,2)	3	(0,1)	7	(0,2)
BENZALKONIUM CHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
BENZYLPENICILLIN	9	(0,4)	8	(0,4)	17	(0,4)
BENZYLPENICILLIN POTASSIUM	1	(0,0)	1	(0,0)	2	(0,0)
BENZYLPENICILLIN SODIUM	0	(0,0)	5	(0,2)	5	(0,1)
BEPOTASTINE BESILATE	2	(0,1)	1	(0,0)	3	(0,1)
BEPOTASTINE SALICYLATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE	6	(0,3)	9	(0,4)	15	(0,3)
BETAMETHASONE DIPROPIONATE	4	(0,2)	2	(0,1)	6	(0,1)
BETAMETHASONE DIPROPIONATE;GENTAMICIN SULFATE	1	(0,0)	2	(0,1)	3	(0,1)
BETAMETHASONE SODIUM PHOSPHATE	5	(0,2)	6	(0,3)	11	(0,3)
BETAMETHASONE SODIUM PHOSPHATE;NEOMYCIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE VALERATE	11	(0,5)	9	(0,4)	20	(0,5)
BETAMETHASONE VALERATE;GENTAMICIN SULFATE	5	(0,2)	10	(0,5)	15	(0,3)
BETAMETHASONE VALERATE;NEOMYCIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
BETAMETHASONE;CHLORAMPHENICOL	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**1.220**	**(56,7)**	**1.207**	**(56,1)**	**2.427**	**(56,4)**
BETAXOLOL HYDROCHLORIDE	4	(0,2)	4	(0,2)	8	(0,2)
BEVACIZUMAB	9	(0,4)	1	(0,0)	10	(0,2)
BIMATOPROST	2	(0,1)	1	(0,0)	3	(0,1)
BLOOD, CALF, DEPROT., LMW PORTION	3	(0,1)	1	(0,0)	4	(0,1)
BORIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
BORIC ACID;POTASSIUM CHLORIDE;SODIUM CARBONATE ANHYDROUS;SODIUM CHLORIDE;SODIUM PHOSPHATE DIBASIC	1	(0,0)	0	(0,0)	1	(0,0)
BRIMONIDINE TARTRATE	7	(0,3)	6	(0,3)	13	(0,3)
BRIMONIDINE TARTRATE;TIMOLOL MALEATE	2	(0,1)	4	(0,2)	6	(0,1)
BRINZOLAMIDE	3	(0,1)	2	(0,1)	5	(0,1)
BRINZOLAMIDE;TIMOLOL MALEATE	2	(0,1)	1	(0,0)	3	(0,1)
BROMFENAC SODIUM	10	(0,5)	9	(0,4)	19	(0,4)
BUPIVACAINE	9	(0,4)	6	(0,3)	15	(0,3)
BUPIVACAINE HYDROCHLORIDE	8	(0,4)	2	(0,1)	10	(0,2)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	1	(0,0)	9	(0,4)	10	(0,2)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE;SODIUM CITRATE DIHYDRATE	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**1.220**	**(56,7)**	**1.207**	**(56,1)**	**2.427**	**(56,4)**
CALCIUM CHLORIDE DIHYDRATE;NEOSTIGMINE METILSULFATE;POTASSIUM ASPARTATE;SODIUM BICARBONATE;SODIUM CHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE	1	(0,0)	2	(0,1)	3	(0,1)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE DIHYDRATE	1	(0,0)	0	(0,0)	1	(0,0)
CARBOMER	5	(0,2)	4	(0,2)	9	(0,2)
CARMELLOSE	1	(0,0)	0	(0,0)	1	(0,0)
CARMELLOSE SODIUM	6	(0,3)	1	(0,0)	7	(0,2)
CARMELLOSE SODIUM;GLYCEROL	1	(0,0)	1	(0,0)	2	(0,0)
CARTEOLOL HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CARTEOLOL HYDROCHLORIDE;LATANOPROST	1	(0,0)	0	(0,0)	1	(0,0)
CEFMENOXIME HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CEFUROXIME	43	(2,0)	42	(2,0)	85	(2,0)
CEFUROXIME SODIUM	19	(0,9)	14	(0,7)	33	(0,8)
CETIRIZINE HYDROCHLORIDE	30	(1,4)	37	(1,7)	67	(1,6)
CETYLPYRIDINIUM CHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
CHLORAMPHENICOL	11	(0,5)	10	(0,5)	21	(0,5)
CHLORHEXIDINE	3	(0,1)	5	(0,2)	8	(0,2)
CHLORHEXIDINE DIACETATE	1	(0,0)	1	(0,0)	2	(0,0)
CHLORHEXIDINE GLUCONATE	6	(0,3)	14	(0,7)	20	(0,5)
CHLORHEXIDINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**1.220**	**(56,7)**	**1.207**	**(56,1)**	**2.427**	**(56,4)**
CHLORPHENAMINE MALEATE;CHONDROITIN SULFATE SODIUM;NEOSTIGMINE METILSULFATE;POTASSIUM ASPARTATE;PYRIDOXINE HYDROCHLORIDE;TOCOPHERYL ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
CHLORTETRACYCLINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
CHONDROITIN SULFATE SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
CHONDROITIN SULFATE SODIUM;FLAVINE ADENINE DINUCLEOTIDE DISODIUM	0	(0,0)	1	(0,0)	1	(0,0)
CHYMOTRYPSIN	0	(0,0)	1	(0,0)	1	(0,0)
CICLOSPORIN	1	(0,0)	4	(0,2)	5	(0,1)
CIPROFLOXACIN	79	(3,7)	92	(4,3)	171	(4,0)
CIPROFLOXACIN HYDROCHLORIDE	14	(0,7)	10	(0,5)	24	(0,6)
CIPROFLOXACIN HYDROCHLORIDE;HYDROCORTISONE	1	(0,0)	0	(0,0)	1	(0,0)
CIPROFLOXACIN LACTATE	0	(0,0)	3	(0,1)	3	(0,1)
CLOBETASONE BUTYRATE	1	(0,0)	2	(0,1)	3	(0,1)
CLONIDINE	4	(0,2)	9	(0,4)	13	(0,3)
CLONIDINE HYDROCHLORIDE	0	(0,0)	6	(0,3)	6	(0,1)
CLOTRIMAZOLE	2	(0,1)	7	(0,3)	9	(0,2)
COCAINE	1	(0,0)	1	(0,0)	2	(0,0)
COLISTIMETHATE SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
COLISTIN	2	(0,1)	1	(0,0)	3	(0,1)
CONBERCEPT	1	(0,0)	0	(0,0)	1	(0,0)
CORTISONE	1	(0,0)	3	(0,1)	4	(0,1)
CORTISONE ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
CROMOGLICATE SODIUM	3	(0,1)	0	(0,0)	3	(0,1)
CROTAMITON;HYDROCORTISONE	2	(0,1)	2	(0,1)	4	(0,1)
CYANOCOBALAMIN	54	(2,5)	54	(2,5)	108	(2,5)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**1.220**	**(56,7)**	**1.207**	**(56,1)**	**2.427**	**(56,4)**
CYCLOPENTOLATE HYDROCHLORIDE	1	(0,0)	2	(0,1)	3	(0,1)
DESONIDE	1	(0,0)	3	(0,1)	4	(0,1)
DEXAMETHASONE	37	(1,7)	37	(1,7)	74	(1,7)
DEXAMETHASONE DIPROPIONATE	3	(0,1)	0	(0,0)	3	(0,1)
DEXAMETHASONE PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
DEXAMETHASONE SODIUM METASULFOBENZOATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM METASULFOBENZOATE;NEOMYCIN SULFATE;PHENYLEPHRINE HYDROCHLORIDE;POLYMYXIN B SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM PHOSPHATE	17	(0,8)	16	(0,7)	33	(0,8)
DEXAMETHASONE SODIUM PHOSPHATE;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE;GENTAMICIN SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
DEXAMETHASONE;NEOMYCIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	3	(0,1)	3	(0,1)	6	(0,1)
DEXAMETHASONE;TOBRAMYCIN	7	(0,3)	6	(0,3)	13	(0,3)
DEXPANTHENOL	3	(0,1)	2	(0,1)	5	(0,1)
DEXPANTHENOL;RETINOL	1	(0,0)	1	(0,0)	2	(0,0)
DEXTRAN 70;HYPROMELLOSE	4	(0,2)	0	(0,0)	4	(0,1)
DICLOFENAC	33	(1,5)	33	(1,5)	66	(1,5)
DICLOFENAC DIETHYLAMINE	12	(0,6)	15	(0,7)	27	(0,6)
DICLOFENAC EPOLAMINE	1	(0,0)	0	(0,0)	1	(0,0)
DICLOFENAC SODIUM	36	(1,7)	30	(1,4)	66	(1,5)
DIFLUPREDNATE	3	(0,1)	3	(0,1)	6	(0,1)
DIMETICONE	13	(0,6)	23	(1,1)	36	(0,8)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**1.220**	**(56,7)**	**1.207**	**(56,1)**	**2.427**	**(56,4)**
DIPOTASSIUM GLYCYRRHIZATE	0	(0,0)	1	(0,0)	1	(0,0)
DIQUAFOSOL TETRASODIUM	2	(0,1)	5	(0,2)	7	(0,2)
DORZOLAMIDE HYDROCHLORIDE	2	(0,1)	0	(0,0)	2	(0,0)
DORZOLAMIDE HYDROCHLORIDE;TIMOLOL MALEATE	3	(0,1)	1	(0,0)	4	(0,1)
EDETIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
EPHEDRINE	5	(0,2)	9	(0,4)	14	(0,3)
EPHEDRINE HYDROCHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
EPHEDRINE SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
EPINASTINE HYDROCHLORIDE	7	(0,3)	5	(0,2)	12	(0,3)
EPINEPHRINE	52	(2,4)	53	(2,5)	105	(2,4)
EPINEPHRINE BITARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
EPINEPHRINE HYDROCHLORIDE	1	(0,0)	5	(0,2)	6	(0,1)
ERYTHROMYCIN	4	(0,2)	5	(0,2)	9	(0,2)
ERYTHROMYCIN ETHYLSUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
ETHYLMORPHINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
FAMCICLOVIR	0	(0,0)	1	(0,0)	1	(0,0)
FLUCONAZOLE	14	(0,7)	15	(0,7)	29	(0,7)
FLUDROCORTISONE ACETATE	2	(0,1)	0	(0,0)	2	(0,0)
FLUOCINOLONE ACETONIDE	4	(0,2)	7	(0,3)	11	(0,3)
FLUORESCEIN	1	(0,0)	1	(0,0)	2	(0,0)
FLUORESCEIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
FLUOROMETHOLONE	13	(0,6)	7	(0,3)	20	(0,5)
FLUOROMETHOLONE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
FLURBIPROFEN	13	(0,6)	11	(0,5)	24	(0,6)
FLURBIPROFEN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
FRAMYCETIN	0	(0,0)	1	(0,0)	1	(0,0)
FUSIDATE SODIUM	3	(0,1)	5	(0,2)	8	(0,2)
FUSIDIC ACID	7	(0,3)	8	(0,4)	15	(0,3)
GANCICLOVIR	2	(0,1)	1	(0,0)	3	(0,1)
GATIFLOXACIN	2	(0,1)	2	(0,1)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**1.220**	**(56,7)**	**1.207**	**(56,1)**	**2.427**	**(56,4)**
GENTAMICIN	17	(0,8)	15	(0,7)	32	(0,7)
GENTAMICIN SULFATE	10	(0,5)	12	(0,6)	22	(0,5)
GENTAMICIN SULFATE;PREDNISOLONE	1	(0,0)	0	(0,0)	1	(0,0)
GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	2	(0,1)	1	(0,0)	3	(0,1)
GLUTATHIONE	11	(0,5)	7	(0,3)	18	(0,4)
GLYCEROL	21	(1,0)	20	(0,9)	41	(1,0)
GLYCYRRHIZIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
GUAIAZULENE	10	(0,5)	4	(0,2)	14	(0,3)
HAMAMELIS VIRGINIANA EXTRACT	1	(0,0)	2	(0,1)	3	(0,1)
HEPARIN	86	(4,0)	111	(5,2)	197	(4,6)
HEPARIN CALCIUM	13	(0,6)	11	(0,5)	24	(0,6)
HEPARIN SODIUM	53	(2,5)	60	(2,8)	113	(2,6)
HEPARINOID	19	(0,9)	9	(0,4)	28	(0,7)
HEXAMIDINE ISETIONATE	1	(0,0)	0	(0,0)	1	(0,0)
HYALURONATE SODIUM	23	(1,1)	17	(0,8)	40	(0,9)
HYALURONATE SODIUM;TREHALOSE	0	(0,0)	1	(0,0)	1	(0,0)
HYDROCORTISONE	38	(1,8)	37	(1,7)	75	(1,7)
HYDROCORTISONE ACETATE	15	(0,7)	9	(0,4)	24	(0,6)
HYDROCORTISONE ACETATE;NEOMYCIN SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
HYDROCORTISONE PROBUTAT	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE SODIUM PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
HYDROCORTISONE SODIUM SUCCINATE	5	(0,2)	13	(0,6)	18	(0,4)
HYETELLOSE	1	(0,0)	0	(0,0)	1	(0,0)
HYETELLOSE;POVIDONE	1	(0,0)	1	(0,0)	2	(0,0)
HYOSCINE	2	(0,1)	7	(0,3)	9	(0,2)
HYOSCINE HYDROBROMIDE	0	(0,0)	2	(0,1)	2	(0,0)
HYPROLOSE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**1.220**	**(56,7)**	**1.207**	**(56,1)**	**2.427**	**(56,4)**
HYPROMELLOSE	4	(0,2)	6	(0,3)	10	(0,2)
INDOMETACIN	14	(0,7)	10	(0,5)	24	(0,6)
INOSINE	0	(0,0)	1	(0,0)	1	(0,0)
IODINE	1	(0,0)	1	(0,0)	2	(0,0)
IODOLECITHIN	1	(0,0)	1	(0,0)	2	(0,0)
ISOSORBIDE	15	(0,7)	5	(0,2)	20	(0,5)
KETOROLAC TROMETHAMINE	21	(1,0)	24	(1,1)	45	(1,0)
KETOTIFEN FUMARATE	6	(0,3)	4	(0,2)	10	(0,2)
LATANOPROST	17	(0,8)	8	(0,4)	25	(0,6)
LEVOBUNOLOL HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
LEVOCABASTINE HYDROCHLORIDE	0	(0,0)	2	(0,1)	2	(0,0)
LEVOFLOXACIN	95	(4,4)	99	(4,6)	194	(4,5)
LEVOFLOXACIN HEMIHYDRATE	8	(0,4)	2	(0,1)	10	(0,2)
LIDOCAINE	61	(2,8)	62	(2,9)	123	(2,9)
LIDOCAINE HYDROCHLORIDE	43	(2,0)	40	(1,9)	83	(1,9)
LIGHT LIQUID PARAFFIN;WHITE SOFT PARAFFIN	1	(0,0)	0	(0,0)	1	(0,0)
LOCAL ANESTHETICS	0	(0,0)	1	(0,0)	1	(0,0)
LOMEFLOXACIN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
LOTEPREDNOL ETABONATE	1	(0,0)	2	(0,1)	3	(0,1)
MACROGOL	29	(1,3)	29	(1,3)	58	(1,3)
MACROGOL 4000	1	(0,0)	7	(0,3)	8	(0,2)
MACROGOL 400;PROPYLENE GLYCOL	0	(0,0)	3	(0,1)	3	(0,1)
MELOXICAM	8	(0,4)	9	(0,4)	17	(0,4)
MESO ZEAXANTHIN;XANTOFYL;ZEAXANTHIN	0	(0,0)	1	(0,0)	1	(0,0)
METHYLETHYLPIRIDINOL	0	(0,0)	1	(0,0)	1	(0,0)
METHYLPREDNISOLONE	46	(2,1)	41	(1,9)	87	(2,0)
METHYLPREDNISOLONE ACETATE	2	(0,1)	3	(0,1)	5	(0,1)
METHYLPREDNISOLONE SODIUM PHOSPHATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**1.220**	**(56,7)**	**1.207**	**(56,1)**	**2.427**	**(56,4)**
MINERALS NOS;VITAMINS NOS	4	(0,2)	10	(0,5)	14	(0,3)
MIRAMISTIN	2	(0,1)	0	(0,0)	2	(0,0)
MOXIFLOXACIN	17	(0,8)	10	(0,5)	27	(0,6)
MOXIFLOXACIN HYDROCHLORIDE	48	(2,2)	30	(1,4)	78	(1,8)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	18	(0,8)	17	(0,8)	35	(0,8)
NANDROLONE DECANOATE	1	(0,0)	0	(0,0)	1	(0,0)
NAPHAZOLINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
NAPHAZOLINE NITRATE	0	(0,0)	1	(0,0)	1	(0,0)
NAPROXEN	10	(0,5)	16	(0,7)	26	(0,6)
NAPROXEN SODIUM	2	(0,1)	4	(0,2)	6	(0,1)
NEOMYCIN	4	(0,2)	2	(0,1)	6	(0,1)
NEOSTIGMINE BROMIDE	0	(0,0)	1	(0,0)	1	(0,0)
NEOSTIGMINE METILSULFATE	7	(0,3)	5	(0,2)	12	(0,3)
NEPAFENAC	2	(0,1)	5	(0,2)	7	(0,2)
NERVE GROWTH FACTOR, MOUSE	1	(0,0)	0	(0,0)	1	(0,0)
NETARSUDIL MESILATE	0	(0,0)	1	(0,0)	1	(0,0)
NIPRADOLOL	0	(0,0)	1	(0,0)	1	(0,0)
NITROFURAL	2	(0,1)	1	(0,0)	3	(0,1)
NORFLOXACIN	4	(0,2)	3	(0,1)	7	(0,2)
OFLOXACIN	15	(0,7)	12	(0,6)	27	(0,6)
OLOPATADINE HYDROCHLORIDE	10	(0,5)	4	(0,2)	14	(0,3)
OTHER OPHTHALMOLOGICALS	1	(0,0)	1	(0,0)	2	(0,0)
OXIGLUTATIONE	2	(0,1)	0	(0,0)	2	(0,0)
OXYBUPROCAINE HYDROCHLORIDE	3	(0,1)	1	(0,0)	4	(0,1)
OXYMETAZOLINE HYDROCHLORIDE	10	(0,5)	4	(0,2)	14	(0,3)
PANCREATIN	11	(0,5)	8	(0,4)	19	(0,4)
PARAFFIN	3	(0,1)	2	(0,1)	5	(0,1)
PARAFFIN SOFT	2	(0,1)	0	(0,0)	2	(0,0)
PARAFFIN, LIQUID	2	(0,1)	4	(0,2)	6	(0,1)
PARAFFIN, LIQUID;PETROLATUM	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**1.220**	**(56,7)**	**1.207**	**(56,1)**	**2.427**	**(56,4)**
PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	3	(0,1)	1	(0,0)	4	(0,1)
PARAFFIN, LIQUID;WHITE SOFT PARAFFIN;WOOL FAT	2	(0,1)	2	(0,1)	4	(0,1)
PARASYMPATHOMIMETICS	1	(0,0)	0	(0,0)	1	(0,0)
PERFLUTREN	0	(0,0)	5	(0,2)	5	(0,1)
PHENYLEPHRINE	11	(0,5)	16	(0,7)	27	(0,6)
PHENYLEPHRINE HYDROCHLORIDE	9	(0,4)	10	(0,5)	19	(0,4)
PHENYLEPHRINE HYDROCHLORIDE;TROPICAMIDE	11	(0,5)	4	(0,2)	15	(0,3)
PICLOXYDINE DIHYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
PILOCARPINE HYDROCHLORIDE	3	(0,1)	0	(0,0)	3	(0,1)
PIRENOXINE	7	(0,3)	4	(0,2)	11	(0,3)
PIROXICAM	1	(0,0)	2	(0,1)	3	(0,1)
PIROXICAM BETADEX	0	(0,0)	1	(0,0)	1	(0,0)
POLIDERIBOTIDE	0	(0,0)	1	(0,0)	1	(0,0)
POLYMYXIN B SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
POLYVINYL ALCOHOL	1	(0,0)	1	(0,0)	2	(0,0)
POLYVINYL ALCOHOL;POVIDONE	0	(0,0)	1	(0,0)	1	(0,0)
POTASSIUM	75	(3,5)	78	(3,6)	153	(3,6)
POTASSIUM CHLORIDE	532	(24,7)	514	(23,9)	1.046	(24,3)
POTASSIUM CHLORIDE;SODIUM CHLORIDE	5	(0,2)	5	(0,2)	10	(0,2)
POTASSIUM IODIDE	0	(0,0)	3	(0,1)	3	(0,1)
POTASSIUM PHOSPHATE DIBASIC;POTASSIUM PHOSPHATE MONOBASIC	1	(0,0)	1	(0,0)	2	(0,0)
POTASSIUM;SODIUM CHLORIDE	1	(0,0)	3	(0,1)	4	(0,1)
POVIDONE	0	(0,0)	1	(0,0)	1	(0,0)
POVIDONE-IODINE	18	(0,8)	8	(0,4)	26	(0,6)
PRANOPROFEN	4	(0,2)	3	(0,1)	7	(0,2)
PREDNISOLONE	84	(3,9)	73	(3,4)	157	(3,6)
PREDNISOLONE ACETATE	3	(0,1)	3	(0,1)	6	(0,1)
PREDNISOLONE HEMISUCCINATE	0	(0,0)	2	(0,1)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**1.220**	**(56,7)**	**1.207**	**(56,1)**	**2.427**	**(56,4)**
PREDNISOLONE SODIUM SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE VALEROACETATE	6	(0,3)	0	(0,0)	6	(0,1)
PREDNISONE	96	(4,5)	97	(4,5)	193	(4,5)
PREDNISONE ACETATE	0	(0,0)	3	(0,1)	3	(0,1)
PROCAINE BENZYLPENICILLIN	0	(0,0)	1	(0,0)	1	(0,0)
PROXYMETACAINE	1	(0,0)	0	(0,0)	1	(0,0)
PROXYMETACAINE HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
RANIBIZUMAB	1	(0,0)	0	(0,0)	1	(0,0)
REBAMIPIDE	19	(0,9)	29	(1,3)	48	(1,1)
RETINOL	1	(0,0)	1	(0,0)	2	(0,0)
RIBOFLAVIN	1	(0,0)	2	(0,1)	3	(0,1)
RICINUS COMMUNIS OIL	1	(0,0)	1	(0,0)	2	(0,0)
RIFAMPICIN	6	(0,3)	6	(0,3)	12	(0,3)
RIFAMYCIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
RIPASUDIL HYDROCHLORIDE DIHYDRATE	2	(0,1)	0	(0,0)	2	(0,0)
SALICYLIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
SEA WATER	0	(0,0)	2	(0,1)	2	(0,0)
SILVER NITRATE	0	(0,0)	1	(0,0)	1	(0,0)
SIROLIMUS	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM CHLORIDE	203	(9,4)	196	(9,1)	399	(9,3)
SODIUM PHOSPHATE DIBASIC DODECAHYDRATE;SODIUM PHOSPHATE MONOBASIC (DIHYDRATE)	4	(0,2)	2	(0,1)	6	(0,1)
SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC	5	(0,2)	5	(0,2)	10	(0,2)
SODIUM PHOSPHATE;SODIUM PHOSPHATE DIBASIC	3	(0,1)	2	(0,1)	5	(0,1)
SULFACETAMIDE	0	(0,0)	1	(0,0)	1	(0,0)
SULFADIAZINE SILVER	7	(0,3)	4	(0,2)	11	(0,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OPHTHALMOLOGICALS	**1.220**	**(56,7)**	**1.207**	**(56,1)**	**2.427**	**(56,4)**
SULFAMETHOXAZOLE	9	(0,4)	10	(0,5)	19	(0,4)
SULFAMETHOXAZOLE SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
SUPROFEN	1	(0,0)	0	(0,0)	1	(0,0)
TAFLUPROST	2	(0,1)	0	(0,0)	2	(0,0)
TETRACYCLINE	2	(0,1)	3	(0,1)	5	(0,1)
TETRACYCLINE HYDROCHLORIDE	4	(0,2)	3	(0,1)	7	(0,2)
TETRYZOLINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
THIOTRIAZOLINE	2	(0,1)	3	(0,1)	5	(0,1)
TIMOLOL	4	(0,2)	3	(0,1)	7	(0,2)
TIMOLOL MALEATE	2	(0,1)	0	(0,0)	2	(0,0)
TOBRAMYCIN	6	(0,3)	3	(0,1)	9	(0,2)
TOBRAMYCIN SULFATE	0	(0,0)	2	(0,1)	2	(0,0)
TOSUFLOXACIN TOSILATE	1	(0,0)	0	(0,0)	1	(0,0)
TRAMAZOLINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
TRANILAST	1	(0,0)	0	(0,0)	1	(0,0)
TRAVOPROST	5	(0,2)	4	(0,2)	9	(0,2)
TRIAMCINOLONE	3	(0,1)	9	(0,4)	12	(0,3)
TRIAMCINOLONE ACETONIDE	14	(0,7)	12	(0,6)	26	(0,6)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
TROPICAMIDE	5	(0,2)	3	(0,1)	8	(0,2)
TRYPAN BLUE	1	(0,0)	0	(0,0)	1	(0,0)
UBIDECARENONE	29	(1,3)	50	(2,3)	79	(1,8)
UNOPROSTONE ISOPROPYL	0	(0,0)	2	(0,1)	2	(0,0)
VACCINIUM MYRTILLUS EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
VANCOMYCIN	58	(2,7)	60	(2,8)	118	(2,7)
VANCOMYCIN HYDROCHLORIDE	14	(0,7)	18	(0,8)	32	(0,7)
VIDARABINE	1	(0,0)	0	(0,0)	1	(0,0)
XANTOFYL	1	(0,0)	0	(0,0)	1	(0,0)
XYLOMETAZOLINE HYDROCHLORIDE	5	(0,2)	4	(0,2)	9	(0,2)
ZINC	1	(0,0)	2	(0,1)	3	(0,1)
ZINC SULFATE	3	(0,1)	4	(0,2)	7	(0,2)
OTOLOGICALS	**612**	**(28,4)**	**599**	**(27,8)**	**1.211**	**(28,1)**
ACETIC ACID	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OTOLOGICALS	**612**	**(28,4)**	**599**	**(27,8)**	**1.211**	**(28,1)**
ALUMINIUM ACETOTARTRATE	2	(0,1)	0	(0,0)	2	(0,0)
BENZOCAINE	3	(0,1)	0	(0,0)	3	(0,1)
BETAMETHASONE	6	(0,3)	9	(0,4)	15	(0,3)
BETAMETHASONE ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE DIPROPIONATE	4	(0,2)	2	(0,1)	6	(0,1)
BETAMETHASONE SODIUM PHOSPHATE	5	(0,2)	6	(0,3)	11	(0,3)
BETAMETHASONE VALERATE	11	(0,5)	9	(0,4)	20	(0,5)
BORIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
CEFMENOXIME HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
CHLORAMPHENICOL	11	(0,5)	10	(0,5)	21	(0,5)
CHLORHEXIDINE	3	(0,1)	5	(0,2)	8	(0,2)
CHLORHEXIDINE DIACETATE	1	(0,0)	1	(0,0)	2	(0,0)
CHLORHEXIDINE GLUCONATE	6	(0,3)	14	(0,7)	20	(0,5)
CHLORHEXIDINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
CHOLINE SALICYLATE	3	(0,1)	1	(0,0)	4	(0,1)
CIPROFLOXACIN	79	(3,7)	92	(4,3)	171	(4,0)
CIPROFLOXACIN HYDROCHLORIDE	14	(0,7)	10	(0,5)	24	(0,6)
CIPROFLOXACIN HYDROCHLORIDE;FLUOCINOLONE ACETONIDE	0	(0,0)	1	(0,0)	1	(0,0)
CIPROFLOXACIN HYDROCHLORIDE;HYDROCORTISONE	1	(0,0)	0	(0,0)	1	(0,0)
CLIOQUINOL;FLUMETASONE PIVALATE	2	(0,1)	0	(0,0)	2	(0,0)
CLOTRIMAZOLE	2	(0,1)	7	(0,3)	9	(0,2)
COCAINE	1	(0,0)	1	(0,0)	2	(0,0)
CROTAMITON;HYDROCORTISONE	2	(0,1)	2	(0,1)	4	(0,1)
DEXAMETHASONE	37	(1,7)	37	(1,7)	74	(1,7)
DEXAMETHASONE DIPROPIONATE	3	(0,1)	0	(0,0)	3	(0,1)
DEXAMETHASONE SODIUM PHOSPHATE	17	(0,8)	16	(0,7)	33	(0,8)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OTOLOGICALS	**612**	**(28,4)**	**599**	**(27,8)**	**1.211**	**(28,1)**
DEXAMETHASONE SODIUM PHOSPHATE;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE;NEOMYCIN SULFATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	3	(0,1)	3	(0,1)	6	(0,1)
DEXAMETHASONE;TOBRAMYCIN	7	(0,3)	6	(0,3)	13	(0,3)
DOCUSATE SODIUM	40	(1,9)	42	(2,0)	82	(1,9)
FLUOCINOLONE ACETONIDE	4	(0,2)	7	(0,3)	11	(0,3)
GENTAMICIN	17	(0,8)	15	(0,7)	32	(0,7)
GENTAMICIN SULFATE	10	(0,5)	12	(0,6)	22	(0,5)
GLYCEROL	21	(1,0)	20	(0,9)	41	(1,0)
GRAMICIDIN;NEOMYCIN;NYSTATIN;TRIAMCINOLONE ACETONIDE	0	(0,0)	2	(0,1)	2	(0,0)
HYDROCORTISONE	38	(1,8)	37	(1,7)	75	(1,7)
HYDROCORTISONE ACETATE	15	(0,7)	9	(0,4)	24	(0,6)
HYDROCORTISONE ACETATE;NEOMYCIN SULFATE	2	(0,1)	0	(0,0)	2	(0,0)
HYDROCORTISONE PROBUTAT	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE SODIUM PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
HYDROCORTISONE SODIUM SUCCINATE	5	(0,2)	13	(0,6)	18	(0,4)
LEVOFLOXACIN	95	(4,4)	99	(4,6)	194	(4,5)
LEVOFLOXACIN HEMIHYDRATE	8	(0,4)	2	(0,1)	10	(0,2)
LIDOCAINE	61	(2,8)	62	(2,9)	123	(2,9)
LIDOCAINE HYDROCHLORIDE	43	(2,0)	40	(1,9)	83	(1,9)
LIDOCAINE HYDROCHLORIDE;PHENAZONE	0	(0,0)	1	(0,0)	1	(0,0)
LOMEFLOXACIN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
MICONAZOLE	6	(0,3)	4	(0,2)	10	(0,2)
MICONAZOLE NITRATE	6	(0,3)	3	(0,1)	9	(0,2)
NEOMYCIN	4	(0,2)	2	(0,1)	6	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SENSORY ORGANS						
OTOLOGICALS	**612**	**(28,4)**	**599**	**(27,8)**	**1.211**	**(28,1)**
NITROFURAL	2	(0,1)	1	(0,0)	3	(0,1)
OFLOXACIN	15	(0,7)	12	(0,6)	27	(0,6)
OLEA EUROPAEA OIL	3	(0,1)	2	(0,1)	5	(0,1)
PARAFFIN, LIQUID	2	(0,1)	4	(0,2)	6	(0,1)
PHENOL	0	(0,0)	3	(0,1)	3	(0,1)
POLYMYXIN B SULFATE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE	84	(3,9)	73	(3,4)	157	(3,6)
PREDNISOLONE ACETATE	3	(0,1)	3	(0,1)	6	(0,1)
PREDNISOLONE SODIUM SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE VALEROACETATE	6	(0,3)	0	(0,0)	6	(0,1)
PROPOLIS	1	(0,0)	1	(0,0)	2	(0,0)
RIFAMYCIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
SALICYLIC ACID	1	(0,0)	2	(0,1)	3	(0,1)
SEA WATER	0	(0,0)	2	(0,1)	2	(0,0)
SODIUM BICARBONATE	104	(4,8)	109	(5,1)	213	(5,0)
SODIUM CHLORIDE	203	(9,4)	196	(9,1)	399	(9,3)
TETRACYCLINE	2	(0,1)	3	(0,1)	5	(0,1)
TETRACYCLINE HYDROCHLORIDE	4	(0,2)	3	(0,1)	7	(0,2)
UREA HYDROGEN PEROXIDE	0	(0,0)	1	(0,0)	1	(0,0)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS						
CALCIUM HOMEOSTASIS	**6**	**(0,3)**	**9**	**(0,4)**	**15**	**(0,3)**
CALCITONIN	0	(0,0)	2	(0,1)	2	(0,0)
CALCITONIN, SALMON	1	(0,0)	2	(0,1)	3	(0,1)
CINACALCET	1	(0,0)	1	(0,0)	2	(0,0)
CINACALCET HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
MAXACALCITOL	1	(0,0)	1	(0,0)	2	(0,0)
PARICALCITOL	1	(0,0)	3	(0,1)	4	(0,1)
TERIPARATIDE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
CORTICOSTEROIDS FOR SYSTEMIC USE	**361**	**(16,8)**	**353**	**(16,4)**	**714**	**(16,6)**
ALDOSTERONE	1	(0,0)	0	(0,0)	1	(0,0)
BECLOMETASONE DIPROPIONATE	42	(2,0)	26	(1,2)	68	(1,6)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS						
CORTICOSTEROIDS FOR SYSTEMIC USE	**361**	**(16,8)**	**353**	**(16,4)**	**714**	**(16,6)**
BETAMETHASONE	6	(0,3)	9	(0,4)	15	(0,3)
BETAMETHASONE ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
BETAMETHASONE ACETATE;BETAMETHASONE SODIUM PHOSPHATE	2	(0,1)	0	(0,0)	2	(0,0)
BETAMETHASONE BUTYRATE PROPIONATE	9	(0,4)	7	(0,3)	16	(0,4)
BETAMETHASONE DIPROPIONATE	4	(0,2)	2	(0,1)	6	(0,1)
BETAMETHASONE DIPROPIONATE;BETAMETHASONE SODIUM PHOSPHATE	4	(0,2)	0	(0,0)	4	(0,1)
BETAMETHASONE SODIUM PHOSPHATE	5	(0,2)	6	(0,3)	11	(0,3)
BETAMETHASONE VALERATE	11	(0,5)	9	(0,4)	20	(0,5)
BETAMETHASONE;DEXCHLORPH ENIRAMINE MALEATE	0	(0,0)	1	(0,0)	1	(0,0)
CORTICOSTEROIDS FOR SYSTEMIC USE	1	(0,0)	4	(0,2)	5	(0,1)
CORTISONE	1	(0,0)	3	(0,1)	4	(0,1)
CORTISONE ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
CROTAMITON;HYDROCORTISONE	2	(0,1)	2	(0,1)	4	(0,1)
DEFLAZACORT	1	(0,0)	4	(0,2)	5	(0,1)
DEXAMETHASONE	37	(1,7)	37	(1,7)	74	(1,7)
DEXAMETHASONE DIPROPIONATE	3	(0,1)	0	(0,0)	3	(0,1)
DEXAMETHASONE PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
DEXAMETHASONE SODIUM METASULFOBENZOATE	1	(0,0)	0	(0,0)	1	(0,0)
DEXAMETHASONE SODIUM PHOSPHATE	17	(0,8)	16	(0,7)	33	(0,8)
FLUDROCORTISONE ACETATE	2	(0,1)	0	(0,0)	2	(0,0)
HYDROCORTISONE	38	(1,8)	37	(1,7)	75	(1,7)
HYDROCORTISONE ACETATE	15	(0,7)	9	(0,4)	24	(0,6)
HYDROCORTISONE BUTYRATE	5	(0,2)	8	(0,4)	13	(0,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS						
CORTICOSTEROIDS FOR SYSTEMIC USE	**361**	**(16,8)**	**353**	**(16,4)**	**714**	**(16,6)**
HYDROCORTISONE HYDROGEN SUCCINATE	1	(0,0)	3	(0,1)	4	(0,1)
HYDROCORTISONE PROBUTAT	1	(0,0)	0	(0,0)	1	(0,0)
HYDROCORTISONE SODIUM PHOSPHATE	1	(0,0)	1	(0,0)	2	(0,0)
HYDROCORTISONE SODIUM SUCCINATE	5	(0,2)	13	(0,6)	18	(0,4)
HYDROCORTISONE;LIDOCAINE	0	(0,0)	2	(0,1)	2	(0,0)
KETOCONAZOLE	5	(0,2)	4	(0,2)	9	(0,2)
LIDOCAINE HYDROCHLORIDE;TRIAMCINOLONE ACETONIDE	2	(0,1)	1	(0,0)	3	(0,1)
MEPREDNISONE	0	(0,0)	1	(0,0)	1	(0,0)
METHYLPREDNISOLONE	46	(2,1)	41	(1,9)	87	(2,0)
METHYLPREDNISOLONE ACETATE	2	(0,1)	3	(0,1)	5	(0,1)
METHYLPREDNISOLONE HEMISUCCINATE	1	(0,0)	0	(0,0)	1	(0,0)
METHYLPREDNISOLONE SODIUM SUCCINATE	33	(1,5)	21	(1,0)	54	(1,3)
PREDNISOLONE	84	(3,9)	73	(3,4)	157	(3,6)
PREDNISOLONE ACETATE	3	(0,1)	3	(0,1)	6	(0,1)
PREDNISOLONE HEMISUCCINATE	0	(0,0)	2	(0,1)	2	(0,0)
PREDNISOLONE SODIUM SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
PREDNISOLONE VALEROACETATE	6	(0,3)	0	(0,0)	6	(0,1)
PREDNISONE	96	(4,5)	97	(4,5)	193	(4,5)
PREDNISONE ACETATE	0	(0,0)	3	(0,1)	3	(0,1)
TRIAMCINOLONE	3	(0,1)	9	(0,4)	12	(0,3)
TRIAMCINOLONE ACETONIDE	14	(0,7)	12	(0,6)	26	(0,6)
PANCREATIC HORMONES	**4**	**(0,2)**	**7**	**(0,3)**	**11**	**(0,3)**
GLUCAGON	3	(0,1)	7	(0,3)	10	(0,2)
GLUCAGON HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS						
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES	**19**	**(0,9)**	**20**	**(0,9)**	**39**	**(0,9)**
DESMOPRESSIN	2	(0,1)	3	(0,1)	5	(0,1)
DESMOPRESSIN ACETATE	4	(0,2)	2	(0,1)	6	(0,1)
LANREOTIDE ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
OCTREOTIDE	2	(0,1)	2	(0,1)	4	(0,1)
OCTREOTIDE ACETATE	2	(0,1)	1	(0,0)	3	(0,1)
SOMATOSTATIN	2	(0,1)	0	(0,0)	2	(0,0)
SOMATOSTATIN ACETATE	0	(0,0)	2	(0,1)	2	(0,0)
SOMATROPIN	1	(0,0)	0	(0,0)	1	(0,0)
TERLIPRESSIN ACETATE	0	(0,0)	2	(0,1)	2	(0,0)
TETRACOSACTIDE	2	(0,1)	0	(0,0)	2	(0,0)
TETRACOSACTIDE ACETATE	0	(0,0)	1	(0,0)	1	(0,0)
VASOPRESSIN	7	(0,3)	7	(0,3)	14	(0,3)
THYROID THERAPY	**284**	**(13,2)**	**291**	**(13,5)**	**575**	**(13,4)**
CARBIMAZOLE	5	(0,2)	3	(0,1)	8	(0,2)
IODINE	1	(0,0)	1	(0,0)	2	(0,0)
LEVOTHYROXINE SODIUM	248	(11,5)	261	(12,1)	509	(11,8)
LEVOTHYROXINE SODIUM;LIOTHYRONINE SODIUM	0	(0,0)	1	(0,0)	1	(0,0)
LEVOTHYROXINE SODIUM;POTASSIUM IODIDE	0	(0,0)	1	(0,0)	1	(0,0)
LIOTHYRONINE SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM IODIDE	0	(0,0)	3	(0,1)	3	(0,1)
POTASSIUM PERCHLORATE	1	(0,0)	0	(0,0)	1	(0,0)
PROPRANOLOL	3	(0,1)	2	(0,1)	5	(0,1)
PROPYLTHIOURACIL	1	(0,0)	1	(0,0)	2	(0,0)
SODIUM PERCHLORATE	1	(0,0)	1	(0,0)	2	(0,0)
THIAMAZOLE	29	(1,3)	21	(1,0)	50	(1,2)
THYROID	0	(0,0)	1	(0,0)	1	(0,0)
VARIOUS						
ALL OTHER NON-THERAPEUTIC PRODUCTS	**245**	**(11,4)**	**225**	**(10,5)**	**470**	**(10,9)**
ASCORBIC ACID	39	(1,8)	28	(1,3)	67	(1,6)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
ALL OTHER NON-THERAPEUTIC PRODUCTS	**245**	**(11,4)**	**225**	**(10,5)**	**470**	**(10,9)**
CHLORINE	1	(0,0)	0	(0,0)	1	(0,0)
ETHANOL	0	(0,0)	2	(0,1)	2	(0,0)
GLUCOSE;POTASSIUM CHLORIDE;POTASSIUM PHOSPHATE DIBASIC;POTASSIUM PHOSPHATE MONOBASIC;SODIUM CHLORIDE;SODIUM LACTATE	1	(0,0)	0	(0,0)	1	(0,0)
HYETELLOSE	1	(0,0)	0	(0,0)	1	(0,0)
HYPROMELLOSE	4	(0,2)	6	(0,3)	10	(0,2)
MENTHOL	1	(0,0)	1	(0,0)	2	(0,0)
OTHER NON-THERAPEUTIC AUXILIARY PRODUCTS	1	(0,0)	0	(0,0)	1	(0,0)
PENICILLIN NOS	6	(0,3)	6	(0,3)	12	(0,3)
PLASTERS	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM CHLORIDE	203	(9,4)	196	(9,1)	399	(9,3)
SODIUM CITRATE	1	(0,0)	2	(0,1)	3	(0,1)
WATER FOR INJECTION	0	(0,0)	2	(0,1)	2	(0,0)
ALL OTHER THERAPEUTIC PRODUCTS	**399**	**(18,5)**	**455**	**(21,2)**	**854**	**(19,8)**
ACETYLCYSTEINE	128	(5,9)	138	(6,4)	266	(6,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**399**	**(18,5)**	**455**	**(21,2)**	**854**	**(19,8)**
ACHILLEA MILLEFOLIUM;ACONITUM NAPELLUS;ARNICA MONTANA;ATROPA BELLADONNA;BELLIS PERENNIS;CALCIUM SULFIDE;CALENDULA OFFICINALIS;ECHINACEA ANGUSTIFOLIA;ECHINACEA PURPUREA;HAMAMELIS VIRGINIANA;HYPERICUM PERFORATUM;MATRICARIA RECUTITA;MERCURIUS SOLUBILIS HAHNEMANNI;SYMPHYTUM OFFICINALE	0	(0,0)	1	(0,0)	1	(0,0)
ACHYRANTHES BIDENTATA ROOT;ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE TUBE;ATRACTYLODES MACROCEPHALA, RHIZOMA;CITRUS RETICULATA PEEL;DENDRANTHEMA MORIFOLIUM FLOWER;ECLIPTA PROSTRATA HERB;GLYCYRRHIZA URALENSIS ROOT WITH RHIZOME;LIGUSTRUM LUCIDUM FRUIT;PINELLIA TERNATA RHIZOME;PORIA COCOS SCLEROTIUM	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**399**	**(18,5)**	**455**	**(21,2)**	**854**	**(19,8)**
ACHYRANTHES BIDENTATA ROOT;CARTHAMUS TINCTORIUS FLOWER;CITRUS RETICULATA FRUIT PEEL;COPTIS CHINENSIS RHIZOME;GLYCYRRHIZA URALENSIS ROOT;PINELLIA TERNATA RHIZOME;PORIA COCOS;PSEUDOSTELLARIA HETEROPHYLLA ROOT;RHEUM PALMATUM ROOT WITH RHIZOME;SALVIA MILTIORRHIZA ROOT	2	(0,1)	4	(0,2)	6	(0,1)
ACONITUM NAPELLUS TUBE;AEGLE MARMELOS FRUIT;AMOMUM SPP. FRUIT;AQUILEGIA VULGARIS HERB;CALCIUM SULFATE;CALENDULA OFFICINALIS FLOWER;CAMPHOR;CETRARIA ISLANDICA STALK;ELETTARIA CARDAMOMUM FRUIT;GLYCYRRHIZA GLABRA ROOT;HEDYCHIUM SPICATUM RHIZOME;LACTUCA SATIVA LEAF;MELIA AZEDARACH FRUIT;PLANTAGO ASIATICA HERB;POLYGONUM AVICULARE HERB;POTENTILLA AUREA HERB;PTEROCARPUS SANTALINUS	0	(0,0)	1	(0,0)	1	(0,0)
ADENOSINE	3	(0,1)	6	(0,3)	9	(0,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**399**	**(18,5)**	**455**	**(21,2)**	**854**	**(19,8)**
ALBIZIA JULIBRISSIN FLOWER;CALCIUM SULFATE;ELEUTHEROCOCCUS SENTICOSUS ROOT WITH RHIZOME;FALLOPIA MULTIFLORA STEM;JUNCUS EFFUSUS STEM PITH;LILIUM SPP.;OPHIOPOGON JAPONICUS ROOT TUBER;OYSTER SHELL;POLYGALA TENUIFOLIA ROOT;PORIA COCOS;REHMANNIA GLUTINOSA ROOT;SALVIA MILTIORRHIZA ROOT WITH RHIZOME;SCHISANDRA CHINENSIS FRUIT;SCROPHULARIA NINGPOENSIS ROOT;ZIZIPHUS JUJUBA SEED	0	(0,0)	1	(0,0)	1	(0,0)
ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;ASTRAGALUS SPP. ROOT;ATRACTYLODES SPP. RHIZOME;CITRUS RETICULATA PEEL;GASTRODIA ELATA TUBER;HORDEUM VULGARE;PANAX GINSENG ROOT;PHELLODENDRON SPP. BARK;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE PROCESSED RHIZOME;ZINGIBER OFFICINALE RHIZOME	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**399**	**(18,5)**	**455**	**(21,2)**	**854**	**(19,8)**
ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;ATRACTYLODES SPP. RHIZOME;BUPLEURUM FALCATUM ROOT;CINNAMOMUM CASSIA BARK;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;POLYPORUS UMBELLATUS SCLEROTIUM;PORIA COCOS SCLEROTIUM;SCUTELLARIA BAICALENSIS ROOT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	1	(0,0)	0	(0,0)	1	(0,0)
ALUMINIUM HYDROXIDE	4	(0,2)	4	(0,2)	8	(0,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**399**	**(18,5)**	**455**	**(21,2)**	**854**	**(19,8)**
ANGELICA ACUTILOBA ROOT;ATRACTYLODES SPP. RHIZOME;CALCIUM SULFATE;CNIDIUM OFFICINALE RHIZOME;EPHEDRA SPP. HERB;FORSYTHIA SPP. FRUIT;GARDENIA JASMINOIDES FRUIT;GLYCYRRHIZA SPP. ROOT;MENTHA CANADENSIS HERB;PAEONIA LACTIFLORA ROOT;PLATYCODON GRANDIFLORUS ROOT;RHEUM SPP. RHIZOME;SAPOSHNIKOVIA DIVARICATA ROOT;SCHIZONEPETA TENUIFOLIA SPIKE;SCUTELLARIA BAICALENSIS ROOT;SODIUM SULFATE;TALC;ZINGIBER	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA DAHURICA ROOT;ARMENIACA VULGARIS VAR. ANSU SEED;BUPLEURUM CHINENSE, ROOT;CORYDALIS BUNGEANA HERB;MENTHA CANADENSIS HERB;PERILLA FRUTESCENS VAR. CRISPA LEAF;PHRAGMITES COMMUNIS RHIZOME;PLATYCODON GRANDIFLORUS ROOT;PUERARIA LOBATA ROOT;SAPOSHNIKOVIA DIVARICATA ROOT;SCHIZONEPETA SPP.	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**399**	**(18,5)**	**455**	**(21,2)**	**854**	**(19,8)**
ANGELICA DAHURICA VAR. FORMOSANA ROOT;DENDRANTHEMA MORIFOLIUM FLOWER;FORSYTHIA SUSPENSA FRUIT;GARDENIA JASMINOIDES FRUIT;LIGUSTICUM CHUANXIONG RHIZOME;MENTHA CANADENSIS HERB;PHELLODENDRON AMURENSE BARK;PLATYCODON GRANDIFLORUS ROOT;RHEUM PALMATUM ROOT WITH RHIZOME;SAPOSHNIKOVIA DIVARICATA ROOT;SCHIZONEPETA TENUIFOLIA HERB;SCUTELLARIA BAICALENSIS ROOT	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA DAHURICA;ATRACTYLODES LANCEA;CHRYSANTHEMUM SPP.;CITRUS MAXIMA;COIX LACRYMA-JOBI SUBSP. MA-YUEN;HERBAL NOS;MAGNOLIA OFFICINALIS;MENTHA CANADENSIS;ORYZA SATIVA;POGOSTEMON SPP.;PORIA COCOS;PUERARIA LOBATA;SAUSSUREA COSTUS;TRIBULUS TERRESTRIS;TRICHOSANTHES SPP.;UNCARIA SPP.	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID	39	(1,8)	28	(1,3)	67	(1,6)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**399**	**(18,5)**	**455**	**(21,2)**	**854**	**(19,8)**
ASTRAGALUS PROPINQUUS	1	(0,0)	4	(0,2)	5	(0,1)
ATROPINE	18	(0,8)	16	(0,7)	34	(0,8)
BOSWELLIA SERRATA OIL;BROMELAINS;COLLAGEN;GLUCOSAMINE HYDROCHLORIDE;GLUCOSAMINE SULFATE;HARPAGOPHYTUM PROCUMBENS;SALIX ALBA;SMILAX OFFICINALIS ROOT POWDER;TANACETUM PARTHENIUM;YUCCA SCHIDIGERA	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM ACETATE	7	(0,3)	7	(0,3)	14	(0,3)
CALCIUM ACETATE;MAGNESIUM CARBONATE	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM CARBONATE	35	(1,6)	42	(2,0)	77	(1,8)
CALCIUM CITRATE;VITAMIN D NOS	1	(0,0)	0	(0,0)	1	(0,0)
CALCIUM FOLINATE	2	(0,1)	2	(0,1)	4	(0,1)
CALCIUM POLYSTYRENE SULFONATE	45	(2,1)	54	(2,5)	99	(2,3)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**399**	**(18,5)**	**455**	**(21,2)**	**854**	**(19,8)**
CALCIUM SULFATE DIHYDRATE;DRYOPTERIS CRASSIRHIZOMA RHIZOME;EPHEDRA SPP. HERB;FORSYTHIA SUSPENSA;GLYCYRRHIZA GLABRA ROOT;HOUTTUYNIA CORDATA HERB;ISATIS TINCTORIA ROOT;LONICERA JAPONICA FLOWER;MENTHOL;POGOSTEMON CABLIN HERB;PRUNUS SPP. SEED;RHEUM SPP.;RHODIOLA CRENULATA	1	(0,0)	3	(0,1)	4	(0,1)
CALCIUM;MAGNESIUM	2	(0,1)	1	(0,0)	3	(0,1)
CALCIUM;VITAMIN D NOS	4	(0,2)	1	(0,0)	5	(0,1)
CARTHAMUS TINCTORIUS;CINNAMOMUM CASSIA;CISTANCHE DESERTICOLA;CURCUMA LONGA;EPIMEDIUM SAGITTATUM;EUCOMMIA ULMOIDES;GLOYDIUS HALYS;LEONURUS JAPONICUS;LINDERA SPP.;PAEONIA LACTIFLORA;PANAX GINSENG;REHMANNIA GLUTINOSA;SAPOSHNIKOVIA DIVARICATA;SYZYGIUM AROMATICUM	0	(0,0)	1	(0,0)	1	(0,0)
CHONDROITIN SULFATE SODIUM	1	(0,0)	1	(0,0)	2	(0,0)
CILASTATIN SODIUM	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**399**	**(18,5)**	**455**	**(21,2)**	**854**	**(19,8)**
COBICISTAT	0	(0,0)	1	(0,0)	1	(0,0)
COPTIS SPP. RHIZOME;CORNUS OFFICINALIS FRUIT;EUPOLYPHAGA STELEOPHAGA;FOSSILIA OSSIS MASTODI;NARDOSTACHYS JATAMANSI ROOT WITH RHIZOME;OPHIOPOGON JAPONICUS ROOT TUBER;PAEONIA SPP. ROOT;PANAX GINSENG ROOT;SALVIA MILTIORRHIZA ROOT WITH RHIZOME;SCHISANDRA SPHENANTHERA FRUIT;TAXILLUS CHINENSIS HERB;ZIZIPHUS JUJUBA VAR. SPINOSA SEED	2	(0,1)	2	(0,1)	4	(0,1)
CYSTEINE	1	(0,0)	0	(0,0)	1	(0,0)
DEXRAZOXANE HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
EDETIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
ETHANOL	0	(0,0)	2	(0,1)	2	(0,0)
FLUMAZENIL	5	(0,2)	6	(0,3)	11	(0,3)
GLUCOSE;INSULIN	1	(0,0)	2	(0,1)	3	(0,1)
GLUTATHIONE	11	(0,5)	7	(0,3)	18	(0,4)
GLYCOPYRRONIUM	2	(0,1)	3	(0,1)	5	(0,1)
GLYCOPYRRONIUM BROMIDE	7	(0,3)	13	(0,6)	20	(0,5)
HONEY	0	(0,0)	1	(0,0)	1	(0,0)
HYDRAZINE	1	(0,0)	0	(0,0)	1	(0,0)
HYDROXOCOBALAMIN	5	(0,2)	3	(0,1)	8	(0,2)
HYDROXOCOBALAMIN ACETATE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**399**	**(18,5)**	**455**	**(21,2)**	**854**	**(19,8)**
HYDROXOCOBALAMIN HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
IMIDAZOLYL ETHANAMIDE PENTANDIOIC ACID	1	(0,0)	1	(0,0)	2	(0,0)
INOSINE	0	(0,0)	1	(0,0)	1	(0,0)
IODINE	1	(0,0)	1	(0,0)	2	(0,0)
IRON	25	(1,2)	29	(1,3)	54	(1,3)
LACTOBACILLUS RHAMNOSUS	6	(0,3)	5	(0,2)	11	(0,3)
LANTHANUM CARBONATE	1	(0,0)	1	(0,0)	2	(0,0)
LEAD	0	(0,0)	1	(0,0)	1	(0,0)
LEVALLORPHAN TARTRATE	1	(0,0)	0	(0,0)	1	(0,0)
MANUKA HONEY	1	(0,0)	0	(0,0)	1	(0,0)
MEGLUMINE SODIUM SUCCINATE	0	(0,0)	1	(0,0)	1	(0,0)
MESNA	1	(0,0)	3	(0,1)	4	(0,1)
MUSK	0	(0,0)	1	(0,0)	1	(0,0)
NALOXONE HYDROCHLORIDE	12	(0,6)	10	(0,5)	22	(0,5)
NALOXONE HYDROCHLORIDE;TILIDINE HYDROCHLORIDE	6	(0,3)	5	(0,2)	11	(0,3)
OTHER THERAPEUTIC PRODUCTS	22	(1,0)	28	(1,3)	50	(1,2)
OXYGEN	55	(2,6)	58	(2,7)	113	(2,6)
PATIROMER	2	(0,1)	1	(0,0)	3	(0,1)
PATIROMER SORBITEX CALCIUM	2	(0,1)	1	(0,0)	3	(0,1)
PENEHYCLIDINE HYDROCHLORIDE	1	(0,0)	0	(0,0)	1	(0,0)
PHENTOLAMINE MESILATE	1	(0,0)	0	(0,0)	1	(0,0)
POLYPEPTIDE	0	(0,0)	1	(0,0)	1	(0,0)
POTASSIUM IODIDE	0	(0,0)	3	(0,1)	3	(0,1)
POTASSIUM PERMANGANATE	3	(0,1)	0	(0,0)	3	(0,1)
PROPOLIS	1	(0,0)	1	(0,0)	2	(0,0)
PROTAMINE SULFATE	8	(0,4)	6	(0,3)	14	(0,3)
RASBURICASE	1	(0,0)	0	(0,0)	1	(0,0)
SCUTELLAREIN GLUCURONIDE	0	(0,0)	1	(0,0)	1	(0,0)
SEVELAMER	2	(0,1)	2	(0,1)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
ALL OTHER THERAPEUTIC PRODUCTS	**399**	**(18,5)**	**455**	**(21,2)**	**854**	**(19,8)**
SEVELAMER CARBONATE	3	(0,1)	1	(0,0)	4	(0,1)
SEVELAMER HYDROCHLORIDE	1	(0,0)	1	(0,0)	2	(0,0)
SIROLIMUS	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM BROMIDE	1	(0,0)	0	(0,0)	1	(0,0)
SODIUM POLYSTYRENE SULFONATE	42	(2,0)	64	(3,0)	106	(2,5)
STEM CELLS NOS	1	(0,0)	0	(0,0)	1	(0,0)
SUGAMMADEX	1	(0,0)	0	(0,0)	1	(0,0)
SUGAMMADEX SODIUM	1	(0,0)	2	(0,1)	3	(0,1)
UNITHIOL	2	(0,1)	0	(0,0)	2	(0,0)
WATER	1	(0,0)	3	(0,1)	4	(0,1)
ALLERGENS	**0**	**(0,0)**	**2**	**(0,1)**	**2**	**(0,0)**
ALLERGENS, INSECT VENOM	0	(0,0)	1	(0,0)	1	(0,0)
HERBAL POLLEN NOS	0	(0,0)	1	(0,0)	1	(0,0)
CONTRAST MEDIA	**43**	**(2,0)**	**49**	**(2,3)**	**92**	**(2,1)**
BARIUM SULFATE	1	(0,0)	2	(0,1)	3	(0,1)
ETHIODIZED OIL	0	(0,0)	1	(0,0)	1	(0,0)
GADOBUTROL	2	(0,1)	1	(0,0)	3	(0,1)
IOBITRIDOL	3	(0,1)	2	(0,1)	5	(0,1)
IODIXANOL	3	(0,1)	8	(0,4)	11	(0,3)
IOHEXOL	14	(0,7)	10	(0,5)	24	(0,6)
IOMEPROL	4	(0,2)	6	(0,3)	10	(0,2)
IOPAMIDOL	8	(0,4)	9	(0,4)	17	(0,4)
IOPROMIDE	6	(0,3)	5	(0,2)	11	(0,3)
IOVERSOL	2	(0,1)	4	(0,2)	6	(0,1)
IOXITALAMATE MEGLUMINE	1	(0,0)	1	(0,0)	2	(0,0)
IOXITALAMATE MEGLUMINE;IOXITALAMATE SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
MEGLUMINE	0	(0,0)	1	(0,0)	1	(0,0)
MEGLUMINE AMIDOTRIZOATE	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
CONTRAST MEDIA	**43**	**(2,0)**	**49**	**(2,3)**	**92**	**(2,1)**
MEGLUMINE AMIDOTRIZOATE;SODIUM AMIDOTRIZOATE	1	(0,0)	1	(0,0)	2	(0,0)
MEGLUMINE GADOPENTETATE	2	(0,1)	0	(0,0)	2	(0,0)
MEGLUMINE GADOTERATE	0	(0,0)	1	(0,0)	1	(0,0)
PERFLUTREN	0	(0,0)	5	(0,2)	5	(0,1)
SULFUR HEXAFLUORIDE	1	(0,0)	1	(0,0)	2	(0,0)
DIAGNOSTIC AGENTS	**267**	**(12,4)**	**257**	**(11,9)**	**524**	**(12,2)**
CAFFEINE	1	(0,0)	1	(0,0)	2	(0,0)
FLUORESCEIN	1	(0,0)	1	(0,0)	2	(0,0)
FLUORESCEIN SODIUM	1	(0,0)	0	(0,0)	1	(0,0)
FOLIC ACID	93	(4,3)	93	(4,3)	186	(4,3)
GLUCOSE	102	(4,7)	94	(4,4)	196	(4,6)
INDIGO CARMINE	2	(0,1)	1	(0,0)	3	(0,1)
INDOCYANINE GREEN	0	(0,0)	1	(0,0)	1	(0,0)
INULIN	0	(0,0)	1	(0,0)	1	(0,0)
MAGNESIUM SULFATE	87	(4,0)	92	(4,3)	179	(4,2)
MANNITOL	17	(0,8)	12	(0,6)	29	(0,7)
SORBITOL	1	(0,0)	0	(0,0)	1	(0,0)
TERIPARATIDE ACETATE	1	(0,0)	0	(0,0)	1	(0,0)
TOLBUTAMIDE	2	(0,1)	1	(0,0)	3	(0,1)
TUBERCULIN	3	(0,1)	2	(0,1)	5	(0,1)
TUBERCULIN PPD	0	(0,0)	2	(0,1)	2	(0,0)
DIAGNOSTIC RADIOPHARMACEUTICALS	**2**	**(0,1)**	**4**	**(0,2)**	**6**	**(0,1)**
GALLIUM (67 GA) CITRATE	0	(0,0)	1	(0,0)	1	(0,0)
IOBENGUANE (123 I)	1	(0,0)	0	(0,0)	1	(0,0)
IOFETAMINE (123 I) HYDROCHLORIDE	0	(0,0)	1	(0,0)	1	(0,0)
IOFLUPANE (123I)	0	(0,0)	1	(0,0)	1	(0,0)
TECHNETIUM (99M TC) SESTAMIBI	0	(0,0)	1	(0,0)	1	(0,0)
TECHNETIUM TC 99M MEDRONATE	1	(0,0)	0	(0,0)	1	(0,0)
GENERAL NUTRIENTS	**150**	**(7,0)**	**161**	**(7,5)**	**311**	**(7,2)**

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
GENERAL NUTRIENTS	**150**	**(7,0)**	**161**	**(7,5)**	**311**	**(7,2)**
(RS)-3 METHYL-2-OXOVALERIANIC ACID CALCIUM;(RS)-3-METHYL-2-OXOBUTYRIC ACID CALCIUM;CALCIUM (RS)-4-METHYL-2-OXOVALERIANAT;CALCIUM 2-OXO-3-PHENYLPROPIONAT;DESMENINOL CALCIUM;HISTIDINE;LYSINE ACETATE;THREONINE;TRYPTOPHAN, L-;TYROSINE	6	(0,3)	12	(0,6)	18	(0,4)
ALANINE;ARGININE;ASPARTIC ACID;GLUTAMIC ACID;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE ACETATE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN, L-;TYROSINE;VALINE	0	(0,0)	1	(0,0)	1	(0,0)
ALANYL GLUTAMINE	1	(0,0)	1	(0,0)	2	(0,0)
AMINO ACIDS NOS	3	(0,1)	6	(0,3)	9	(0,2)
AMINO ACIDS NOS;CARBOHYDRATES NOS;ELECTROLYTES NOS;LIPIDS NOS	0	(0,0)	1	(0,0)	1	(0,0)
AMINO ACIDS NOS;CARTHAMUS TINCTORIUS OIL;FRUCTOSE;GLYCINE MAX SEED OIL;MINERALS NOS;VITAMINS NOS	1	(0,0)	0	(0,0)	1	(0,0)
AMINO ACIDS NOS;MINERALS NOS;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)
AMINO ACIDS NOS;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)
ARGININE HYDROCHLORIDE	2	(0,1)	2	(0,1)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
GENERAL NUTRIENTS	**150**	**(7,0)**	**161**	**(7,5)**	**311**	**(7,2)**
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM;CARBOHYDRATES NOS;CHLORIDE;CHOLINE;CHROMIUM;COLECALCIFEROL;COPPER;FATS NOS;FIBRE, DIETARY;FLUORINE;FOLIC ACID;IODINE;IRON;MAGNESIUM;MANGANESE;MOLYBDENUM;NICOTINIC ACID;PANTOTHENIC ACID;PHOSPHORUS;PHYTOMENADIONE;POTASSIUM;PROTEINS NOS;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SELENIUM;SODIUM;VITAMIN B1	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM;CARBOHYDRATES NOS;CHLORIDE;CHROMIUM;COLECALCIFEROL;COPPER;FATS NOS;FLUORINE;FOLIC ACID;IODINE;IRON;MAGNESIUM;MANGANESE;MOLYBDENUM;NICOTINIC ACID;PANTOTHENIC ACID;PHOSPHORUS;PHYTOMENADIONE;POTASSIUM;PROTEINS NOS;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SELENIUM;SODIUM;VITAMIN B1 NOS;VITAMIN B12 NOS;VITAMIN E NOS;ZINC	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
GENERAL NUTRIENTS	**150**	**(7,0)**	**161**	**(7,5)**	**311**	**(7,2)**
ASCORBIC ACID;BIOTIN;CALCIUM;CARBOHYDRATES NOS;CHLORIDE;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;FATS NOS;FOLIC ACID;IRON;MAGNESIUM;MANGANESE;NICOTINAMIDE;PANTOTHENIC ACID;PHOSPHORUS;POTASSIUM;PROTEINS NOS;PYRIDOXINE;RETINOL;RIBOFLAVIN;SODIUM;THIAMINE;TOCOPHEROL;ZINC	1	(0,0)	0	(0,0)	1	(0,0)
ASCORBIC ACID;BIOTIN;CALCIUM;CARBOHYDRATES NOS;CHLORINE;CHOLINE;CHROMIUM;COPPER;FATS NOS;FOLIC ACID;FRUCTOOLIGOSACCHARIDES;IRON;LEVOCARNITINE;MAGNESIUM;MANGANESE;MOLYBDENUM;NICOTINIC ACID;PANTOTHENIC ACID;PHOSPHORUS;POTASSIUM;PROTEINS NOS;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SELENIUM;SODIUM;TURIN;VITAMIN B1 NOS;VITAMIN B12 NOS;VITAMIN D NOS;VITAMIN E NOS;VITAMIN K NOS;ZINC	1	(0,0)	1	(0,0)	2	(0,0)
ASPARTATE CALCIUM	1	(0,0)	1	(0,0)	2	(0,0)
ASPARTIC ACID	0	(0,0)	1	(0,0)	1	(0,0)

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(Incidence > 0% in One or More Treatment Groups)
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Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
GENERAL NUTRIENTS	**150**	**(7,0)**	**161**	**(7,5)**	**311**	**(7,2)**
BIOTIN;CALCIUM HYDROXIDE;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE;CAROTENOIDS NOS;CHOLINE CHLORIDE;CHROMIC CHLORIDE;COLECALCIFEROL;COPPER GLUCONATE;CYANOCOBALAMIN;DL-ALPHA TOCOPHERYL ACETATE;FOLIC ACID;HERBAL OIL NOS;IRON;MAGNESIUM CHLORIDE;MAGNESIUM HYDROXIDE;MALTODEXTRIN;MANGANESE SULFATE;NICOTINAMIDE;PHYTOMENADIONE;POTASSIUM CITRATE;POTASSIUM HYDROXIDE;POTASSIUM IODIDE;PROTEINS	0	(0,0)	1	(0,0)	1	(0,0)
CALCIUM CASEINATE;FRUCTOOLIGOSACCHARIDES;FRUCTOSE;GLYCINE MAX FIBRE;GLYCINE MAX OIL;HELIANTHUS ANNUUS OIL;INOSITOL;LEVOCARNITINE;MALTODEXTRIN;MINERALS NOS;TAURINE;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)
CARBOHYDRATES NOS;CHOLINE;FATS NOS;MINERALS NOS;PROTEINS NOS;TAURINE;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)

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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
GENERAL NUTRIENTS	**150**	**(7,0)**	**161**	**(7,5)**	**311**	**(7,2)**
CARBOHYDRATES NOS;CHOLINE;FATS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	0	(0,0)	2	(0,1)	2	(0,0)
CARBOHYDRATES NOS;ELECTROLYTES NOS;FATTY ACIDS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	0	(0,0)	1	(0,0)	1	(0,0)
CARBOHYDRATES NOS;FATS NOS;FIBRE INSOLUBLE;FIBRE SOLUBLE;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	1	(0,0)	2	(0,1)	3	(0,1)
CARBOHYDRATES NOS;FATS NOS;FIBRE, DIETARY;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	1	(0,0)	0	(0,0)	1	(0,0)
CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;PROTEIN;VITAMINS NOS	0	(0,0)	3	(0,1)	3	(0,1)
CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	5	(0,2)	4	(0,2)	9	(0,2)
CARBOHYDRATES NOS;FATTY ACIDS NOS;FIBRE SOLUBLE;MINERALS NOS;PROTEINS NOS	1	(0,0)	0	(0,0)	1	(0,0)
CARBOHYDRATES NOS;FATTY ACIDS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	1	(0,0)	3	(0,1)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
GENERAL NUTRIENTS	**150**	**(7,0)**	**161**	**(7,5)**	**311**	**(7,2)**
CARBOHYDRATES NOS;LIPIDS NOS;MINERALS NOS;PROTEINS NOS	1	(0,0)	3	(0,1)	4	(0,1)
CASEIN HYDROLYSATE;COCOS NUCIFERA OIL;GLUCOSE;GLYCINE MAX EXTRACT;LECITHIN;MINERALS NOS;VITAMINS NOS	1	(0,0)	0	(0,0)	1	(0,0)
CASEIN;CHOLINE CHLORIDE;GLUCOSE;HERBAL OIL NOS;LECITHIN;LEVOCARNITINE;MALTODEXTRIN;MEDIUM-CHAIN TRIGLYCERIDES;MINERALS NOS;SUCROSE;TAURINE;VITAMINS NOS	1	(0,0)	2	(0,1)	3	(0,1)
CYSTEINE	1	(0,0)	0	(0,0)	1	(0,0)
CYSTEINE HYDROCHLORIDE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE ACETATE;METHIONINE;PHENYLALANINE;THREONINE;TRYPTOPHAN, L-;VALINE	2	(0,1)	1	(0,0)	3	(0,1)
FATS NOS	1	(0,0)	3	(0,1)	4	(0,1)
FATTY ACIDS NOS	1	(0,0)	1	(0,0)	2	(0,0)
FISH OIL	1	(0,0)	0	(0,0)	1	(0,0)
FRUCTOSE	1	(0,0)	1	(0,0)	2	(0,0)
GLUCOSE	102	(4,7)	94	(4,4)	196	(4,6)
GLYCINE	2	(0,1)	1	(0,0)	3	(0,1)
HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE ACETATE;METHIONINE;PHENYLALANINE;THREONINE;TRYPTOPHAN, L-;VALINE	1	(0,0)	0	(0,0)	1	(0,0)
INULIN	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
GENERAL NUTRIENTS	**150**	**(7,0)**	**161**	**(7,5)**	**311**	**(7,2)**
ISOLEUCINE;LEUCINE;VALINE	0	(0,0)	1	(0,0)	1	(0,0)
LECITHIN	1	(0,0)	1	(0,0)	2	(0,0)
LINOLEIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
MESO ZEAXANTHIN;XANTOFYL;ZEAXANTHIN	0	(0,0)	1	(0,0)	1	(0,0)
MINERALS NOS;VITAMINS NOS	4	(0,2)	10	(0,5)	14	(0,3)
NUTRIENTS NOS	11	(0,5)	5	(0,2)	16	(0,4)
OTHER COMBINATIONS OF NUTRIENTS	1	(0,0)	0	(0,0)	1	(0,0)
POTASSIUM ASPARTATE	11	(0,5)	17	(0,8)	28	(0,7)
PROTEIN	1	(0,0)	1	(0,0)	2	(0,0)
PROTEIN HYDROLYSATE	1	(0,0)	0	(0,0)	1	(0,0)
HOMEOPATHIC PREPARATION	**800**	**(37,2)**	**770**	**(35,8)**	**1.570**	**(36,5)**
ARNICA MONTANA	0	(0,0)	1	(0,0)	1	(0,0)
ASCORBIC ACID	39	(1,8)	28	(1,3)	67	(1,6)
BORIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
CAPSAICIN	3	(0,1)	2	(0,1)	5	(0,1)
CHARCOAL, ACTIVATED	6	(0,3)	4	(0,2)	10	(0,2)
CIMICIFUGA SPP.;COCCULUS SPP.;CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS;HOMEOPATHICS NOS;LILIUM LANCIFOLIUM;PASSIFLORA INCARNATA;PLATINUM;STRYCHNOS IGNATII;VALERIANA OFFICINALIS	0	(0,0)	1	(0,0)	1	(0,0)
CITRIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
CORTISONE	1	(0,0)	3	(0,1)	4	(0,1)
CORTISONE ACETATE	1	(0,0)	1	(0,0)	2	(0,0)
CYANOCOBALAMIN	54	(2,5)	54	(2,5)	108	(2,5)
CYNARA CARDUNCULUS	0	(0,0)	1	(0,0)	1	(0,0)
CYSTEINE	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
HOMEOPATHIC PREPARATION	**800**	**(37,2)**	**770**	**(35,8)**	**1.570**	**(36,5)**
EPINEPHRINE	52	(2,4)	53	(2,5)	105	(2,4)
ESTRIOL	3	(0,1)	2	(0,1)	5	(0,1)
GINKGO BILOBA	6	(0,3)	3	(0,1)	9	(0,2)
HERBAL POLLEN NOS	0	(0,0)	1	(0,0)	1	(0,0)
IRON	25	(1,2)	29	(1,3)	54	(1,3)
LEAD	0	(0,0)	1	(0,0)	1	(0,0)
NITRIC ACID	0	(0,0)	1	(0,0)	1	(0,0)
PARAFFIN, LIQUID	2	(0,1)	4	(0,2)	6	(0,1)
PELARGONIUM SIDOIDES	1	(0,0)	1	(0,0)	2	(0,0)
PETASITES HYBRIDUS;PICEA ABIES;PLANTAGO LANCEOLATA	0	(0,0)	1	(0,0)	1	(0,0)
POTASSIUM	75	(3,5)	78	(3,6)	153	(3,6)
POTASSIUM CHLORIDE	532	(24,7)	514	(23,9)	1.046	(24,3)
POTASSIUM PHOSPHATE DIBASIC	4	(0,2)	5	(0,2)	9	(0,2)
PROPOLIS	1	(0,0)	1	(0,0)	2	(0,0)
RIBOFLAVIN	1	(0,0)	2	(0,1)	3	(0,1)
SELENIUM	1	(0,0)	2	(0,1)	3	(0,1)
SILICON DIOXIDE	1	(0,0)	1	(0,0)	2	(0,0)
SILVER NITRATE	0	(0,0)	1	(0,0)	1	(0,0)
SILYBUM MARIANUM	0	(0,0)	5	(0,2)	5	(0,1)
SODIUM CHLORIDE	203	(9,4)	196	(9,1)	399	(9,3)
THYROID	0	(0,0)	1	(0,0)	1	(0,0)
TIN	0	(0,0)	1	(0,0)	1	(0,0)
UBIDECARENONE	29	(1,3)	50	(2,3)	79	(1,8)
UREA	17	(0,8)	10	(0,5)	27	(0,6)
VACCINIUM MYRTILLUS EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
VISCUM ALBUM	1	(0,0)	0	(0,0)	1	(0,0)
ZINC	1	(0,0)	2	(0,1)	3	(0,1)
ZINC GLUCONATE	1	(0,0)	0	(0,0)	1	(0,0)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
ABELMOSCHUS MANIHOT FLOWER	0	(0,0)	1	(0,0)	1	(0,0)
ABELMOSCHUS MOSCHATUS	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
ABIES ALBA OIL;DAUCUS CAROTA;HUMULUS LUPULUS;MENTHA X PIPERITA OIL;ORIGANUM VULGARE;PICEA ABIES OIL;RICINUS COMMUNIS OIL	1	(0,0)	0	(0,0)	1	(0,0)
ACHYRANTHES BIDENTATA;CARTHAMUS TINCTORIUS;CITRUS RETICULATA;COPTIS CHINENSIS;GLYCYRRHIZA URALENSIS;PINELLIA TERNATA;PORIA COCOS;PSEUDOSTELLARIA HETEROPHYLLA;RHEUM PALMATUM;SALVIA MILTIORRHIZA	0	(0,0)	1	(0,0)	1	(0,0)
ACONITUM CARMICHAELII	1	(0,0)	0	(0,0)	1	(0,0)
ACONITUM CARMICHAELII ROOT;PANAX GINSENG ROOT	5	(0,2)	1	(0,0)	6	(0,1)
ACONITUM PENDULUM;BENZOIN;OXYTROPIS FALCATA;PHYLLANTHUS EMBLICA;RHEUM SPP.;TERMINALIA BELLIRICA;TERMINALIA CHEBULA;TINOSPORA SINENSIS	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
ACONITUM SPP. PROCESSED ROOT;ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;CINNAMOMUM CASSIA BARK;CORNUS OFFICINALIS FRUIT;DIOSCOREA SPP. RHIZOME;PAEONIA X SUFFRUTICOSA ROOT BARK;PORIA COCOS SCLEROTIUM;REHMANNIA GLUTINOSA ROOT	0	(0,0)	2	(0,1)	2	(0,0)
ACONITUM SPP. PROCESSED ROOT;ASARUM SPP. ROOT;EPHEDRA SPP. HERB	0	(0,0)	1	(0,0)	1	(0,0)
ACORUS CALAMUS RHIZOME;MENTHA X PIPERITA LEAF;RHAMNUS FRANGULA BARK;URTICA DIOICA LEAF;VALERIANA OFFICINALIS ROOT WITH RHIZOME	1	(0,0)	0	(0,0)	1	(0,0)
ADENOPHORA SPP. ROOT;ANDROGRAPHIS PANICULATA HERB;ELAEAGNUS PUNGENS;EPHEDRA SPP. HERB;PAPAVER SOMNIFERUM;PLATYCODON GRANDIFLORUS ROOT;PSEUDOSTELLARIA HETEROPHYLLA ROOT;STEMONA SPP. ROOT;VITEX NEGUNDO FRUIT	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
ADIANTUM CAPILLUS-VENERIS;APIUM GRAVEOLENS SEED;CYMBOPOGON DISTANS;FOENICULUM VULGARE DRY FRUIT;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;HYSSOPUS OFFICINALIS;ROSA RUGOSA BUD;TRIGONELLA FOENUM-GRAECUM SEED;URTICA SPP.	0	(0,0)	1	(0,0)	1	(0,0)
AESCULUS HIPPOCASTANUM SEED;SERENOA REPENS;SOLIDAGO VIRGAUREA	0	(0,0)	1	(0,0)	1	(0,0)
AESCULUS HIPPOCASTANUM;HAMAMELIS VIRGINIANA;RUSCUS ACULEATUS;VITIS VINIFERA	0	(0,0)	1	(0,0)	1	(0,0)
AGASTACHE RUGOSA HERB;IMPERATA CYLINDRICA VAR. MAJOR RHIZOME;LEONURUS JAPONICUS HERB;SMILAX GLABRA RHIZOME;STYPHNOLOBIUM JAPONICUM FLOWER	1	(0,0)	0	(0,0)	1	(0,0)
AKEBIA SPP. STEM;ANGELICA ACUTILOBA ROOT;ASARUM SPP. ROOT;CINNAMOMUM CASSIA BARK;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;TETRADIUM RUTICARPUM FRUIT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE TUBE;CORNUS OFFICINALIS FRUIT;DIOSCOREA POLYSTACHYA RHIZOME;GLEHNIA LITTORALIS ROOT;OPHIOPOGON JAPONICUS ROOT TUBER;PAEONIA X SUFFRUTICOSA ROOT BARK;PORIA COCOS SCLEROTIUM;REHMANNIA GLUTINOSA PROCESSED ROOT TUBER	0	(0,0)	1	(0,0)	1	(0,0)
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;ATRACTYLODES MACROCEPHALA;CINNAMOMUM CASSIA;POLYPORUS UMBELLATUS;PORIA COCOS	1	(0,0)	1	(0,0)	2	(0,0)
ALISMA PLANTAGO-AQUATICA VAR. ORIENTALE TUBER;ATRACTYLODES LANCEA RHIZOME;CINNAMOMUM CASSIA BARK;POLYPORUS UMBELLATUS SCLEROTIUM;PORIA COCOS SCLEROTIUM	0	(0,0)	1	(0,0)	1	(0,0)
ALLIUM MACROSTEMON BULB;BUXUS SPP.;GINKGO BILOBA LEAF;LITSEA LANCILIMBA;SALVIA MILTIORRHIZA ROOT WITH RHIZOME	1	(0,0)	0	(0,0)	1	(0,0)
ALLIUM SATIVUM	1	(0,0)	3	(0,1)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
ALOE FEROX;CARUM CARVI;CICHORIUM INTYBUS;CUMINUM CYMINUM;FOENICULUM VULGARE;SENNA ALEXANDRINA;TARAXACUM OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
ALOE VERA;ANGELICA SINENSIS ROOT;ATRACTYLODES MACROCEPHALA;CISTANCHE DESERTICOLA;CITRUS AURANTIUM UNRIPE FRUIT;MORUS ALBA FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
ALOE VERA;ANGELICA SINENSIS;BAPHICACANTHUS CUSIA;COPTIS CHINENSIS;GARDENIA JASMINOIDES;GENTIANA SCABRA;PHELLODENDRON AMURENSE;RHEUM PALMATUM;SAUSSUREA COSTUS;SCUTELLARIA BAICALENSIS	0	(0,0)	1	(0,0)	1	(0,0)
ALOE VERA;GERANIUM THUNBERGII;POGOSTEMON CABLIN LEAF	0	(0,0)	1	(0,0)	1	(0,0)
ALTHAEA OFFICINALIS EXTRACT	1	(0,0)	3	(0,1)	4	(0,1)
ALUM;BAPHICACANTHUS CUSIA LEAF;BORNEOL	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
AMBER;CODONOPSIS PILOSULA ROOT;NARDOSTACHYS JATAMANSI ROOT WITH RHIZOME;PANAX NOTOGINSENG ROOT;POLYGONATUM SIBIRICUM ROOT	5	(0,2)	0	(0,0)	5	(0,1)
AMOMUM VILLOSUM FRUIT;CINNAMOMUM CASSIA BARK;FOENICULUM VULGARE FRUIT;MAGNESIUM CARBONATE;MENTHOL;MONASCUS PURPUREUS;RHEUM PALMATUM ROOT WITH RHIZOME;SODIUM BICARBONATE;TALC;TARTARIC ACID	1	(0,0)	0	(0,0)	1	(0,0)
ANDROGRAPHIS PANICULATA HERB;HEDYOTIS DIFFUSA HERB;HELICTERES ANGUSTIFOLIA ROOT	1	(0,0)	0	(0,0)	1	(0,0)
ANDROGRAPHIS PANICULATA HERB;ISODON LOPHANTHOIDES HERB;PICRASMA QUASSIOIDES LEAF WITH TWIG	0	(0,0)	2	(0,1)	2	(0,0)
ANDROGRAPHIS PANICULATA;FORSYTHIA SUSPENSA;ISATIS INDIGOTICA;LONICERA JAPONICA	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
ANGELICA ACUTILOBA ROOT;ASTRAGALUS SPP. ROOT;ATRACTYLODES SPP. RHIZOME;BUPLEURUM FALCATUM ROOT;CIMICIFUGA SPP. RHIZOME;CITRUS RETICULATA PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;ZINGIBER OFFICINALE PROCESSED RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	2	(0,1)	2	(0,0)
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CITRUS RETICULATA PEEL;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	1	(0,0)	0	(0,0)	1	(0,0)
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
ANGELICA DAHURICA ROOT;ARECA CATECHU PEEL;ATRACTYLODES SPP. RHIZOME;CITRUS RETICULATA FRUIT PEEL;GLYCYRRHIZA URALENSIS;MAGNOLIA OFFICINALIS BARK;PERILLA FRUTESCENS;PINELLIA TERNATA RHIZOME;POGOSTEMON CABLIN HERB OIL;PORIA COCOS	1	(0,0)	1	(0,0)	2	(0,0)
ANGELICA DAHURICA;ANGELICA SINENSIS;ASTRAGALUS PROPINQUUS;ATRACTYLODES LANCEA RHIZOME;CARTHAMUS TINCTORIUS;PAEONIA LACTIFLORA;PAEONIA X SUFFRUTICOSA BARK;PANAX NOTOGINSENG;PORTULACA OLERACEA;PRUNUS PERSICA SEED;SAPOSHNIKOVIA DIVARICATA	1	(0,0)	0	(0,0)	1	(0,0)
ANGELICA DAHURICA;ASTRAGALUS PROPINQUUS;CHRYSANTHEMUM INDICUM;GLYCYRRHIZA SPP.;LIGUSTICUM CHUANXIONG;MAGNOLIA SPP.;PLATYCARYA STROBILACEA;PRUNELLA VULGARIS;SAPOSHNIKOVIA DIVARICATA	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA SINENSIS	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
ANGELICA SINENSIS ROOT;ASTRAGALUS PROPINQUUS ROOT;EPIMEDIUM BREVICORNU HERB;GELATIN;LESPEDEZA BUERGERI;SOPHORA FLAVESCENS ROOT;ZIZIPHUS JUJUBA FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA SINENSIS ROOT;BORNEOL;CARTHAMUS TINCTORIUS FLOWER;LIGUSTICUM CHUANXIONG RHIZOME;PANAX GINSENG ROOT	0	(0,0)	1	(0,0)	1	(0,0)
ANGELICA SINENSIS ROOT;CARTHAMUS TINCTORIUS FLOWER;LIGUSTICUM CHUANXIONG RHIZOME;PAEONIA LACTIFLORA SUN DRIED ROOT;SALVIA MILTIORRHIZA ROOT	1	(0,0)	1	(0,0)	2	(0,0)
ANGELICA SPP.	0	(0,0)	1	(0,0)	1	(0,0)
ANIMAL FECES NOS;BOMBYX MORI	1	(0,0)	0	(0,0)	1	(0,0)
ANIMAL HORN NOS;BEAR BILE;FORSYTHIA SUSPENSA FRUIT;LONICERA JAPONICA FLOWER;SCUTELLARIA BAICALENSIS ROOT	1	(0,0)	0	(0,0)	1	(0,0)
ARCTIUM LAPPA	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
ARCTIUM LAPPA FRUIT;CICADA SLOUGH;EPHEDRA SPP. HERB;ERIOBOTRYA JAPONICA LEAF;PERILLA FRUTESCENS FRUIT;PERILLA FRUTESCENS LEAF;PEUCEDANUM PRAERUPTORUM ROOT;PHERETIMA SPP.;SCHISANDRA CHINENSIS FRUIT	3	(0,1)	3	(0,1)	6	(0,1)
ARECA CATECHU SEED;CITRUS AURANTIUM UNRIPE FRUIT;LINDERA AGGREGATA ROOT;SAUSSUREA COSTUS ROOT	1	(0,0)	2	(0,1)	3	(0,1)
ARNICA MONTANA	0	(0,0)	1	(0,0)	1	(0,0)
ARTEMISIA ARGYI LEAF	4	(0,2)	4	(0,2)	8	(0,2)
ARTEMISIA SPP. HERB;BUPLEURUM CHINENSE, ROOT;ISATIS INDIGOTICA ROOT;SCHISANDRA CHINENSIS FRUIT;SWINE BILE;VIGNA RADIATA	1	(0,0)	0	(0,0)	1	(0,0)
ASARUM HETEROTROPOIDES	1	(0,0)	0	(0,0)	1	(0,0)
ASARUM SPP. ROOT;CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;PINELLIA TERNATA TUBER;SCHISANDRA CHINENSIS FRUIT;ZINGIBER OFFICINALE RHIZOME	2	(0,1)	2	(0,1)	4	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
ASPARAGUS COCHINCHINENSIS ROOT TUBER;GLYCYRRHIZA URALENSIS ROOT WITH RHIZOME;LONICERA CONFUSA FLOWER BUD;OPHIOPOGON JAPONICUS ROOT TUBER;SCROPHULARIA NINGPOENSIS ROOT	0	(0,0)	1	(0,0)	1	(0,0)
ASTER AGERATOIDES;FIRMIANA SIMPLEX;GENTIANA RHODANTHA;HEDYOTIS DIFFUSA;PEUCEDANUM PRAERUPTORUM;SCUTELLARIA BAICALENSIS;STEMONA SESSILIFOLIA	2	(0,1)	1	(0,0)	3	(0,1)
ASTRAGALUS MONGHOLICUS ROOT	0	(0,0)	1	(0,0)	1	(0,0)
ASTRAGALUS MONGHOLICUS ROOT;ATRACTYLODES MACROCEPHALA, RHIZOMA;SAPOSHNIKOVIA DIVARICATA ROOT	1	(0,0)	0	(0,0)	1	(0,0)
ASTRAGALUS MONGHOLICUS ROOT;CODONOPSIS PILOSULA ROOT	0	(0,0)	1	(0,0)	1	(0,0)
ASTRAGALUS MONGHOLICUS ROOT;CODONOPSIS PILOSULA ROOT;SCHISANDRA CHINENSIS FRUIT;ZIZIPHUS JUJUBA VAR. SPINOSA SEED	0	(0,0)	2	(0,1)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
ASTRAGALUS MONGHOLICUS ROOT;CRATAEGUS PINNATIFIDA FRUIT;LIGUSTICUM CHUANXIONG RHIZOME;OPHIOPOGON JAPONICUS ROOT TUBER;PANAX GINSENG ROOT;SALVIA MILTIORRHIZA ROOT;SCHISANDRA CHINENSIS FRUIT	2	(0,1)	0	(0,0)	2	(0,0)
ASTRAGALUS MONGHOLICUS ROOT;DALBERGIA ODORIFERA OIL;PANAX NOTOGINSENG ROOT;SALVIA MILTIORRHIZA ROOT	3	(0,1)	5	(0,2)	8	(0,2)
ASTRAGALUS MONGHOLICUS ROOT;DIOSCOREA OPPOSITIFOLIA RHIZOME;GLIBENCLAMIDE;PUERARIA LOBATA ROOT;REHMANNIA GLUTINOSA ROOT;SCHISANDRA SPHENANTHERA FRUIT;TRICHOSANTHES SPP. ROOT;ZEA MAYS STYLE	0	(0,0)	1	(0,0)	1	(0,0)
ASTRAGALUS PROPINQUUS	1	(0,0)	4	(0,2)	5	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
ATRACTYLODES LANCEA RHIZOME;CITRUS RETICULATA PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	1	(0,0)	3	(0,1)	4	(0,1)
ATRACTYLODES MACROCEPHALA	1	(0,0)	0	(0,0)	1	(0,0)
ATRACTYLODES MACROCEPHALA, RHIZOMA;BUPLEURUM CHINENSE, ROOT;CITRUS AURANTIUM SUBMATURE FRUIT;CRATAEGUS PINNATIFIDA FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
ATRACTYLODES MACROCEPHALA, RHIZOMA;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;LEVOGLUTAMIDE;PANAX GINSENG ROOT;PORIA COCOS SCLEROTIUM	1	(0,0)	0	(0,0)	1	(0,0)
BAICALIN;BUFFALO HORN;CHOLIC ACID;CONCHA MARGARITIFERA;GARDENIA JASMINOIDES FRUIT;HYODEOXYCHOLIC ACID;ISATIS INDIGOTICA ROOT;LONICERA JAPONICA FLOWER	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
BERBERINE HYDROCHLORIDE;RHEUM PALMATUM ROOT WITH RHIZOME;SCUTELLARIA BAICALENSIS ROOT EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
BIDENS BITERNATA;CAFFEINE;CHLORPHENAMINE MALEATE;CHRYSANTHEMUM INDICUM FLOWER;ILEX ASPRELLA ROOT;MELICOPE PTELEIFOLIA;MENTHA CANADENSIS OIL;PARACETAMOL	1	(0,0)	1	(0,0)	2	(0,0)
BIDENS TRIPARTITA HERB;HYPERICUM PERFORATUM HERB;ROSA SPP. FRUIT;VACCINIUM VITIS-IDAEA LEAF	1	(0,0)	0	(0,0)	1	(0,0)
BORIC ACID;BORNEOL;CITRULLUS LANATUS;COPTIS SPP.;FRITILLARIA THUNBERGII;GLYCYRRHIZA SPP.;INDIGO;IRIS DOMESTICA;MENTHOL;PHELLODENDRON CHINENSE;RHEUM SPP.;SAPINDUS MUKOROSSI;SCUTELLARIA BAICALENSIS;SODIUM SULFATE;SOPHORA TONKINENSIS	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
BORNEOL;BOSWELLIA SACRA RESIN;CENTIPEDE;CICADA SLOUGH;DALBERGIA ODORIFERA;EUPOLYPHAGA STELEOPHAGA;LEECH EXTRACT;MESOBUTHUS MARTENSII;PAEONIA SPP. ROOT;PANAX GINSENG ROOT;SANTALUM ALBUM HEARTWOOD;ZIZIPHUS JUJUBA VAR. SPINOSA SEED	0	(0,0)	1	(0,0)	1	(0,0)
BORNEOL;BUFFALO HORN;COPTIS SPP. RHIZOME;COW BEZOAR;CURCUMA SPP. ROOT TUBER;GARDENIA JASMINOIDES FRUIT;MERCURY SULFIDE;MUSK;PEARL;REALGAR;SCUTELLARIA BAICALENSIS ROOT	1	(0,0)	0	(0,0)	1	(0,0)
BORNEOL;CINNAMOMUM CASSIA BARK;COW BEZOAR;LIQUIDAMBAR ORIENTALIS RESIN;MUSK;PANAX GINSENG EXTRACT;TOAD VENOM	3	(0,1)	10	(0,5)	13	(0,3)
BORNEOL;CURCUMA SPP. TUBER;GARDENIA JASMINOIDES FRUIT;MUSK	2	(0,1)	1	(0,0)	3	(0,1)
BORNEOL;LIGUSTICUM CHUANXIONG RHIZOME	3	(0,1)	0	(0,0)	3	(0,1)
BORNEOL;PANAX NOTOGINSENG ROOT;SALVIA MILTIORRHIZA ROOT	3	(0,1)	2	(0,1)	5	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
BOSWELLIA SACRA;COMMIPHORA MYRRHA RESIN;COW BEZOAR;MUSK	0	(0,0)	1	(0,0)	1	(0,0)
BOSWELLIA SERRATA;CURCUMA LONGA	1	(0,0)	0	(0,0)	1	(0,0)
BRASSICA JUNCEA	0	(0,0)	1	(0,0)	1	(0,0)
BUPLEURUM CHINENSE, ROOT	0	(0,0)	1	(0,0)	1	(0,0)
CANNABIS SATIVA FRUIT;CITRUS SPP. UNRIPE FRUIT;MAGNOLIA SPP. BARK;PAEONIA LACTIFLORA ROOT;PRUNUS SPP. SEED;RHEUM SPP. RHIZOME	0	(0,0)	2	(0,1)	2	(0,0)
CANNABIS SATIVA OIL	0	(0,0)	1	(0,0)	1	(0,0)
CARTHAMUS TINCTORIUS FLOWER;SALVIA MILTIORRHIZA ROOT	1	(0,0)	3	(0,1)	4	(0,1)
CENTAURIUM ERYTHRAEA;LEVISTICUM OFFICINALE;ROSMARINUS OFFICINALIS	1	(0,0)	0	(0,0)	1	(0,0)
CHLORPHENAMINE MALEATE;FICUS MICROCARPA VAR. PUSILLIFOLIA LEAF	1	(0,0)	0	(0,0)	1	(0,0)
CINNAMOMUM CASSIA BARK;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;NUPHAR JAPONICA RHIZOME;QUERCUS SPP. BARK;RHEUM SPP. RHIZOME;SYZYGIUM AROMATICUM FLOWER BUD	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;PUERARIA LOBATA ROOT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	1	(0,0)	4	(0,2)	5	(0,1)
CINNAMOMUM CASSIA BARK;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;PRUNUS SPP. SEED	0	(0,0)	1	(0,0)	1	(0,0)
CINNAMOMUM CASSIA BARK;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;RHEUM SPP. RHIZOME;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
CINNAMOMUM VERUM;CITRUS AURANTIUM;MELISSA OFFICINALIS;PASSIFLORA ALATA	3	(0,1)	3	(0,1)	6	(0,1)
CISTANCHE DESERTICOLA STEM;CITRUS AURANTIUM SUBMATURE FRUIT;FALLOPIA MULTIFLORA ROOT TUBER;HONEY	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
CISTANCHE DESERTICOLA STEM;CUSCUTA CHINENSIS SEED;MORINDA OFFICINALIS ROOT;PLANTAGO ASIATICA SEED;PORIA COCOS SCLEROTIUM;SCHISANDRA CHINENSIS FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
CITRUS AURANTIUM UNRIPE FRUIT;MAGNOLIA OFFICINALIS BARK;RHEUM PALMATUM RHIZOME;SAUSSUREA COSTUS ROOT	1	(0,0)	0	(0,0)	1	(0,0)
CITRUS AURANTIUM;CRATAEGUS MONOGYNA FRUIT;CYMBOPOGON CITRATUS;MATRICARIA RECUTITA FLOWER;MENTHA SPICATA LEAF;ROSA CENTIFOLIA;RUBUS FRUTICOSUS LEAF;TILIA SPP. FLOWER	1	(0,0)	0	(0,0)	1	(0,0)
CITRUS MAXIMA;CYNANCHUM STAUNTONII;DELPHINIUM GRANDIFLORUM;GLYCYRRHIZA SPP.;PINELLIA TERNATA;PORIA COCOS;PRUNUS SPP.;SCHISANDRA CHINENSIS	1	(0,0)	0	(0,0)	1	(0,0)
CITRUS RETICULATA PEEL;CRATAEGUS PINNATIFIDA FRUIT;DIOSCOREA POLYSTACHYA RHIZOME;HORDEUM VULGARE SPROUT;PSEUDOSTELLARIA HETEROPHYLLA RHIZOME	4	(0,2)	0	(0,0)	4	(0,1)

Participants With Specific Concomitant Medications
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
CITRUS RETICULATA;GLYCYRRHIZA SPP.;PINELLIA TERNATA;PORIA COCOS;ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
CODONOPSIS PILOSULA	1	(0,0)	0	(0,0)	1	(0,0)
COLCHICUM AUTUMNALE	0	(0,0)	1	(0,0)	1	(0,0)
COLCHICUM AUTUMNALE TINCTURE	0	(0,0)	1	(0,0)	1	(0,0)
COPTIS CHINENSIS RHIZOME;ISATIS INDIGOTICA ROOT;PHELLODENDRON AMURENSE BARK;RHEUM PALMATUM ROOT WITH RHIZOME;SCUTELLARIA BAICALENSIS ROOT	1	(0,0)	0	(0,0)	1	(0,0)
COPTIS SPP. RHIZOME;HEDERA HELIX LEAF	0	(0,0)	2	(0,1)	2	(0,0)
CORDYCEPS SINENSIS	14	(0,7)	11	(0,5)	25	(0,6)
CORYDALIS BUNGEANA HERB;ISATIS INDIGOTICA ROOT;SCUTELLARIA BAICALENSIS ROOT;TARAXACUM MONGOLICUM HERB	5	(0,2)	2	(0,1)	7	(0,2)
CORYDALIS YANHUSUO TUBER;IPOMOEA NIL SEED	3	(0,1)	1	(0,0)	4	(0,1)
CRATAEGUS LAEVIGATA	1	(0,0)	1	(0,0)	2	(0,0)
CRATAEGUS SPP. EXTRACT	1	(0,0)	2	(0,1)	3	(0,1)
CROCUS SATIVUS	0	(0,0)	1	(0,0)	1	(0,0)
CUCURBITA PEPO SEED;CUCURBITA PEPO SEED OIL;SERENOA REPENS FRUIT	0	(0,0)	1	(0,0)	1	(0,0)
CUCURBITA PEPO SEED;GLYCINE MAX	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
CURCUMA LONGA	3	(0,1)	1	(0,0)	4	(0,1)
CURCUMA LONGA;CYNARA CARDUNCULUS;SILYBUM MARIANUM	0	(0,0)	1	(0,0)	1	(0,0)
CYAMOPSIS TETRAGONOLOBA GUM	0	(0,0)	1	(0,0)	1	(0,0)
CYNANCHUM STAUNTONII ROOT WITH RHIZOME;ERIOBOTRYA JAPONICA LEAF;MENTHOL;MORUS ALBA ROOT BARK;PAPAVER SOMNIFERUM PEEL;PLATYCODON GRANDIFLORUS ROOT;STEMONA SESSILIFOLIA ROOT TUBER	5	(0,2)	11	(0,5)	16	(0,4)
CYNARA CARDUNCULUS	0	(0,0)	1	(0,0)	1	(0,0)
DIOSCOREA SPP.	0	(0,0)	1	(0,0)	1	(0,0)
DIOSPYROS KAKI LEAF	0	(0,0)	1	(0,0)	1	(0,0)
DIPYRIDAMOLE;GINKGO BILOBA	1	(0,0)	1	(0,0)	2	(0,0)
ELEUTHEROCOCCUS SENTICOSUS ROOT WITH RHIZOME;HYPERICUM PERFORATUM HERB	1	(0,0)	0	(0,0)	1	(0,0)
ERIGERON BREVISCAPUS	0	(0,0)	1	(0,0)	1	(0,0)
ERIGERON BREVISCAPUS HERB;OPHIOPOGON JAPONICUS;PANAX GINSENG ROOT;SCHISANDRA CHINENSIS FRUIT	3	(0,1)	0	(0,0)	3	(0,1)
ERIOBOTRYA JAPONICA	0	(0,0)	2	(0,1)	2	(0,0)
EUCOMMIA ULMOIDES	1	(0,0)	0	(0,0)	1	(0,0)
FALLOPIA MULTIFLORA	1	(0,0)	0	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
FORSYTHIA SUSPENSA FRUIT;OPHIOPOGON JAPONICUS ROOT TUBER;REHMANNIA GLUTINOSA ROOT TUBER;SCROPHULARIA NINGPOENSIS ROOT;SCUTELLARIA BAICALENSIS ROOT	2	(0,1)	1	(0,0)	3	(0,1)
GANODERMA LUCIDUM	0	(0,0)	1	(0,0)	1	(0,0)
GARDENIA JASMINOIDES FRUIT;ISATIS INDIGOTICA ROOT;PHELLODENDRON CHINENSE BARK;SCUTELLARIA BAICALENSIS ROOT;STERCULIA LYCHNOPHORA SEED	0	(0,0)	1	(0,0)	1	(0,0)
GASTRODIA ELATA	0	(0,0)	2	(0,1)	2	(0,0)
GENTIANA LUTEA ROOT;PRIMULA SPP. FLOWER;RUMEX SPP. HERB;SAMBUCUS NIGRA FLOWER;VERBENA OFFICINALIS HERB	2	(0,1)	0	(0,0)	2	(0,0)
GENTIANA LUTEA ROOT;PRIMULA SPP.;RUMEX SPP.;SAMBUCUS NIGRA FLOWER;VERBENA OFFICINALIS	0	(0,0)	1	(0,0)	1	(0,0)
GINKGO BILOBA	6	(0,3)	3	(0,1)	9	(0,2)
GINKGO BILOBA EXTRACT	1	(0,0)	4	(0,2)	5	(0,1)
GINKGO BILOBA LEAF EXTRACT	1	(0,0)	1	(0,0)	2	(0,0)
GINSENG NOS	0	(0,0)	1	(0,0)	1	(0,0)
GLYCINE MAX SEED OIL	0	(0,0)	1	(0,0)	1	(0,0)
GLYCYRRHIZA GLABRA	1	(0,0)	2	(0,1)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
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Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
GLYCYRRHIZA GLABRA;HUMULUS LUPULUS;LEONURUS SPP.;MENTHA X PIPERITA;VALERIANA OFFICINALIS	0	(0,0)	1	(0,0)	1	(0,0)
GLYCYRRHIZA GLABRA;PANAX GINSENG;PLATYCODON GRANDIFLORUS;POLYGALA SENEGA;PRUNUS ARMENIACA;UNCARIA GAMBIR	0	(0,0)	1	(0,0)	1	(0,0)
GLYCYRRHIZA GLABRA;PLATYCODON GRANDIFLORUS;POLYGALA SENEGA;PRUNUS ARMENIACA SEED	0	(0,0)	1	(0,0)	1	(0,0)
GLYCYRRHIZA SPP. ROOT;OPHIOPOGON JAPONICUS TUBER;ORYZA SATIVA FRUIT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;ZIZIPHUS JUJUBA VAR. INERMIS FRUIT	1	(0,0)	1	(0,0)	2	(0,0)
GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT	3	(0,1)	10	(0,5)	13	(0,3)
GLYCYRRHIZA SPP. ROOT;RHEUM SPP. RHIZOME	0	(0,0)	1	(0,0)	1	(0,0)
GLYCYRRHIZA URALENSIS	1	(0,0)	1	(0,0)	2	(0,0)
GUAREA GUIDONIA	1	(0,0)	1	(0,0)	2	(0,0)
HAMAMELIS VIRGINIANA EXTRACT	1	(0,0)	2	(0,1)	3	(0,1)
HEDERA HELIX	1	(0,0)	1	(0,0)	2	(0,0)
HEDERA HELIX EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
HERBAL NOS	1	(0,0)	1	(0,0)	2	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
HERBAL POLLEN NOS	0	(0,0)	1	(0,0)	1	(0,0)
HOUTTUYNIA CORDATA	0	(0,0)	1	(0,0)	1	(0,0)
HUMULUS LUPULUS EXTRACT;PASSIFLORA INCARNATA EXTRACT;VALERIANA OFFICINALIS EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
ILLICIUM VERUM;LESPEDEZA CAPITATA	0	(0,0)	1	(0,0)	1	(0,0)
ISATIS INDIGOTICA	0	(0,0)	1	(0,0)	1	(0,0)
ISATIS INDIGOTICA ROOT	0	(0,0)	1	(0,0)	1	(0,0)
KRILL OIL	0	(0,0)	1	(0,0)	1	(0,0)
LAMIOPHLOMIS ROTATA ROOT WITH RHIZOME	0	(0,0)	1	(0,0)	1	(0,0)
LESPEDEZA CAPITATA	0	(0,0)	1	(0,0)	1	(0,0)
LINUM USITATISSIMUM	1	(0,0)	0	(0,0)	1	(0,0)
LINUM USITATISSIMUM SEED	0	(0,0)	1	(0,0)	1	(0,0)
LONICERA JAPONICA FLOWER BUD;RHEUM PALMATUM ROOT WITH RHIZOME;SANGUISORBA OFFICINALIS ROOT;SCUTELLARIA BAICALENSIS ROOT;SIEGESBECKIA ORIENTALIS HERB;STYPHNOLOBIUM JAPONICUM FLOWER	1	(0,0)	0	(0,0)	1	(0,0)
LONICERA JAPONICA FLOWER BUD;SCUTELLARIA BAICALENSIS ROOT EXTRACT	0	(0,0)	2	(0,1)	2	(0,0)
MATRICARIA RECUTITA;MELALEUCA ALTERNIFOLIA	0	(0,0)	1	(0,0)	1	(0,0)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
MELISSA OFFICINALIS;MENTHA X PIPERITA;VALERIANA OFFICINALIS	1	(0,0)	0	(0,0)	1	(0,0)
MENTHA CANADENSIS OIL	0	(0,0)	1	(0,0)	1	(0,0)
MENTHA X PIPERITA OIL	1	(0,0)	0	(0,0)	1	(0,0)
MONASCUS PURPUREUS	1	(0,0)	0	(0,0)	1	(0,0)
OLEA EUROPAEA OIL	3	(0,1)	2	(0,1)	5	(0,1)
OPHIOPOGON JAPONICUS ROOT TUBER;PANAX GINSENG	12	(0,6)	12	(0,6)	24	(0,6)
OPHIOPOGON JAPONICUS ROOT TUBER;PANAX GINSENG ROOT;SCHISANDRA CHINENSIS FRUIT	1	(0,0)	7	(0,3)	8	(0,2)
OPHIOPOGON JAPONICUS;PANAX GINSENG	1	(0,0)	1	(0,0)	2	(0,0)
PANAX GINSENG	1	(0,0)	0	(0,0)	1	(0,0)
PANAX GINSENG ROOT;ZANTHOXYLUM PIPERITUM PERICARP;ZINGIBER OFFICINALE PROCESSED RHIZOME	4	(0,2)	3	(0,1)	7	(0,2)
PANAX GINSENG TOTAL GINSENOSIDE EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
PANAX NOTOGINSENG	3	(0,1)	1	(0,0)	4	(0,1)
PANAX NOTOGINSENG ROOT	1	(0,0)	1	(0,0)	2	(0,0)
PELARGONIUM SIDOIDES	1	(0,0)	1	(0,0)	2	(0,0)
PERIPLANETA AMERICANA	1	(0,0)	1	(0,0)	2	(0,0)
PLANTAGO OVATA	1	(0,0)	7	(0,3)	8	(0,2)
PLANTAGO OVATA HUSK	3	(0,1)	1	(0,0)	4	(0,1)
PLANTAGO OVATA;SENNA SPP.	1	(0,0)	0	(0,0)	1	(0,0)
PLATYCODON GRANDIFLORUS	5	(0,2)	4	(0,2)	9	(0,2)
PLATYCODON GRANDIFLORUS ROOT FLUID EXTRACT	3	(0,1)	6	(0,3)	9	(0,2)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
POLYGALA SENEGA	1	(0,0)	0	(0,0)	1	(0,0)
PORIA COCOS	0	(0,0)	1	(0,0)	1	(0,0)
PRUNUS ARMENIACA SEED EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
PRUNUS SEROTINA BARK	0	(0,0)	1	(0,0)	1	(0,0)
REHMANNIA GLUTINOSA ROOT TUBER	0	(0,0)	1	(0,0)	1	(0,0)
RHEUM PALMATUM	0	(0,0)	1	(0,0)	1	(0,0)
RICINUS COMMUNIS OIL	1	(0,0)	1	(0,0)	2	(0,0)
SALVIA MILTIORRHIZA	1	(0,0)	0	(0,0)	1	(0,0)
SALVIA MILTIORRHIZA ROOT	0	(0,0)	1	(0,0)	1	(0,0)
SENNA ALEXANDRINA	16	(0,7)	25	(1,2)	41	(1,0)
SENNA ALEXANDRINA EXTRACT	1	(0,0)	1	(0,0)	2	(0,0)
SERENOA REPENS	6	(0,3)	1	(0,0)	7	(0,2)
SERENOA REPENS EXTRACT	4	(0,2)	4	(0,2)	8	(0,2)
SERENOA REPENS EXTRACT;URTICA DIOICA EXTRACT	1	(0,0)	1	(0,0)	2	(0,0)
SESAMUM INDICUM SEED OIL	1	(0,0)	0	(0,0)	1	(0,0)
SILYBUM MARIANUM	0	(0,0)	5	(0,2)	5	(0,1)
STERCULIA URENS	1	(0,0)	0	(0,0)	1	(0,0)
STERCULIA URENS GUM	0	(0,0)	2	(0,1)	2	(0,0)
THESIUM CHINENSE HERB	0	(0,0)	1	(0,0)	1	(0,0)
TRIBULUS TERRESTRIS	0	(0,0)	1	(0,0)	1	(0,0)
TRICHOSANTHES KIRILOWII	0	(0,0)	1	(0,0)	1	(0,0)
TRICHOSANTHES KIRILOWII EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
TRIGONELLA FOENUM-GRAECUM	0	(0,0)	1	(0,0)	1	(0,0)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	46	(2,1)	53	(2,5)	99	(2,3)
VACCINIUM MACROCARPON	0	(0,0)	2	(0,1)	2	(0,0)
VACCINIUM MYRTILLUS EXTRACT	1	(0,0)	0	(0,0)	1	(0,0)
VALERIANA OFFICINALIS	2	(0,1)	1	(0,0)	3	(0,1)

Participants With Specific Concomitant Medications
(Incidence > 0% in One or More Treatment Groups)
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
VARIOUS						
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	**185**	**(8,6)**	**217**	**(10,1)**	**402**	**(9,3)**
VISCUM ALBUM	1	(0,0)	0	(0,0)	1	(0,0)
VISCUM ALBUM EXTRACT	0	(0,0)	1	(0,0)	1	(0,0)
VITIS VINIFERA EXTRACT	4	(0,2)	3	(0,1)	7	(0,2)
XANTHIUM SIBIRICUM	1	(0,0)	0	(0,0)	1	(0,0)
ZINGIBER OFFICINALE	1	(0,0)	0	(0,0)	1	(0,0)
ZIZIPHUS JUJUBA	1	(0,0)	0	(0,0)	1	(0,0)

Every participant is counted a single time for each applicable specific concomitant medication. A participant with multiple concomitant medications within a medication category is counted a single time for that category. Each specific concomitant medication is listed under all relevant medication classes based on the medication's generic name, regardless of route of administration or reason for use. A medication that is not mapped to a second level therapeutic subgroup is classified under Other

A medication class or specific medication appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding

a: Database Cutoff Date: 18JUN2019

1.6 Standard of Care for Heart Failure Treatment at Baseline

Table 1.6-1
Standard of Care for Heart Failure Treatment at Baseline
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
Subjects in population	2158		2158		4316	
Subjects with data	2154		2155		4309	
With one or more SOC treatments	2150	(99,8)	2154	(100,0)	4304	(99,9)
With no SOC treatment	4	(0,2)	1	(0,0)	5	(0,1)
Beta Blocker						
Yes	2008	(93,2)	2009	(93,2)	4017	(93,2)
No	146	(6,8)	146	(6,8)	292	(6,8)
Reasons for not on the treatment						
Contraindication	26	(1,2)	13	(0,6)	39	(0,9)
Side Effect or Treatment Intolerance	27	(1,3)	41	(1,9)	68	(1,6)
Subject or physician preference	80	(3,7)	78	(3,6)	158	(3,7)
Other	13	(0,6)	14	(0,6)	27	(0,6)
ACE-I or ARB						
Yes	1562	(72,5)	1578	(73,2)	3140	(72,9)
No	592	(27,5)	577	(26,8)	1169	(27,1)
Reasons for not on the treatment						
Contraindication	46	(2,1)	22	(1,0)	68	(1,6)
Side Effect or Treatment Intolerance	75	(3,5)	84	(3,9)	159	(3,7)
Subject currently taking the combination of Sacubitril/Valsartan	199	(9,2)	190	(8,8)	389	(9,0)
Subject or physician preference	242	(11,2)	247	(11,5)	489	(11,3)
Other	30	(1,4)	34	(1,6)	64	(1,5)
MRA						
Yes	1531	(71,1)	1584	(73,5)	3115	(72,3)
No	623	(28,9)	571	(26,5)	1194	(27,7)
Reasons for not on the treatment						
Contraindication	53	(2,5)	54	(2,5)	107	(2,5)
Not Indicated by treatment guidelines	97	(4,5)	87	(4,0)	184	(4,3)
Side Effect or Treatment Intolerance	66	(3,1)	70	(3,2)	136	(3,2)
Subject or physician preference	372	(17,3)	328	(15,2)	700	(16,2)
Other	35	(1,6)	32	(1,5)	67	(1,6)
Sacubitril/Valsartan						
Yes	330	(15,3)	330	(15,3)	660	(15,3)
No	1824	(84,7)	1825	(84,7)	3649	(84,7)
Reasons for not on the treatment						
Contraindication	56	(2,6)	32	(1,5)	88	(2,0)

Standard of Care for Heart Failure Treatment at Baseline
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Total	
	n	(%)	n	(%)	n	(%)
Sacubitril/Valsartan						
Not Indicated by treatment guidelines	419	(19,5)	438	(20,3)	857	(19,9)
Side Effect or Treatment Intolerance	45	(2,1)	44	(2,0)	89	(2,1)
Subject or physician preference	773	(35,9)	760	(35,3)	1533	(35,6)
Treatment Not Available	416	(19,3)	400	(18,6)	816	(18,9)
Other	115	(5,3)	151	(7,0)	266	(6,2)
ICD						
Yes	644	(29,9)	654	(30,3)	1298	(30,1)
No	1510	(70,1)	1501	(69,7)	3011	(69,9)
Reasons for not on the treatment						
Not Indicated by treatment guidelines	657	(30,5)	663	(30,8)	1320	(30,6)
Side Effect or Treatment Intolerance	6	(0,3)	5	(0,2)	11	(0,3)
Subject or physician preference	551	(25,6)	566	(26,3)	1117	(25,9)
Treatment Not Available	172	(8,0)	150	(7,0)	322	(7,5)
Other	124	(5,8)	117	(5,4)	241	(5,6)
Biventricular Pacemaker						
Yes	325	(15,1)	339	(15,7)	664	(15,4)
No	1829	(84,9)	1816	(84,3)	3645	(84,6)
Reasons for not on the treatment						
Not Indicated by treatment guidelines	912	(42,3)	943	(43,8)	1855	(43,0)
Side Effect or Treatment Intolerance	7	(0,3)	5	(0,2)	12	(0,3)
Subject or physician preference	617	(28,6)	610	(28,3)	1227	(28,5)
Treatment Not Available	166	(7,7)	139	(6,5)	305	(7,1)
Other	127	(5,9)	119	(5,5)	246	(5,7)
Standard of Care Device						
No Device	1414	(65,6)	1416	(65,7)	2830	(65,7)
ICD Only	415	(19,3)	400	(18,6)	815	(18,9)
Biventricular Pacemaker Only	96	(4,5)	85	(3,9)	181	(4,2)
ICD and Biventricular Pacemaker	229	(10,6)	254	(11,8)	483	(11,2)
Any RAS Inhibitor (ACE-I or ARB or Sacubitril/Valsartan)						
Yes	1880	(87,3)	1895	(87,9)	3775	(87,6)
No	274	(12,7)	260	(12,1)	534	(12,4)

Standard of Care for Heart Failure Treatment at Baseline
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
Two or more SOC Medications						
Yes	1973	(91,6)	1989	(92,3)	3962	(91,9)
No	181	(8,4)	166	(7,7)	347	(8,1)
MRA + Any RAS Inhibitor	79	(3,7)	87	(4,0)	166	(3,9)
Beta Blocker + Any RAS Inhibitor	456	(21,2)	425	(19,7)	881	(20,4)
MRA + Beta Blocker	137	(6,4)	132	(6,1)	269	(6,2)
MRA + Beta Blocker + Any RAS Inhibitor	1301	(60,4)	1345	(62,4)	2646	(61,4)

a: Database Cutoff Date: 18JUN2019

ACE-I: Angiotensin-Converting Enzyme Inhibitor; ARB: Angiotensin II Receptor Blocker; ICD: Implantable Cardioverter-Defibrillators; MRA: Mineralocorticoid Receptor Antagonist; RAS: Renin-Angiotensin System; SOC: Standard of Care

1.7 Standard of Care for Heart Failure Treatment During Follow-Up

Table 1.7-1
Standard of Care for Heart Failure Treatment During Follow-Up
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
Participants in population	2158		2158		4316	
Participants with Follow Up	2140		2139		4279	
With SOC during Follow Up	2137	(99,9)	2136	(99,9)	4273	(99,9)
Without SOC during Follow Up	3	(0,1)	3	(0,1)	6	(0,1)
Day 2 to Day 21	**2140[b]**		**2139[b]**		**4279[b]**	
Participant with any SOC Medication	2135	(99,8)	2136	(99,9)	4271	(99,8)
Beta Blocker	2003	(93,6)	1994	(93,2)	3997	(93,4)
ACE-I or ARB	1567	(73,2)	1577	(73,7)	3144	(73,5)
MRA	1546	(72,2)	1600	(74,8)	3146	(73,5)
Sacubitril/Valsartan	343	(16,0)	345	(16,1)	688	(16,1)
Day 22 to Day 56	**2119[b]**		**2114[b]**		**4233[b]**	
Participant with any SOC Medication	2115	(99,8)	2109	(99,8)	4224	(99,8)
Beta Blocker	1983	(93,6)	1975	(93,4)	3958	(93,5)
ACE-I or ARB	1549	(73,1)	1551	(73,4)	3100	(73,2)
MRA	1532	(72,3)	1574	(74,5)	3106	(73,4)
Sacubitril/Valsartan	342	(16,1)	372	(17,6)	714	(16,9)
Day 57 to Week 16	**2015[b]**		**2013[b]**		**4028[b]**	
Participant with any SOC Medication	2008	(99,7)	2009	(99,8)	4017	(99,7)
Beta Blocker	1879	(93,3)	1879	(93,3)	3758	(93,3)
ACE-I or ARB	1467	(72,8)	1455	(72,3)	2922	(72,5)
MRA	1466	(72,8)	1503	(74,7)	2969	(73,7)
Sacubitril/Valsartan	351	(17,4)	379	(18,8)	730	(18,1)
Week 17 to Week 32	**1972[b]**		**1961[b]**		**3933[b]**	
Participant with any SOC Medication	1963	(99,5)	1954	(99,6)	3917	(99,6)
Beta Blocker	1835	(93,1)	1837	(93,7)	3672	(93,4)
ACE-I or ARB	1419	(72,0)	1404	(71,6)	2823	(71,8)
MRA	1437	(72,9)	1476	(75,3)	2913	(74,1)
Sacubitril/Valsartan	388	(19,7)	411	(21,0)	799	(20,3)
Week 33 to Week 48	**1705[b]**		**1690[b]**		**3395[b]**	
Participant with any SOC Medication	1693	(99,3)	1679	(99,3)	3372	(99,3)
Beta Blocker	1574	(92,3)	1578	(93,4)	3152	(92,8)
ACE-I or ARB	1190	(69,8)	1188	(70,3)	2378	(70,0)
MRA	1215	(71,3)	1266	(74,9)	2481	(73,1)
Sacubitril/Valsartan	333	(19,5)	354	(20,9)	687	(20,2)
Week 49 to Week 64	**1298[b]**		**1280[b]**		**2578[b]**	
Participant with any SOC Medication	1286	(99,1)	1270	(99,2)	2556	(99,1)
Beta Blocker	1201	(92,5)	1190	(93,0)	2391	(92,7)

Standard of Care for Heart Failure Treatment During Follow-Up
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
ACE-I or ARB	892	(68,7)	904	(70,6)	1796	(69,7)
MRA	918	(70,7)	941	(73,5)	1859	(72,1)
Sacubitril/Valsartan	265	(20,4)	266	(20,8)	531	(20,6)
Week 65 to Week 80	**965[b]**		**940[b]**		**1905[b]**	
Participant with any SOC Medication	952	(98,7)	932	(99,1)	1884	(98,9)
Beta Blocker	891	(92,3)	867	(92,2)	1758	(92,3)
ACE-I or ARB	665	(68,9)	648	(68,9)	1313	(68,9)
MRA	672	(69,6)	670	(71,3)	1342	(70,4)
Sacubitril/Valsartan	191	(19,8)	191	(20,3)	382	(20,1)
Week 81 to Week 96	**739[b]**		**722[b]**		**1461[b]**	
Participant with any SOC Medication	730	(98,8)	712	(98,6)	1442	(98,7)
Beta Blocker	687	(93,0)	666	(92,2)	1353	(92,6)
ACE-I or ARB	519	(70,2)	501	(69,4)	1020	(69,8)
MRA	523	(70,8)	505	(69,9)	1028	(70,4)
Sacubitril/Valsartan	141	(19,1)	144	(19,9)	285	(19,5)
Week 97 to Week 112	**506[b]**		**489[b]**		**995[b]**	
Participant with any SOC Medication	501	(99,0)	480	(98,2)	981	(98,6)
Beta Blocker	474	(93,7)	450	(92,0)	924	(92,9)
ACE-I or ARB	355	(70,2)	333	(68,1)	688	(69,1)
MRA	361	(71,3)	350	(71,6)	711	(71,5)
Sacubitril/Valsartan	94	(18,6)	100	(20,4)	194	(19,5)
Week 113 to Week 128	**285[b]**		**252[b]**		**537[b]**	
Participant with any SOC Medication	281	(98,6)	245	(97,2)	526	(98,0)
Beta Blocker	267	(93,7)	231	(91,7)	498	(92,7)
ACE-I or ARB	189	(66,3)	164	(65,1)	353	(65,7)
MRA	203	(71,2)	180	(71,4)	383	(71,3)
Sacubitril/Valsartan	54	(18,9)	55	(21,8)	109	(20,3)
Week 129 to Week 144	**65[b]**		**48[b]**		**113[b]**	
Participant with any SOC Medication	64	(98,5)	47	(97,9)	111	(98,2)
Beta Blocker	61	(93,8)	44	(91,7)	105	(92,9)
ACE-I or ARB	44	(67,7)	33	(68,8)	77	(68,1)
MRA	49	(75,4)	30	(62,5)	79	(69,9)
Sacubitril/Valsartan	14	(21,5)	13	(27,1)	27	(23,9)

a: Database Cutoff Date: 18JUN2019

b: Participants with follow-up in the corresponding time period

ACE-I: Angiotensin-Converting Enzyme Inhibitor; ARB: Angiotensin II Receptor Blocker; MRA: Mineralocorticoid Receptor Antagonist; SOC: Standard of Care

1.8 Standard of Care for Heart Failure Dose Modification During Follow-Up

Table 1.8-1
Standard of Care for Heart Failure Dose Modification During Follow-up
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
Subjects with data	2.104		2.101		4.205	
No standard of care dose reductions or discontinuation	1.160	(55,1)	1.142	(54,4)	2.302	(54,7)
Standard of care dose reductions or discontinuation at one or more visit	944	(44,9)	959	(45,6)	1.903	(45,3)
Due to hypotension	96	(4,6)	84	(4,0)	180	(4,3)
Due to subject or physician preference	739	(35,1)	752	(35,8)	1.491	(35,5)
Due to other reason(s)	278	(13,2)	310	(14,8)	588	(14,0)
Day 14						
Subjects with data	2.049		2.033		4.082	
No dose reductions or discontinuation	1.968	(96,0)	1.965	(96,7)	3.933	(96,3)
Dose reductions or discontinuation	81	(4,0)	68	(3,3)	149	(3,7)
Due to hypotension	9	(0,4)	8	(0,4)	17	(0,4)
Due to subject or physician preference	47	(2,3)	38	(1,9)	85	(2,1)
Due to other reason(s)	26	(1,3)	22	(1,1)	48	(1,2)
Day 28						
Subjects with data	2.043		2.052		4.095	
No dose reductions or discontinuation	1.832	(89,7)	1.818	(88,6)	3.650	(89,1)
Dose reductions or discontinuation	211	(10,3)	234	(11,4)	445	(10,9)
Due to hypotension	18	(0,9)	17	(0,8)	35	(0,9)
Due to subject or physician preference	154	(7,5)	172	(8,4)	326	(8,0)
Due to other reason(s)	44	(2,2)	51	(2,5)	95	(2,3)
Week 16						
Subjects with data	1.869		1.895		3.764	
No dose reductions or discontinuation	1.482	(79,3)	1.494	(78,8)	2.976	(79,1)
Dose reductions or discontinuation	387	(20,7)	401	(21,2)	788	(20,9)
Due to hypotension	25	(1,3)	25	(1,3)	50	(1,3)
Due to subject or physician preference	285	(15,2)	280	(14,8)	565	(15,0)
Due to other reason(s)	88	(4,7)	109	(5,8)	197	(5,2)
Week 32						
Subjects with data	1.558		1.558		3.116	
No dose reductions or discontinuation	1.229	(78,9)	1.221	(78,4)	2.450	(78,6)
Dose reductions or discontinuation	329	(21,1)	337	(21,6)	666	(21,4)
Due to hypotension	20	(1,3)	15	(1,0)	35	(1,1)
Due to subject or physician preference	246	(15,8)	244	(15,7)	490	(15,7)
Due to other reason(s)	70	(4,5)	85	(5,5)	155	(5,0)
Week 48						
Subjects with data	1.134		1.103		2.237	

Standard of Care for Heart Failure Dose Modification During Follow-up
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
Week 48						
No dose reductions or discontinuation	923	(81,4)	877	(79,5)	1.800	(80,5)
Dose reductions or discontinuation	211	(18,6)	226	(20,5)	437	(19,5)
Due to hypotension	12	(1,1)	10	(0,9)	22	(1,0)
Due to subject or physician preference	157	(13,8)	169	(15,3)	326	(14,6)
Due to other reason(s)	45	(4,0)	51	(4,6)	96	(4,3)
Week 64						
Subjects with data	830		787		1.617	
No dose reductions or discontinuation	688	(82,9)	630	(80,1)	1.318	(81,5)
Dose reductions or discontinuation	142	(17,1)	157	(19,9)	299	(18,5)
Due to hypotension	13	(1,6)	8	(1,0)	21	(1,3)
Due to subject or physician preference	105	(12,7)	115	(14,6)	220	(13,6)
Due to other reason(s)	26	(3,1)	35	(4,4)	61	(3,8)
Week 80						
Subjects with data	612		592		1.204	
No dose reductions or discontinuation	520	(85,0)	494	(83,4)	1.014	(84,2)
Dose reductions or discontinuation	92	(15,0)	98	(16,6)	190	(15,8)
Due to hypotension	4	(0,7)	12	(2,0)	16	(1,3)
Due to subject or physician preference	72	(11,8)	64	(10,8)	136	(11,3)
Due to other reason(s)	18	(2,9)	24	(4,1)	42	(3,5)
Week 96						
Subjects with data	416		389		805	
No dose reductions or discontinuation	356	(85,6)	342	(87,9)	698	(86,7)
Dose reductions or discontinuation	60	(14,4)	47	(12,1)	107	(13,3)
Due to hypotension	6	(1,4)	1	(0,3)	7	(0,9)
Due to subject or physician preference	42	(10,1)	37	(9,5)	79	(9,8)
Due to other reason(s)	13	(3,1)	9	(2,3)	22	(2,7)
Week 112						
Subjects with data	227		187		414	
No dose reductions or discontinuation	191	(84,1)	165	(88,2)	356	(86,0)
Dose reductions or discontinuation	36	(15,9)	22	(11,8)	58	(14,0)
Due to hypotension	1	(0,4)	2	(1,1)	3	(0,7)
Due to subject or physician preference	27	(11,9)	15	(8,0)	42	(10,1)
Due to other reason(s)	10	(4,4)	5	(2,7)	15	(3,6)
Week 128						
Subjects with data	45		30		75	
No dose reductions or discontinuation	40	(88,9)	28	(93,3)	68	(90,7)
Dose reductions or discontinuation	5	(11,1)	2	(6,7)	7	(9,3)

Standard of Care for Heart Failure Dose Modification During Follow-up
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
Week 128						
Due to hypotension	0	(0,0)	0	(0,0)	0	(0,0)
Due to subject or physician preference	4	(8,9)	2	(6,7)	6	(8,0)
Due to other reason(s)	1	(2,2)	0	(0,0)	1	(1,3)

Counts and percentages reported at each visit only include those reported during the time window associated with that visit

Standard of Care is per PI discretion based on locally relevant guidelines

1.9 Treatment Compliance

Table 1.9-1
Summary of Treatment Compliance
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
Participants in population	2152		2151		4303	
Treatment compliance						
≤20%	7	(0,3)	12	(0,6)	19	(0,4)
>20% to ≤40%	10	(0,5)	14	(0,7)	24	(0,6)
>40% to ≤60%	26	(1,2)	26	(1,2)	52	(1,2)
>60% to ≤80%	90	(4,2)	90	(4,2)	180	(4,2)
>80% to ≤90%	153	(7,1)	176	(8,2)	329	(7,6)
>90% to ≤100%	1866	(86,7)	1833	(85,2)	3699	(86,0)
Summary statistics for treatment compliance (%)						
Mean	95,2		94,8		95,0	
SD	10,4		11,4		10,9	
Median	99,2		99,1		99,1	
Min; Max	1,4;100,0		4,7;100,0		1,4;100,0	

a: Database Cutoff Date: 18JUN2019
Max: Maximum; Min: Minimum; SD: Standard Deviation

1.10 Standard of Care for Heart Failure Dose Increase/New Medication Start During Follow-up

Table 1.10-1
Standard of Care Dose Increase or New Therapy Start
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
Subjects with data	2155		2156		4311	
No standard of care dose increases or start of new medication	1312	(60,9)	1263	(58,6)	2575	(59,7)
Standard of care dose increase or start of new medication	843	(39,1)	893	(41,4)	1736	(40,3)

a: Database Cut-off Date: 18JUN2019

Dose increase: for each medication name, an increase in daily dose compared with baseline record for this medication name, at any post-baseline visit

New medication class start: at any post-baseline visit, occurrence of a new medication class (as presented in a standard of care for heart failure summaries) compared with medication class

SOC: Standard of Care

1.11 Standard of Care for Heart Failure Treatment at Baseline

Table 1.11-1
Standard of Care for Heart Failure Treatment at Baseline
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Total**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**
Subjects in population	2158		2158		4316	
Subjects with data	2154		2155		4309	
Two or more SOC Medications with individual RAS Inhibitors						
No	181	(8,4)	166	(7,7)	347	(8,1)
Yes	1973	(91,6)	1989	(92,3)	3962	(91,9)
MRA + ACE-I/ARB	63	(2,9)	64	(3,0)	127	(2,9)
Beta Blocker + S/V	96	(4,5)	63	(2,9)	159	(3,7)
Beta Blocker + ACE-I/ARB	363	(16,9)	364	(16,9)	727	(16,9)
MRA + Beta Blocker	137	(6,4)	132	(6,1)	269	(6,2)
MRA + Beta Blocker + S/V	209	(9,7)	233	(10,8)	442	(10,3)
MRA + Beta Blocker + ACE-I/ARB	1100	(51,1)	1122	(52,1)	2222	(51,6)
MRA + S/V	16	(0,7)	24	(1,1)	40	(0,9)

a: Database Cutoff Date: 18JUN2019

Participants receiving both Sacubitril/Valsartan and ACE-I/ARB are counted once for each corresponding category

ACE-I: Angiotensin-Converting Enzyme Inhibitor; ARB: Angiotensin II Receptor Blocker; MRA: Mineralocorticoid Receptor Antagonist; S/V: Sacubitril/Valsartan; SOC: Standard of Care

1.12 Extent of Exposure to Vericiguat

Table 1.12-1
Extent of Exposure to Vericiguat by Planned Dose
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study:MK-1242-001[a]											
Vericiguat	**≤2 wks**	**> 2 wks to 4 wks**	**> 4 wks to 16 wks**	**>16 wks to 32 wks**	**> 32 wks to 1 yr**	**>1 yr to 2 yrs**	**>2 yrs to 3 yrs**	**> 3 yrs**	**Total Subjects**	**Duration (days) Min; Max**	**Mean Duration (days)**
Any Dose	62	68	238	350	476	691	267	0	2152	1;964	375,7
2.5 mg	1022	717	274	81	36	15	5	0	2150	1;918	35,8
5 mg	985	435	328	117	44	44	2	0	1955	1;861	50,0
10 mg	43	34	198	379	358	570	177	0	1759	1;935	360,0

a: Database Cutoff Date: 18JUN2019
Each subject who received at least one dose of Vericiguat (including doses other than 2.5, 5, or 10 mg) is counted in the "Any Dose" row
Each subject is counted once in each specific dose category row, corresponding to the actual dose(s) received
Within each applicable specific dose row, the subject is counted once in the column that reflects the duration of exposure to that specific dose
Duration of exposure is calculated assuming one day of dosing on days of exposure
Max: Maximum; Min: Minimum

1.13 Extent of Exposure to Placebo

Table 1.13-1
Extent of Exposure to Placebo
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study:MK-1242-001[a]											
Placebo	**≤2 wks**	**> 2 wks to 4 wks**	**> 4 wks to 16 wks**	**>16 wks to 32 wks**	**> 32 wks to 1 yr**	**>1 yr to 2 yrs**	**>2 yrs to 3 yrs**	**> 3 yrs**	**Total Subjects**	**Duration (days) Min; Max**	**Mean Duration (days)**
Any Dose	71	47	222	372	515	689	235	0	2151	1;938	371,1
a: Database Cutoff Date: 18JUN2019 Duration of exposure is calculated assuming one day of dosing on days of exposure Max: Maximum; Min: Minimum											

1.14 Follow-up Time and Observation Periods for ITT Population with Screening Ejection Fraction <40%

Table 1.14-1
Summary of Observation Period
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat	Placebo
Follow-up Time (Months)[b]		
N	2158	2158
Mean (SD)	15,2 (8,0)	15,0 (7,9)
Median (Q1; Q3)	13,8 (8,4; 21,9)	13,4 (8,5; 21,8)
Min; Max	0,1; 32,3	0,2; 31,6
Observation Period (Months)		
CEC Confirmed Cardiovascular Death[c]		
N	2158	2158
Mean (SD)	15,2 (8,0)	15,0 (7,9)
Median (Q1; Q3)	13,8 (8,4; 21,9)	13,4 (8,3; 21,7)
Min; Max	0,1; 32,3	0,2; 31,6
CEC Confirmed All Cause Mortality[c]		
N	2158	2158
Mean (SD)	15,2 (8,0)	15,0 (7,9)
Median (Q1; Q3)	13,8 (8,4; 21,9)	13,4 (8,3; 21,7)
Min; Max	0,1; 32,3	0,2; 31,6
First Event of CEC Confirmed CV Death or Heart Failure Hospitalization[c]		
N	2158	2158
Mean (SD)	12,6 (8,4)	12,1 (8,4)
Median (Q1; Q3)	11,0 (6,4; 19,1)	10,2 (5,8; 18,4)
Min; Max	0,0; 32,3	0,0; 31,6
First Event of CEC Confirmed All Cause Death or Heart Failure Hospitalization[c]		
N	2158	2158
Mean (SD)	12,6 (8,4)	12,1 (8,4)
Median (Q1; Q3)	11,0 (6,4; 19,1)	10,2 (5,8; 18,4)
Min; Max	0,0; 32,3	0,0; 31,6
First Event of CEC Confirmed CV Death, MI Hospitalization or Stroke Hospitalization[c]		
N	2158	2158
Mean (SD)	14,9 (8,1)	14,6 (7,9)
Median (Q1; Q3)	13,5 (8,2; 21,4)	13,0 (8,0; 21,4)
Min; Max	0,0; 32,3	0,0; 31,6
First Event of CEC Confirmed HF Hospitalization or Urgent HF Visit[d]		
N	2158	2158
Mean (SD)	12,4 (8,5)	11,9 (8,3)
Median (Q1; Q3)	10,7 (6,2; 18,9)	10,0 (5,6; 17,9)
Min; Max	0,0; 32,3	0,0; 31,6
First Event of CEC Confirmed HF Hospitalization[d]		
N	2158	2158
Mean (SD)	12,6 (8,4)	12,0 (8,3)

Summary of Observation Period
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**	**Placebo**
Median (Q1; Q3)	11,0 (6,4; 19,1)	10,2 (5,8; 18,3)
Min; Max	0,0; 32,3	0,0; 31,6
First and Recurrent Event of CEC Confirmed HF Hospitalization[d]		
N	2158	2158
Mean (SD)	15,1 (8,0)	14,9 (7,9)
Median (Q1; Q3)	13,7 (8,3; 21,9)	13,3 (8,3; 21,7)
Min; Max	0,0; 32,3	0,0; 31,6
First Event of CEC Confirmed Urgent HF Visit[d]		
N	2158	2158
Mean (SD)	14,6 (8,1)	14,4 (8,0)
Median (Q1; Q3)	13,2 (8,0; 21,1)	12,8 (7,9; 21,0)
Min; Max	0,0; 32,3	0,0; 31,6
First Event of CEC Confirmed CV Hospitalization[d]		
N	2158	2158
Mean (SD)	11,6 (8,4)	10,8 (8,2)
Median (Q1; Q3)	9,6 (5,1; 17,5)	8,9 (3,9; 16,3)
Min; Max	0,0; 32,3	0,0; 31,6
First Event of CEC Confirmed MI Hospitalization[d]		
N	2158	2158
Mean (SD)	14,9 (8,1)	14,7 (7,9)
Median (Q1; Q3)	13,5 (8,3; 21,6)	13,1 (8,2; 21,5)
Min; Max	0,0; 32,3	0,0; 31,6
First Event of CEC Confirmed Stroke Hospitalization[d]		
N	2158	2158
Mean (SD)	15,0 (8,1)	14,8 (7,9)
Median (Q1; Q3)	13,6 (8,3; 21,8)	13,2 (8,3; 21,6)
Min; Max	0,0; 32,3	0,0; 31,6

N = Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

a: Database Cutoff Date: 18JUN2019

b: Calculated from date of randomization to date of death or data cut-off date if the participant is still alive at the time of data cut-off

c: Calculated from date of randomization to date of first occurrence of the endpoint event, last available information on the endpoint event, or primary completion (data cut-off) date if no endpoint event was observed for the participant

d: Calculated from date of randomization to date of first occurrence of the endpoint event, date of death, last available information on the endpoint event, or primary completion (data cut-off) date if no endpoint event was observed for the participant

CEC:Clinical Events Committee; Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile;
SD: Standard Deviation

1.15 Follow-up Time and Observation Periods for ASaT Population with Screening Ejection Fraction <40%

Table 1.15-1
Summary of Observation Period
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat	Placebo
Duration of Treatment [b] (Months)		
N[c]	2152	2151
Mean (SD)	13,3 (8,6)	13,2 (8,3)
Median (Q1; Q3)	11,8 (7,0; 20,0)	11,5 (7,2; 19,8)
Min; Max	0,0; 33,0	0,0; 32,4
Follow-up Time (Months)[d]		
N[c]	2152	2151
Mean (SD)	15,2 (8,0)	15,0 (7,9)
Median (Q1; Q3)	13,8 (8,4; 21,9)	13,4 (8,5; 21,8)
Min; Max	0,1; 32,3	0,2; 31,6
Observation Period (Months)		
Adverse Event[e]		
N[c]	2152	2151
Mean (SD)	13,1 (8,4)	12,9 (8,1)
Median (Q1; Q3)	11,4 (6,7; 19,7)	11,3 (6,8; 19,5)
Min; Max	0,1; 32,3	0,2; 31,2
Serious Adverse Event[e]		
N[c]	2152	2151
Mean (SD)	13,1 (8,4)	12,9 (8,1)
Median (Q1; Q3)	11,4 (6,7; 19,7)	11,3 (6,8; 19,5)
Min; Max	0,1; 32,3	0,2; 31,2
EQ-5D Visual Analog Scale[f]		
N[g]	2115	2117
Mean (SD)	9,8 (6,6)	9,8 (6,5)
Median (Q1; Q3)	10,3 (4,1; 11,3)	10,3 (4,1; 11,3)
Min; Max	0,0; 28,5	0,0; 29,9
KCCQ[f]		
N[g]	2115	2119
Mean (SD)	9,8 (6,6)	9,8 (6,5)
Median (Q1; Q3)	10,4 (4,1; 11,3)	10,4 (4,1; 11,3)
Min; Max	0,0; 28,5	0,0; 29,9

a: Database Cutoff Date: 18JUN2019
b: Calculated from date of first dose until date of last dose
c: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
d: Calculated from date of first dose until date of death or data cut-off date if the participant is still alive at the time of data cut-off
e: Calculated from date of first dose to the earliest of the date of last dose + 14 days, date of death, or the data cut-off date if the participant was still alive at the time of data cut-off
f: Calculated from date of first dose to the earliest of the date of last questionnaire assessment
g: Number of participants with at least one questionnaire assessment in ASaT population with screening ejection fraction < 40%
EQ-5D: EuroQol 5 Dimensions; KCCQ: Kansas City Cardiomyopathy Questionnaire; Max: Maximum; Min: Minimum;
Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

1.16 Summary Statistics in Weight (kg) Over Time

Table 1.16-1
Summary Statistics in Weight (kg) Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Weight	Study: MK-1242-001[a]	
	Vericiguat N[b]=2152	Placebo N[b]=2151
Baseline		
N[c]	2152	2148
Mean (SD)	78,4 (20,2)	79,2 (20,9)
Median (Q1;Q3)	76,0 (64,3;89,0)	76,4 (65,2;90,2)
Min; Max	32,50;181,60	34,20;195,00
Day 14		
N[c]	2113	2109
Mean (SD)	78,5 (20,2)	79,4 (21,9)
Median (Q1;Q3)	75,8 (64,4;89,0)	76,0 (65,3;90,2)
Min; Max	32,70;182,20	34,60;414,80
Day 28		
N[c]	2059	2056
Mean (SD)	78,7 (20,2)	79,3 (20,8)
Median (Q1;Q3)	76,0 (65,0;89,0)	76,0 (65,5;90,0)
Min; Max	32,20;183,30	34,00;196,86
Week 16		
N[c]	1914	1924
Mean (SD)	79,0 (20,9)	79,6 (20,6)
Median (Q1;Q3)	76,2 (64,8;90,0)	76,8 (66,0;90,7)
Min; Max	32,90;318,00	31,80;199,13
Week 32		
N[c]	1615	1605
Mean (SD)	79,5 (20,6)	80,4 (21,2)
Median (Q1;Q3)	77,0 (65,0;90,0)	77,1 (66,0;91,8)

Min; Max	33,70;192,70	30,10;189,60
Week 48		
N[c]	1177	1160
Mean (SD)	79,5 (20,7)	80,6 (21,2)
Median (Q1;Q3)	77,0 (65,0;90,6)	78,0 (66,0;92,0)
Min; Max	31,30;170,55	33,00;192,30
Week 64		
N[c]	864	833
Mean (SD)	80,9 (21,3)	81,6 (21,0)
Median (Q1;Q3)	77,9 (65,8;93,0)	79,0 (67,2;93,0)
Min; Max	31,90;182,35	27,65;193,80
Week 80		
N[c]	646	634
Mean (SD)	81,9 (21,3)	82,8 (21,3)

Summary Statistics in Weight (kg) Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Weight	Study: MK-1242-001[a]	
	Vericiguat N[b]=2152	**Placebo N[b]=2151**
Median (Q1;Q3)	79,3 (67,0;94,0)	80,0 (68,0;95,1)
Min; Max	30,00;164,80	38,50;174,80
Week 96		
N[c]	436	419
Mean (SD)	81,6 (21,3)	83,9 (22,8)
Median (Q1;Q3)	78,5 (66,3;93,0)	80,9 (67,0;98,2)
Min; Max	31,40;173,00	40,50;193,20
Week 112		
N[c]	239	202
Mean (SD)	81,1 (21,5)	86,2 (23,8)
Median (Q1;Q3)	77,4 (66,5;94,0)	82,6 (70,8;99,8)
Min; Max	31,50;161,94	42,70;173,00
Week 128		
N[c]	49	33
Mean (SD)	79,7 (16,1)	82,0 (21,9)
Median (Q1;Q3)	75,8 (69,7;92,0)	78,0 (69,5;93,0)
Min; Max	48,50;114,00	44,50;133,00

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Number of participants with non-missing assessments at the specific timepoint
Baseline is defined as last value obtained prior to the first dose of study treatment during treatment phase
Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

1.17 Summary Statistics in Systolic Blood Pressure (mm Hg) Over Time

Table 1.17-1
Summary Statistics in Systolic Blood Pressure (mm Hg) Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40% and medical history of Hypertension

Systolic Blood Pressure	Study: MK-1242-001[a]	
	Vericiguat N[b]=1685	**Placebo N[b]=1678**
Baseline		
N[c]	1685	1678
Mean (SD)	122,0 (15,7)	122,3 (15,5)
Median (Q1;Q3)	120,0 (110,0;131,0)	120,0 (110,0;132,0)
Min; Max	93,00;192,00	93,00;216,00
Day 14		
N[c]	1684	1676
Mean (SD)	118,7 (17,0)	120,4 (17,3)
Median (Q1;Q3)	117,0 (106,5;130,0)	119,0 (108,0;131,0)
Min; Max	63,00;198,00	71,00;214,00
Day 28		
N[c]	1620	1609
Mean (SD)	118,3 (17,3)	120,0 (17,5)
Median (Q1;Q3)	116,5 (106,0;130,0)	118,0 (108,0;130,0)
Min; Max	77,00;197,00	70,00;202,00
Week 16		
N[c]	1496	1509
Mean (SD)	120,7 (18,3)	121,9 (18,1)
Median (Q1;Q3)	119,0 (108,0;132,0)	121,0 (109,0;134,0)
Min; Max	68,00;214,00	70,00;189,00
Week 32		
N[c]	1267	1283
Mean (SD)	121,6 (18,0)	122,5 (18,6)
Median (Q1;Q3)	120,0 (109,0;133,0)	121,0 (109,0;134,0)
Min; Max	74,00;193,00	72,00;214,00

Week 48		
N[c] Mean (SD) Median (Q1;Q3) Min; Max	918 122,5 (18,5) 121,0 (109,0;134,0) 70,00;199,00	937 123,4 (18,9) 123,0 (110,0;135,0) 66,00;197,00
Week 64		
N[c] Mean (SD) Median (Q1;Q3) Min; Max	685 121,5 (18,1) 121,0 (108,0;133,0) 74,00;185,00	666 122,6 (17,7) 122,0 (110,0;134,0) 76,00;187,00
Week 80		
N[c] Mean (SD)	504 121,6 (17,8)	507 122,3 (17,2)

Summary Statistics in Systolic Blood Pressure (mm Hg) Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40% and medical history of Hypertension

Systolic Blood Pressure	**Study: MK-1242-001[a]**	
	Vericiguat N[b]=1685	**Placebo N[b]=1678**
Median (Q1;Q3)	122,0 (107,5;133,0)	122,0 (110,0;133,0)
Min; Max	71,00;212,00	78,00;182,00
Week 96		
N[c]	340	335
Mean (SD)	123,3 (18,4)	123,4 (17,1)
Median (Q1;Q3)	122,0 (109,5;134,0)	122,0 (112,0;134,0)
Min; Max	78,00;181,00	65,00;180,00
Week 112		
N[c]	184	155
Mean (SD)	121,9 (17,6)	121,5 (16,3)
Median (Q1;Q3)	122,0 (109,5;132,0)	120,0 (110,0;132,0)
Min; Max	73,00;164,00	81,00;185,00
Week 128		
N[c]	38	28
Mean (SD)	121,0 (18,0)	119,0 (13,3)
Median (Q1;Q3)	118,0 (109,0;135,0)	120,0 (112,5;126,5)
Min; Max	89,00;165,00	92,00;146,00

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and medical history of Hypertension
c: Number of participants with non-missing assessments at the specific timepoint
Baseline is defined as last value obtained prior to the first dose of study treatment during treatment phase
Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

1.18 Summary Statistics in Diastolic Blood Pressure (mm Hg) Over Time

Table 1.18-1
Summary Statistics in Diastolic Blood Pressure (mm Hg) Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40% and medical history of Hypertension

Diastolic Blood Pressure	Study: MK-1242-001[a]	
	Vericiguat N[b]=1685	**Placebo N[b]=1678**
Baseline		
N[c]	1685	1678
Mean (SD)	72,9 (11,0)	73,8 (11,1)
Median (Q1;Q3)	72,0 (65,0;80,0)	73,0 (66,0;81,0)
Min; Max	29,00;117,00	44,00;117,00
Day 14		
N[c]	1684	1676
Mean (SD)	70,9 (11,4)	72,3 (11,5)
Median (Q1;Q3)	70,0 (62,0;79,0)	72,0 (64,0;80,0)
Min; Max	23,00;120,00	34,00;132,00
Day 28		
N[c]	1620	1609
Mean (SD)	70,2 (11,3)	72,0 (11,5)
Median (Q1;Q3)	70,0 (62,0;78,0)	71,0 (64,0;79,0)
Min; Max	19,00;113,00	38,00;137,00
Week 16		
N[c]	1496	1509
Mean (SD)	71,3 (11,9)	72,7 (12,3)
Median (Q1;Q3)	71,0 (63,0;79,0)	72,0 (64,0;81,0)
Min; Max	30,00;149,00	38,00;139,00
Week 32		
N[c]	1267	1283
Mean (SD)	71,5 (12,0)	73,2 (11,9)
Median (Q1;Q3)	71,0 (63,0;79,0)	73,0 (65,0;81,0)
Min; Max	30,00;120,00	37,00;124,00

Week 48		
N[c]	918	937
Mean (SD)	72,0 (12,1)	72,9 (12,5)
Median (Q1;Q3)	71,0 (64,0;80,0)	73,0 (64,0;81,0)
Min; Max	8,00;113,00	40,00;127,00
Week 64		
N[c]	684	666
Mean (SD)	71,1 (11,4)	72,5 (11,9)
Median (Q1;Q3)	70,0 (63,0;79,0)	72,0 (64,0;80,0)
Min; Max	36,00;108,00	36,00;118,00
Week 80		
N[c]	504	507
Mean (SD)	71,6 (11,5)	72,8 (11,6)

Summary Statistics in Diastolic Blood Pressure (mm Hg) Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40% and medical history of Hypertension

Diastolic Blood Pressure	**Study: MK-1242-001[a]**	
	Vericiguat N[b]=1685	**Placebo N[b]=1678**
Median (Q1;Q3)	71,0 (63,5;79,0)	73,0 (65,0;80,0)
Min; Max	40,00;119,00	41,00;120,00
Week 96		
N[c]	340	335
Mean (SD)	71,8 (11,6)	73,7 (11,7)
Median (Q1;Q3)	71,0 (64,0;79,0)	74,0 (66,0;82,0)
Min; Max	40,00;117,00	46,00;112,00
Week 112		
N[c]	184	155
Mean (SD)	71,0 (10,6)	72,1 (12,2)
Median (Q1;Q3)	70,5 (64,5;78,5)	72,0 (63,0;80,0)
Min; Max	47,00;104,00	45,00;113,00
Week 128		
N[c]	38	28
Mean (SD)	70,8 (8,6)	71,9 (12,5)
Median (Q1;Q3)	70,5 (65,0;75,0)	73,0 (61,0;81,5)
Min; Max	55,00;87,00	49,00;94,00

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and medical history of Hypertension
c: Number of participants with non-missing assessments at the specific timepoint
Baseline is defined as last value obtained prior to the first dose of study treatment during treatment phase
Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

1.19 Summary Statistics in Hemoglobin A1c (%) Over Time

Table 1.19-1
Summary Statistics in Hemoglobin A1c (%) Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40% and medical history of Diabetes Mellitus

Hemoglobin A1c	**Study: MK-1242-001[a]**	
	Vericiguat N[b]=1047	**Placebo N[b]=984**
Baseline		
N[c]	1002	947
Mean (SD)	7,6 (1,6)	7,6 (1,6)
Median (Q1;Q3)	7,2 (6,5;8,4)	7,2 (6,5;8,3)
Min; Max	4,70;16,00	4,00;16,20
Week 16		
N[c]	874	838
Mean (SD)	7,4 (1,8)	7,5 (1,7)
Median (Q1;Q3)	6,9 (6,2;8,1)	7,1 (6,4;8,3)
Min; Max	4,50;18,90	4,00;15,00
Week 32		
N[c]	699	664
Mean (SD)	7,5 (1,7)	7,6 (1,8)
Median (Q1;Q3)	7,0 (6,2;8,2)	7,1 (6,4;8,5)
Min; Max	4,00;16,80	4,40;15,90
Week 48		
N[c]	514	479
Mean (SD)	7,5 (1,8)	7,6 (1,8)
Median (Q1;Q3)	7,0 (6,2;8,1)	7,2 (6,4;8,3)
Min; Max	4,70;16,70	4,70;15,00
Week 96		
N[c]	171	158
Mean (SD)	7,5 (1,5)	7,8 (1,7)
Median (Q1;Q3)	7,1 (6,4;8,4)	7,4 (6,6;8,8)
Min; Max	5,10;15,20	5,00;13,20

Week 144		
N[c]	0	1
Mean (SD)		9,9 (.)
Median (Q1;Q3)		9,9 (9,9;9,9)
Min; Max		9,90;9,90

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and medical history of Diabetes Mellitus

c: Number of participants with non-missing assessments at the specific timepoint

Baseline is defined as last value obtained prior to the first dose of study treatment during treatment phase

Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

MORTALITY AND MORBIDITY

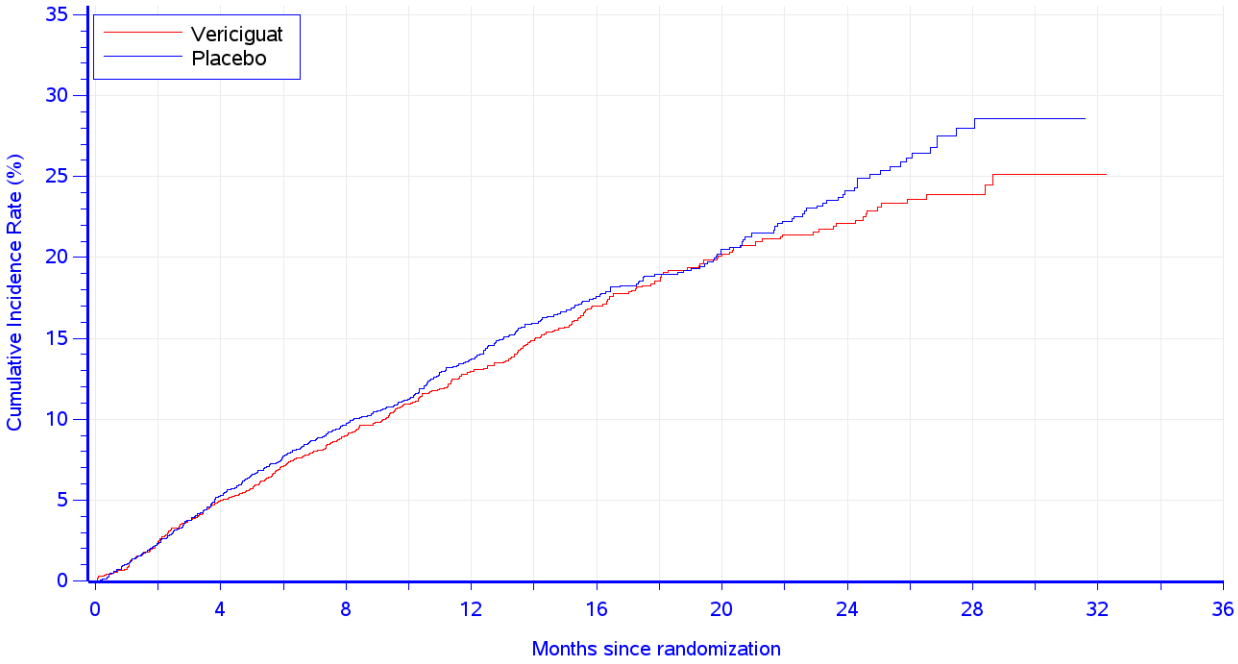
2.1 CEC Confirmed Cardiovascular Death

Table 2.14.1-1
Time to CEC Confirmed Cardiovascular Death
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat				Placebo				Vericiguat vs. Placebo	
	N[b]	Participants with Event n (%)	Annual %[c]	Median Time[d] in months [95 %-CI]	N[b]	Participants with Event n (%)	Annual %[c]	Median Time[d] in months [95 %-CI]	Hazard Ratio [95 %-CI][e]	p-Value[f]
CV Death	2158	358 (16,6)	13,1	Not reached [.; .]	2158	384 (17,8)	14,3	Not reached [.; .]	0,92 [0,80; 1,06]	0,256
Heart Failure	2158	149 (6,9)			2158	176 (8,2)				
Myocardial Infarction	2158	8 (0,4)			2158	10 (0,5)				
Other Cardiovascular Event	2158	12 (0,6)			2158	7 (0,3)				
Stroke	2158	6 (0,3)			2158	14 (0,6)				
Sudden Cardiac Death	2158	89 (4,1)			2158	93 (4,3)				
Undetermined Cause Of Death	2158	94 (4,4)			2158	84 (3,9)				

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular

Figure 2.14.1-1
Kaplan-Meier Plot Time to CEC Confirmed Cardiovascular Death
ITT Population Participants with Screening Ejection Fraction < 40%



Number at Risk										
Vericiguat	2158	2027	1678	1241	908	663	414	161	1	0
Placebo	2158	2024	1664	1223	892	652	395	129	0	0

Based on data up to the primary completion date (18JUN2019).

Table 2.14.1-2
Time to CEC Confirmed Cardiovascular Death
On-Treatment Analysis Censored at 14 Days after Study Drug Discontinuation
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
CV Death	2152	191 (8,9)	8,2	Not reached [.; .]	2151	209 (9,7)	9,0	Not reached [.; .]	0,91 [0,75; 1,11]	0,340
Heart Failure	2152	66 (3,1)			2151	82 (3,8)				
Myocardial Infarction	2152	6 (0,3)			2151	8 (0,4)				
Other Cardiovascular Event	2152	9 (0,4)			2151	5 (0,2)				
Stroke	2152	3 (0,1)			2151	7 (0,3)				
Sudden Cardiac Death	2152	71 (3,3)			2151	65 (3,0)				
Undetermined Cause Of Death	2152	36 (1,7)			2151	42 (2,0)				

a: Database Cut-off Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular

Table 2.14.1-3
Time to CEC Confirmed Cardiovascular Death
All Data through Last Study Visit
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
CV Death	2158	386 (17,9)	13,4	Not reached [.; .]	2158	403 (18,7)	14,1	Not reached [.; .]	0,95 [0,82; 1,09]	0,431
Heart Failure	2158	167 (7,7)			2158	185 (8,6)				
Myocardial Infarction	2158	9 (0,4)			2158	10 (0,5)				
Other Cardiovascular Event	2158	12 (0,6)			2158	8 (0,4)				
Stroke	2158	7 (0,3)			2158	14 (0,6)				
Sudden Cardiac Death	2158	94 (4,4)			2158	99 (4,6)				
Undetermined Cause Of Death	2158	97 (4,5)			2158	87 (4,0)				

a: Database Cut-off Date: 31OCT2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular

Table 2.14.1-4
Time to CEC Confirmed Cardiovascular Death
On-Treatment Analysis Censored at 14 Days after Study Drug Discontinuation - All Data through Last Study Visit
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
CV Death	2152	199 (9,2)	8,1	Not reached [.; .]	2151	220 (10,2)	9,0	Not reached [.; .]	0,90 [0,74; 1,09]	0,283
Heart Failure	2152	70 (3,3)			2151	84 (3,9)				
Myocardial Infarction	2152	7 (0,3)			2151	8 (0,4)				
Other Cardiovascular Event	2152	9 (0,4)			2151	6 (0,3)				
Stroke	2152	3 (0,1)			2151	7 (0,3)				
Sudden Cardiac Death	2152	73 (3,4)			2151	70 (3,3)				
Undetermined Cause Of Death	2152	37 (1,7)			2151	45 (2,1)				

a: Database Cut-off Date: 31OCT2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular

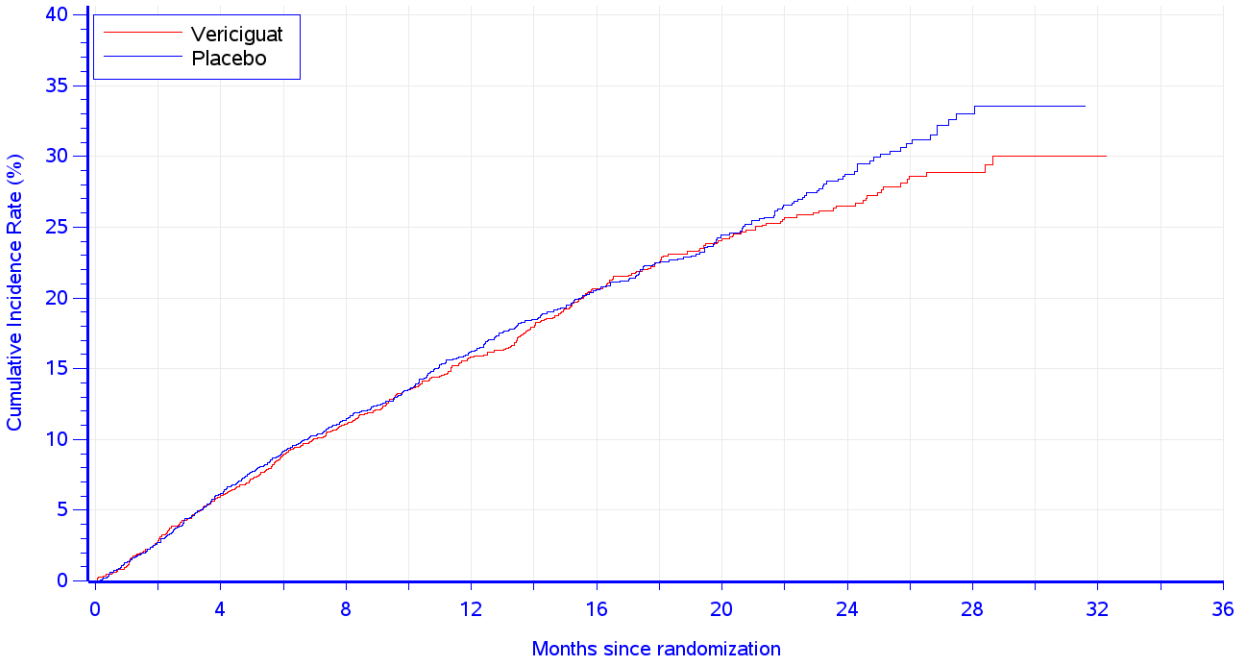
2.2 CEC Confirmed All Cause Mortality

Table 2.14.1-1
Time to CEC Confirmed All-cause Mortality
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
All-Cause Death	2158	443 (20,5)	16,2	Not reached [.; .]	2158	464 (21,5)	17,2	Not reached [.; .]	0,94 [0,83; 1,07]	0,363

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval

Figure 2.14.1-1
Kaplan-Meier Plot Time to CEC Confirmed All-cause Mortality
ITT Population Participants with Screening Ejection Fraction < 40%



Number at Risk										
Vericiguat	2158	2027	1678	1241	908	663	414	161	1	0
Placebo	2158	2024	1664	1223	892	652	395	129	0	0

Based on data up to the primary completion date (18JUN2019).

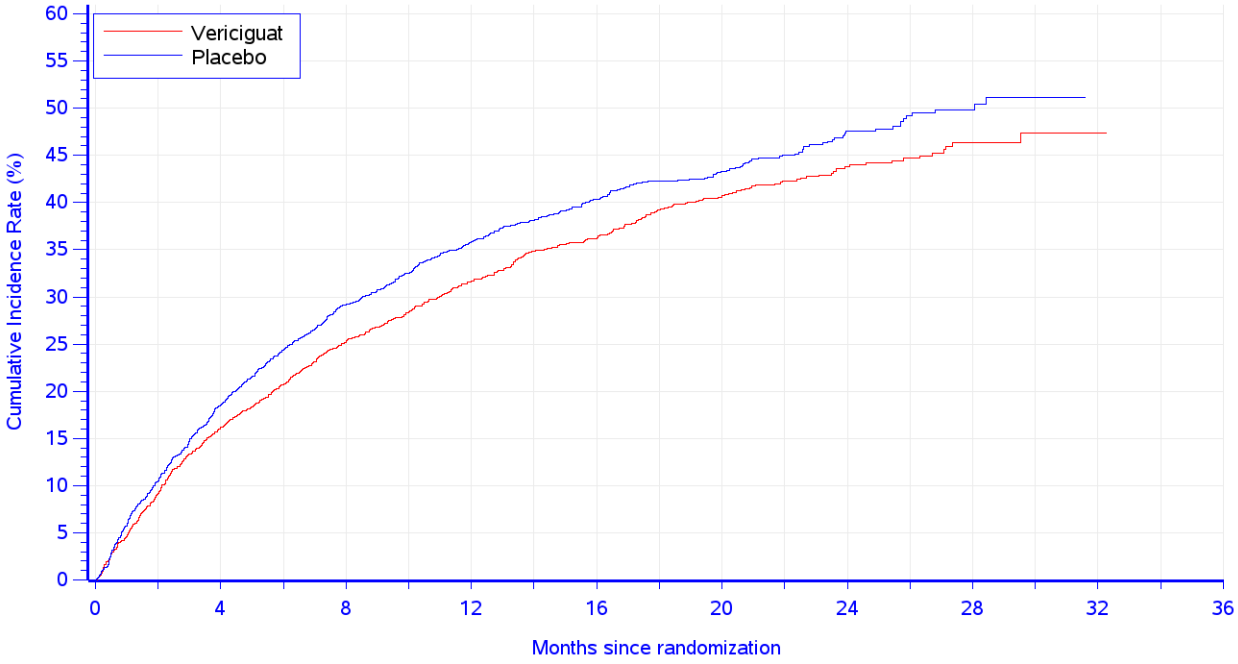
2.3 CEC Confirmed Cardiovascular Death or First Heart Failure Hospitalization

Table 2.14.1-1
Time to First Event of CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
CV Death or HF Hospitalization	2158	773 (35,8)	34,0	Not reached [29,5; .]	2158	851 (39,4)	39,3	28,1 [23,9; .]	0,88 [0,80; 0,97]	0,008
Cardiovascular Death	2158	171 (7,9)			2158	192 (8,9)				
Heart Failure Hospitalization	2158	602 (27,9)			2158	659 (30,5)				

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular; HF: Heart failure

Figure 2.14.1-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%



Number at Risk

Vericiguat									
2158	1789	1380	980	703	495	298	110	1	0
Placebo									
2158	1740	1308	918	648	471	271	91	0	0

Based on data up to the primary completion date (18JUN2019).

Table 2.14.1-2
Time to CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization
On-Treatment Analysis Censored at 14 Days after Study Drug Discontinuation
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
CV Death or HF Hospitalization	2152	636 (29,6)	31,3	Not reached [.; .]	2151	703 (32,7)	35,8	Not reached [.; .]	0,89 [0,80; 0,99]	0,033
Cardiovascular Death	2152	117 (5,4)			2151	128 (6,0)				
Heart Failure Hospitalization	2152	519 (24,1)			2151	575 (26,7)				

a: Database Cut-off Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular; HF: Heart failure

Table 2.14.1-3
Time to CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization
All Data through Last Study Visit
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
CV Death or HF Hospitalization	2158	802 (37,2)	33,5	31,1 [29,5; .]	2158	880 (40,8)	38,5	28,1 [23,9; .]	0,88 [0,80; 0,97]	0,008
Cardiovascular Death	2158	181 (8,4)			2158	203 (9,4)				
Heart Failure Hospitalization	2158	621 (28,8)			2158	677 (31,4)				

a: Database Cut-off Date: 31OCT2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular; HF: Heart failure

Table 2.14.1-4
Time to CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization
On-Treatment Analysis Censored at 14 Days after Study Drug Discontinuation - All Data through Last Study Visit
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
CV Death or HF Hospitalization	2152	656 (30,5)	30,9	Not reached [31,1; .]	2151	725 (33,7)	35,2	Not reached [29,8; .]	0,89 [0,80; 0,99]	0,028
Cardiovascular Death	2152	123 (5,7)			2151	137 (6,4)				
Heart Failure Hospitalization	2152	533 (24,8)			2151	588 (27,3)				

a: Database Cut-off Date: 31OCT2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular; HF: Heart failure

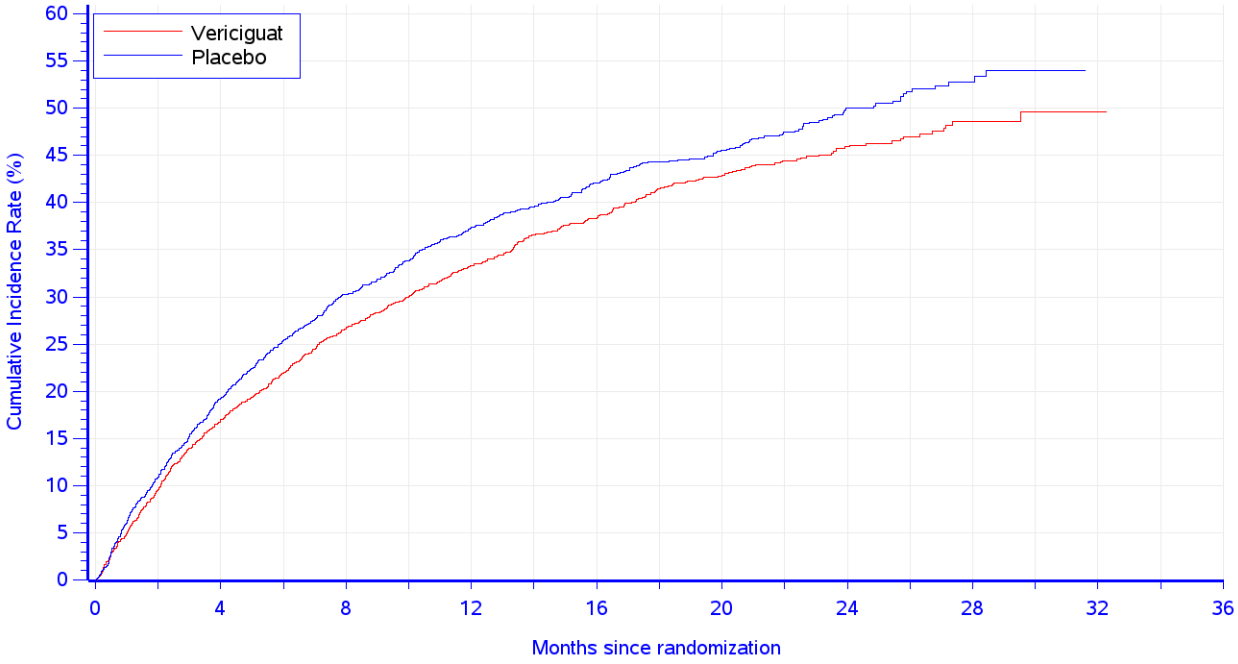
2.4 CEC Confirmed All-cause Mortality or First Heart Failure Hospitalization

Table 2.14.1-1
Time to First Event of CEC Confirmed All-cause Mortality or Heart Failure Hospitalization
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
All-Cause Death or HF Hospitalization	2158	825 (38,2)	36,3	Not reached [26,3; .]	2158	902 (41,8)	41,6	24,0 [22,3; 28,1]	0,88 [0,80; 0,97]	0,010
All-cause Mortality	2158	223 (10,3)			2158	243 (11,3)				
Heart Failure Hospitalization	2158	602 (27,9)			2158	659 (30,5)				

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; HF: Heart failure

Figure 2.14.1-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed All-cause Mortality or Heart Failure Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%



Number at Risk									
Vericiguat									
2158	1789	1380	980	703	495	298	110	1	0
Placebo									
2158	1740	1308	918	648	471	271	91	0	0

Based on data up to the primary completion date (18JUN2019).

Table 2.14.1-2
Time to First Event of CEC Confirmed All-cause Mortality or Heart Failure Hospitalization
On-Treatment Analysis Censored at 14 Days after Study Drug Discontinuation
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
All-Cause Death or HF Hospitalization	2152	664 (30,9)	32,7	Not reached [.; .]	2151	726 (33,8)	37,0	Not reached [.; .]	0,90 [0,81; 1,00]	0,048
All-cause Mortality	2152	145 (6,7)			2151	151 (7,0)				
Heart Failure Hospitalization	2152	519 (24,1)			2151	575 (26,7)				

a: Database Cut-off Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; HF: Heart failure

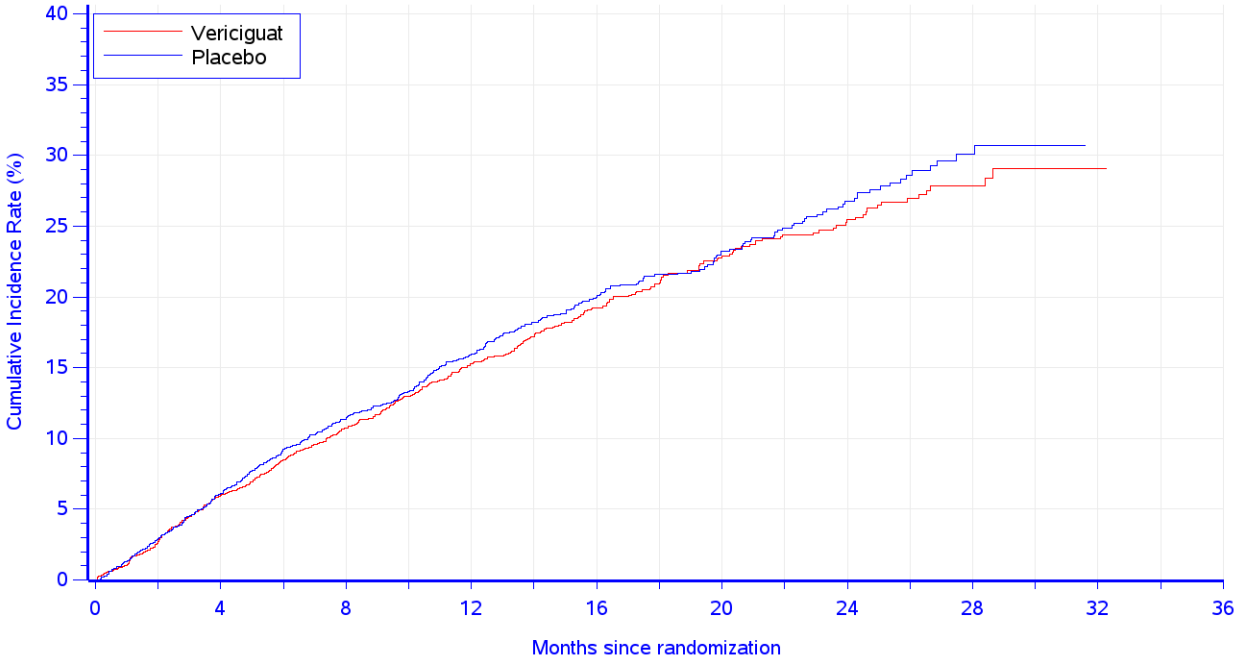
2.5 CEC Confirmed CV Death, First MI Hospitalization or Stroke Hospitalization

Table 2.14.1-1
Time to First Event of CEC Confirmed CV Death, MI Hospitalization or Stroke Hospitalization
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
CV Death, MI or Stroke Hospitalization	2158	413 (19,1)	15,5	Not reached [.; .]	2158	430 (19,9)	16,4	Not reached [.; .]	0,95 [0,83; 1,08]	0,414
Cardiovascular Death	2158	344 (15,9)			2158	362 (16,8)				
MI Hospitalization	2158	38 (1,8)			2158	37 (1,7)				
Stroke Hospitalization	2158	31 (1,4)			2158	31 (1,4)				

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular; MI: Myocardial infarction

Figure 2.14.1-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed CV Death, MI Hospitalization or Stroke Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%



Number at Risk									
Vericiguat									
2158	2003	1644	1211	881	637	394	154	1	0
Placebo									
2158	2004	1627	1184	856	621	378	125	0	0

Based on data up to the primary completion date (18JUN2019).

Table 2.14.1-2
Time to First Event of CEC Confirmed CV Death, MI Hospitalization or Stroke Hospitalization
On-Treatment Analysis Censored at 14 Days after Study Drug Discontinuation
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
CV Death, MI or Stroke Hospitalization	2152	246 (11,4)	10,7	Not reached [.; .]	2151	263 (12,2)	11,5	Not reached [.; .]	0,93 [0,78; 1,11]	0,413
Cardiovascular Death	2152	183 (8,5)			2151	202 (9,4)				
MI Hospitalization	2152	35 (1,6)			2151	31 (1,4)				
Stroke Hospitalization	2152	28 (1,3)			2151	30 (1,4)				

a: Database Cut-off Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular; MI: Myocardial infarction

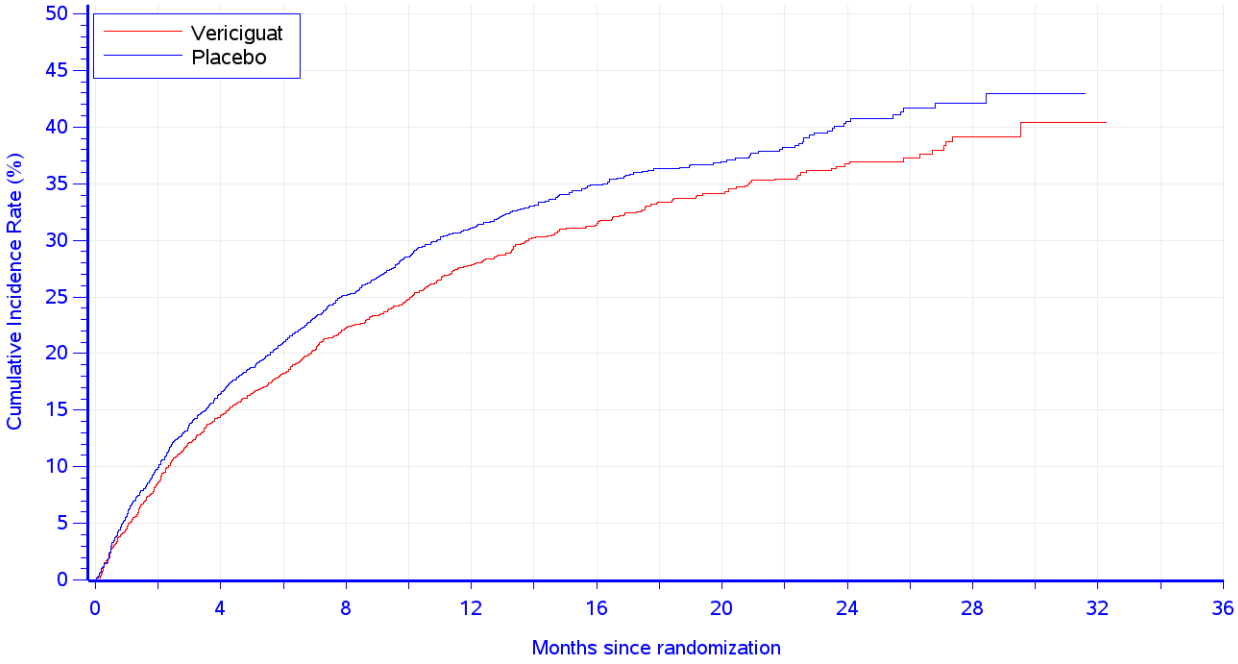
2.6 First CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit

Table 2.14.1-1
Time to First Event of CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat				Placebo				Vericiguat vs. Placebo	
	N[b]	Participants with Event n (%)	Annual %[c]	Median Time[d] in months [95 %-CI]	N[b]	Participants with Event n (%)	Annual %[c]	Median Time[d] in months [95 %-CI]	Hazard Ratio [95 %-CI][e]	p-Value[f]
HF Hospitalization or Urgent HF visit	2158	634 (29,4)	28,3	Not reached [.; .]	2158	697 (32,3)	32,7	Not reached [.; .]	0,88 [0,79; 0,98]	0,022
Heart Failure Hospitalization	2158	556 (25,8)			2158	621 (28,8)				
Urgent Heart Failure Visit	2158	78 (3,6)			2158	76 (3,5)				

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; HF: Heart failure

Figure 2.14.1-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit
ITT Population Participants with Screening Ejection Fraction < 40%



Number at Risk									
Vericiguat									
2158	1761	1355	956	684	488	291	109	1	0
Placebo									
2158	1719	1292	898	631	458	262	90	0	0

Based on data up to the primary completion date (18JUN2019).

Table 2.14.1-2
Time to First Event of CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit
On-Treatment Analysis Censored at 14 Days after Study Drug Discontinuation
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
HF Hospitalization or Urgent HF visit	2152	554 (25,7)	27,6	Not reached [.; .]	2151	614 (28,5)	31,7	Not reached [.; .]	0,89 [0,79; 1,00]	0,045
Heart Failure Hospitalization	2152	484 (22,5)			2151	543 (25,2)				
Urgent Heart Failure Visit	2152	70 (3,3)			2151	71 (3,3)				

a: Database Cut-off Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; HF: Heart failure

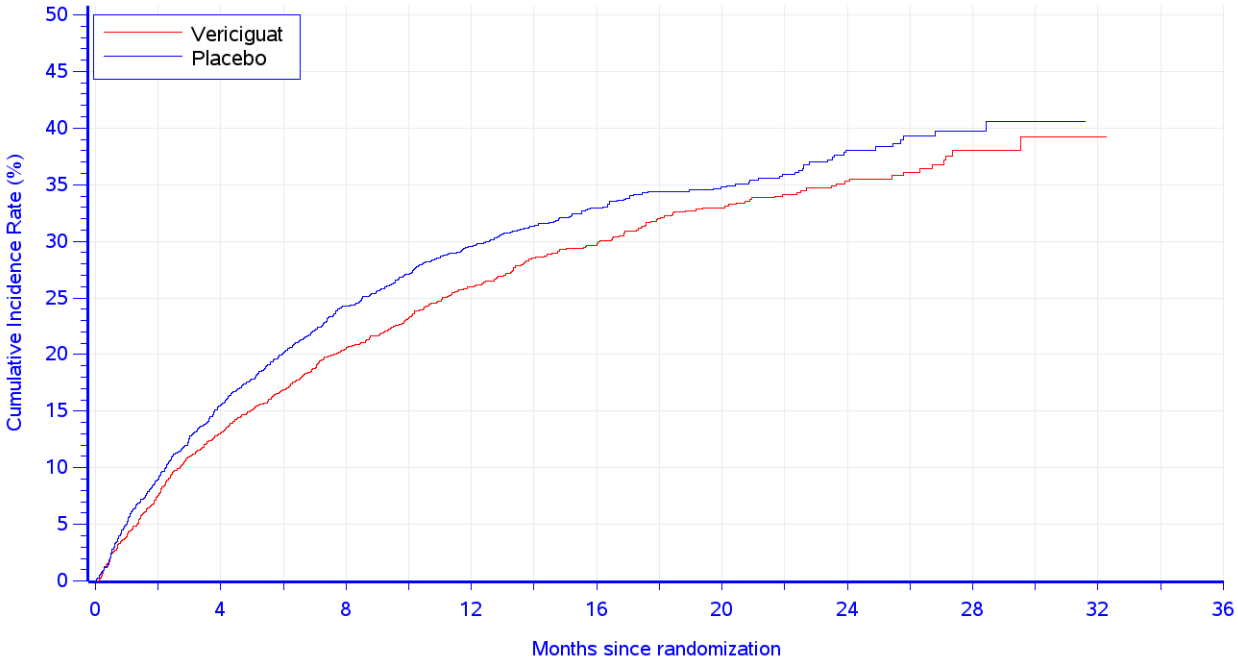
2.7 First CEC Confirmed Heart Failure Hospitalization

Table 2.14.1-1
Time to First Event of CEC Confirmed Heart Failure Hospitalization
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
HF Hospitalization	2158	602 (27,9)	26,5	Not reached [.; .]	2158	659 (30,5)	30,4	Not reached [.; .]	0,88 [0,79; 0,99]	0,029

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; HF: Heart failure

Figure 2.14.1-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed Heart Failure Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%



Number at Risk										
Vericiguat	2158	1788	1379	979	702	495	298	110	1	0
Placebo	2158	1739	1307	917	647	470	270	91	0	0

Based on data up to the primary completion date (18JUN2019).

Table 2.14.1-2
Time to First Event of CEC Confirmed Heart Failure Hospitalization
On-Treatment Analysis Censored at 14 Days after Study Drug Discontinuation
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
HF Hospitalization	2152	519 (24,1)	25,6	Not reached [.; .]	2151	575 (26,7)	29,3	Not reached [.; .]	0,89 [0,79; 1,00]	0,055

a: Database Cut-off Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; HF: Heart failure

Table 2.14.1-3
Time to First Event of CEC Confirmed Heart Failure Hospitalization
All Data through Last Study Visit
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
HF Hospitalization	2158	621 (28,8)	25,9	Not reached [.; .]	2158	677 (31,4)	29,7	Not reached [31,1; .]	0,89 [0,79; 0,99]	0,030

a: Database Cut-off Date: 31OCT2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; HF: Heart failure

Table 2.14.1-4
Time to First Event of CEC Confirmed Heart Failure Hospitalization
On-Treatment Analysis Censored at 14 Days after Study Drug Discontinuation - All Data through Last Study Visit
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
HF Hospitalization	2152	533 (24,8)	25,1	Not reached [.; .]	2151	588 (27,3)	28,6	Not reached [.; .]	0,89 [0,79; 1,00]	0,058

a: Database Cut-off Date: 31OCT2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; HF: Heart failure

2.8 First and Recurrent CEC Confirmed Heart Failure Hospitalization

Table 2.14.1-1
Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization
ITT Population
Participants with Screening Ejection Fraction < 40%

Study:MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs Placebo**	
	N[b]	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI] [d,e]**	**p-Value[e]**
Total events [f]	2158	1049 (48,6)	2716,8	38,6	2158	1203 (55,7)	2680,5	44,9	0,86 [0,79; 0,95]	0,001
Participants with only one event	2158	369 (17,1)			2158	376 (17,4)				
Participants with only two events	2158	135 (6,3)			2158	156 (7,2)				
Participants with only three events	2158	48 (2,2)			2158	67 (3,1)				
Participants with only ≥ four events	2158	50 (2,3)			2158	60 (2,8)				

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total events per 100 participant years of follow up
d: Vericiguat over placebo
e: Calculated based on Andersen-Gill model controlling for stratification factors (defined by region and race). Robust standard errors are used to account for correlations of event times within a participant
f: Total number of heart failure hospitalizations (first and recurrent)
CEC: Clinical Events Committee; CI: Confidence Interval

Table 2.14.1-2
Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization
On-Treatment Analysis Censored at 14 Days after Study Drug Discontinuation
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study:MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs Placebo**	
	N[b]	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI] [d,e]**	**p-Value[e]**
Total events [f]	2152	814 (37,8)	2340,3	34,8	2151	952 (44,3)	2316,5	41,1	0,85 [0,77; 0,94]	0,002
Participants with only one event	2152	345 (16,0)			2151	361 (16,8)				
Participants with only two events	2152	108 (5,0)			2151	126 (5,9)				
Participants with only three events	2152	37 (1,7)			2151	52 (2,4)				
Participants with only ≥ four events	2152	29 (1,3)			2151	36 (1,7)				

a: Database Cut-off Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Total events per 100 participant years of follow up

d: Vericiguat over placebo

e: Calculated based on Andersen-Gill model controlling for stratification factors (defined by region and race). Robust standard errors are used to account for correlations of event times within a participant

f: Total number of heart failure hospitalizations (first and recurrent)

CEC: Clinical Events Committee; CI: Confidence Interval

Table 2.14.1-3
Sensitivity Analyses (WLW model) for Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat (N[b]=2158)**	**Placebo (N[b]=2158)**	**Vericiguat vs. Placebo**	
			Hazard Ratio[c] [95% CI]	**p-Value[c]**
Number of subjects with first event	773	851	0,88 [0,80; 0,97]	-
Number of subjects with second event	505	581	0,85 [0,75; 0,95]	-
Number of subjects with third event	417	471	0,87 [0,76; 0,99]	-
Number of subjects with fourth event	385	425	0,89 [0,78; 1,02]	-
Test of equality of hazard ratio across first four events				0,374
Average hazard ratio across first four events			0,88 [0,80; 0,97]	0,008

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Hazard ratio (Vericiguat over Placebo), confidence interval, and p-value based on Wei, Lin, Weissfeld (WLW) method controlling for stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; ITT: Intention-to-Treat

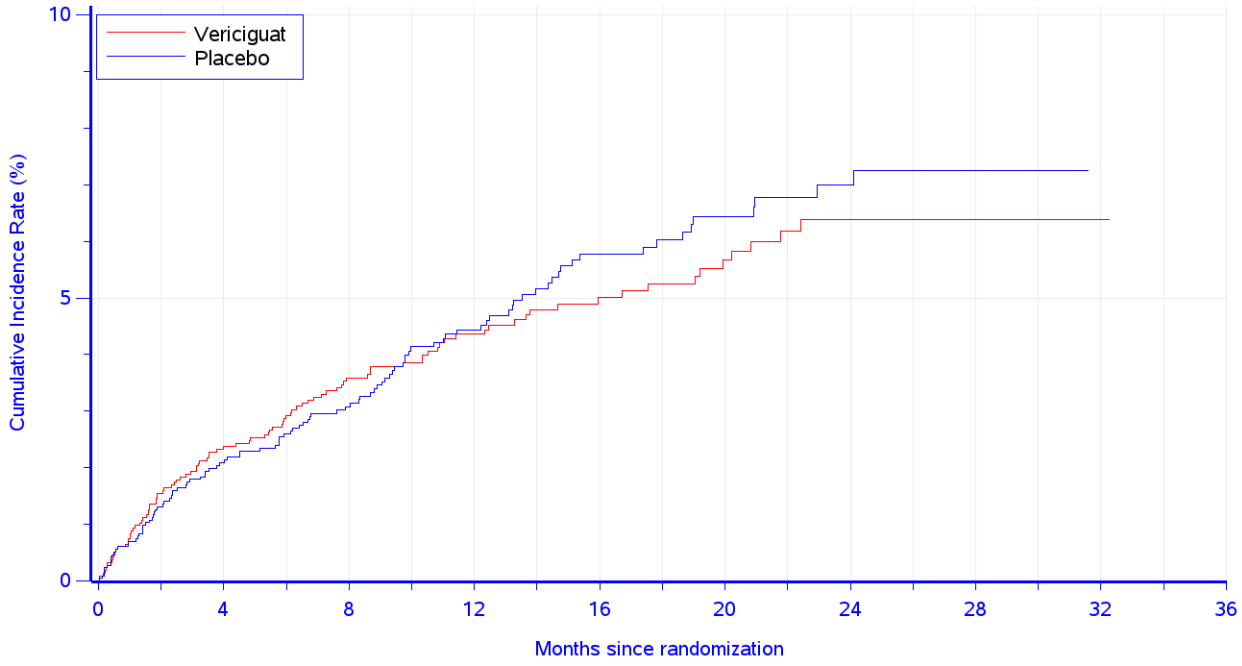
2.9 First CEC Confirmed Urgent Heart Failure Visit

Table 2.14.1-1
Time to First Event of CEC Confirmed Urgent Heart Failure Visit
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
Urgent HF Visit	2158	100 (4,6)	3,8	Not reached [.; .]	2158	106 (4,9)	4,1	Not reached [.; .]	0,94 [0,71; 1,23]	0,655

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; HF: Heart failure

Figure 2.14.1-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed Urgent Heart Failure Visit
ITT Population Participants with Screening Ejection Fraction < 40%



Number at Risk									
Vericiguat									
2158	1980	1618	1180	857	622	380	149	1	0
Placebo									
2158	1978	1604	1162	838	614	367	124	0	0

Based on data up to the primary completion date (18JUN2019).

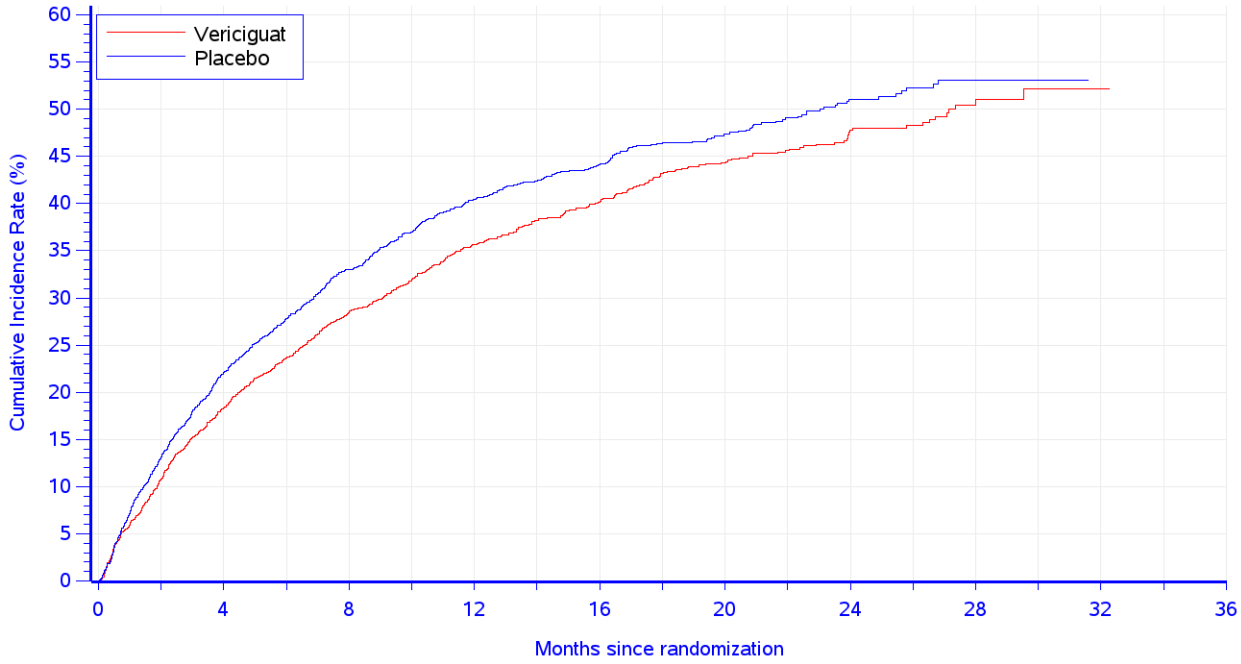
2.10 First CEC Confirmed Cardiovascular Hospitalization

Table 2.14.1-1
Time to First Event of CEC Confirmed Cardiovascular Hospitalization
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
CV Hospitalization	2158	823 (38,1)	39,5	27,1 [23,9; .]	2158	899 (41,7)	46,2	23,2 [20,1; .]	0,87 [0,79; 0,96]	0,005

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular

Figure 2.14.1-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed Cardiovascular Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%



Number at Risk										
Vericiguat										
	2158	1692	1263	870	619	427	243	87	1	0
Placebo										
	2158	1615	1173	788	556	383	217	71	0	0

Based on data up to the primary completion date (18JUN2019).

2.11 Total Number of CEC Confirmed Heart Failure Hospitalizations

Table 2.14.1-1
Total Number of CEC Confirmed Heart Failure Hospitalizations
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat (N[b]=2158)**			**Placebo (N[b]=2158)**			**Vericiguat vs. Placebo**	
	n[c]	**Total Follow-up Time (years)[d]**	**Annual %[e]**	**n[c]**	**Total Follow-up Time (years)[d]**	**Annual %[e]**	**IRR [95% CI][f]**	**p-Value[f]**
Total Number of HF Hospitalizations	1049	2716,8	38,6	1203	2680,5	44,9	0,86 [0,75; 0,99]	0,031

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Number of events in the study arm including the first event and recurrent events

d: From randomization to the last study follow up date or death during the study, whichever is earlier

e: Total events per 100 participants years of follow up

f: Incidence rate ratio (IRR) comparing Vericiguat over Placebo. 95% CI is the 95% confidence interval for the estimate. P-value was calculated based on negative binomial regression model with covariates for treatment and stratification factor and adjusted by subject follow up duration

CEC: Clinical Events Committee; CI: Confidence Interval; HF: Heart failure; IRR: Incidence Rate Rato; ITT: Intention-to-Treat

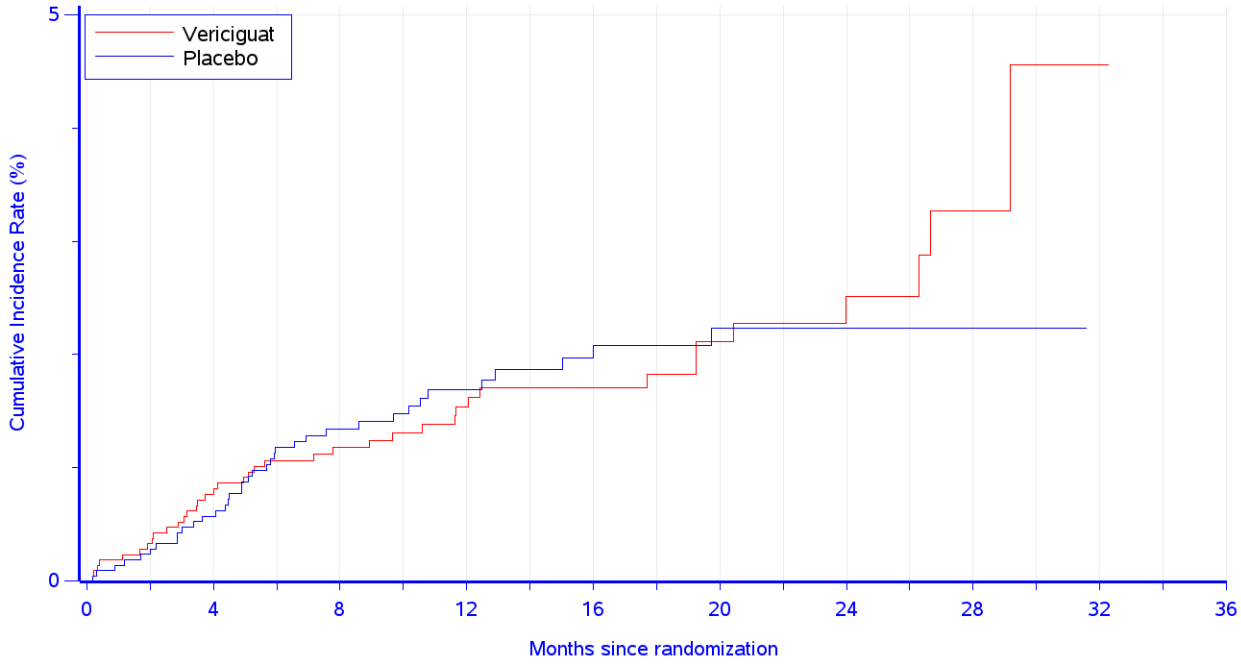
2.12 First CEC Confirmed MI Hospitalization

Table 2.14.1-1
Time to First Event of CEC Confirmed MI Hospitalization
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
MI Hospitalization	2158	39 (1,8)	1,5	Not reached [.; .]	2158	37 (1,7)	1,4	Not reached [.; .]	1,04 [0,66; 1,63]	0,863

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; MI: Myocardial infarction

Figure 2.14.1-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed MI Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%



Number at Risk										
Vericiguat										
	2158	2010	1654	1220	887	645	401	155	1	0
Placebo										
	2158	2010	1638	1197	869	633	382	126	0	0

Based on data up to the primary completion date (18JUN2019).

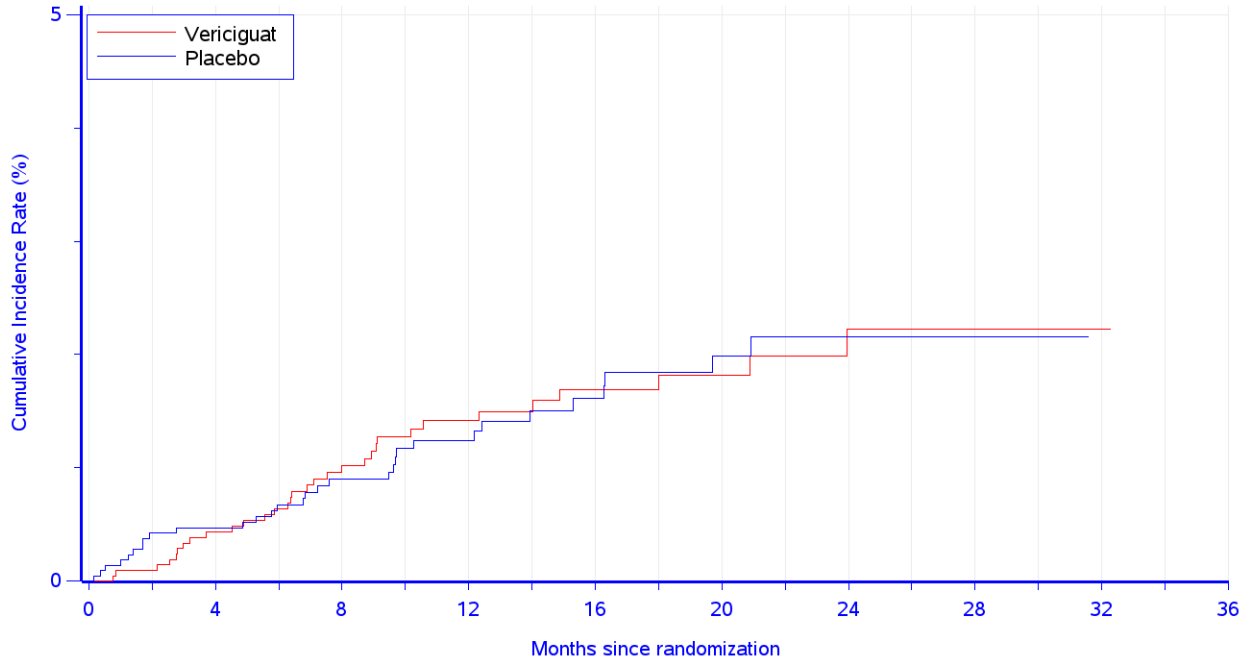
2.13 First CEC Confirmed Stroke Hospitalization

Table 2.14.1-1
Time to First Event of CEC Confirmed Stroke Hospitalization
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
Stroke Hospitalization	2158	32 (1,5)	1,2	Not reached [.; .]	2158	31 (1,4)	1,2	Not reached [.; .]	1,02 [0,62; 1,68]	0,930

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval

Figure 2.14.1-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed Stroke Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%



Number at Risk										
Vericiguat										
	2158	2015	1658	1223	893	650	401	159	1	0
Placebo										
	2158	2014	1646	1203	872	633	384	127	0	0

Based on data up to the primary completion date (18JUN2019).

2.14 Subgroup Analyses for Mortality and Morbidity Time-to-Event Endpoints

2.14.1 CEC Confirmed Cardiovascular Death

2.14.1.1 Consistency of Treatment Effect – Summary.

Table 2.14.1-1
Overview of Subgroup Analyses for Time to CEC Confirmed Cardiovascular Death,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
Efficacy - Time to Event						
CV Death	0,827	0,051	0,129	0,445	0,078	0,653

Overview of Subgroup Analyses for Time to CEC Confirmed Cardiovascular Death,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
Efficacy - Time to Event							
CV Death	0,954	0,396	0,063	0,866	0,143	0,936	0,589

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CV: Cardiovascular; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.1.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 2.14.1-2
Analyses of Time to CEC Confirmed Cardiovascular Death for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Age category 1											
<65	834	114 (13,7)	10,8	Not reached [-; -]	854	130 (15,2)	12,1	Not reached [-; -]	0,90 [0,70; 1,15]	0,365	0,827
≥65	1324	244 (18,4)	14,6	Not reached [-; -]	1304	254 (19,5)	15,8	Not reached [-; -]	0,93 [0,78; 1,11]	0,389	
Age category 2											
<75	1523	222 (14,6)	11,5	Not reached [-; -]	1538	268 (17,4)	13,9	Not reached [-; -]	0,83 [0,69; 0,99]	0,036	0,051
≥75	635	136 (21,4)	17,1	Not reached [-; -]	620	116 (18,7)	15,1	Not reached [-; -]	1,12 [0,88; 1,44]	0,375	
Gender											
Male	1661	294 (17,7)	14,0	Not reached [-; -]	1658	300 (18,1)	14,4	Not reached [-; -]	0,97 [0,83; 1,14]	0,734	0,129
Female	497	64 (12,9)	10,2	Not reached [-; -]	500	84 (16,8)	13,8	Not reached [-; -]	0,74 [0,53; 1,02]	0,066	

Analyses of Time to CEC Confirmed Cardiovascular Death for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Geographic Region											
Asia Pacific	511	76 (14,9)	12,6	Not reached [-; -]	503	62 (12,3)	10,2	Not reached [-; -]	1,23 [0,88; 1,73]	0,220	0,445
Eastern Europe	722	142 (19,7)	15,2	Not reached [-; -]	718	162 (22,6)	17,9	Not reached [-; -]	0,85 [0,68; 1,07]	0,165	
Latin and South America	316	48 (15,2)	13,7	Not reached [-; -]	324	57 (17,6)	15,8	Not reached [-; -]	0,87 [0,59; 1,28]	0,476	
North America	243	33 (13,6)	10,1	Not reached [-; -]	244	39 (16,0)	12,2	Not reached [-; -]	0,83 [0,52; 1,32]	0,415	
Western Europe	366	59 (16,1)	11,5	Not reached [-; -]	369	64 (17,3)	12,9	Not reached [-; -]	0,89 [0,63; 1,27]	0,515	
Index Event											
HF Hospitalization 3-6 Months	390	56 (14,4)	10,7	Not reached [-; -]	365	69 (18,9)	14,1	Not reached [-; -]	0,76 [0,54; 1,09]	0,151	0,078
HF Hospitalization within 3 Months	1441	261 (18,1)	14,7	Not reached [-; -]	1478	259 (17,5)	14,4	Not reached [-; -]	1,03 [0,86; 1,22]	0,760	
IV diuretic for HF (without hospitalization) within 3 Months	327	41 (12,5)	9,4	Not reached [-; -]	315	56 (17,8)	13,9	Not reached [-; -]	0,67 [0,45; 1,00]	0,117	

Analyses of Time to CEC Confirmed Cardiovascular Death for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category											
≤30	213	54 (25,4)	22,2	Not reached [-; -]	203	54 (26,6)	24,2	Not reached [-; -]	0,90 [0,62; 1,32]	0,590	0,653
>30 to ≤60	882	156 (17,7)	13,7	Not reached [-; -]	895	181 (20,2)	15,9	Not reached [-; -]	0,86 [0,70; 1,07]	0,180	
>60	1021	141 (13,8)	10,9	Not reached [-; -]	1024	141 (13,8)	10,9	Not reached [-; -]	1,00 [0,79; 1,26]	0,939	
NYHA Group at Baseline											
Class I or II	1241	147 (11,8)	9,1	Not reached [-; -]	1271	165 (13,0)	10,1	Not reached [-; -]	0,91 [0,73; 1,13]	0,383	0,954
Class III or IV	915	211 (23,1)	18,9	Not reached [-; -]	887	219 (24,7)	20,6	Not reached [-; -]	0,91 [0,76; 1,10]	0,372	
Use of Sacubitril /Valsartan at Baseline											
Yes	330	47 (14,2)	12,2	Not reached [-; -]	330	58 (17,6)	15,8	Not reached [-; -]	0,78 [0,53; 1,15]	0,188	0,396
No	1824	309 (16,9)	13,2	Not reached [-; -]	1825	326 (17,9)	14,1	Not reached [-; -]	0,94 [0,80; 1,10]	0,429	

Analyses of Time to CEC Confirmed Cardiovascular Death for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
NT-pro BNP (pg/mL) Baseline Grp: Central Lab											
Q1 (≤1556)	489	29 (5,9)	4,2	Not reached [-; -]	507	41 (8,1)	5,8	Not reached [-; -]	0,72 [0,45; 1,16]	0,208	0,063
Q2 (1556 - 2816)	520	53 (10,2)	7,5	Not reached [-; -]	494	65 (13,2)	10,0	Not reached [-; -]	0,76 [0,53; 1,09]	0,138	
Q3 (2816 - 5314)	511	77 (15,1)	12,0	Not reached [-; -]	520	97 (18,7)	15,1	Not reached [-; -]	0,80 [0,59; 1,08]	0,138	
Q4 (>5314)	548	186 (33,9)	32,5	28,6 [26,5; -]	524	153 (29,2)	27,6	Not reached [28,1; -]	1,16 [0,93; 1,43]	0,199	
Baseline Ejection Fraction Group 2											
<35	1725	306 (17,7)	14,1	Not reached [-; -]	1741	326 (18,7)	15,3	Not reached [-; -]	0,92 [0,79; 1,08]	0,329	0,866
≥35	433	52 (12,0)	9,3	Not reached [-; -]	417	58 (13,9)	10,4	Not reached [-; -]	0,89 [0,61; 1,30]	0,636	

Analyses of Time to CEC Confirmed Cardiovascular Death for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Race group											
White	1350	232 (17,2)	12,8	Not reached [-; -]	1359	270 (19,9)	15,3	Not reached [-; -]	0,84 [0,70; 1,00]	0,048	0,143
Asian	500	79 (15,8)	13,6	Not reached [-; -]	475	62 (13,1)	11,1	Not reached [-; -]	1,22 [0,87; 1,70]	0,237	
Black	111	14 (12,6)	11,2	Not reached [24,5; -]	118	21 (17,8)	15,3	Not reached [26,9; -]	0,73 [0,37; 1,44]	0,376	
Other	196	33 (16,8)	15,8	Not reached [-; -]	206	31 (15,0)	13,1	Not reached [-; -]	1,19 [0,73; 1,95]	0,456	
CCSA class at Randomization											
No Angina	1849	294 (15,9)	12,7	Not reached [-; -]	1856	318 (17,1)	13,9	Not reached [-; -]	0,91 [0,78; 1,07]	0,243	0,936
Angina Class 1 or 2	265	52 (19,6)	14,4	Not reached [-; -]	261	53 (20,3)	14,9	Not reached [-; -]	0,98 [0,67; 1,44]	0,979	
Angina Class 3 or 4	44	12 (27,3)	23,5	Not reached [-; -]	41	13 (31,7)	24,2	Not reached [19,8; -]	0,94 [0,43; 2,06]	0,870	

Analyses of Time to CEC Confirmed Cardiovascular Death for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus											
Yes	1051	191 (18,2)	14,6	Not reached [-; -]	985	202 (20,5)	16,7	Not reached [-; -]	0,88 [0,72; 1,07]	0,188	0,589
No	1107	167 (15,1)	11,7	Not reached [-; -]	1173	182 (15,5)	12,3	Not reached [-; -]	0,95 [0,77; 1,18]	0,690	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total participants with an event per 100 participants years at risk

d: From product-limit (Kaplan-Meier) method

e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction

f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.1.3 CEC Confirmed Cardiovascular Death for Participants with baseline NT-proBNP values ≤ 5314 pg/mL

Table 2.14-3
Time to CEC Confirmed Cardiovascular Death
ITT Population
Participants with Screening Ejection Fraction < 40% and baseline NT-proBNP values ≤ 5314 pg/mL

Study: MK-1242-001[a]	Vericiguat				Placebo				Vericiguat vs. Placebo	
	N[b]	Participants with Event n (%)	Annual %[c]	Median Time[d] in months [95 %-CI]	N[b]	Participants with Event n (%)	Annual %[c]	Median Time[d] in months [95 %-CI]	Hazard Ratio [95 %-CI][e]	p-Value[f]
CV Death	1520	159 (10,5)	7,8	Not reached [.; .]	1521	203 (13,3)	10,2	Not reached [.; .]	0,77 [0,62; 0,94]	0,012
Heart Failure	1520	69 (4,5)			1521	99 (6,5)				
Myocardial Infarction	1520	4 (0,3)			1521	5 (0,3)				
Other Cardiovascular Event	1520	6 (0,4)			1521	4 (0,3)				
Stroke	1520	0 (0,0)			1521	6 (0,4)				
Sudden Cardiac Death	1520	35 (2,3)			1521	56 (3,7)				
Undetermined Cause Of Death	1520	45 (3,0)			1521	33 (2,2)				

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40% and baseline NT-proBNP values ≤ 5314 pg/mL
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular; NT-proBNP: N-terminal pro-brain natriuretic peptide

2.14.2 CEC Confirmed All Cause Mortality

2.14.2.1 Consistency of Treatment Effect – Summary.

Table 2.14.2-1
Overview of Subgroup Analyses for Time to All Cause Mortality,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
Efficacy - Time to Event						
All-Cause Death	0,863	0,186	0,172	0,169	0,075	0,697

Overview of Subgroup Analyses for Time to All Cause Mortality,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
Efficacy - Time to Event							
All-Cause Death	0,687	0,602	0,105	n.a.	0,077	0,934	0,720

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; eGFR: Estimated glomerular filtration rate; HF: Heart failure; n.a.: not applicable (when estimation not possible); NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.2.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 2.14.2-2
Analyses of Time to All Cause Mortality for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat				Placebo				Vericiguat vs. Placebo		
All-Cause Death	N[b]	Participants with Event n (%)	Annual %[c]	Median Time in months [95 %-CI][d]	N[b]	Participants with Event n (%)	Annual %[c]	Median Time in months [95 %-CI][d]	Hazard Ratio [95 %-CI][e]	p-Value[f]	p-Value for Interaction Test[g]
Age category 1											
<65	834	132 (15,8)	12,5	Not reached [-; -]	854	146 (17,1)	13,5	Not reached [-; -]	0,92 [0,73; 1,17]	0,474	0,863
≥65	1324	311 (23,5)	18,6	Not reached [-; -]	1304	318 (24,4)	19,7	Not reached [-; -]	0,94 [0,81; 1,10]	0,463	
Age category 2											
<75	1523	274 (18,0)	14,2	Not reached [-; -]	1538	311 (20,2)	16,2	Not reached [-; -]	0,88 [0,75; 1,03]	0,116	0,186
≥75	635	169 (26,6)	21,2	Not reached [-; -]	620	153 (24,7)	20,0	Not reached [-; -]	1,06 [0,85; 1,32]	0,658	
Gender											
Male	1661	360 (21,7)	17,1	Not reached [-; -]	1658	362 (21,8)	17,4	Not reached [-; -]	0,99 [0,85; 1,14]	0,842	0,172
Female	497	83 (16,7)	13,2	Not reached [-; -]	500	102 (20,4)	16,7	Not reached [-; -]	0,79 [0,59; 1,05]	0,108	

Analyses of Time to All Cause Mortality for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
All-Cause Death	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Geographic Region											
Asia Pacific	511	95 (18,6)	15,7	Not reached [-; -]	503	73 (14,5)	12,0	Not reached [-; -]	1,31 [0,97; 1,78]	0,082	0,169
Eastern Europe	722	167 (23,1)	17,8	Not reached [-; -]	718	194 (27,0)	21,5	Not reached [-; -]	0,84 [0,68; 1,03]	0,092	
Latin and South America	316	60 (19,0)	17,2	Not reached [-; -]	324	66 (20,4)	18,3	Not reached [26,1; -]	0,94 [0,66; 1,33]	0,721	
North America	243	39 (16,0)	11,9	Not reached [-; -]	244	48 (19,7)	15,0	Not reached [27,5; -]	0,80 [0,52; 1,22]	0,279	
Western Europe	366	82 (22,4)	16,0	Not reached [-; -]	369	83 (22,5)	16,8	Not reached [-; -]	0,96 [0,70; 1,30]	0,759	
Index Event											
HF Hospitalization 3-6 Months	390	73 (18,7)	14,0	Not reached [-; -]	365	86 (23,6)	17,6	Not reached [-; -]	0,80 [0,58; 1,09]	0,169	0,075
HF Hospitalization within 3 Months	1441	322 (22,3)	18,2	Not reached [-; -]	1478	315 (21,3)	17,5	Not reached [-; -]	1,04 [0,89; 1,22]	0,614	
IV diuretic for HF (without hospitalization) within 3 Months	327	48 (14,7)	11,1	Not reached [-; -]	315	63 (20,0)	15,7	Not reached [-; -]	0,70 [0,48; 1,01]	0,119	

Analyses of Time to All Cause Mortality for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
All-Cause Death	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category											
≤30	213	75 (35,2)	30,8	Not reached [21,4; -]	203	76 (37,4)	34,0	Not reached [20,6; -]	0,89 [0,65; 1,23]	0,529	0,697
>30 to ≤60	882	192 (21,8)	16,9	Not reached [-; -]	895	213 (23,8)	18,7	Not reached [-; -]	0,90 [0,74; 1,10]	0,297	
>60	1021	168 (16,5)	12,9	Not reached [-; -]	1024	166 (16,2)	12,9	Not reached [-; -]	1,01 [0,82; 1,25]	0,875	
NYHA Group at Baseline											
Class I or II	1241	191 (15,4)	11,9	Not reached [-; -]	1271	202 (15,9)	12,4	Not reached [-; -]	0,96 [0,79; 1,17]	0,704	0,687
Class III or IV	915	252 (27,5)	22,6	Not reached [-; -]	887	262 (29,5)	24,7	Not reached [28,1; -]	0,91 [0,77; 1,08]	0,299	
Use of Sacubitril /Valsartan at Baseline											
Yes	330	55 (16,7)	14,3	Not reached [-; -]	330	62 (18,8)	16,9	Not reached [-; -]	0,86 [0,60; 1,23]	0,355	0,602
No	1824	386 (21,2)	16,5	Not reached [-; -]	1825	402 (22,0)	17,3	Not reached [-; -]	0,95 [0,83; 1,09]	0,473	

Analyses of Time to All Cause Mortality for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
All-Cause Death	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
NT-pro BNP (pg/mL) Baseline Grp: Central Lab											
Q1 (≤1556)	489	36 (7,4)	5,2	Not reached [-; -]	507	47 (9,3)	6,7	Not reached [-; -]	0,78 [0,50; 1,20]	0,283	0,105
Q2 (1556 - 2816)	520	64 (12,3)	9,0	Not reached [-; -]	494	79 (16,0)	12,1	Not reached [-; -]	0,75 [0,54; 1,04]	0,086	
Q3 (2816 - 5314)	511	100 (19,6)	15,6	Not reached [-; -]	520	113 (21,7)	17,6	Not reached [-; -]	0,89 [0,68; 1,17]	0,394	
Q4 (>5314)	548	228 (41,6)	39,8	23,1 [17,0; -]	524	192 (36,6)	34,6	28,1 [22,6; -]	1,13 [0,93; 1,37]	0,238	
Baseline Ejection Fraction Group 2											
<35	1725	376 (21,8)	17,3	Not reached [-; -]	1741	393 (22,6)	18,4	Not reached [-; -]	0,94 [0,82; 1,08]	0,406	n.a.
≥35	433	67 (15,5)	12,0	Not reached [-; -]	417	71 (17,0)	12,7	Not reached [-; -]	0,94 [0,67; 1,31]	0,828	

Analyses of Time to All Cause Mortality for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
All-Cause Death	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Race group											
White	1350	289 (21,4)	15,9	Not reached [-; -]	1359	332 (24,4)	18,9	Not reached [-; -]	0,85 [0,72; 0,99]	0,041	0,077
Asian	500	97 (19,4)	16,8	Not reached [-; -]	475	73 (15,4)	13,1	Not reached [-; -]	1,27 [0,94; 1,72]	0,118	
Black	111	17 (15,3)	13,6	Not reached [24,5; -]	118	22 (18,6)	16,0	Not reached [26,9; -]	0,85 [0,45; 1,60]	0,629	
Other	196	40 (20,4)	19,1	Not reached [-; -]	206	37 (18,0)	15,7	Not reached [-; -]	1,21 [0,78; 1,90]	0,391	
CCSA class at Randomization											
No Angina	1849	367 (19,8)	15,8	Not reached [-; -]	1856	387 (20,9)	17,0	Not reached [-; -]	0,93 [0,81; 1,08]	0,337	0,934
Angina Class 1 or 2	265	63 (23,8)	17,4	Not reached [-; -]	261	64 (24,5)	18,0	Not reached [-; -]	0,98 [0,70; 1,39]	0,994	
Angina Class 3 or 4	44	13 (29,5)	25,5	Not reached [-; -]	41	13 (31,7)	24,2	Not reached [19,8; -]	1,03 [0,48; 2,23]	0,869	

Analyses of Time to All Cause Mortality for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
All-Cause Death	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus											
Yes	1051	244 (23,2)	18,6	Not reached [-; -]	985	248 (25,2)	20,5	Not reached [-; -]	0,91 [0,76; 1,09]	0,313	0,720
No	1107	199 (18,0)	14,0	Not reached [-; -]	1173	216 (18,4)	14,6	Not reached [-; -]	0,96 [0,79; 1,16]	0,740	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total participants with an event per 100 participants years at risk

d: From product-limit (Kaplan-Meier) method

e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction

f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; n.a.: not applicable (when estimation not possible); NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.3 CEC Confirmed Cardiovascular Death or First Heart Failure Hospitalization

2.14.3.1 Consistency of Treatment Effect – Summary.

Table 2.14.3-1
Overview of Subgroup Analyses for Time to First Event of CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization, Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
Efficacy - Time to Event						
CV Death or HF Hospitalization	0,169	**0,016[b]**	0,856	0,696	0,126	0,256

Overview of Subgroup Analyses for Time to First Event of CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization, Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
Efficacy - Time to Event							
CV Death or HF Hospitalization	0,312	0,915	**< 0,001[b]**	0,915	0,870	0,602	0,605

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CV: Cardiovascular; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.3.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 2.14.3-2
Analyses of Time to First Event of CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death or HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Age category 1											
<65	834	265 (31,8)	29,7	Not reached [29,5; -]	854	321 (37,6)	37,7	Not reached [25,8; -]	0,80 [0,68; 0,94]	0,007	0,169
≥65	1324	508 (38,4)	36,7	Not reached [23,7; -]	1304	530 (40,6)	40,3	25,7 [22,6; -]	0,92 [0,82; 1,04]	0,181	
Gender											
Male	1661	618 (37,2)	35,5	Not reached [27,1; -]	1658	676 (40,8)	40,7	25,8 [22,6; -]	0,88 [0,79; 0,98]	0,023	0,856
Female	497	155 (31,2)	29,2	Not reached [-; -]	500	175 (35,0)	34,4	Not reached [25,7; -]	0,86 [0,69; 1,07]	0,216	

Analyses of Time to First Event of CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death or HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Geographic Region											
Asia Pacific	511	184 (36,0)	36,4	29,5 [24,6; -]	503	184 (36,6)	37,5	Not reached [23,4; -]	0,98 [0,79; 1,20]	0,806	0,696
Eastern Europe	722	268 (37,1)	34,2	Not reached [26,3; -]	718	303 (42,2)	41,6	23,9 [19,8; -]	0,84 [0,71; 0,99]	0,040	
Latin and South America	316	87 (27,5)	28,3	Not reached [-; -]	324	109 (33,6)	36,1	26,1 [19,8; -]	0,79 [0,59; 1,04]	0,091	
North America	243	89 (36,6)	34,0	Not reached [23,6; -]	244	103 (42,2)	41,5	25,7 [16,4; -]	0,83 [0,62; 1,10]	0,186	
Western Europe	366	145 (39,6)	34,9	Not reached [21,7; -]	369	152 (41,2)	38,2	28,1 [20,6; -]	0,92 [0,74; 1,16]	0,487	
Index Event											
HF Hospitalization 3-6 Months	390	122 (31,3)	26,9	Not reached [27,1; -]	365	138 (37,8)	33,8	Not reached [20,7; -]	0,81 [0,63; 1,03]	0,097	0,126
HF Hospitalization within 3 Months	1441	569 (39,5)	39,7	27,4 [21,1; -]	1478	607 (41,1)	42,6	25,8 [23,2; -]	0,94 [0,83; 1,05]	0,255	
IV diuretic for HF (without hospitalization) within 3 Months	327	82 (25,1)	21,2	Not reached [-; -]	315	106 (33,7)	31,5	Not reached [23,9; -]	0,70 [0,52; 0,93]	0,033	
eGFR (mL/min/1.73 m^2) Category											
≤30	213	117 (54,9)	68,3	12,1 [7,6; 17,6]	203	107 (52,7)	65,9	10,7 [7,8; 20,6]	1,04 [0,80; 1,35]	0,686	0,256
>30 to ≤60	882	333 (37,8)	35,8	Not reached [24,1; -]	895	395 (44,1)	44,2	22,6 [19,5; 26,8]	0,82 [0,71; 0,95]	0,008	
>60	1021	312 (30,6)	27,6	Not reached [-; -]	1024	333 (32,5)	30,7	Not reached [-; -]	0,91 [0,78; 1,07]	0,288	

Analyses of Time to First Event of CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death or HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
NYHA Group at Baseline											
Class I or II	1241	382 (30,8)	28,0	Not reached [-; -]	1271	418 (32,9)	30,7	Not reached [-; -]	0,92 [0,80; 1,05]	0,215	0,312
Class III or IV	915	391 (42,7)	43,2	22,4 [18,0; -]	887	433 (48,8)	53,6	17,1 [13,5; 20,7]	0,83 [0,72; 0,95]	0,011	
Use of Sacubitril /Valsartan at Baseline											
Yes	330	125 (37,9)	40,3	23,7 [16,5; -]	330	139 (42,1)	47,9	19,7 [13,3; -]	0,86 [0,68; 1,10]	0,257	0,915
No	1824	646 (35,4)	33,0	Not reached [29,5; -]	1825	712 (39,0)	38,0	Not reached [24,9; -]	0,88 [0,79; 0,98]	0,017	
Baseline Ejection Fraction Group 2											
<35	1725	637 (36,9)	35,4	Not reached [26,7; -]	1741	703 (40,4)	41,1	26,1 [23,4; -]	0,88 [0,79; 0,97]	0,015	0,915
≥35	433	136 (31,4)	28,7	Not reached [-; -]	417	148 (35,5)	32,3	Not reached [23,9; -]	0,89 [0,70; 1,12]	0,325	

Analyses of Time to First Event of CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death or HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Race group											
White	1350	503 (37,3)	33,3	Not reached [27,1; -]	1359	552 (40,6)	38,7	28,1 [23,6; -]	0,88 [0,78; 0,99]	0,033	0,870
Asian	500	177 (35,4)	36,2	29,5 [24,6; -]	475	177 (37,3)	39,4	Not reached [22,6; -]	0,93 [0,75; 1,14]	0,471	
Black	111	36 (32,4)	37,4	Not reached [20,6; -]	118	48 (40,7)	44,6	22,8 [12,5; -]	0,82 [0,53; 1,26]	0,372	
Other	196	57 (29,1)	32,0	Not reached [-; -]	206	74 (35,9)	40,4	Not reached [17,1; -]	0,79 [0,56; 1,12]	0,177	
CCSA class at Randomization											
No Angina	1849	660 (35,7)	34,3	Not reached [27,4; -]	1856	722 (38,9)	39,1	26,8 [23,9; -]	0,89 [0,80; 0,99]	0,027	0,602
Angina Class 1 or 2	265	98 (37,0)	32,5	Not reached [26,7; -]	261	108 (41,4)	38,3	28,4 [20,6; -]	0,86 [0,66; 1,13]	0,348	
Angina Class 3 or 4	44	15 (34,1)	32,4	Not reached [11,7; -]	41	21 (51,2)	51,4	19,8 [6,0; -]	0,63 [0,33; 1,23]	0,257	

Analyses of Time to First Event of CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death or HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus											
Yes	1051	418 (39,8)	39,2	26,7 [20,5; -]	985	420 (42,6)	44,6	23,4 [20,6; -]	0,89 [0,78; 1,02]	0,090	0,605
No	1107	355 (32,1)	29,4	Not reached [-; -]	1173	431 (36,7)	35,2	Not reached [25,7; -]	0,85 [0,74; 0,98]	0,024	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total participants with an event per 100 participants years at risk

d: From product-limit (Kaplan-Meier) method

e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction

f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.3.3 Results for Subgroups With Interaction P-value < 0.05

Table 2.14.3-3
Analyses of Time to First Event of CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death or HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Age category 2											
<75	1523	507 (33,3)	31,2	Not reached [-; -]	1538	604 (39,3)	39,0	Not reached [23,5; -]	0,81 [0,72; 0,91]	< 0,001	0,016
≥75	635	266 (41,9)	40,9	23,1 [19,3; -]	620	247 (39,8)	40,0	28,1 [20,9; -]	1,05 [0,88; 1,24]	0,651	

Analyses of Time to First Event of CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death or HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
NT-pro BNP (pg/mL) Baseline Grp: Central Lab											
Q1 (≤1556)	489	106 (21,7)	17,1	Not reached [-; -]	507	141 (27,8)	23,6	Not reached [-; -]	0,74 [0,57; 0,95]	0,019	< 0,001
Q2 (1556 - 2816)	520	140 (26,9)	22,8	Not reached [-; -]	494	173 (35,0)	32,4	Not reached [28,4; -]	0,72 [0,57; 0,89]	0,003	
Q3 (2816 - 5314)	511	180 (35,2)	34,0	Not reached [27,1; -]	520	223 (42,9)	45,0	23,6 [16,9; -]	0,77 [0,63; 0,94]	0,009	
Q4 (>5314)	548	315 (57,5)	74,0	10,2 [8,4; 12,0]	524	268 (51,1)	63,2	13,4 [9,8; 19,5]	1,17 [0,99; 1,37]	0,074	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total participants with an event per 100 participants years at risk

d: From product-limit (Kaplan-Meier) method

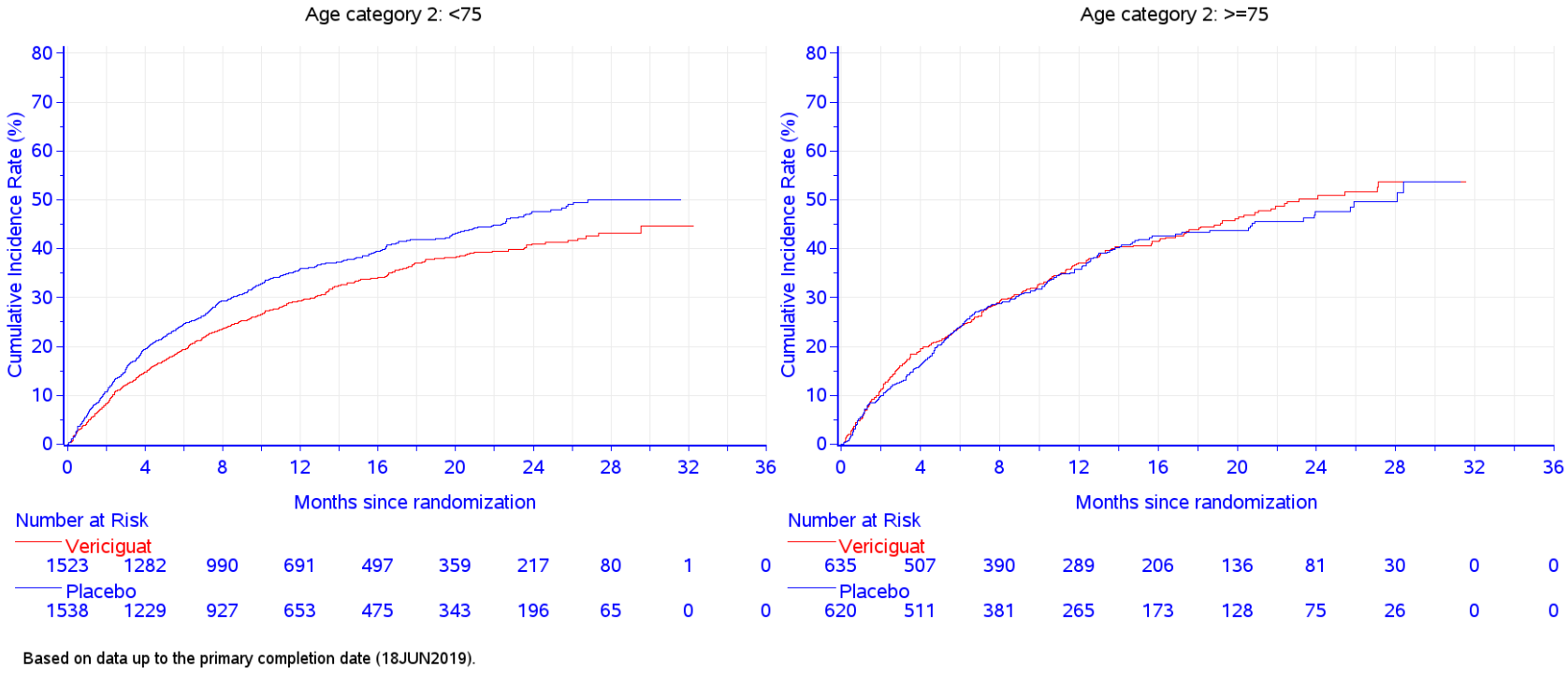
e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction

f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

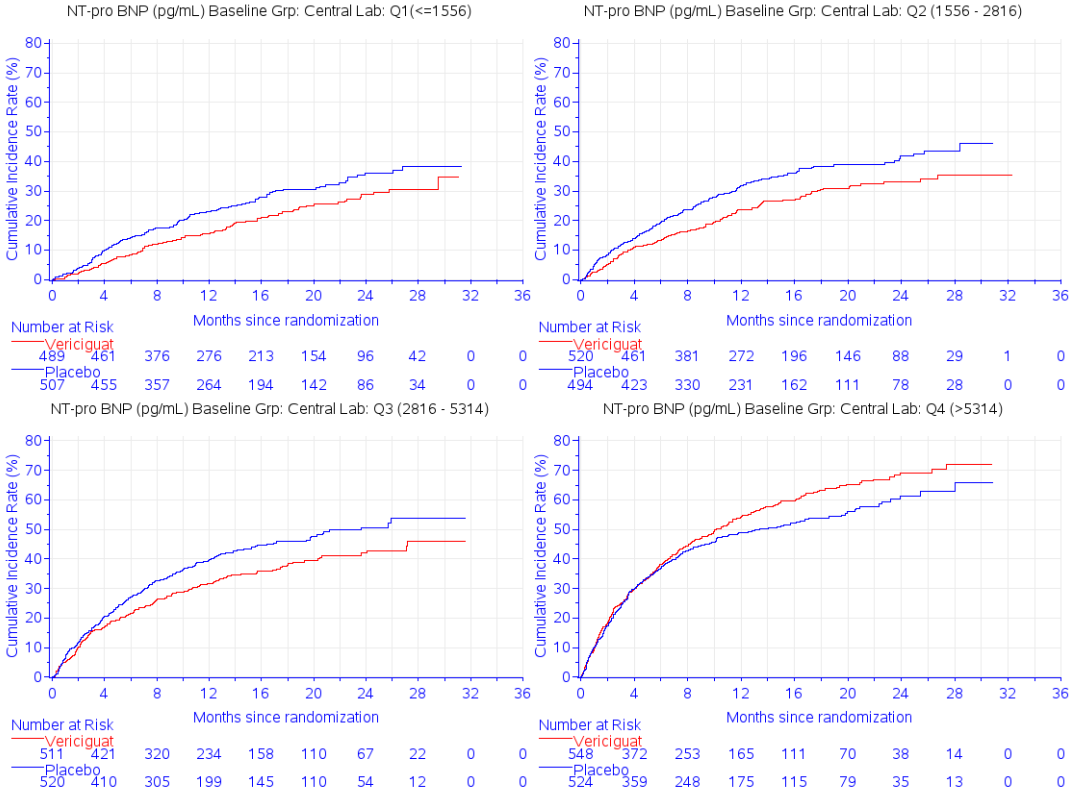
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

Figure 2.14.3-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%
By Age category



Based on data up to the primary completion date (18JUN2019).

Figure 2.14.3-2
Kaplan-Meier Plot Time to First Event of CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%
By NT-pro BNP (pg/mL) Baseline Grp: Central Lab



Based on data up to the primary completion date (18JUN2019).

2.14.3.4 CEC Confirmed Cardiovascular Death or First Heart Failure Hospitalization for Participants with baseline NT-proBNP values ≤ 5314 pg/mL

Table 2.14-4
Time to First Event of CEC Confirmed Cardiovascular Death or Heart Failure Hospitalization
ITT Population
Participants with Screening Ejection Fraction < 40% and baseline NT-proBNP values ≤ 5314 pg/mL

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
CV Death or HF Hospitalization	1520	426 (28,0)	24,2	Not reached [.; .]	1521	537 (35,3)	33,0	Not reached [28,4; .]	0,74 [0,65; 0,84]	< 0,001
Cardiovascular Death	1520	78 (5,1)			1521	93 (6,1)				
Heart Failure Hospitalization	1520	348 (22,9)			1521	444 (29,2)				

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40% and baseline NT-proBNP values ≤ 5314 pg/mL
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide

2.14.4 CEC Confirmed All-cause Mortality or First Heart Failure Hospitalization

2.14.4.1 Consistency of Treatment Effect – Summary.

Table 2.14.4-1
Overview of Subgroup Analyses for Time to First Event of CEC Confirmed All-cause Mortality or Heart Failure Hospitalization, Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
Efficacy - Time to Event						
All-Cause Death or HF Hospitalization	0,320	0,088	0,859	0,659	0,100	0,332

Overview of Subgroup Analyses for Time to First Event of CEC Confirmed All-cause Mortality or Heart Failure Hospitalization, Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
Efficacy - Time to Event							
All-Cause Death or HF Hospitalization	0,258	0,927	**0,001[b]**	0,971	0,918	0,599	0,662

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.4.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 2.14.4-2
Analyses of Time to First Event of CEC Confirmed All-cause Mortality or Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
All-Cause Death or HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Age category 1											
<65	834	279 (33,5)	31,3	Not reached [29,5; -]	854	327 (38,3)	38,4	Not reached [24,9; -]	0,83 [0,71; 0,97]	0,018	0,320
≥65	1324	546 (41,2)	39,5	27,1 [20,9; -]	1304	575 (44,1)	43,7	22,6 [19,7; 25,5]	0,91 [0,81; 1,03]	0,121	
Age category 2											
<75	1523	542 (35,6)	33,4	Not reached [29,5; -]	1538	626 (40,7)	40,4	25,5 [22,6; -]	0,83 [0,74; 0,94]	0,002	0,088
≥75	635	283 (44,6)	43,5	21,1 [17,3; 27,1]	620	276 (44,5)	44,7	23,4 [15,5; 28,1]	1,00 [0,84; 1,17]	0,898	
Gender											
Male	1661	658 (39,6)	37,8	29,5 [23,7; -]	1658	715 (43,1)	43,1	23,2 [20,4; 26,8]	0,89 [0,80; 0,99]	0,026	0,859
Female	497	167 (33,6)	31,4	Not reached [27,4; -]	500	187 (37,4)	36,8	Not reached [22,8; -]	0,87 [0,70; 1,07]	0,221	

Analyses of Time to First Event of CEC Confirmed All-cause Mortality or Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
All-Cause Death or HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Geographic Region											
Asia Pacific	511	195 (38,2)	38,5	29,5 [20,2; -]	503	192 (38,2)	39,1	Not reached [22,6; -]	0,99 [0,81; 1,21]	0,921	0,659
Eastern Europe	722	283 (39,2)	36,2	Not reached [23,5; -]	718	321 (44,7)	44,0	21,2 [17,2; 26,8]	0,84 [0,71; 0,98]	0,031	
Latin and South America	316	97 (30,7)	31,5	Not reached [-; -]	324	117 (36,1)	38,7	26,1 [18,6; -]	0,82 [0,62; 1,07]	0,136	
North America	243	94 (38,7)	35,9	27,4 [18,8; -]	244	109 (44,7)	43,9	22,6 [16,4; -]	0,83 [0,63; 1,09]	0,168	
Western Europe	366	156 (42,6)	37,5	25,7 [20,3; -]	369	163 (44,2)	41,0	23,9 [17,6; -]	0,93 [0,74; 1,15]	0,488	
Index Event											
HF Hospitalization 3-6 Months	390	136 (34,9)	30,0	Not reached [25,7; -]	365	151 (41,4)	37,0	23,4 [17,4; -]	0,82 [0,65; 1,04]	0,111	0,100
HF Hospitalization within 3 Months	1441	603 (41,8)	42,0	23,6 [19,4; -]	1478	639 (43,2)	44,9	23,9 [20,6; 26,8]	0,94 [0,84; 1,05]	0,287	
IV diuretic for HF (without hospitalization) within 3 Months	327	86 (26,3)	22,3	Not reached [-; -]	315	112 (35,6)	33,3	Not reached [22,6; -]	0,69 [0,52; 0,91]	0,022	

Analyses of Time to First Event of CEC Confirmed All-cause Mortality or Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
All-Cause Death or HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category											
≤30	213	126 (59,2)	73,5	9,6 [7,2; 13,6]	203	122 (60,1)	75,1	9,6 [6,9; 12,6]	0,98 [0,77; 1,26]	0,980	0,332
>30 to ≤60	882	353 (40,0)	37,9	Not reached [20,6; -]	895	416 (46,5)	46,5	20,4 [16,4; 23,9]	0,82 [0,72; 0,95]	0,008	
>60	1021	334 (32,7)	29,6	Not reached [29,5; -]	1024	347 (33,9)	32,0	Not reached [-; -]	0,94 [0,81; 1,09]	0,446	
NYHA Group at Baseline											
Class I or II	1241	410 (33,0)	30,0	Not reached [29,5; -]	1271	444 (34,9)	32,6	Not reached [28,4; -]	0,92 [0,81; 1,06]	0,265	0,258
Class III or IV	915	415 (45,4)	45,8	20,3 [16,9; 25,7]	887	458 (51,6)	56,7	15,6 [12,6; 18,6]	0,83 [0,73; 0,95]	0,010	
Use of Sacubitril /Valsartan at Baseline											
Yes	330	129 (39,1)	41,6	23,7 [16,5; -]	330	142 (43,0)	48,9	19,7 [13,2; 25,9]	0,87 [0,69; 1,11]	0,281	0,927
No	1824	694 (38,0)	35,4	Not reached [27,1; -]	1825	760 (41,6)	40,6	24,9 [22,6; -]	0,88 [0,80; 0,98]	0,019	

Analyses of Time to First Event of CEC Confirmed All-cause Mortality or Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat				Placebo				Vericiguat vs. Placebo		
All-Cause Death or HF Hospitalization	N[b]	Participants with Event n (%)	Annual %[c]	Median Time in months [95 %-CI][d]	N[b]	Participants with Event n (%)	Annual %[c]	Median Time in months [95 %-CI][d]	Hazard Ratio [95 %-CI][e]	p-Value[f]	p-Value for Interaction Test[g]
Baseline Ejection Fraction Group 2											
<35	1725	681 (39,5)	37,9	27,1 [23,7; -]	1741	745 (42,8)	43,6	23,6 [20,7; 26,8]	0,88 [0,80; 0,98]	0,019	0,971
≥35	433	144 (33,3)	30,3	Not reached [-; -]	417	157 (37,6)	34,2	Not reached [22,4; -]	0,89 [0,71; 1,11]	0,320	
Race group											
White	1350	534 (39,6)	35,4	Not reached [25,4; -]	1359	590 (43,4)	41,3	23,9 [20,6; 28,1]	0,87 [0,78; 0,98]	0,020	0,918
Asian	500	188 (37,6)	38,5	29,5 [20,2; -]	475	185 (38,9)	41,2	25,8 [22,4; -]	0,94 [0,77; 1,15]	0,556	
Black	111	39 (35,1)	40,5	Not reached [14,1; -]	118	49 (41,5)	45,6	22,6 [12,5; -]	0,87 [0,57; 1,32]	0,529	
Other	196	64 (32,7)	36,0	Not reached [-; -]	206	78 (37,9)	42,5	Not reached [16,4; -]	0,84 [0,60; 1,17]	0,297	
CCSA class at Randomization											
No Angina	1849	704 (38,1)	36,5	29,5 [24,6; -]	1856	766 (41,3)	41,5	24,0 [21,9; 28,1]	0,89 [0,80; 0,99]	0,028	0,599
Angina Class 1 or 2	265	106 (40,0)	35,2	Not reached [24,1; -]	261	115 (44,1)	40,8	25,7 [16,4; -]	0,88 [0,67; 1,14]	0,400	
Angina Class 3 or 4	44	15 (34,1)	32,4	Not reached [11,7; -]	41	21 (51,2)	51,4	19,8 [6,0; -]	0,63 [0,33; 1,23]	0,257	

Analyses of Time to First Event of CEC Confirmed All-cause Mortality or Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
All-Cause Death or HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus											
Yes	1051	447 (42,5)	41,9	22,7 [18,5; -]	985	448 (45,5)	47,6	20,9 [17,1; 24,9]	0,89 [0,78; 1,02]	0,090	0,662
No	1107	378 (34,1)	31,3	Not reached [29,5; -]	1173	454 (38,7)	37,0	28,4 [23,9; -]	0,86 [0,75; 0,98]	0,033	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total participants with an event per 100 participants years at risk

d: From product-limit (Kaplan-Meier) method

e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction

f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

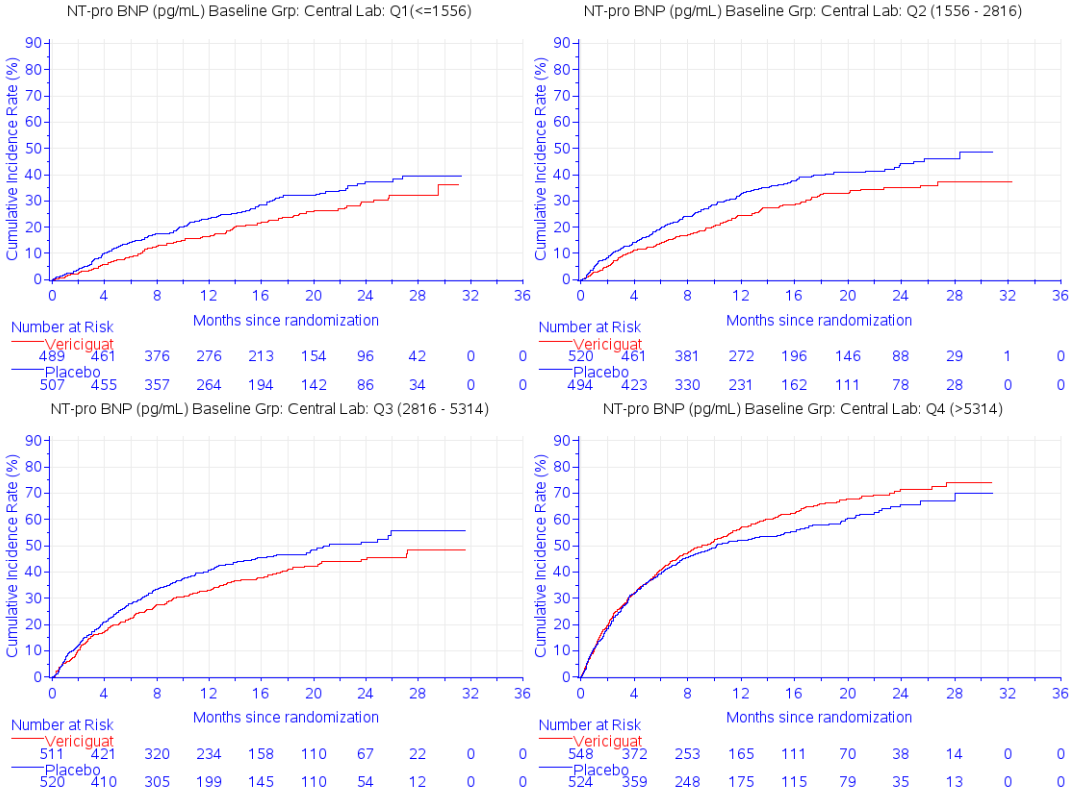
2.14.4.3 Results for Subgroups With Interaction P-value < 0.05

Table 2.14.4-3
Analyses of Time to First Event of CEC Confirmed All-cause Mortality or Heart Failure Hospitalization for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
All-Cause Death or HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
NT-pro BNP (pg/mL) Baseline Grp: Central Lab											
Q1 (≤1556)	489	111 (22,7)	17,9	Not reached [-; -]	507	145 (28,6)	24,3	Not reached [-; -]	0,75 [0,59; 0,96]	0,024	0,001
Q2 (1556 - 2816)	520	148 (28,5)	24,1	Not reached [-; -]	494	181 (36,6)	33,9	Not reached [24,9; -]	0,72 [0,58; 0,90]	0,003	
Q3 (2816 - 5314)	511	193 (37,8)	36,5	Not reached [23,7; -]	520	231 (44,4)	46,6	20,7 [15,6; -]	0,80 [0,66; 0,97]	0,019	
Q4 (>5314)	548	339 (61,9)	79,6	9,1 [7,4; 11,0]	524	296 (56,5)	69,8	10,2 [8,1; 15,2]	1,14 [0,97; 1,33]	0,131	

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
g: P-value from the likelihood ratio test for treatment-by-subgroup interaction
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

Figure 2.14.4-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed All-cause Mortality or Heart Failure Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%
By NT-pro BNP (pg/mL) Baseline Grp: Central Lab



Based on data up to the primary completion date (18JUN2019).

2.14.5 CEC Confirmed CV Death, First MI Hospitalization or Stroke Hospitalization

2.14.5.1 Consistency of Treatment Effect – Summary.

Table 2.14.5-1
Overview of Subgroup Analyses for Time to First Event of CEC Confirmed CV Death, MI Hospitalization or Stroke Hospitalization, Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
Efficacy - Time to Event						
CV Death, MI or Stroke Hospitalization	0,965	0,128	0,250	0,318	0,129	0,498

Overview of Subgroup Analyses for Time to First Event of CEC Confirmed CV Death, MI Hospitalization or Stroke Hospitalization, Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
Efficacy - Time to Event							
CV Death, MI or Stroke Hospitalization	0,850	0,609	0,298	0,663	0,285	0,975	0,750

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CV: Cardiovascular; eGFR: Estimated glomerular filtration rate; HF: Heart failure; MI: Myocardial infarction; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.5.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 2.14.5-2
Analyses of Time to First Event of CEC Confirmed CV Death, MI Hospitalization or Stroke Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death, MI or Stroke Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Age category 1											
<65	834	135 (16,2)	13,1	Not reached [-; -]	854	147 (17,2)	14,0	Not reached [-; -]	0,94 [0,74; 1,19]	0,572	0,965
≥65	1324	278 (21,0)	17,0	Not reached [-; -]	1304	283 (21,7)	18,0	Not reached [-; -]	0,95 [0,80; 1,12]	0,484	
Age category 2											
<75	1523	262 (17,2)	13,9	Not reached [-; -]	1538	299 (19,4)	15,9	Not reached [-; -]	0,88 [0,74; 1,03]	0,109	0,128
≥75	635	151 (23,8)	19,2	Not reached [-; -]	620	131 (21,1)	17,5	Not reached [-; -]	1,10 [0,87; 1,38]	0,476	
Gender											
Male	1661	333 (20,0)	16,2	Not reached [-; -]	1658	334 (20,1)	16,4	Not reached [-; -]	0,99 [0,85; 1,15]	0,832	0,250
Female	497	80 (16,1)	13,1	Not reached [-; -]	500	96 (19,2)	16,1	Not reached [-; -]	0,81 [0,60; 1,09]	0,170	

Analyses of Time to First Event of CEC Confirmed CV Death, MI Hospitalization or Stroke Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death, MI or Stroke Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Geographic Region											
Asia Pacific	511	88 (17,2)	14,7	Not reached [-; -]	503	70 (13,9)	11,7	Not reached [-; -]	1,26 [0,92; 1,72]	0,150	0,318
Eastern Europe	722	167 (23,1)	18,2	Not reached [-; -]	718	176 (24,5)	19,9	Not reached [-; -]	0,92 [0,75; 1,14]	0,451	
Latin and South America	316	52 (16,5)	15,1	Not reached [-; -]	324	65 (20,1)	18,6	Not reached [26,1; -]	0,81 [0,57; 1,17]	0,260	
North America	243	38 (15,6)	12,0	Not reached [-; -]	244	48 (19,7)	15,4	Not reached [-; -]	0,78 [0,51; 1,20]	0,249	
Western Europe	366	68 (18,6)	13,7	Not reached [-; -]	369	71 (19,2)	14,7	Not reached [-; -]	0,93 [0,67; 1,30]	0,659	
Index Event											
HF Hospitalization 3-6 Months	390	66 (16,9)	12,9	Not reached [-; -]	365	76 (20,8)	16,0	Not reached [-; -]	0,82 [0,59; 1,13]	0,256	0,129
HF Hospitalization within 3 Months	1441	299 (20,7)	17,3	Not reached [-; -]	1478	293 (19,8)	16,7	Not reached [-; -]	1,04 [0,88; 1,22]	0,652	
IV diuretic for HF (without hospitalization) within 3 Months	327	48 (14,7)	11,2	Not reached [-; -]	315	61 (19,4)	15,4	Not reached [-; -]	0,72 [0,49; 1,05]	0,178	

Analyses of Time to First Event of CEC Confirmed CV Death, MI Hospitalization or Stroke Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death, MI or Stroke Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category											
≤30	213	62 (29,1)	26,3	Not reached [23,6; -]	203	56 (27,6)	25,3	Not reached [-; -]	1,02 [0,71; 1,47]	0,896	0,498
>30 to ≤60	882	179 (20,3)	16,1	Not reached [-; -]	895	205 (22,9)	18,6	Not reached [-; -]	0,87 [0,71; 1,06]	0,165	
>60	1021	165 (16,2)	12,9	Not reached [-; -]	1024	161 (15,7)	12,7	Not reached [-; -]	1,02 [0,82; 1,27]	0,780	
NYHA Group at Baseline											
Class I or II	1241	175 (14,1)	11,1	Not reached [-; -]	1271	191 (15,0)	12,0	Not reached [-; -]	0,93 [0,75; 1,14]	0,451	0,850
Class III or IV	915	238 (26,0)	21,8	Not reached [-; -]	887	239 (26,9)	23,0	Not reached [-; -]	0,95 [0,79; 1,14]	0,588	
Use of Sacubitril /Valsartan at Baseline											
Yes	330	60 (18,2)	16,2	Not reached [-; -]	330	68 (20,6)	19,0	Not reached [-; -]	0,87 [0,61; 1,23]	0,405	0,609
No	1824	351 (19,2)	15,3	Not reached [-; -]	1825	362 (19,8)	16,0	Not reached [-; -]	0,96 [0,83; 1,11]	0,551	

Analyses of Time to First Event of CEC Confirmed CV Death, MI Hospitalization or Stroke Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death, MI or Stroke Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
NT-pro BNP (pg/mL) Baseline Grp: Central Lab											
Q1 (≤1556)	489	40 (8,2)	5,8	Not reached [-; -]	507	55 (10,8)	8,0	Not reached [-; -]	0,73 [0,49; 1,10]	0,158	0,298
Q2 (1556 - 2816)	520	70 (13,5)	10,1	Not reached [-; -]	494	73 (14,8)	11,3	Not reached [-; -]	0,90 [0,65; 1,25]	0,533	
Q3 (2816 - 5314)	511	96 (18,8)	15,5	Not reached [-; -]	520	106 (20,4)	17,0	Not reached [-; -]	0,92 [0,69; 1,21]	0,537	
Q4 (>5314)	548	193 (35,2)	34,3	28,6 [21,1; -]	524	165 (31,5)	30,6	Not reached [28,1; -]	1,10 [0,89; 1,36]	0,381	
Baseline Ejection Fraction Group 2											
<35	1725	345 (20,0)	16,2	Not reached [-; -]	1741	363 (20,9)	17,4	Not reached [-; -]	0,93 [0,81; 1,08]	0,360	0,663
≥35	433	68 (15,7)	12,4	Not reached [-; -]	417	67 (16,1)	12,3	Not reached [-; -]	1,01 [0,72; 1,42]	0,841	

Analyses of Time to First Event of CEC Confirmed CV Death, MI Hospitalization or Stroke Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death, MI or Stroke Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Race group											
White	1350	270 (20,0)	15,3	Not reached [-; -]	1359	297 (21,9)	17,2	Not reached [-; -]	0,89 [0,76; 1,05]	0,171	0,285
Asian	500	89 (17,8)	15,5	Not reached [-; -]	475	70 (14,7)	12,8	Not reached [-; -]	1,21 [0,88; 1,65]	0,236	
Black	111	17 (15,3)	14,0	Not reached [24,5; -]	118	25 (21,2)	19,0	Not reached [26,9; -]	0,73 [0,40; 1,36]	0,316	
Other	196	37 (18,9)	18,0	Not reached [-; -]	206	38 (18,4)	16,8	Not reached [-; -]	1,06 [0,68; 1,67]	0,802	
CCSA class at Randomization											
No Angina	1849	341 (18,4)	15,0	Not reached [-; -]	1856	353 (19,0)	15,8	Not reached [-; -]	0,95 [0,82; 1,11]	0,521	0,975
Angina Class 1 or 2	265	59 (22,3)	16,7	Not reached [-; -]	261	63 (24,1)	18,6	Not reached [-; -]	0,91 [0,64; 1,30]	0,762	
Angina Class 3 or 4	44	13 (29,5)	25,7	Not reached [-; -]	41	14 (34,1)	26,7	Not reached [19,8; -]	0,93 [0,44; 1,99]	0,825	

Analyses of Time to First Event of CEC Confirmed CV Death, MI Hospitalization or Stroke Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Death, MI or Stroke Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus											
Yes	1051	229 (21,8)	18,1	Not reached [-; -]	985	224 (22,7)	18,9	Not reached [-; -]	0,96 [0,80; 1,15]	0,635	0,750
No	1107	184 (16,6)	13,1	Not reached [-; -]	1173	206 (17,6)	14,2	Not reached [-; -]	0,92 [0,75; 1,12]	0,431	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total participants with an event per 100 participants years at risk

d: From product-limit (Kaplan-Meier) method

e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction

f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular; eGFR: Estimated glomerular filtration rate; HF: Heart failure; MI: Myocardial infarction; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.6 First CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit

2.14.6.1 Consistency of Treatment Effect – Summary.

Table 2.14.6-1
Overview of Subgroup Analyses for Time to First Event of CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit, Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
Efficacy - Time to Event						
HF Hospitalization or Urgent HF visit	0,074	**0,026[b]**	0,918	0,285	0,295	0,210

Overview of Subgroup Analyses for Time to First Event of CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit, Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
Efficacy - Time to Event							
HF Hospitalization or Urgent HF visit	0,133	0,548	**0,001[b]**	0,794	0,510	0,257	0,992

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.6.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 2.14.6-2
Analyses of Time to First Event of CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
HF Hospitalization or Urgent HF visit	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Age category 1											
<65	834	216 (25,9)	24,6	Not reached [-; -]	854	272 (31,9)	32,5	Not reached [-; -]	0,77 [0,65; 0,93]	0,005	0,074
≥65	1324	418 (31,6)	30,8	Not reached [-; -]	1304	425 (32,6)	32,9	Not reached [-; -]	0,95 [0,83; 1,09]	0,430	
Gender											
Male	1661	509 (30,6)	29,7	Not reached [-; -]	1658	559 (33,7)	34,2	Not reached [-; -]	0,88 [0,78; 0,99]	0,033	0,918
Female	497	125 (25,2)	23,9	Not reached [-; -]	500	138 (27,6)	27,6	Not reached [-; -]	0,89 [0,70; 1,13]	0,442	

Analyses of Time to First Event of CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
HF Hospitalization or Urgent HF visit	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Geographic Region											
Asia Pacific	511	159 (31,1)	32,0	Not reached [29,5; -]	503	169 (33,6)	35,2	Not reached [24,0; -]	0,92 [0,74; 1,14]	0,430	0,285
Eastern Europe	722	194 (26,9)	25,0	Not reached [-; -]	718	230 (32,0)	32,0	Not reached [-; -]	0,80 [0,66; 0,97]	0,026	
Latin and South America	316	60 (19,0)	19,8	Not reached [-; -]	324	80 (24,7)	26,9	Not reached [-; -]	0,74 [0,53; 1,04]	0,083	
North America	243	84 (34,6)	32,6	Not reached [25,8; -]	244	95 (38,9)	39,0	Not reached [21,9; -]	0,85 [0,63; 1,14]	0,259	
Western Europe	366	137 (37,4)	33,9	Not reached [22,5; -]	369	123 (33,3)	31,4	Not reached [-; -]	1,09 [0,85; 1,39]	0,492	
Index Event											
HF Hospitalization 3-6 Months	390	100 (25,6)	22,4	Not reached [-; -]	365	107 (29,3)	26,6	Not reached [-; -]	0,86 [0,65; 1,13]	0,292	0,295
HF Hospitalization within 3 Months	1441	460 (31,9)	32,4	Not reached [29,5; -]	1478	495 (33,5)	35,2	Not reached [-; -]	0,93 [0,82; 1,05]	0,246	
IV diuretic for HF (without hospitalization) within 3 Months	327	74 (22,6)	20,0	Not reached [-; -]	315	95 (30,2)	29,5	Not reached [-; -]	0,71 [0,53; 0,97]	0,076	
eGFR (mL/min/1.73 m^2) Category											
≤30	213	104 (48,8)	62,3	13,1 [8,7; 21,7]	203	91 (44,8)	57,9	17,1 [9,9; -]	1,08 [0,82; 1,43]	0,455	0,210
>30 to ≤60	882	276 (31,3)	30,0	Not reached [-; -]	895	328 (36,6)	37,5	Not reached [24,1; -]	0,81 [0,69; 0,95]	0,012	
>60	1021	244 (23,9)	22,0	Not reached [-; -]	1024	265 (25,9)	24,7	Not reached [-; -]	0,91 [0,76; 1,08]	0,306	

Analyses of Time to First Event of CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
HF Hospitalization or Urgent HF visit	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
NYHA Group at Baseline											
Class I or II	1241	330 (26,6)	24,4	Not reached [-; -]	1271	348 (27,4)	25,9	Not reached [-; -]	0,95 [0,82; 1,10]	0,518	0,133
Class III or IV	915	304 (33,2)	34,4	Not reached [-; -]	887	349 (39,3)	44,2	25,7 [20,9; -]	0,80 [0,69; 0,94]	0,009	
Use of Sacubitril /Valsartan at Baseline											
Yes	330	113 (34,2)	37,5	Not reached [23,7; -]	330	115 (34,8)	40,6	25,8 [18,7; -]	0,95 [0,73; 1,23]	0,734	0,548
No	1824	519 (28,5)	26,9	Not reached [-; -]	1825	581 (31,8)	31,5	Not reached [-; -]	0,87 [0,77; 0,97]	0,020	
Baseline Ejection Fraction Group 2											
<35	1725	520 (30,1)	29,4	Not reached [-; -]	1741	569 (32,7)	33,8	Not reached [-; -]	0,89 [0,79; 1,00]	0,051	0,794
≥35	433	114 (26,3)	24,5	Not reached [-; -]	417	128 (30,7)	28,6	Not reached [-; -]	0,85 [0,66; 1,10]	0,222	

Analyses of Time to First Event of CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
HF Hospitalization or Urgent HF visit	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Race group											
White	1350	416 (30,8)	28,0	Not reached [-; -]	1359	439 (32,3)	31,2	Not reached [-; -]	0,92 [0,80; 1,05]	0,207	0,510
Asian	500	146 (29,2)	30,4	Not reached [29,5; -]	475	158 (33,3)	36,1	Not reached [24,0; -]	0,85 [0,68; 1,07]	0,163	
Black	111	29 (26,1)	30,3	Not reached [-; -]	118	35 (29,7)	32,6	25,7 [22,8; -]	0,91 [0,55; 1,48]	0,723	
Other	196	43 (21,9)	24,6	Not reached [-; -]	206	65 (31,6)	36,3	Not reached [19,0; -]	0,68 [0,46; 0,99]	0,044	
CCSA class at Randomization											
No Angina	1849	548 (29,6)	29,0	Not reached [-; -]	1856	593 (32,0)	32,7	Not reached [-; -]	0,90 [0,80; 1,01]	0,082	0,257
Angina Class 1 or 2	265	78 (29,4)	26,0	Not reached [-; -]	261	88 (33,7)	31,7	Not reached [28,4; -]	0,83 [0,61; 1,12]	0,300	
Angina Class 3 or 4	44	8 (18,2)	17,8	Not reached [-; -]	41	16 (39,0)	40,2	Not reached [8,9; -]	0,46 [0,20; 1,07]	0,139	

Analyses of Time to First Event of CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
HF Hospitalization or Urgent HF visit	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus											
Yes	1051	345 (32,8)	32,8	Not reached [-; -]	985	352 (35,7)	38,3	Not reached [26,8; -]	0,87 [0,75; 1,01]	0,074	0,992
No	1107	289 (26,1)	24,4	Not reached [-; -]	1173	345 (29,4)	28,5	Not reached [-; -]	0,87 [0,75; 1,02]	0,104	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total participants with an event per 100 participants years at risk

d: From product-limit (Kaplan-Meier) method

e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction

f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.6.3 Results for Subgroups With Interaction P-value < 0.05

Table 2.14.6-3
Analyses of Time to First Event of CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
HF Hospitalization or Urgent HF visit	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Age category 2											
<75	1523	417 (27,4)	26,1	Not reached [-; -]	1538	497 (32,3)	32,6	Not reached [-; -]	0,81 [0,71; 0,92]	0,002	0,026
≥75	635	217 (34,2)	34,0	Not reached [27,1; -]	620	200 (32,3)	33,0	Not reached [28,4; -]	1,06 [0,87; 1,28]	0,575	

Analyses of Time to First Event of CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
HF Hospitalization or Urgent HF visit	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
NT-pro BNP (pg/mL) Baseline Grp: Central Lab											
Q1 (≤1556)	489	94 (19,2)	15,3	Not reached [-; -]	507	129 (25,4)	21,8	Not reached [-; -]	0,72 [0,55; 0,94]	0,017	0,001
Q2 (1556 - 2816)	520	127 (24,4)	21,2	Not reached [-; -]	494	149 (30,2)	28,5	Not reached [-; -]	0,75 [0,59; 0,95]	0,016	
Q3 (2816 - 5314)	511	148 (29,0)	28,4	Not reached [-; -]	520	188 (36,2)	38,4	Not reached [25,7; -]	0,76 [0,61; 0,94]	0,010	
Q4 (>5314)	548	234 (42,7)	56,0	16,7 [11,9; 26,3]	524	197 (37,6)	47,6	25,5 [20,9; -]	1,19 [0,98; 1,44]	0,079	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total participants with an event per 100 participants years at risk

d: From product-limit (Kaplan-Meier) method

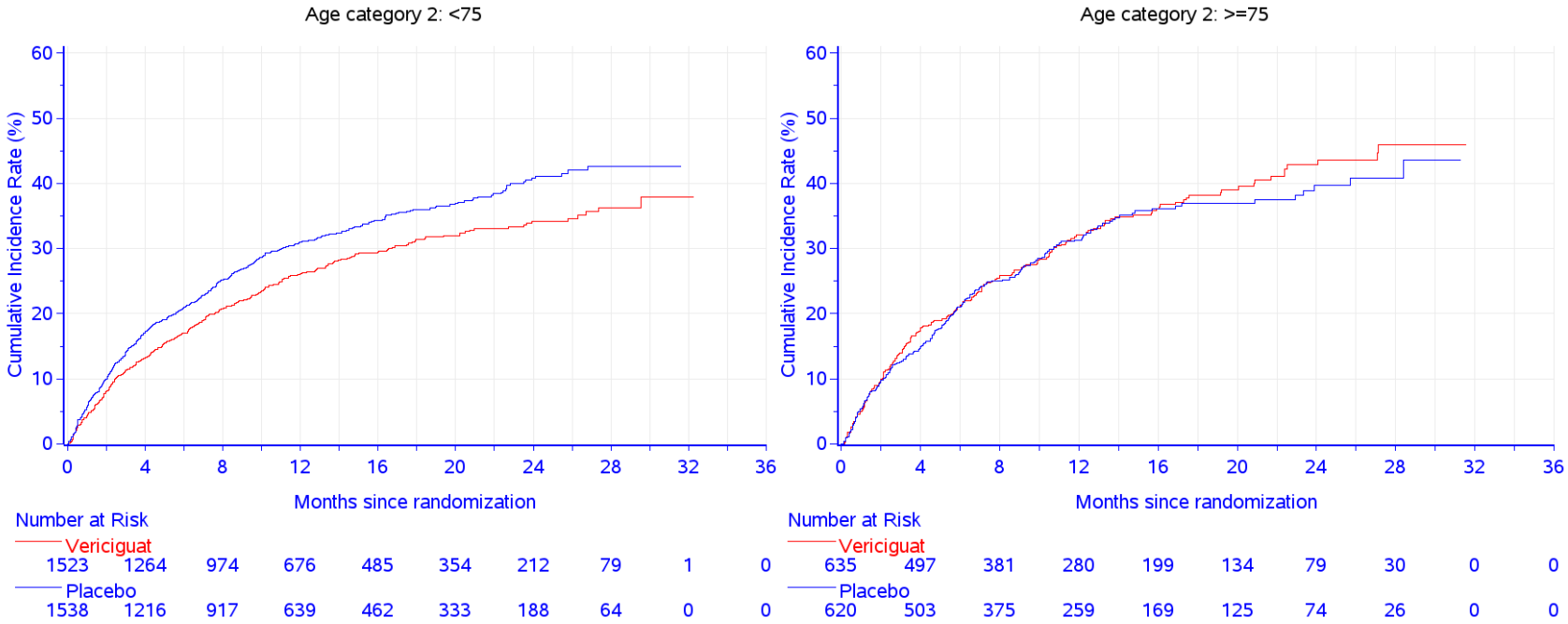
e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction

f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

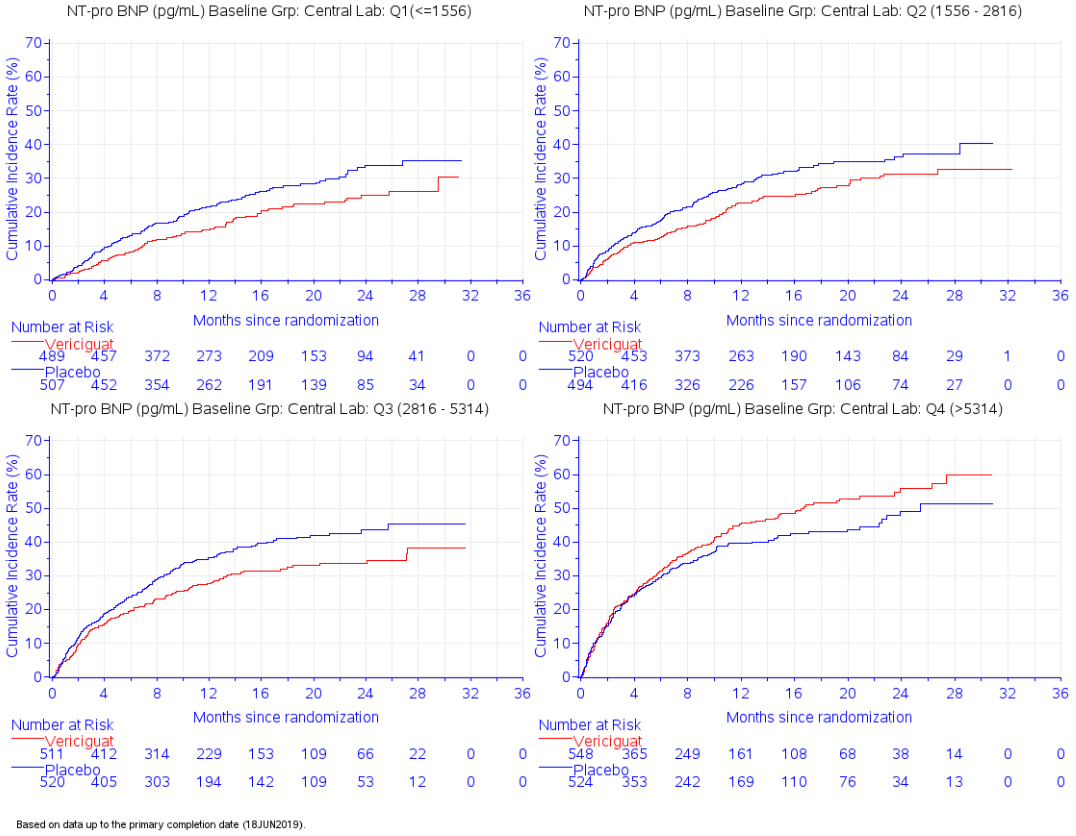
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

Figure 2.14.6-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit
ITT Population Participants with Screening Ejection Fraction < 40%
By Age category



Based on data up to the primary completion date (18JUN2019).

Figure 2.14.6-2
Kaplan-Meier Plot Time to First Event of CEC Confirmed Heart Failure Hospitalization or Urgent Heart Failure Visit
ITT Population Participants with Screening Ejection Fraction < 40%
By NT-pro BNP (pg/mL) Baseline Grp: Central Lab



Based on data up to the primary completion date (18JUN2019).

2.14.7 First CEC Confirmed Heart Failure Hospitalization

2.14.7.1 Consistency of Treatment Effect – Summary.

Table 2.14.7-1
Overview of Subgroup Analyses for Time to First Event of CEC Confirmed Heart Failure Hospitalization,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
Efficacy - Time to Event						
HF Hospitalization	0,063	**0,017[b]**	0,914	0,289	0,134	0,222

Overview of Subgroup Analyses for Time to First Event of CEC Confirmed Heart Failure Hospitalization,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
Efficacy - Time to Event							
HF Hospitalization	0,107	0,669	**< 0,001[b]**	0,917	0,582	0,138	0,647

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.7.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 2.14.7-2
Analyses of Time to First Event of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Age category 1											
<65	834	203 (24,3)	22,8	Not reached [-; -]	854	257 (30,1)	30,2	Not reached [-; -]	0,77 [0,64; 0,92]	0,004	0,063
≥65	1324	399 (30,1)	28,9	Not reached [-; -]	1304	402 (30,8)	30,6	Not reached [-; -]	0,96 [0,83; 1,10]	0,489	
Gender											
Male	1661	484 (29,1)	27,8	Not reached [-; -]	1658	530 (32,0)	31,9	Not reached [-; -]	0,88 [0,78; 1,00]	0,042	0,914
Female	497	118 (23,7)	22,2	Not reached [-; -]	500	129 (25,8)	25,4	Not reached [-; -]	0,89 [0,70; 1,15]	0,461	

Analyses of Time to First Event of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Geographic Region											
Asia Pacific	511	149 (29,2)	29,4	Not reached [29,5; -]	503	157 (31,2)	32,0	Not reached [-; -]	0,93 [0,74; 1,16]	0,497	0,289
Eastern Europe	722	189 (26,2)	24,2	Not reached [-; -]	718	221 (30,8)	30,3	Not reached [-; -]	0,82 [0,67; 0,99]	0,041	
Latin and South America	316	55 (17,4)	18,0	Not reached [-; -]	324	76 (23,5)	25,3	Not reached [-; -]	0,71 [0,50; 1,01]	0,057	
North America	243	81 (33,3)	30,9	Not reached [25,8; -]	244	91 (37,3)	36,7	Not reached [22,6; -]	0,85 [0,63; 1,15]	0,290	
Western Europe	366	128 (35,0)	30,8	Not reached [27,1; -]	369	114 (30,9)	28,7	Not reached [-; -]	1,09 [0,85; 1,40]	0,517	
Index Event											
HF Hospitalization 3-6 Months	390	94 (24,1)	20,8	Not reached [-; -]	365	101 (27,7)	24,8	Not reached [-; -]	0,85 [0,64; 1,13]	0,282	0,134
HF Hospitalization within 3 Months	1441	449 (31,2)	31,3	Not reached [-; -]	1478	476 (32,2)	33,5	Not reached [-; -]	0,94 [0,83; 1,07]	0,357	
IV diuretic for HF (without hospitalization) within 3 Months	327	59 (18,0)	15,3	Not reached [-; -]	315	82 (26,0)	24,4	Not reached [-; -]	0,66 [0,47; 0,92]	0,031	
eGFR (mL/min/1.73 m^2) Category											
≤30	213	99 (46,5)	57,8	13,6 [9,6; 26,7]	203	84 (41,4)	51,7	24,0 [10,3; -]	1,12 [0,84; 1,50]	0,388	0,222
>30 to ≤60	882	266 (30,2)	28,6	Not reached [-; -]	895	310 (34,6)	34,7	Not reached [28,4; -]	0,83 [0,71; 0,98]	0,033	
>60	1021	228 (22,3)	20,2	Not reached [-; -]	1024	254 (24,8)	23,5	Not reached [-; -]	0,88 [0,73; 1,05]	0,178	

Analyses of Time to First Event of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
NYHA Group at Baseline											
Class I or II	1241	314 (25,3)	23,0	Not reached [-; -]	1271	327 (25,7)	24,0	Not reached [-; -]	0,96 [0,82; 1,12]	0,628	0,107
Class III or IV	915	288 (31,5)	31,8	Not reached [-; -]	887	332 (37,4)	41,2	Not reached [22,8; -]	0,80 [0,68; 0,94]	0,009	
Use of Sacubitril /Valsartan at Baseline											
Yes	330	103 (31,2)	33,2	Not reached [23,7; -]	330	106 (32,1)	36,5	Not reached [25,5; -]	0,93 [0,71; 1,22]	0,627	0,669
No	1824	497 (27,2)	25,4	Not reached [-; -]	1825	553 (30,3)	29,5	Not reached [-; -]	0,87 [0,77; 0,98]	0,029	
Baseline Ejection Fraction Group 2											
<35	1725	494 (28,6)	27,5	Not reached [-; -]	1741	543 (31,2)	31,8	Not reached [-; -]	0,88 [0,78; 1,00]	0,043	0,917
≥35	433	108 (24,9)	22,8	Not reached [-; -]	417	116 (27,8)	25,3	Not reached [-; -]	0,90 [0,69; 1,16]	0,399	

Analyses of Time to First Event of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Race group											
White	1350	397 (29,4)	26,3	Not reached [-; -]	1359	417 (30,7)	29,2	Not reached [-; -]	0,92 [0,80; 1,05]	0,224	0,582
Asian	500	137 (27,4)	28,1	Not reached [29,5; -]	475	147 (30,9)	32,7	Not reached [25,8; -]	0,86 [0,68; 1,09]	0,216	
Black	111	28 (25,2)	29,1	Not reached [-; -]	118	35 (29,7)	32,5	25,7 [22,8; -]	0,87 [0,53; 1,43]	0,615	
Other	196	40 (20,4)	22,5	Not reached [-; -]	206	60 (29,1)	32,7	Not reached [-; -]	0,68 [0,46; 1,02]	0,059	
CCSA class at Randomization											
No Angina	1849	520 (28,1)	27,0	Not reached [-; -]	1856	561 (30,2)	30,4	Not reached [-; -]	0,90 [0,80; 1,02]	0,092	0,138
Angina Class 1 or 2	265	76 (28,7)	25,2	Not reached [-; -]	261	83 (31,8)	29,5	Not reached [28,4; -]	0,86 [0,63; 1,18]	0,430	
Angina Class 3 or 4	44	6 (13,6)	12,9	Not reached [-; -]	41	15 (36,6)	36,7	Not reached [9,5; -]	0,36 [0,14; 0,93]	0,090	

Analyses of Time to First Event of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus											
Yes	1051	329 (31,3)	30,8	Not reached [-; -]	985	328 (33,3)	34,8	Not reached [-; -]	0,90 [0,77; 1,05]	0,165	0,647
No	1107	273 (24,7)	22,7	Not reached [-; -]	1173	331 (28,2)	27,0	Not reached [-; -]	0,85 [0,73; 1,00]	0,061	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total participants with an event per 100 participants years at risk

d: From product-limit (Kaplan-Meier) method

e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction

f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.7.3 Results for Subgroups With Interaction P-value < 0.05

Table 2.14.7-3
Analyses of Time to First Event of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Age category 2											
<75	1523	393 (25,8)	24,2	Not reached [-; -]	1538	470 (30,6)	30,4	Not reached [-; -]	0,81 [0,71; 0,92]	0,002	0,017
≥75	635	209 (32,9)	32,2	Not reached [27,1; -]	620	189 (30,5)	30,6	Not reached [-; -]	1,08 [0,89; 1,31]	0,477	

Analyses of Time to First Event of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
HF Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
NT-pro BNP (pg/mL) Baseline Grp: Central Lab											
Q1 (≤1556)	489	89 (18,2)	14,3	Not reached [-; -]	507	125 (24,7)	21,0	Not reached [-; -]	0,70 [0,53; 0,92]	0,012	< 0,001
Q2 (1556 - 2816)	520	116 (22,3)	19,0	Not reached [-; -]	494	138 (27,9)	25,8	Not reached [-; -]	0,74 [0,58; 0,95]	0,017	
Q3 (2816 - 5314)	511	143 (28,0)	27,0	Not reached [-; -]	520	181 (34,8)	36,5	Not reached [25,7; -]	0,75 [0,61; 0,94]	0,010	
Q4 (>5314)	548	224 (40,9)	52,6	19,2 [13,8; 26,3]	524	185 (35,3)	43,6	Not reached [22,6; -]	1,21 [1,00; 1,48]	0,056	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total participants with an event per 100 participants years at risk

d: From product-limit (Kaplan-Meier) method

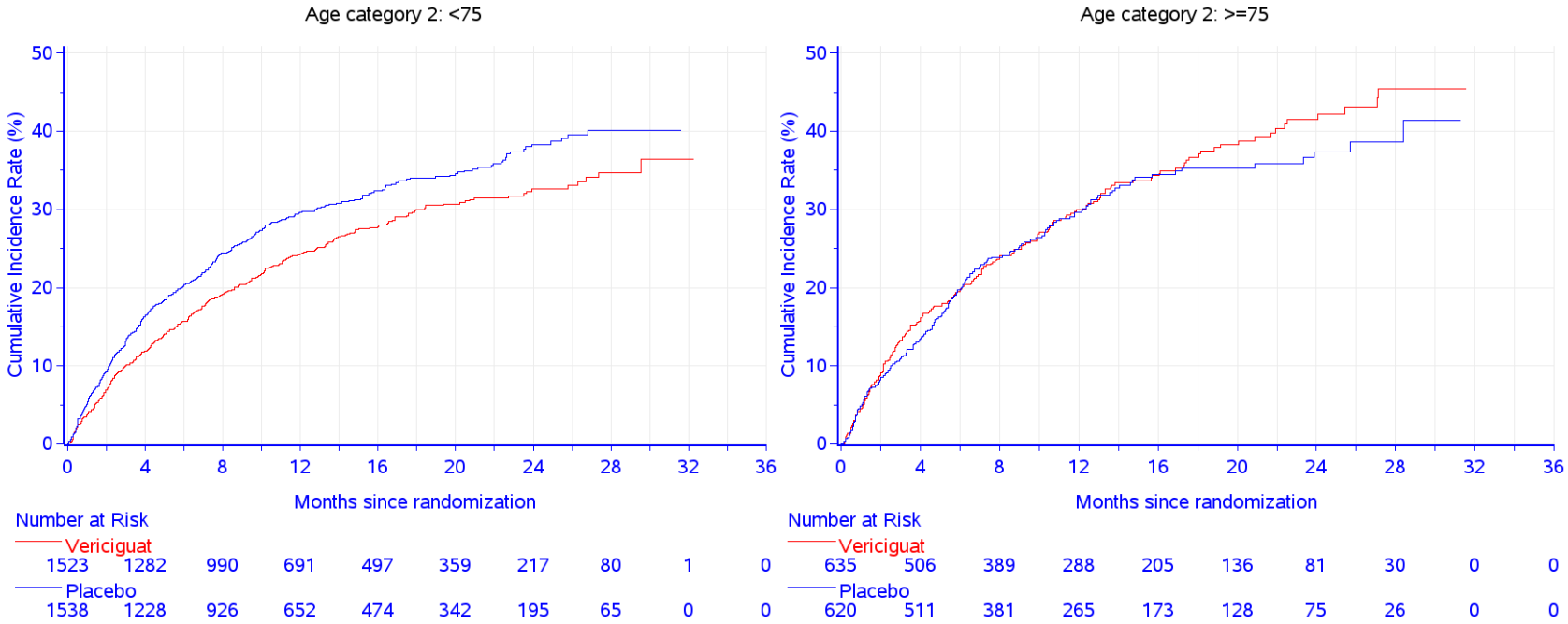
e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction

f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

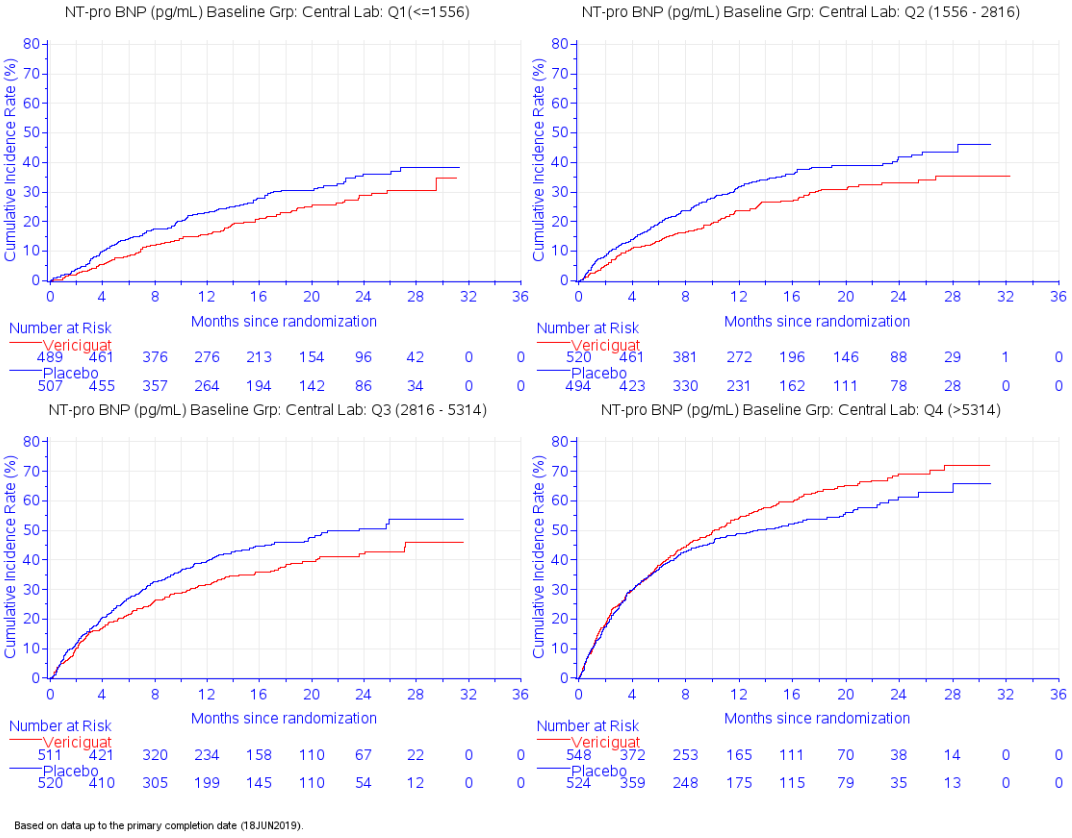
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

Figure 2.14.7-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed Heart Failure Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%
By Age category



Based on data up to the primary completion date (18JUN2019).

Figure 2.14.7-2
Kaplan-Meier Plot Time to First Event of CEC Confirmed Heart Failure Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%
By NT-pro BNP (pg/mL) Baseline Grp: Central Lab



Based on data up to the primary completion date (18JUN2019).

2.14.7.4 First CEC Confirmed Heart Failure Hospitalization for Participants with baseline NT-proBNP values ≤ 5314 pg/mL

Table 2.14-4
Time to First Event of CEC Confirmed Heart Failure Hospitalization
ITT Population
Participants with Screening Ejection Fraction < 40% and baseline NT-proBNP values ≤ 5314 pg/mL

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**	
	N[b]	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time[d] in months [95 %-CI]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**
HF Hospitalization	1520	348 (22,9)	19,8	Not reached [.; .]	1521	444 (29,2)	27,3	Not reached [.; .]	0,73 [0,64; 0,84]	< 0,001

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40% and baseline NT-proBNP values ≤ 5314 pg/mL
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox regression model with treatment as a covariate stratified by stratification factors (defined by region and race)
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
CEC: Clinical Events Committee; CI: Confidence Interval; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide

2.14.8 First and Recurrent CEC Confirmed Heart Failure Hospitalization

2.14.8.1 Consistency of Treatment Effect – Summary.

Table 2.14.8-1
Overview of Subgroup Analyses for Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization, Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
Efficacy - Time to Event						
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	0,363	**0,010[b]**	0,713	**0,019[b]**	0,124	0,093

Overview of Subgroup Analyses for Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization, Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
Efficacy - Time to Event							
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	0,120	**0,010[b]**	**0,005[b]**	0,268	0,309	0,052	0,951

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.8.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 2.14.8-2
Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat				Placebo				Vericiguat vs. Placebo		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
Age category 1											
<65											
Total events[g]	834	383 (45,9)	1052,1	36,4	854	478 (56,0)	1070,5	44,7	0,82 [0,71; 0,95]	0,009	0,363
Participants with only one event	834	118 (14,1)			854	143 (16,7)					
Participants with only two events	834	41 (4,9)			854	67 (7,8)					
Participants with only three events	834	21 (2,5)			854	24 (2,8)					
Participants with only ≥ four events	834	23 (2,8)			854	23 (2,7)					
≥65											
Total events[g]	1324	666 (50,3)	1664,7	40,0	1304	725 (55,6)	1609,9	45,0	0,89 [0,80; 1,00]	0,045	
Participants with only one event	1324	251 (19,0)			1304	233 (17,9)					
Participants with only two events	1324	94 (7,1)			1304	89 (6,8)					
Participants with only three events	1324	27 (2,0)			1304	43 (3,3)					
Participants with only ≥ four events	1324	27 (2,0)			1304	37 (2,8)					

Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
Gender											
Male											
Total events[g]	1661	839 (50,5)	2091,7	40,1	1658	971 (58,6)	2073,5	46,8	0,86 [0,78; 0,95]	0,003	0,713
Participants with only one event	1661	300 (18,1)			1658	300 (18,1)					
Participants with only two events	1661	104 (6,3)			1658	127 (7,7)					
Participants with only three events	1661	42 (2,5)			1658	55 (3,3)					
Participants with only ≥ four events	1661	38 (2,3)			1658	48 (2,9)					
Female											
Total events[g]	497	210 (42,3)	625,2	33,6	500	232 (46,4)	607,0	38,2	0,89 [0,73; 1,09]	0,267	
Participants with only one event	497	69 (13,9)			500	76 (15,2)					
Participants with only two events	497	31 (6,2)			500	29 (5,8)					
Participants with only three events	497	6 (1,2)			500	12 (2,4)					
Participants with only ≥ four events	497	12 (2,4)			500	12 (2,4)					
Index Event											
HF Hospitalization 3-6 Months											
Total events[g]	390	160 (41,0)	518,4	30,9	365	173 (47,4)	484,9	35,7	0,87 [0,70; 1,09]	0,225	0,124
Participants with only one event	390	56 (14,4)			365	60 (16,4)					
Participants with only two events	390	25 (6,4)			365	28 (7,7)					
Participants with only three events	390	6 (1,5)			365	6 (1,6)					
Participants with only ≥ four events	390	7 (1,8)			365	7 (1,9)					

Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
HF Hospitalization within 3 Months											
Total events[g]	1441	799 (55,4)	1765,2	45,3	1478	903 (61,1)	1793,7	50,3	0,90 [0,81; 1,00]	0,049	
Participants with only one event	1441	272 (18,9)			1478	262 (17,7)					
Participants with only two events	1441	98 (6,8)			1478	111 (7,5)					
Participants with only three events	1441	39 (2,7)			1478	54 (3,7)					
Participants with only ≥ four events	1441	40 (2,8)			1478	49 (3,3)					
IV diuretic for HF (without hospitalization) within 3 Months											
Total events[g]	327	90 (27,5)	433,2	20,8	315	127 (40,3)	401,8	31,6	0,67 [0,51; 0,89]	0,005	
Participants with only one event	327	41 (12,5)			315	54 (17,1)					
Participants with only two events	327	12 (3,7)			315	17 (5,4)					
Participants with only three events	327	3 (0,9)			315	7 (2,2)					
Participants with only ≥ four events	327	3 (0,9)			315	4 (1,3)					

Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
eGFR (mL/min/1.73 m^2) Category											
≤30											
Total events[g]	213	174 (81,7)	242,0	71,9	203	167 (82,3)	223,3	74,8	0,96 [0,75; 1,22]	0,736	0,093
Participants with only one event	213	56 (26,3)			203	43 (21,2)					
Participants with only two events	213	26 (12,2)			203	22 (10,8)					
Participants with only three events	213	11 (5,2)			203	10 (4,9)					
Participants with only ≥ four events	213	6 (2,8)			203	9 (4,4)					
>30 to ≤60											
Total events[g]	882	451 (51,1)	1133,1	39,8	895	580 (64,8)	1137,2	51,0	0,79 [0,69; 0,90]	< 0,001	
Participants with only one event	882	169 (19,2)			895	162 (18,1)					
Participants with only two events	882	55 (6,2)			895	85 (9,5)					
Participants with only three events	882	19 (2,2)			895	32 (3,6)					
Participants with only ≥ four events	882	23 (2,6)			895	31 (3,5)					
>60											
Total events[g]	1021	409 (40,1)	1294,2	31,6	1024	435 (42,5)	1282,8	33,9	0,94 [0,81; 1,09]	0,401	
Participants with only one event	1021	138 (13,5)			1024	165 (16,1)					
Participants with only two events	1021	52 (5,1)			1024	47 (4,6)					
Participants with only three events	1021	18 (1,8)			1024	24 (2,3)					
Participants with only ≥ four events	1021	20 (2,0)			1024	18 (1,8)					

Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
NYHA Group at Baseline											
Class I or II											
Total events[g]	1241	513 (41,3)	1604,3	32,0	1271	561 (44,1)	1623,5	34,6	0,92 [0,81; 1,05]	0,216	0,120
Participants with only one event	1241	207 (16,7)			1271	198 (15,6)					
Participants with only two events	1241	64 (5,2)			1271	70 (5,5)					
Participants with only three events	1241	22 (1,8)			1271	36 (2,8)					
Participants with only ≥ four events	1241	21 (1,7)			1271	23 (1,8)					
Class III or IV											
Total events[g]	915	536 (58,6)	1110,2	48,3	887	642 (72,4)	1057,0	60,7	0,81 [0,71; 0,92]	0,001	
Participants with only one event	915	162 (17,7)			887	178 (20,1)					
Participants with only two events	915	71 (7,8)			887	86 (9,7)					
Participants with only three events	915	26 (2,8)			887	31 (3,5)					
Participants with only ≥ four events	915	29 (3,2)			887	37 (4,2)					

Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat				Placebo				Vericiguat vs. Placebo		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
Baseline Ejection Fraction Group 2											
<35											
Total events[g]	1725	884 (51,2)	2157,2	41,0	1741	994 (57,1)	2123,5	46,8	0,88 [0,80; 0,97]	0,013	0,268
Participants with only one event	1725	299 (17,3)			1741	307 (17,6)					
Participants with only two events	1725	113 (6,6)			1741	130 (7,5)					
Participants with only three events	1725	35 (2,0)			1741	58 (3,3)					
Participants with only ≥ four events	1725	47 (2,7)			1741	48 (2,8)					
≥35											
Total events[g]	433	165 (38,1)	559,6	29,5	417	209 (50,1)	557,0	37,5	0,78 [0,63; 0,97]	0,023	
Participants with only one event	433	70 (16,2)			417	69 (16,5)					
Participants with only two events	433	22 (5,1)			417	26 (6,2)					
Participants with only three events	433	13 (3,0)			417	9 (2,2)					
Participants with only ≥ four events	433	3 (0,7)			417	12 (2,9)					
Race group											
White											
Total events[g]	1350	658 (48,7)	1804,0	36,5	1359	765 (56,3)	1754,0	43,6	0,84 [0,76; 0,94]	0,003	0,309
Participants with only one event	1350	247 (18,3)			1359	238 (17,5)					
Participants with only two events	1350	94 (7,0)			1359	98 (7,2)					
Participants with only three events	1350	30 (2,2)			1359	43 (3,2)					
Participants with only ≥ four events	1350	26 (1,9)			1359	38 (2,8)					

Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
Asian											
Total events[g]	500	267 (53,4)	578,9	46,1	475	263 (55,4)	554,9	47,4	0,97 [0,80; 1,16]	0,732	
Participants with only one event	500	80 (16,0)			475	82 (17,3)					
Participants with only two events	500	30 (6,0)			475	37 (7,8)					
Participants with only three events	500	10 (2,0)			475	15 (3,2)					
Participants with only ≥ four events	500	17 (3,4)			475	13 (2,7)					
Black											
Total events[g]	111	57 (51,4)	122,9	46,4	118	70 (59,3)	136,0	51,5	0,90 [0,62; 1,31]	0,578	
Participants with only one event	111	15 (13,5)			118	18 (15,3)					
Participants with only two events	111	6 (5,4)			118	10 (8,5)					
Participants with only three events	111	4 (3,6)			118	3 (2,5)					
Participants with only ≥ four events	111	3 (2,7)			118	4 (3,4)					
Other											
Total events[g]	196	67 (34,2)	209,0	32,1	206	105 (51,0)	235,6	44,6	0,71 [0,51; 0,98]	0,040	
Participants with only one event	196	27 (13,8)			206	38 (18,4)					
Participants with only two events	196	5 (2,6)			206	11 (5,3)					
Participants with only three events	196	4 (2,0)			206	6 (2,9)					
Participants with only ≥ four events	196	4 (2,0)			206	5 (2,4)					

Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
CCSA class at Randomization											
No Angina											
Total events[g]	1849	916 (49,5)	2306,1	39,7	1856	1022 (55,1)	2273,1	45,0	0,89 [0,81; 0,98]	0,018	0,052
Participants with only one event	1849	313 (16,9)			1856	315 (17,0)					
Participants with only two events	1849	122 (6,6)			1856	141 (7,6)					
Participants with only three events	1849	41 (2,2)			1856	58 (3,1)					
Participants with only ≥ four events	1849	44 (2,4)			1856	47 (2,5)					
Angina Class 1 or 2											
Total events[g]	265	123 (46,4)	359,8	34,2	261	155 (59,4)	354,2	43,8	0,77 [0,59; 1,00]	0,050	
Participants with only one event	265	52 (19,6)			261	51 (19,5)					
Participants with only two events	265	13 (4,9)			261	14 (5,4)					
Participants with only three events	265	5 (1,9)			261	7 (2,7)					
Participants with only ≥ four events	265	6 (2,3)			261	11 (4,2)					

Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
Angina Class 3 or 4											
Total events[g]	44	10 (22,7)	51,0	19,6	41	26 (63,4)	53,2	48,9	0,41 [0,18; 0,90]	0,026	
Participants with only one event	44	4 (9,1)			41	10 (24,4)					
Participants with only two events	44	- (-)			41	1 (2,4)					
Participants with only three events	44	2 (4,5)			41	2 (4,9)					
Participants with only ≥ four events	44	- (-)			41	2 (4,9)					
Medical History of Diabetes Mellitus											
Yes											
Total events[g]	1051	596 (56,7)	1303,3	45,7	985	650 (66,0)	1208,3	53,8	0,85 [0,76; 0,97]	0,012	0,951
Participants with only one event	1051	189 (18,0)			985	170 (17,3)					
Participants with only two events	1051	79 (7,5)			985	85 (8,6)					
Participants with only three events	1051	33 (3,1)			985	37 (3,8)					
Participants with only ≥ four events	1051	28 (2,7)			985	36 (3,7)					

Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
No											
Total events[g]	1107	453 (40,9)	1413,5	32,0	1173	553 (47,1)	1472,1	37,6	0,86 [0,75; 0,98]	0,024	
Participants with only one event	1107	180 (16,3)			1173	206 (17,6)					
Participants with only two events	1107	56 (5,1)			1173	71 (6,1)					
Participants with only three events	1107	15 (1,4)			1173	30 (2,6)					
Participants with only ≥ four events	1107	22 (2,0)			1173	24 (2,0)					

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total events per 100 participant years of follow up

d: Vericiguat over placebo

e: Calculated based on Andersen-Gill model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction. Robust standard errors are used to account for correlations of event times within a participant

f: P-value from the likelihood ratio test for treatment-by-subgroup interaction

g: Total number of heart failure hospitalizations (first and recurrent)

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; IRR: Incidence Rate Rato; ITT: Intention-to-Treat; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.8.3 Results for Subgroups With Interaction P-value < 0.05

Table 2.14.8-3
Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
Age category 2											
<75											
Total events[g]	1523	705 (46,3)	1922,0	36,7	1538	872 (56,7)	1915,1	45,5	0,81 [0,72; 0,90]	< 0,001	0,010
Participants with only one event	1523	239 (15,7)			1538	270 (17,6)					
Participants with only two events	1523	82 (5,4)			1538	106 (6,9)					
Participants with only three events	1523	33 (2,2)			1538	49 (3,2)					
Participants with only ≥ four events	1523	39 (2,6)			1538	45 (2,9)					
≥75											
Total events[g]	635	344 (54,2)	794,8	43,3	620	331 (53,4)	765,4	43,2	1,02 [0,87; 1,20]	0,811	
Participants with only one event	635	130 (20,5)			620	106 (17,1)					
Participants with only two events	635	53 (8,3)			620	50 (8,1)					
Participants with only three events	635	15 (2,4)			620	18 (2,9)					
Participants with only ≥ four events	635	11 (1,7)			620	15 (2,4)					

Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
Geographic Region											
Asia Pacific											
Total events[g]	511	290 (56,8)	603,7	48,0	503	285 (56,7)	608,9	46,8	1,02 [0,85; 1,22]	0,816	0,019
Participants with only one event	511	86 (16,8)			503	84 (16,7)					
Participants with only two events	511	33 (6,5)			503	42 (8,3)					
Participants with only three events	511	12 (2,3)			503	17 (3,4)					
Participants with only ≥ four events	511	18 (3,5)			503	14 (2,8)					
Eastern Europe											
Total events[g]	722	321 (44,5)	936,3	34,3	718	398 (55,4)	902,1	44,1	0,79 [0,67; 0,92]	0,003	
Participants with only one event	722	116 (16,1)			718	125 (17,4)					
Participants with only two events	722	42 (5,8)			718	54 (7,5)					
Participants with only three events	722	16 (2,2)			718	24 (3,3)					
Participants with only ≥ four events	722	15 (2,1)			718	18 (2,5)					
Latin and South America											
Total events[g]	316	89 (28,2)	346,5	25,7	324	134 (41,4)	358,9	37,3	0,69 [0,52; 0,91]	0,008	
Participants with only one event	316	36 (11,4)			324	46 (14,2)					
Participants with only two events	316	11 (3,5)			324	15 (4,6)					
Participants with only three events	316	3 (0,9)			324	9 (2,8)					
Participants with only ≥ four events	316	5 (1,6)			324	6 (1,9)					

Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
North America											
Total events[g]	243	141 (58,0)	322,2	43,8	244	183 (75,0)	317,2	57,7	0,77 [0,61; 0,97]	0,028	
Participants with only one event	243	47 (19,3)			244	49 (20,1)					
Participants with only two events	243	22 (9,1)			244	23 (9,4)					
Participants with only three events	243	7 (2,9)			244	10 (4,1)					
Participants with only ≥ four events	243	5 (2,1)			244	9 (3,7)					
Western Europe											
Total events[g]	366	208 (56,8)	508,2	40,9	369	203 (55,0)	493,3	41,2	1,00 [0,81; 1,23]	0,979	
Participants with only one event	366	84 (23,0)			369	72 (19,5)					
Participants with only two events	366	27 (7,4)			369	22 (6,0)					
Participants with only three events	366	10 (2,7)			369	7 (1,9)					
Participants with only ≥ four events	366	7 (1,9)			369	13 (3,5)					

Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
Use of Sacubitril /Valsartan at Baseline											
Yes											
Total events[g]	330	202 (61,2)	381,3	53,0	330	178 (53,9)	365,0	48,8	1,10 [0,89; 1,36]	0,397	0,010
Participants with only one event	330	60 (18,2)			330	60 (18,2)					
Participants with only two events	330	17 (5,2)			330	31 (9,4)					
Participants with only three events	330	12 (3,6)			330	11 (3,3)					
Participants with only ≥ four events	330	14 (4,2)			330	4 (1,2)					
No											
Total events[g]	1824	844 (46,3)	2332,1	36,2	1825	1025 (56,2)	2311,7	44,3	0,82 [0,74; 0,91]	< 0,001	
Participants with only one event	1824	308 (16,9)			1825	316 (17,3)					
Participants with only two events	1824	117 (6,4)			1825	125 (6,8)					
Participants with only three events	1824	36 (2,0)			1825	56 (3,1)					
Participants with only ≥ four events	1824	36 (2,0)			1825	56 (3,1)					
NT-pro BNP (pg/mL) Baseline Grp: Central Lab											
Q1 (≤1556)											
Total events[g]	489	149 (30,5)	695,5	21,4	507	208 (41,0)	699,1	29,8	0,73 [0,59; 0,91]	0,005	0,005
Participants with only one event	489	61 (12,5)			507	82 (16,2)					
Participants with only two events	489	17 (3,5)			507	26 (5,1)					
Participants with only three events	489	6 (1,2)			507	7 (1,4)					
Participants with only ≥ four events	489	5 (1,0)			507	10 (2,0)					

Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
Q2 (1556 - 2816)											
Total events[g]	520	199 (38,3)	705,1	28,2	494	255 (51,6)	652,2	39,1	0,72 [0,59; 0,88]	0,001	
Participants with only one event	520	68 (13,1)			494	76 (15,4)					
Participants with only two events	520	30 (5,8)			494	34 (6,9)					
Participants with only three events	520	11 (2,1)			494	15 (3,0)					
Participants with only ≥ four events	520	7 (1,3)			494	13 (2,6)					
Q3 (2816 - 5314)											
Total events[g]	511	268 (52,4)	638,5	42,0	520	337 (64,8)	639,5	52,7	0,79 [0,66; 0,95]	0,010	
Participants with only one event	511	86 (16,8)			520	98 (18,8)					
Participants with only two events	511	29 (5,7)			520	41 (7,9)					
Participants with only three events	511	13 (2,5)			520	26 (5,0)					
Participants with only ≥ four events	511	15 (2,9)			520	16 (3,1)					

Analyses of Time to Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Total Events (First and Recurrent) of CEC Confirmed Heart Failure Hospitalization	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**N[b]**	**Participants with Event n (%)**	**Total Follow-up Time (years)**	**Annual %[c]**	**Hazard Ratio [95% CI][d,e]**	**p-Value[e]**	**p-Value for Interaction Test[f]**
Q4 (>5314)											
Total events[g]	548	377 (68,8)	570,0	66,1	524	357 (68,1)	553,7	64,5	1,04 [0,88; 1,22]	0,635	
Participants with only one event	548	138 (25,2)			524	100 (19,1)					
Participants with only two events	548	49 (8,9)			524	49 (9,4)					
Participants with only three events	548	17 (3,1)			524	17 (3,2)					
Participants with only ≥ four events	548	20 (3,6)			524	19 (3,6)					

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total events per 100 participant years of follow up

d: Vericiguat over placebo

e: Calculated based on Andersen-Gill model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction. Robust standard errors are used to account for correlations of event times within a participant

f: P-value from the likelihood ratio test for treatment-by-subgroup interaction

g: Total number of heart failure hospitalizations (first and recurrent)

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; IRR: Incidence Rate Rato; ITT: Intention-to-Treat; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.9 First CEC Confirmed Urgent Heart Failure Visit

2.14.9.1 Consistency of Treatment Effect – Summary.

Table 2.14.9-1
Overview of Subgroup Analyses for Time to First Event of Urgent Heart Failure Visit,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
Efficacy - Time to Event						
Urgent HF Visit	0,072	0,265	0,205	0,482	0,823	0,130

Overview of Subgroup Analyses for Time to First Event of Urgent Heart Failure Visit,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
Efficacy - Time to Event							
Urgent HF Visit	0,488	0,561	0,983	0,584	0,256	0,770	0,052

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.9.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 2.14.9-2
Analyses of Time to First Event of Urgent Heart Failure Visit for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Urgent HF Visit	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Age category 1											
<65	834	25 (3,0)	2,4	Not reached [-; -]	854	40 (4,7)	3,9	Not reached [-; -]	0,64 [0,39; 1,06]	0,087	0,072
≥65	1324	75 (5,7)	4,7	Not reached [-; -]	1304	66 (5,1)	4,3	Not reached [-; -]	1,11 [0,79; 1,54]	0,539	
Age category 2											
<75	1523	59 (3,9)	3,2	Not reached [-; -]	1538	71 (4,6)	3,8	Not reached [-; -]	0,83 [0,59; 1,17]	0,319	0,265
≥75	635	41 (6,5)	5,4	Not reached [-; -]	620	35 (5,6)	4,7	Not reached [-; -]	1,15 [0,73; 1,80]	0,439	
Gender											
Male	1661	75 (4,5)	3,7	Not reached [-; -]	1658	87 (5,2)	4,3	Not reached [-; -]	0,85 [0,63; 1,16]	0,328	0,205
Female	497	25 (5,0)	4,1	Not reached [-; -]	500	19 (3,8)	3,2	Not reached [-; -]	1,32 [0,72; 2,39]	0,349	

Analyses of Time to First Event of Urgent Heart Failure Visit for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Urgent HF Visit	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Geographic Region											
Asia Pacific	511	31 (6,1)	5,4	Not reached [-; -]	503	35 (7,0)	6,0	Not reached [-; -]	0,88 [0,54; 1,43]	0,606	0,482
Eastern Europe	722	20 (2,8)	2,2	Not reached [-; -]	718	19 (2,6)	2,1	Not reached [-; -]	1,04 [0,55; 1,95]	0,902	
Latin and South America	316	13 (4,1)	3,9	Not reached [-; -]	324	15 (4,6)	4,3	Not reached [-; -]	0,90 [0,43; 1,89]	0,787	
North America	243	13 (5,3)	4,2	Not reached [-; -]	244	21 (8,6)	7,1	Not reached [-; -]	0,60 [0,30; 1,20]	0,152	
Western Europe	366	23 (6,3)	4,7	Not reached [-; -]	369	16 (4,3)	3,3	Not reached [-; -]	1,42 [0,75; 2,69]	0,269	
Index Event											
HF Hospitalization 3-6 Months	390	19 (4,9)	3,7	Not reached [-; -]	365	17 (4,7)	3,6	Not reached [-; -]	1,05 [0,54; 2,01]	0,834	0,823
HF Hospitalization within 3 Months	1441	50 (3,5)	2,9	Not reached [-; -]	1478	59 (4,0)	3,4	Not reached [-; -]	0,86 [0,59; 1,25]	0,462	
IV diuretic for HF (without hospitalization) within 3 Months	327	31 (9,5)	7,7	Not reached [-; -]	315	30 (9,5)	8,0	Not reached [-; -]	1,01 [0,61; 1,67]	0,968	

Analyses of Time to First Event of Urgent Heart Failure Visit for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Urgent HF Visit	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category											
≤30	213	15 (7,0)	6,5	Not reached [-; -]	203	16 (7,9)	7,6	Not reached [-; -]	0,88 [0,43; 1,78]	0,819	0,130
>30 to ≤60	882	43 (4,9)	3,9	Not reached [-; -]	895	58 (6,5)	5,3	Not reached [-; -]	0,74 [0,50; 1,10]	0,144	
>60	1021	40 (3,9)	3,2	Not reached [-; -]	1024	29 (2,8)	2,3	Not reached [-; -]	1,39 [0,86; 2,24]	0,163	
NYHA Group at Baseline											
Class I or II	1241	53 (4,3)	3,4	Not reached [-; -]	1271	63 (5,0)	4,0	Not reached [-; -]	0,86 [0,60; 1,24]	0,414	0,488
Class III or IV	915	47 (5,1)	4,4	Not reached [-; -]	887	43 (4,8)	4,2	Not reached [-; -]	1,04 [0,69; 1,58]	0,864	
Use of Sacubitril /Valsartan at Baseline											
Yes	330	21 (6,4)	5,7	Not reached [-; -]	330	18 (5,5)	5,1	Not reached [-; -]	1,12 [0,60; 2,10]	0,633	0,561
No	1824	79 (4,3)	3,5	Not reached [-; -]	1825	87 (4,8)	3,9	Not reached [-; -]	0,91 [0,67; 1,23]	0,545	

Analyses of Time to First Event of Urgent Heart Failure Visit for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat				Placebo				Vericiguat vs. Placebo		
Urgent HF Visit	N[b]	Participants with Event n (%)	Annual %[c]	Median Time in months [95 %-CI][d]	N[b]	Participants with Event n (%)	Annual %[c]	Median Time in months [95 %-CI][d]	Hazard Ratio [95 %-CI][e]	p-Value[f]	p-Value for Interaction Test[g]
NT-pro BNP (pg/mL) Baseline Grp: Central Lab											
Q1 (≤1556)	489	14 (2,9)	2,0	Not reached [-; -]	507	16 (3,2)	2,3	Not reached [-; -]	0,89 [0,43; 1,82]	0,753	0,983
Q2 (1556 - 2816)	520	29 (5,6)	4,3	Not reached [-; -]	494	29 (5,9)	4,6	Not reached [-; -]	0,92 [0,55; 1,53]	0,726	
Q3 (2816 - 5314)	511	23 (4,5)	3,7	Not reached [-; -]	520	24 (4,6)	3,9	Not reached [-; -]	0,97 [0,54; 1,71]	0,907	
Q4 (>5314)	548	31 (5,7)	5,7	Not reached [-; -]	524	30 (5,7)	5,7	Not reached [-; -]	1,04 [0,63; 1,71]	0,814	
Baseline Ejection Fraction Group 2											
<35	1725	82 (4,8)	3,9	Not reached [-; -]	1741	84 (4,8)	4,1	Not reached [-; -]	0,97 [0,72; 1,32]	0,890	0,584
≥35	433	18 (4,2)	3,3	Not reached [-; -]	417	22 (5,3)	4,1	Not reached [-; -]	0,80 [0,43; 1,50]	0,460	

Analyses of Time to First Event of Urgent Heart Failure Visit for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Urgent HF Visit	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Race group											
White	1350	61 (4,5)	3,5	Not reached [-; -]	1359	52 (3,8)	3,0	Not reached [-; -]	1,17 [0,81; 1,69]	0,418	0,256
Asian	500	27 (5,4)	4,9	Not reached [-; -]	475	31 (6,5)	5,9	Not reached [-; -]	0,82 [0,49; 1,38]	0,449	
Black	111	2 (1,8)	1,7	Not reached [-; -]	118	6 (5,1)	4,6	Not reached [-; -]	0,36 [0,07; 1,78]	0,192	
Other	196	10 (5,1)	5,1	Not reached [-; -]	206	17 (8,3)	7,7	Not reached [-; -]	0,65 [0,30; 1,41]	0,280	
CCSA class at Randomization											
No Angina	1849	88 (4,8)	4,0	Not reached [-; -]	1856	91 (4,9)	4,1	Not reached [-; -]	0,97 [0,72; 1,30]	0,843	0,770
Angina Class 1 or 2	265	10 (3,8)	2,8	Not reached [-; -]	261	13 (5,0)	3,8	Not reached [-; -]	0,71 [0,31; 1,61]	0,412	
Angina Class 3 or 4	44	2 (4,5)	4,0	Not reached [-; -]	41	2 (4,9)	4,0	Not reached [-; -]	1,09 [0,15; 7,75]	0,942	

Analyses of Time to First Event of Urgent Heart Failure Visit for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat				Placebo				Vericiguat vs. Placebo		
Urgent HF Visit	N[b]	Participants with Event n (%)	Annual %[c]	Median Time in months [95 %-CI][d]	N[b]	Participants with Event n (%)	Annual %[c]	Median Time in months [95 %-CI][d]	Hazard Ratio [95 %-CI][e]	p-Value[f]	p-Value for Interaction Test[g]
Medical History of Diabetes Mellitus											
Yes	1051	47 (4,5)	3,7	Not reached [-; -]	985	60 (6,1)	5,2	Not reached [-; -]	0,72 [0,49; 1,05]	0,092	0,052
No	1107	53 (4,8)	3,9	Not reached [-; -]	1173	46 (3,9)	3,2	Not reached [-; -]	1,23 [0,83; 1,83]	0,269	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total participants with an event per 100 participants years at risk

d: From product-limit (Kaplan-Meier) method

e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction

f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.10 First CEC Confirmed Cardiovascular Hospitalization

2.14.10.1 Consistency of Treatment Effect – Summary.

Table 2.14.10-1
Overview of Subgroup Analyses for Time to First Event of CEC Confirmed Cardiovascular Hospitalization,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
Efficacy - Time to Event						
CV Hospitalization	0,180	0,057	0,965	0,441	0,400	0,414

Overview of Subgroup Analyses for Time to First Event of CEC Confirmed Cardiovascular Hospitalization,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
Efficacy - Time to Event							
CV Hospitalization	0,793	0,291	**0,009[b]**	0,724	0,385	0,254	0,832

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CV: Cardiovascular; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.10.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 2.14.10-2
Analyses of Time to First Event of CEC Confirmed Cardiovascular Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Age category 1											
<65	834	297 (35,6)	36,5	29,5 [26,3; -]	854	352 (41,2)	46,7	23,0 [20,0; -]	0,80 [0,69; 0,94]	0,005	0,180
≥65	1324	526 (39,7)	41,3	24,1 [20,9; -]	1304	547 (41,9)	45,9	23,5 [17,6; -]	0,92 [0,81; 1,03]	0,152	
Age category 2											
<75	1523	558 (36,6)	37,8	29,5 [26,3; -]	1538	646 (42,0)	46,7	23,0 [20,1; 26,8]	0,82 [0,73; 0,92]	< 0,001	0,057
≥75	635	265 (41,7)	43,4	22,4 [17,4; -]	620	253 (40,8)	44,8	23,9 [16,0; -]	1,00 [0,84; 1,19]	0,976	
Gender											
Male	1661	661 (39,8)	41,5	26,3 [21,7; -]	1658	720 (43,4)	48,4	20,9 [16,9; 25,5]	0,87 [0,79; 0,97]	0,012	0,965
Female	497	162 (32,6)	32,8	Not reached [27,4; -]	500	179 (35,8)	39,0	Not reached [22,6; -]	0,87 [0,70; 1,07]	0,226	

Analyses of Time to First Event of CEC Confirmed Cardiovascular Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Geographic Region											
Asia Pacific	511	191 (37,4)	40,0	27,1 [22,4; -]	503	212 (42,1)	47,7	22,3 [15,0; -]	0,85 [0,70; 1,04]	0,106	0,441
Eastern Europe	722	278 (38,5)	39,6	Not reached [20,0; -]	718	311 (43,3)	48,3	20,9 [16,2; 26,8]	0,84 [0,72; 0,99]	0,042	
Latin and South America	316	89 (28,2)	30,8	Not reached [-; -]	324	106 (32,7)	38,4	Not reached [20,7; -]	0,81 [0,61; 1,08]	0,147	
North America	243	97 (39,9)	39,4	27,4 [16,4; -]	244	115 (47,1)	51,4	16,5 [10,7; -]	0,79 [0,61; 1,04]	0,090	
Western Europe	366	168 (45,9)	45,2	20,7 [14,8; 26,5]	369	155 (42,0)	43,4	26,6 [16,9; -]	1,05 [0,85; 1,31]	0,663	
Index Event											
HF Hospitalization 3-6 Months	390	136 (34,9)	32,9	Not reached [23,9; -]	365	140 (38,4)	38,2	Not reached [22,6; -]	0,88 [0,69; 1,11]	0,328	0,400
HF Hospitalization within 3 Months	1441	596 (41,4)	45,4	20,9 [17,7; 27,1]	1478	648 (43,8)	50,9	20,1 [16,3; 24,9]	0,90 [0,81; 1,01]	0,073	
IV diuretic for HF (without hospitalization) within 3 Months	327	91 (27,8)	25,3	Not reached [-; -]	315	111 (35,2)	36,2	Not reached [20,7; -]	0,73 [0,56; 0,97]	0,059	

Analyses of Time to First Event of CEC Confirmed Cardiovascular Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category											
≤30	213	111 (52,1)	67,1	11,0 [7,2; 20,9]	203	100 (49,3)	65,3	10,3 [7,8; 20,9]	1,04 [0,80; 1,37]	0,673	0,414
>30 to ≤60	882	362 (41,0)	42,8	23,9 [18,0; -]	895	411 (45,9)	51,4	16,4 [14,1; 21,6]	0,85 [0,74; 0,98]	0,025	
>60	1021	339 (33,2)	32,8	Not reached [27,1; -]	1024	369 (36,0)	38,0	Not reached [25,6; -]	0,88 [0,76; 1,02]	0,112	
NYHA Group at Baseline											
Class I or II	1241	420 (33,8)	32,9	Not reached [27,4; -]	1271	468 (36,8)	38,2	Not reached [24,9; -]	0,88 [0,77; 1,00]	0,049	0,793
Class III or IV	915	402 (43,9)	49,7	18,8 [15,7; 23,8]	887	431 (48,6)	59,8	14,3 [11,8; 18,0]	0,85 [0,75; 0,98]	0,032	
Use of Sacubitril /Valsartan at Baseline											
Yes	330	130 (39,4)	44,7	27,4 [16,0; -]	330	153 (46,4)	61,3	12,7 [10,1; 25,5]	0,77 [0,61; 0,98]	0,046	0,291
No	1824	691 (37,9)	38,6	28,0 [24,0; -]	1825	746 (40,9)	44,1	24,0 [20,9; -]	0,89 [0,80; 0,99]	0,028	

Analyses of Time to First Event of CEC Confirmed Cardiovascular Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Baseline Ejection Fraction Group 2											
<35	1725	674 (39,1)	41,1	26,5 [22,4; -]	1741	735 (42,2)	47,8	21,9 [18,0; 25,8]	0,88 [0,79; 0,98]	0,017	0,724
≥35	433	149 (34,4)	33,4	Not reached [-; -]	417	164 (39,3)	40,0	Not reached [20,9; -]	0,84 [0,67; 1,05]	0,130	
Race group											
White	1350	547 (40,5)	40,1	26,3 [20,9; -]	1359	570 (41,9)	44,3	23,6 [20,4; -]	0,92 [0,82; 1,04]	0,182	0,385
Asian	500	176 (35,2)	38,0	28,0 [23,9; -]	475	199 (41,9)	48,9	21,6 [14,6; -]	0,79 [0,65; 0,97]	0,025	
Black	111	38 (34,2)	42,0	Not reached [14,1; -]	118	48 (40,7)	52,9	19,6 [10,3; -]	0,81 [0,53; 1,24]	0,358	
Other	196	61 (31,1)	36,5	Not reached [18,6; -]	206	82 (39,8)	50,2	Not reached [15,5; -]	0,73 [0,52; 1,01]	0,060	
CCSA class at Randomization											
No Angina	1849	698 (37,8)	39,3	27,1 [23,5; -]	1856	756 (40,7)	45,2	23,9 [20,4; -]	0,89 [0,80; 0,98]	0,020	0,254
Angina Class 1 or 2	265	110 (41,5)	40,9	Not reached [13,9; -]	261	118 (45,2)	49,1	21,2 [12,3; -]	0,86 [0,66; 1,12]	0,440	
Angina Class 3 or 4	44	15 (34,1)	37,3	22,9 [11,6; -]	41	25 (61,0)	71,6	10,8 [3,0; -]	0,52 [0,27; 0,98]	0,036	

Analyses of Time to First Event of CEC Confirmed Cardiovascular Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
CV Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus											
Yes	1051	435 (41,4)	44,2	23,5 [17,7; 28,0]	985	439 (44,6)	51,8	19,4 [15,7; 24,9]	0,87 [0,77; 1,00]	0,044	0,832
No	1107	388 (35,0)	35,2	Not reached [27,1; -]	1173	460 (39,2)	41,8	Not reached [22,3; -]	0,86 [0,75; 0,98]	0,027	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total participants with an event per 100 participants years at risk

d: From product-limit (Kaplan-Meier) method

e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction

f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

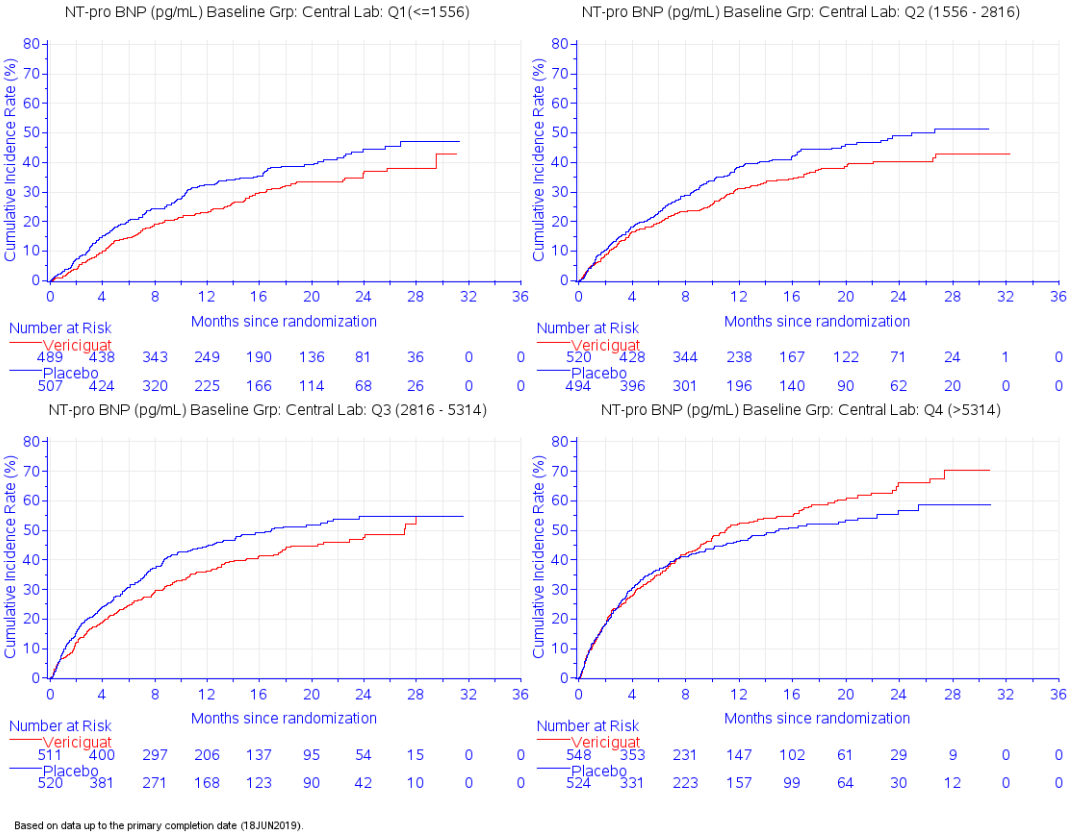
2.14.10.3 Results for Subgroups With Interaction P-value < 0.05

Table 2.14.10-3
Analyses of Time to First Event of CEC Confirmed Cardiovascular Hospitalization for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat				Placebo				Vericiguat vs. Placebo		
CV Hospitalization	N[b]	Participants with Event n (%)	Annual %[c]	Median Time in months [95 %-CI][d]	N[b]	Participants with Event n (%)	Annual %[c]	Median Time in months [95 %-CI][d]	Hazard Ratio [95 %-CI][e]	p-Value[f]	p-Value for Interaction Test[g]
NT-pro BNP (pg/mL) Baseline Grp: Central Lab											
Q1 (≤1556)	489	142 (29,0)	24,8	Not reached [29,5; -]	507	179 (35,3)	33,6	Not reached [23,9; -]	0,76 [0,61; 0,95]	0,016	0,009
Q2 (1556 - 2816)	520	174 (33,5)	31,5	Not reached [-; -]	494	198 (40,1)	41,1	26,6 [19,0; -]	0,78 [0,64; 0,96]	0,014	
Q3 (2816 - 5314)	511	200 (39,1)	41,3	27,1 [18,4; -]	520	238 (45,8)	53,7	16,9 [12,4; -]	0,79 [0,65; 0,95]	0,011	
Q4 (>5314)	548	273 (49,8)	69,3	11,0 [9,4; 14,8]	524	239 (45,6)	62,0	15,0 [11,0; 24,0]	1,12 [0,94; 1,33]	0,201	

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
g: P-value from the likelihood ratio test for treatment-by-subgroup interaction
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; CV: Cardiovascular; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

Figure 2.14.10-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed Cardiovascular Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%
By NT-pro BNP (pg/mL) Baseline Grp: Central Lab



Based on data up to the primary completion date (18JUN2019).

2.14.11 Total Number of CEC Confirmed Heart Failure Hospitalizations

2.14.11.1 Consistency of Treatment Effect – Summary.

Table 2.14.11-1
Overview of Subgroup Analyses for Total Number of CEC Confirmed Heart Failure Hospitalizations,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
Efficacy Morbidity - Total Number of HFH						
Total Number of HF Hospitalizations	0,826	0,055	0,558	0,159	0,301	0,207

Overview of Subgroup Analyses for Total Number of CEC Confirmed Heart Failure Hospitalizations,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
Efficacy Morbidity - Total Number of HFH							
Total Number of HF Hospitalizations	0,417	0,078	0,137	0,596	0,746	0,254	0,851

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.11.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 2.14.11-2
Analyses of Total Number of CEC Confirmed Heart Failure Hospitalizations for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat (N[b]=2158)**			**Placebo (N[b]=2158)**			**Vericiguat vs. Placebo**		
Total Number of HF Hospitalizations	**n[c]**	**Total Follow-up Time (years)[d]**	**Annual %[e]**	**n[c]**	**Total Follow-up Time (years)[d]**	**Annual %[e]**	**IRR [95% CI][f]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Age category 1									
<65	383	1052,1	36,4	478	1070,5	44,7	0,84 [0,68; 1,05]	0,122	0,826
≥65	666	1664,7	40,0	725	1609,9	45,0	0,87 [0,73; 1,03]	0,115	
Age category 2									
<75	705	1922,0	36,7	872	1915,1	45,5	0,79 [0,67; 0,93]	0,004	0,055
≥75	344	794,8	43,3	331	765,4	43,2	1,06 [0,82; 1,35]	0,673	
Gender									
Male	839	2091,7	40,1	971	2073,5	46,8	0,88 [0,76; 1,03]	0,105	0,558
Female	210	625,2	33,6	232	607,0	38,2	0,80 [0,60; 1,07]	0,133	
Geographic Region									
Asia Pacific	290	603,7	48,0	285	608,9	46,8	1,06 [0,81; 1,38]	0,692	0,159
Eastern Europe	321	936,3	34,3	398	902,1	44,1	0,76 [0,60; 0,97]	0,026	
Latin and South America	89	346,5	25,7	134	358,9	37,3	0,67 [0,45; 0,98]	0,038	
North America	141	322,2	43,8	183	317,2	57,7	0,78 [0,53; 1,13]	0,191	
Western Europe	208	508,2	40,9	203	493,3	41,2	1,05 [0,76; 1,44]	0,780	
Index Event									
HF Hospitalization 3-6 Months	160	518,4	30,9	173	484,9	35,7	0,87 [0,62; 1,21]	0,398	0,301
HF Hospitalization within 3 Months	799	1765,2	45,3	903	1793,7	50,3	0,90 [0,77; 1,06]	0,202	
IV diuretic for HF (without hospitalization) within 3 Months	90	433,2	20,8	127	401,8	31,6	0,65 [0,44; 0,95]	0,028	

Analyses of Total Number of CEC Confirmed Heart Failure Hospitalizations for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat (N[b]=2158)**			**Placebo (N[b]=2158)**			**Vericiguat vs. Placebo**		
Total Number of HF Hospitalizations	**n[c]**	**Total Follow-up Time (years)[d]**	**Annual %[e]**	**n[c]**	**Total Follow-up Time (years)[d]**	**Annual %[e]**	**IRR [95% CI][f]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category									
≤30	174	242,0	71,9	167	223,3	74,8	1,01 [0,68; 1,49]	0,980	0,207
>30 to ≤60	451	1133,1	39,8	580	1137,2	51,0	0,76 [0,62; 0,93]	0,008	
>60	409	1294,2	31,6	435	1282,8	33,9	0,96 [0,79; 1,18]	0,698	
NYHA Group at Baseline									
Class I or II	513	1604,3	32,0	561	1623,5	34,6	0,91 [0,76; 1,09]	0,296	0,417
Class III or IV	536	1110,2	48,3	642	1057,0	60,7	0,81 [0,67; 0,99]	0,041	
Use of Sacubitril /Valsartan at Baseline									
Yes	202	381,3	53,0	178	365,0	48,8	1,13 [0,81; 1,58]	0,477	0,078
No	844	2332,1	36,2	1025	2311,7	44,3	0,81 [0,70; 0,94]	0,006	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	149	695,5	21,4	208	699,1	29,8	0,69 [0,51; 0,93]	0,014	0,137
Q2 (1556 - 2816)	199	705,1	28,2	255	652,2	39,1	0,72 [0,55; 0,95]	0,020	
Q3 (2816 - 5314)	268	638,5	42,0	337	639,5	52,7	0,79 [0,61; 1,03]	0,078	
Q4 (>5314)	377	570,0	66,1	357	553,7	64,5	1,04 [0,81; 1,33]	0,780	
Baseline Ejection Fraction Group 2									
<35	884	2157,2	41,0	994	2123,5	46,8	0,87 [0,75; 1,02]	0,078	0,596
≥35	165	559,6	29,5	209	557,0	37,5	0,80 [0,58; 1,09]	0,153	

Analyses of Total Number of CEC Confirmed Heart Failure Hospitalizations for Subgroups With P-value for Interaction test ≥ 0.05 ITT Population Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat (N[b]=2158)**			**Placebo (N[b]=2158)**			**Vericiguat vs. Placebo**		
Total Number of HF Hospitalizations	**n[c]**	**Total Follow-up Time (years)[d]**	**Annual %[e]**	**n[c]**	**Total Follow-up Time (years)[d]**	**Annual %[e]**	**IRR [95% CI][f]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Race group									
White	658	1804,0	36,5	765	1754,0	43,6	0,85 [0,72; 1,01]	0,060	0,746
Asian	267	578,9	46,1	263	554,9	47,4	0,97 [0,73; 1,28]	0,814	
Black	57	122,9	46,4	70	136,0	51,5	0,90 [0,51; 1,60]	0,723	
Other	67	209,0	32,1	105	235,6	44,6	0,73 [0,46; 1,15]	0,175	
CCSA class at Randomization									
No Angina	916	2306,1	39,7	1022	2273,1	45,0	0,89 [0,77; 1,03]	0,110	0,254
Angina Class 1 or 2	123	359,8	34,2	155	354,2	43,8	0,77 [0,52; 1,13]	0,184	
Angina Class 3 or 4	10	51,0	19,6	26	53,2	48,9	0,38 [0,13; 1,12]	0,080	
Medical History of Diabetes Mellitus									
Yes	596	1303,3	45,7	650	1208,3	53,8	0,86 [0,72; 1,04]	0,129	0,851
No	453	1413,5	32,0	553	1472,1	37,6	0,84 [0,70; 1,02]	0,077	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Number of events in the study arm including the first event and recurrent events

d: From randomization to the last study follow up date or death during the study, whichever is earlier

e: Total events per 100 participants years of follow up

f: Incidence rate ratio (IRR) comparing Vericiguat over Placebo. 95% CI is the 95% confidence interval for the estimate. P-value was calculated based on negative binomial regression model with covariates for treatment and stratification factor, interaction term for treatment-by-subgroup and adjusted by subject follow up duration

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; IRR: Incidence Rate Rato; ITT: Intention-to-Treat; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.12 First CEC Confirmed MI Hospitalization

2.14.12.1 Consistency of Treatment Effect – Summary.

Table 2.14.12-1
Overview of Subgroup Analyses for Time to First Event of CEC Confirmed MI Hospitalization,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
Efficacy - Time to Event						
MI Hospitalization	0,141	0,084	0,157	0,266	0,895	0,225

Overview of Subgroup Analyses for Time to First Event of CEC Confirmed MI Hospitalization,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
Efficacy - Time to Event							
MI Hospitalization	0,518	0,328	**0,003[b]**	0,052	0,434	0,770	**0,008[b]**

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; eGFR: Estimated glomerular filtration rate; HF: Heart failure; MI: Myocardial infarction; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.12.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 2.14.12-2
Analyses of Time to First Event of CEC Confirmed MI Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
MI Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Age category 1											
<65	834	16 (1,9)	1,5	Not reached [-; -]	854	10 (1,2)	0,9	Not reached [-; -]	1,67 [0,76; 3,67]	0,176	0,141
≥65	1324	23 (1,7)	1,4	Not reached [-; -]	1304	27 (2,1)	1,7	Not reached [-; -]	0,81 [0,47; 1,42]	0,433	
Age category 2											
<75	1523	30 (2,0)	1,6	Not reached [-; -]	1538	22 (1,4)	1,2	Not reached [-; -]	1,36 [0,79; 2,36]	0,273	0,084
≥75	635	9 (1,4)	1,1	Not reached [-; -]	620	15 (2,4)	2,0	Not reached [-; -]	0,58 [0,25; 1,32]	0,137	
Gender											
Male	1661	30 (1,8)	1,4	Not reached [-; -]	1658	33 (2,0)	1,6	Not reached [-; -]	0,90 [0,55; 1,48]	0,680	0,157
Female	497	9 (1,8)	1,5	Not reached [-; -]	500	4 (0,8)	0,7	Not reached [-; -]	2,20 [0,68; 7,16]	0,180	

Analyses of Time to First Event of CEC Confirmed MI Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
MI Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Geographic Region											
Asia Pacific	511	9 (1,8)	1,5	Not reached [-; -]	503	5 (1,0)	0,8	Not reached [-; -]	1,80 [0,60; 5,38]	0,284	0,266
Eastern Europe	722	19 (2,6)	2,1	Not reached [-; -]	718	14 (1,9)	1,6	Not reached [-; -]	1,32 [0,66; 2,63]	0,449	
Latin and South America	316	3 (0,9)	0,9	Not reached [-; -]	324	6 (1,9)	1,7	Not reached [-; -]	0,51 [0,13; 2,03]	0,330	
North America	243	3 (1,2)	0,9	Not reached [-; -]	244	8 (3,3)	2,5	Not reached [-; -]	0,37 [0,10; 1,40]	0,134	
Western Europe	366	5 (1,4)	1,0	Not reached [-; -]	369	4 (1,1)	0,8	Not reached [-; -]	1,23 [0,33; 4,57]	0,760	
Index Event											
HF Hospitalization 3-6 Months	390	7 (1,8)	1,4	Not reached [-; -]	365	7 (1,9)	1,5	Not reached [-; -]	0,95 [0,33; 2,71]	0,824	0,895
HF Hospitalization within 3 Months	1441	26 (1,8)	1,5	Not reached [-; -]	1478	26 (1,8)	1,5	Not reached [-; -]	1,02 [0,59; 1,75]	0,929	
IV diuretic for HF (without hospitalization) within 3 Months	327	6 (1,8)	1,4	Not reached [-; -]	315	4 (1,3)	1,0	Not reached [-; -]	1,37 [0,39; 4,87]	0,504	

Analyses of Time to First Event of CEC Confirmed MI Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
MI Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category											
≤30	213	7 (3,3)	3,0	Not reached [-; -]	203	3 (1,5)	1,3	Not reached [-; -]	2,08 [0,54; 8,06]	0,276	0,225
>30 to ≤60	882	16 (1,8)	1,4	Not reached [-; -]	895	22 (2,5)	2,0	Not reached [-; -]	0,73 [0,38; 1,39]	0,358	
>60	1021	16 (1,6)	1,2	Not reached [-; -]	1024	11 (1,1)	0,9	Not reached [-; -]	1,46 [0,68; 3,14]	0,332	
NYHA Group at Baseline											
Class I or II	1241	18 (1,5)	1,1	Not reached [-; -]	1271	20 (1,6)	1,2	Not reached [-; -]	0,90 [0,47; 1,70]	0,766	0,518
Class III or IV	915	21 (2,3)	1,9	Not reached [-; -]	887	17 (1,9)	1,6	Not reached [-; -]	1,21 [0,64; 2,30]	0,542	
Use of Sacubitril /Valsartan at Baseline											
Yes	330	11 (3,3)	2,9	Not reached [-; -]	330	7 (2,1)	1,9	Not reached [-; -]	1,57 [0,61; 4,05]	0,320	0,328
No	1824	28 (1,5)	1,2	Not reached [-; -]	1825	30 (1,6)	1,3	Not reached [-; -]	0,92 [0,55; 1,54]	0,751	

Analyses of Time to First Event of CEC Confirmed MI Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
MI Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Baseline Ejection Fraction Group 2											
<35	1725	25 (1,4)	1,2	Not reached [-; -]	1741	31 (1,8)	1,5	Not reached [-; -]	0,80 [0,47; 1,36]	0,402	0,052
≥35	433	14 (3,2)	2,5	Not reached [-; -]	417	6 (1,4)	1,1	Not reached [-; -]	2,28 [0,88; 5,94]	0,086	
Race group											
White	1350	27 (2,0)	1,5	Not reached [-; -]	1359	23 (1,7)	1,3	Not reached [-; -]	1,15 [0,66; 2,01]	0,615	0,434
Asian	500	8 (1,6)	1,4	Not reached [-; -]	475	5 (1,1)	0,9	Not reached [-; -]	1,53 [0,50; 4,68]	0,459	
Black	111	2 (1,8)	1,6	Not reached [-; -]	118	3 (2,5)	2,2	Not reached [-; -]	0,73 [0,12; 4,37]	0,714	
Other	196	2 (1,0)	1,0	Not reached [-; -]	206	6 (2,9)	2,6	Not reached [-; -]	0,36 [0,07; 1,77]	0,189	

Analyses of Time to First Event of CEC Confirmed MI Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
MI Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
CCSA class at Randomization											
No Angina	1849	31 (1,7)	1,4	Not reached [-; -]	1856	27 (1,5)	1,2	Not reached [-; -]	1,14 [0,68; 1,91]	0,634	0,770
Angina Class 1 or 2	265	7 (2,6)	2,0	Not reached [-; -]	261	9 (3,4)	2,6	Not reached [-; -]	0,76 [0,28; 2,04]	0,702	
Angina Class 3 or 4	44	1 (2,3)	2,0	Not reached [-; -]	41	1 (2,4)	1,9	Not reached [-; -]	0,96 [0,06; 15,35]	0,987	

a: Database Cut-off Date: 18JUN2019
b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%
c: Total participants with an event per 100 participants years at risk
d: From product-limit (Kaplan-Meier) method
e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction
f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)
g: P-value from the likelihood ratio test for treatment-by-subgroup interaction
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; MI: Myocardial infarction; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.12.3 Results for Subgroups With Interaction P-value < 0.05

Table 2.14.12-3
Analyses of Time to First Event of CEC Confirmed MI Hospitalization for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
MI Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
NT-pro BNP (pg/mL) Baseline Grp: Central Lab											
Q1 (≤1556)	489	4 (0,8)	0,6	Not reached [-; -]	507	10 (2,0)	1,5	Not reached [-; -]	0,41 [0,13; 1,31]	0,135	0,003
Q2 (1556 - 2816)	520	12 (2,3)	1,7	Not reached [-; -]	494	3 (0,6)	0,5	Not reached [-; -]	3,75 [1,06; 13,30]	0,029	
Q3 (2816 - 5314)	511	15 (2,9)	2,4	Not reached [-; -]	520	7 (1,3)	1,1	Not reached [-; -]	2,16 [0,88; 5,30]	0,073	
Q4 (>5314)	548	7 (1,3)	1,2	Not reached [-; -]	524	15 (2,9)	2,8	Not reached [-; -]	0,44 [0,18; 1,08]	0,104	

Analyses of Time to First Event of CEC Confirmed MI Hospitalization for Subgroups
With P-value for Interaction test < 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
MI Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus											
Yes	1051	31 (2,9)	2,4	Not reached [-; -]	985	18 (1,8)	1,5	Not reached [-; -]	1,62 [0,91; 2,89]	0,102	0,008
No	1107	8 (0,7)	0,6	Not reached [-; -]	1173	19 (1,6)	1,3	Not reached [-; -]	0,44 [0,19; 0,99]	0,044	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total participants with an event per 100 participants years at risk

d: From product-limit (Kaplan-Meier) method

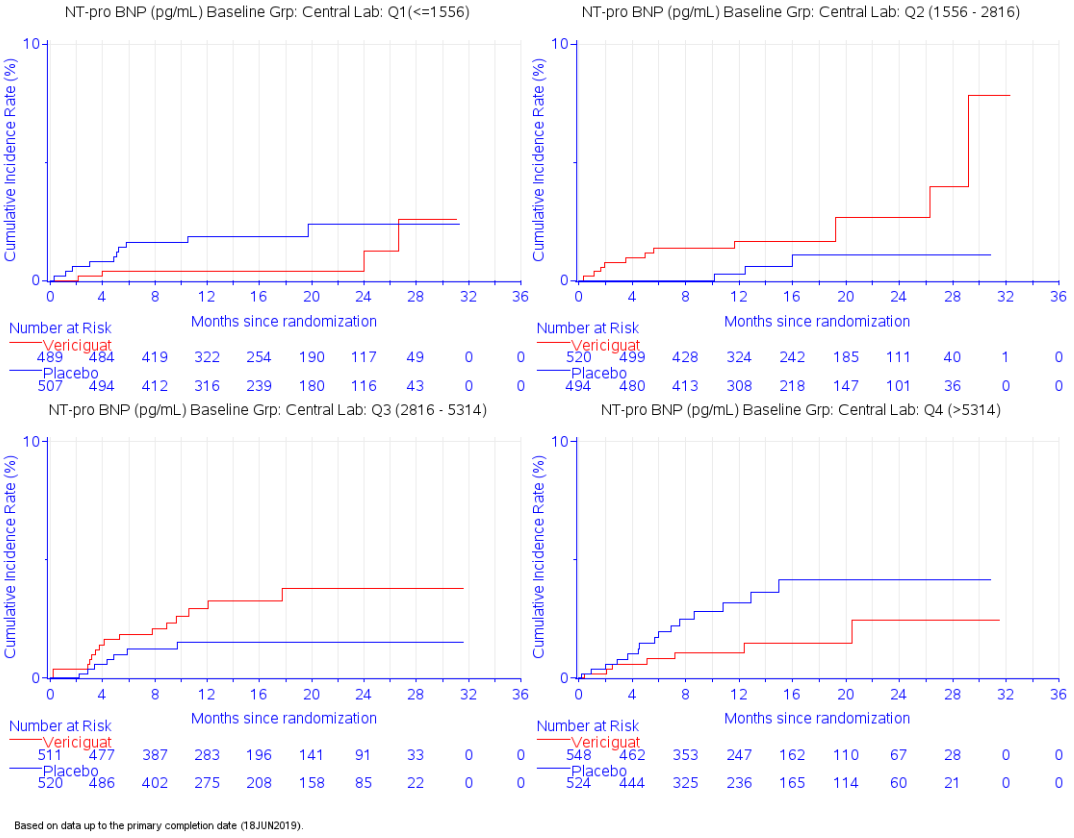
e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction

f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

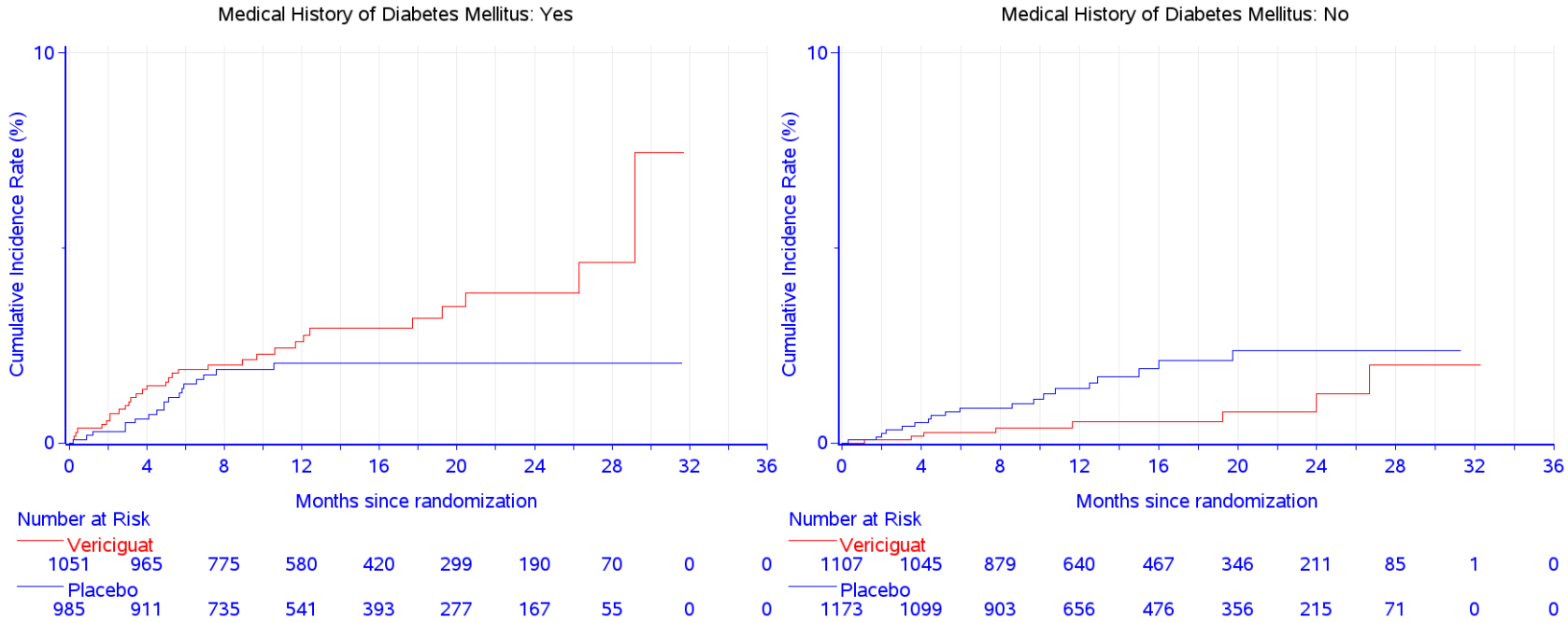
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; MI: Myocardial infarction; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

Figure 2.14.12-1
Kaplan-Meier Plot Time to First Event of CEC Confirmed MI Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%
By NT-pro BNP (pg/mL) Baseline Grp: Central Lab



Based on data up to the primary completion date (18JUN2019).

Figure 2.14.12-2
Kaplan-Meier Plot Time to First Event of CEC Confirmed MI Hospitalization
ITT Population Participants with Screening Ejection Fraction < 40%
By Medical History of Diabetes Mellitus



Based on data up to the primary completion date (18JUN2019).

2.14.13 First CEC Confirmed Stroke Hospitalization

2.14.13.1 Consistency of Treatment Effect – Summary.

Table 2.14.13-1
Overview of Subgroup Analyses for Time to First Event of CEC Confirmed Stroke Hospitalization,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
Efficacy - Time to Event						
Stroke Hospitalization	0,964	0,466	0,888	0,957	0,211	0,837

Overview of Subgroup Analyses for Time to First Event of CEC Confirmed Stroke Hospitalization,
Treatment by Subgroup Interactions
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
Efficacy - Time to Event							
Stroke Hospitalization	0,990	0,925	0,851	0,701	0,848	0,214	0,742

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

2.14.13.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 2.14.13-2
Analyses of Time to First Event of CEC Confirmed Stroke Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Stroke Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Age category 1											
<65	834	13 (1,6)	1,2	Not reached [-; -]	854	13 (1,5)	1,2	Not reached [-; -]	1,01 [0,47; 2,19]	0,994	0,964
≥65	1324	19 (1,4)	1,1	Not reached [-; -]	1304	18 (1,4)	1,1	Not reached [-; -]	1,04 [0,54; 1,98]	0,889	
Age category 2											
<75	1523	22 (1,4)	1,2	Not reached [-; -]	1538	24 (1,6)	1,3	Not reached [-; -]	0,92 [0,51; 1,64]	0,730	0,466
≥75	635	10 (1,6)	1,3	Not reached [-; -]	620	7 (1,1)	0,9	Not reached [-; -]	1,39 [0,53; 3,66]	0,474	
Gender											
Male	1661	23 (1,4)	1,1	Not reached [-; -]	1658	22 (1,3)	1,1	Not reached [-; -]	1,05 [0,58; 1,88]	0,886	0,888
Female	497	9 (1,8)	1,5	Not reached [-; -]	500	9 (1,8)	1,5	Not reached [-; -]	0,97 [0,38; 2,44]	0,965	

Analyses of Time to First Event of CEC Confirmed Stroke Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Stroke Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Geographic Region											
Asia Pacific	511	7 (1,4)	1,2	Not reached [-; -]	503	7 (1,4)	1,2	Not reached [-; -]	1,00 [0,35; 2,86]	0,998	0,957
Eastern Europe	722	13 (1,8)	1,4	Not reached [-; -]	718	10 (1,4)	1,1	Not reached [-; -]	1,28 [0,56; 2,91]	0,559	
Latin and South America	316	5 (1,6)	1,5	Not reached [-; -]	324	5 (1,5)	1,4	Not reached [-; -]	1,03 [0,30; 3,56]	0,965	
North America	243	2 (0,8)	0,6	Not reached [-; -]	244	3 (1,2)	1,0	Not reached [-; -]	0,67 [0,11; 3,99]	0,641	
Western Europe	366	5 (1,4)	1,0	Not reached [-; -]	369	6 (1,6)	1,2	Not reached [-; -]	0,81 [0,25; 2,66]	0,724	
Index Event											
HF Hospitalization 3-6 Months	390	6 (1,5)	1,2	Not reached [-; -]	365	3 (0,8)	0,6	Not reached [-; -]	1,92 [0,48; 7,68]	0,327	0,211
HF Hospitalization within 3 Months	1441	25 (1,7)	1,4	Not reached [-; -]	1478	24 (1,6)	1,4	Not reached [-; -]	1,06 [0,61; 1,86]	0,824	
IV diuretic for HF (without hospitalization) within 3 Months	327	1 (0,3)	0,2	Not reached [-; -]	315	4 (1,3)	1,0	Not reached [-; -]	0,23 [0,03; 2,06]	0,158	

Analyses of Time to First Event of CEC Confirmed Stroke Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Stroke Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category											
≤30	213	3 (1,4)	1,2	Not reached [-; -]	203	4 (2,0)	1,8	Not reached [-; -]	0,70 [0,16; 3,14]	0,683	0,837
>30 to ≤60	882	15 (1,7)	1,3	Not reached [-; -]	895	13 (1,5)	1,2	Not reached [-; -]	1,16 [0,55; 2,44]	0,685	
>60	1021	14 (1,4)	1,1	Not reached [-; -]	1024	14 (1,4)	1,1	Not reached [-; -]	1,00 [0,48; 2,10]	0,968	
NYHA Group at Baseline											
Class I or II	1241	18 (1,5)	1,1	Not reached [-; -]	1271	18 (1,4)	1,1	Not reached [-; -]	1,03 [0,53; 1,98]	0,961	0,990
Class III or IV	915	14 (1,5)	1,3	Not reached [-; -]	887	13 (1,5)	1,2	Not reached [-; -]	1,02 [0,48; 2,17]	0,960	
Use of Sacubitril /Valsartan at Baseline											
Yes	330	6 (1,8)	1,6	Not reached [-; -]	330	6 (1,8)	1,7	Not reached [-; -]	0,98 [0,31; 3,03]	0,923	0,925
No	1824	26 (1,4)	1,1	Not reached [-; -]	1825	25 (1,4)	1,1	Not reached [-; -]	1,04 [0,60; 1,79]	0,905	

Analyses of Time to First Event of CEC Confirmed Stroke Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat				Placebo				Vericiguat vs. Placebo		
Stroke Hospitalization	N[b]	Participants with Event n (%)	Annual %[c]	Median Time in months [95 %-CI][d]	N[b]	Participants with Event n (%)	Annual %[c]	Median Time in months [95 %-CI][d]	Hazard Ratio [95 %-CI][e]	p-Value[f]	p-Value for Interaction Test[g]
NT-pro BNP (pg/mL) Baseline Grp: Central Lab											
Q1 (≤1556)	489	7 (1,4)	1,0	Not reached [-; -]	507	6 (1,2)	0,9	Not reached [-; -]	1,18 [0,40; 3,51]	0,774	0,851
Q2 (1556 - 2816)	520	10 (1,9)	1,4	Not reached [-; -]	494	6 (1,2)	0,9	Not reached [-; -]	1,59 [0,58; 4,37]	0,400	
Q3 (2816 - 5314)	511	6 (1,2)	0,9	Not reached [-; -]	520	7 (1,3)	1,1	Not reached [-; -]	0,87 [0,29; 2,58]	0,833	
Q4 (>5314)	548	9 (1,6)	1,6	Not reached [-; -]	524	9 (1,7)	1,6	Not reached [-; -]	0,96 [0,38; 2,42]	0,863	
Baseline Ejection Fraction Group 2											
<35	1725	28 (1,6)	1,3	Not reached [-; -]	1741	26 (1,5)	1,2	Not reached [-; -]	1,07 [0,63; 1,82]	0,835	0,701
≥35	433	4 (0,9)	0,7	Not reached [-; -]	417	5 (1,2)	0,9	Not reached [-; -]	0,81 [0,22; 3,01]	0,747	

Analyses of Time to First Event of CEC Confirmed Stroke Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Stroke Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Race group											
White	1350	22 (1,6)	1,2	Not reached [-; -]	1359	18 (1,3)	1,0	Not reached [-; -]	1,21 [0,65; 2,25]	0,548	0,848
Asian	500	6 (1,2)	1,0	Not reached [-; -]	475	7 (1,5)	1,3	Not reached [-; -]	0,82 [0,27; 2,43]	0,698	
Black	111	1 (0,9)	0,8	Not reached [-; -]	118	2 (1,7)	1,5	Not reached [-; -]	0,54 [0,05; 5,93]	0,614	
Other	196	3 (1,5)	1,5	Not reached [-; -]	206	4 (1,9)	1,7	Not reached [-; -]	0,83 [0,19; 3,72]	0,817	
CCSA class at Randomization											
No Angina	1849	28 (1,5)	1,2	Not reached [-; -]	1856	22 (1,2)	1,0	Not reached [-; -]	1,27 [0,72; 2,21]	0,407	0,214
Angina Class 1 or 2	265	3 (1,1)	0,8	Not reached [-; -]	261	8 (3,1)	2,3	Not reached [-; -]	0,37 [0,10; 1,40]	0,149	
Angina Class 3 or 4	44	1 (2,3)	2,0	Not reached [-; -]	41	1 (2,4)	1,9	Not reached [-; -]	1,03 [0,06; 16,51]	0,975	

Analyses of Time to First Event of CEC Confirmed Stroke Hospitalization for Subgroups
With P-value for Interaction test ≥ 0.05
ITT Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**				**Placebo**				**Vericiguat vs. Placebo**		
Stroke Hospitalization	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**N[b]**	**Participants with Event n (%)**	**Annual %[c]**	**Median Time in months [95 %-CI][d]**	**Hazard Ratio [95 %-CI][e]**	**p-Value[f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus											
Yes	1051	17 (1,6)	1,3	Not reached [-; -]	985	17 (1,7)	1,4	Not reached [-; -]	0,94 [0,48; 1,85]	0,847	0,742
No	1107	15 (1,4)	1,1	Not reached [-; -]	1173	14 (1,2)	1,0	Not reached [-; -]	1,11 [0,54; 2,31]	0,790	

a: Database Cut-off Date: 18JUN2019

b: Number of participants: intention-to-treat (ITT) population with screening ejection fraction < 40%

c: Total participants with an event per 100 participants years at risk

d: From product-limit (Kaplan-Meier) method

e: Based on Cox proportional hazard model with covariates of the stratification factors (defined by region and race), treatment, subgroup, and treatment-by-subgroup interaction

f: From two-sided log-rank test stratified by the stratification factors (defined by region and race)

g: P-value from the likelihood ratio test for treatment-by-subgroup interaction

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CEC: Clinical Events Committee; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

PATIENT REPORTED OUTCOMES

3.1 Summaries of Completion, Compliance and Imputation

3.1.1 Completion and Compliance for EQ5D VAS

Table 3.1-1
Completion and Compliance of EQ-5D Questionnaire by Visit and by Treatment Group
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]		Vericiguat N[b]= 2152		Placebo N[b]= 2151	
	Category	n	(%)[c]	n	(%)[c]
Baseline	**Expected to complete questionnaires[d]**	**2150**	**(99,91)**	**2150**	**(99,95)**
	Completed	2035	(94,56)	2020	(93,91)
	Compliance (% in those expected to complete questionnaires)[e]	2035	(94,65)	2020	(93,95)
	Not Completed	115	(5,34)	130	(6,04)
	Participant did not complete due to disease under study	0	(0,00)	1	(0,05)
	Not completed due to site staff error	9	(0,42)	9	(0,42)
	Participant in hospital or hospice	0	(0,00)	0	(0,00)
	Participant was physically unable to complete	6	(0,28)	4	(0,19)
	Participant lost to follow-up/unable to contact	0	(0,00)	1	(0,05)
	Participant did not complete due to side effect of treatment	0	(0,00)	0	(0,00)
	Participant refused for other reasons	2	(0,09)	2	(0,09)
	Other	27	(1,25)	41	(1,91)
	With visit, no record	71	(3,30)	72	(3,35)
	Missing by design[f]	**2**	**(0,09)**	**1**	**(0,05)**
	Translation not available in participant's language	2	(0,09)	1	(0,05)
	Participant died	0	(0,00)	0	(0,00)
Day 28	**Expected to complete questionnaires[d]**	**2116**	**(98,33)**	**2111**	**(98,14)**
	Completed	1911	(88,80)	1900	(88,33)
	Compliance (% in those expected to complete questionnaires)[e]	1911	(90,31)	1900	(90,00)
	Not Completed	205	(9,53)	211	(9,81)
	Participant did not complete due to disease under study	1	(0,05)	0	(0,00)
	Not completed due to site staff error	26	(1,21)	31	(1,44)
	Participant in hospital or hospice	1	(0,05)	3	(0,14)
	Participant was physically unable to complete	15	(0,70)	7	(0,33)
	Participant lost to follow-up/unable to contact	1	(0,05)	0	(0,00)
	Participant did not complete due to side effect of treatment	0	(0,00)	0	(0,00)
	Participant refused for other reasons	14	(0,65)	2	(0,09)
	Other	32	(1,49)	37	(1,72)
	With visit, no record	115	(5,34)	131	(6,09)
	Missing by design[f]	**36**	**(1,67)**	**40**	**(1,86)**
	Translation not available in participant's language	2	(0,09)	2	(0,09)
	Participant died	34	(1,58)	38	(1,77)

Completion and Compliance of EQ-5D Questionnaire by Visit and by Treatment Group
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]		Vericiguat N[b]= 2152		Placebo N[b]= 2151	
	Category	**n**	**(%)[c]**	**n**	**(%)[c]**
Week 16	**Expected to complete questionnaires[d]**	**2032**	**(94,42)**	**2036**	**(94,65)**
	Completed	1787	(83,04)	1814	(84,33)
	Compliance (% in those expected to complete questionnaires)[e]	1787	(87,94)	1814	(89,10)
	Not Completed	245	(11,38)	222	(10,32)
	Participant did not complete due to disease under study	0	(0,00)	4	(0,19)
	Not completed due to site staff error	23	(1,07)	12	(0,56)
	Participant in hospital or hospice	3	(0,14)	2	(0,09)
	Participant was physically unable to complete	12	(0,56)	8	(0,37)
	Participant lost to follow-up/unable to contact	0	(0,00)	1	(0,05)
	Participant did not complete due to side effect of treatment	0	(0,00)	0	(0,00)
	Participant refused for other reasons	10	(0,46)	8	(0,37)
	Other	45	(2,09)	48	(2,23)
	With visit, no record	152	(7,06)	139	(6,46)
	Missing by design[f]	**120**	**(5,58)**	**115**	**(5,35)**
	Translation not available in participant's language	3	(0,14)	2	(0,09)
	Participant died	117	(5,44)	113	(5,25)
Week 32	**Expected to complete questionnaires[d]**	**1790**	**(83,18)**	**1772**	**(82,38)**
	Completed	1500	(69,70)	1481	(68,85)
	Compliance (% in those expected to complete questionnaires)[e]	1500	(83,80)	1481	(83,58)
	Not Completed	290	(13,48)	291	(13,53)
	Participant did not complete due to disease under study	0	(0,00)	3	(0,14)
	Not completed due to site staff error	16	(0,74)	16	(0,74)
	Participant in hospital or hospice	2	(0,09)	7	(0,33)
	Participant was physically unable to complete	13	(0,60)	16	(0,74)
	Participant lost to follow-up/unable to contact	0	(0,00)	1	(0,05)
	Participant did not complete due to side effect of treatment	0	(0,00)	0	(0,00)
	Participant refused for other reasons	16	(0,74)	9	(0,42)
	Other	36	(1,67)	46	(2,14)
	With visit, no record	207	(9,62)	193	(8,97)
	Missing by design[f]	**182**	**(8,46)**	**200**	**(9,30)**
	Translation not available in participant's language	0	(0,00)	1	(0,05)
	Participant died	182	(8,46)	199	(9,25)

Completion and Compliance of EQ-5D Questionnaire by Visit and by Treatment Group
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]		Vericiguat N[b]= 2152		Placebo N[b]= 2151	
	Category	**n**	**(%)[c]**	**n**	**(%)[c]**
Week 48	**Expected to complete questionnaires[d]**	**1657**	**(77,00)**	**1634**	**(75,96)**
	Completed	1087	(50,51)	1077	(50,07)
	Compliance (% in those expected to complete questionnaires)[e]	1087	(65,60)	1077	(65,91)
	Not Completed	570	(26,49)	557	(25,89)
	Participant did not complete due to disease under study	1	(0,05)	4	(0,19)
	Not completed due to site staff error	12	(0,56)	13	(0,60)
	Participant in hospital or hospice	6	(0,28)	4	(0,19)
	Participant was physically unable to complete	16	(0,74)	11	(0,51)
	Participant lost to follow-up/unable to contact	0	(0,00)	2	(0,09)
	Participant did not complete due to side effect of treatment	1	(0,05)	0	(0,00)
	Participant refused for other reasons	14	(0,65)	20	(0,93)
	Other	57	(2,65)	52	(2,42)
	With visit, no record	463	(21,51)	451	(20,97)
	Missing by design[f]	**224**	**(10,41)**	**241**	**(11,20)**
	Translation not available in participant's language	0	(0,00)	0	(0,00)
	Participant died	224	(10,41)	241	(11,20)
Week 96	**Expected to complete questionnaires[d]**	**1451**	**(67,43)**	**1440**	**(66,95)**
	Completed	351	(16,31)	348	(16,18)
	Compliance (% in those expected to complete questionnaires)[e]	351	(24,19)	348	(24,17)
	Not Completed	1100	(51,12)	1092	(50,77)
	Participant did not complete due to disease under study	0	(0,00)	2	(0,09)
	Not completed due to site staff error	20	(0,93)	20	(0,93)
	Participant in hospital or hospice	2	(0,09)	0	(0,00)
	Participant was physically unable to complete	4	(0,19)	1	(0,05)
	Participant lost to follow-up/unable to contact	4	(0,19)	3	(0,14)
	Participant did not complete due to side effect of treatment	0	(0,00)	0	(0,00)
	Participant refused for other reasons	8	(0,37)	8	(0,37)
	Other	25	(1,16)	27	(1,26)
	With visit, no record	1037	(48,19)	1031	(47,93)
	Missing by design[f]	**293**	**(13,62)**	**312**	**(14,50)**
	Translation not available in participant's language	0	(0,00)	0	(0,00)
	Participant died	293	(13,62)	312	(14,50)

Completion and Compliance of EQ-5D Questionnaire by Visit and by Treatment Group
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]		Vericiguat N[b]= 2152		Placebo N[b]= 2151	
	Category	**n**	**(%)[c]**	**n**	**(%)[c]**
Week 144	**Expected to complete questionnaires[d]**	**1611**	**(74,86)**	**1629**	**(75,73)**
	Completed	1	(0,05)	3	(0,14)
	Compliance (% in those expected to complete questionnaires)[e]	1	(0,06)	3	(0,18)
	Not Completed	1610	(74,81)	1626	(75,59)
	Participant did not complete due to disease under study	0	(0,00)	0	(0,00)
	Not completed due to site staff error	0	(0,00)	1	(0,05)
	Participant in hospital or hospice	0	(0,00)	0	(0,00)
	Participant was physically unable to complete	0	(0,00)	0	(0,00)
	Participant lost to follow-up/unable to contact	0	(0,00)	0	(0,00)
	Participant did not complete due to side effect of treatment	0	(0,00)	0	(0,00)
	Participant refused for other reasons	1	(0,05)	0	(0,00)
	Other	0	(0,00)	0	(0,00)
	With visit, no record	1609	(74,77)	1625	(75,55)
	Missing by design[f]	**307**	**(14,27)**	**319**	**(14,83)**
	Translation not available in participant's language	0	(0,00)	0	(0,00)
	Participant died	307	(14,27)	319	(14,83)

a: Database Cut-off Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Calculated as n/N for all categories except compliance rate

d: Expected to complete questionnaire includes all participants who do not have missing data because of missing by design

e: Compliance is the proportion of participants who completed the questionnaire among those who are expected to complete the questionnaire at this time point

f: Reasons for data missing by design includes: death and translation not available in participant's language

Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

EQ-5D: EuroQol Group 5-Dimensional

3.1.2 Completion and Compliance for KCCQ

Table 3.1-2
Completion and Compliance of KCCQ Questionnaire by Visit and by Treatment Group
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]		Vericiguat N[b]= 2152		Placebo N[b]= 2151	
	Category	**n**	**(%)[c]**	**n**	**(%)[c]**
Baseline	**Expected to complete questionnaires[d]**	**2150**	**(99,91)**	**2150**	**(99,95)**
	Completed	2040	(94,80)	2032	(94,47)
	Compliance (% in those expected to complete questionnaires)[e]	2040	(94,88)	2032	(94,51)
	Not Completed	110	(5,11)	118	(5,49)
	Participant did not complete due to disease under study	0	(0,00)	0	(0,00)
	Not completed due to site staff error	7	(0,33)	6	(0,28)
	Participant in hospital or hospice	0	(0,00)	0	(0,00)
	Participant was physically unable to complete	6	(0,28)	4	(0,19)
	Participant lost to follow-up/unable to contact	0	(0,00)	1	(0,05)
	Participant did not complete due to side effect of treatment	0	(0,00)	0	(0,00)
	Participant refused for other reasons	1	(0,05)	1	(0,05)
	Other	22	(1,02)	34	(1,58)
	With visit, no record	74	(3,44)	72	(3,35)
	Missing by design[f]	**2**	**(0,09)**	**1**	**(0,05)**
	Translation not available in participant's language	2	(0,09)	1	(0,05)
	Participant died	0	(0,00)	0	(0,00)
Day 28	**Expected to complete questionnaires[d]**	**2116**	**(98,33)**	**2111**	**(98,14)**
	Completed	1922	(89,31)	1909	(88,75)
	Compliance (% in those expected to complete questionnaires)[e]	1922	(90,83)	1909	(90,43)
	Not Completed	194	(9,01)	202	(9,39)
	Participant did not complete due to disease under study	1	(0,05)	0	(0,00)
	Not completed due to site staff error	26	(1,21)	28	(1,30)
	Participant in hospital or hospice	1	(0,05)	3	(0,14)
	Participant was physically unable to complete	15	(0,70)	7	(0,33)
	Participant lost to follow-up/unable to contact	0	(0,00)	0	(0,00)
	Participant did not complete due to side effect of treatment	0	(0,00)	0	(0,00)
	Participant refused for other reasons	12	(0,56)	2	(0,09)
	Other	27	(1,25)	32	(1,49)
	With visit, no record	112	(5,20)	130	(6,04)
	Missing by design[f]	**36**	**(1,67)**	**40**	**(1,86)**
	Translation not available in participant's language	2	(0,09)	2	(0,09)
	Participant died	34	(1,58)	38	(1,77)

Completion and Compliance of KCCQ Questionnaire by Visit and by Treatment Group
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]		Vericiguat N[b]= 2152		Placebo N[b]= 2151	
	Category	**n**	**(%)[c]**	**n**	**(%)[c]**
Week 16	**Expected to complete questionnaires[d]**	**2032**	**(94,42)**	**2036**	**(94,65)**
	Completed	1802	(83,74)	1822	(84,70)
	Compliance (% in those expected to complete questionnaires)[e]	1802	(88,68)	1822	(89,49)
	Not Completed	230	(10,69)	214	(9,95)
	Participant did not complete due to disease under study	0	(0,00)	4	(0,19)
	Not completed due to site staff error	14	(0,65)	10	(0,46)
	Participant in hospital or hospice	3	(0,14)	2	(0,09)
	Participant was physically unable to complete	12	(0,56)	8	(0,37)
	Participant lost to follow-up/unable to contact	0	(0,00)	1	(0,05)
	Participant did not complete due to side effect of treatment	0	(0,00)	0	(0,00)
	Participant refused for other reasons	9	(0,42)	9	(0,42)
	Other	39	(1,81)	42	(1,95)
	With visit, no record	153	(7,11)	138	(6,42)
	Missing by design[f]	**120**	**(5,58)**	**115**	**(5,35)**
	Translation not available in participant's language	3	(0,14)	2	(0,09)
	Participant died	117	(5,44)	113	(5,25)
Week 32	**Expected to complete questionnaires[d]**	**1790**	**(83,18)**	**1772**	**(82,38)**
	Completed	1506	(69,98)	1490	(69,27)
	Compliance (% in those expected to complete questionnaires)[e]	1506	(84,13)	1490	(84,09)
	Not Completed	284	(13,20)	282	(13,11)
	Participant did not complete due to disease under study	0	(0,00)	3	(0,14)
	Not completed due to site staff error	12	(0,56)	15	(0,70)
	Participant in hospital or hospice	2	(0,09)	7	(0,33)
	Participant was physically unable to complete	13	(0,60)	16	(0,74)
	Participant lost to follow-up/unable to contact	0	(0,00)	1	(0,05)
	Participant did not complete due to side effect of treatment	0	(0,00)	0	(0,00)
	Participant refused for other reasons	15	(0,70)	8	(0,37)
	Other	35	(1,63)	38	(1,77)
	With visit, no record	207	(9,62)	194	(9,02)
	Missing by design[f]	**182**	**(8,46)**	**200**	**(9,30)**
	Translation not available in participant's language	0	(0,00)	1	(0,05)
	Participant died	182	(8,46)	199	(9,25)

Completion and Compliance of KCCQ Questionnaire by Visit and by Treatment Group
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]		Vericiguat N[b]= 2152		Placebo N[b]= 2151	
	Category	**n**	**(%)[c]**	**n**	**(%)[c]**
Week 48	**Expected to complete questionnaires[d]**	**1657**	**(77,00)**	**1634**	**(75,96)**
	Completed	1093	(50,79)	1086	(50,49)
	Compliance (% in those expected to complete questionnaires)[e]	1093	(65,96)	1086	(66,46)
	Not Completed	564	(26,21)	548	(25,48)
	Participant did not complete due to disease under study	1	(0,05)	4	(0,19)
	Not completed due to site staff error	10	(0,46)	8	(0,37)
	Participant in hospital or hospice	6	(0,28)	4	(0,19)
	Participant was physically unable to complete	16	(0,74)	11	(0,51)
	Participant lost to follow-up/unable to contact	0	(0,00)	2	(0,09)
	Participant did not complete due to side effect of treatment	1	(0,05)	0	(0,00)
	Participant refused for other reasons	14	(0,65)	19	(0,88)
	Other	53	(2,46)	49	(2,28)
	With visit, no record	463	(21,51)	451	(20,97)
	Missing by design[f]	**224**	**(10,41)**	**241**	**(11,20)**
	Translation not available in participant's language	0	(0,00)	0	(0,00)
	Participant died	224	(10,41)	241	(11,20)
Week 96	**Expected to complete questionnaires[d]**	**1450**	**(67,38)**	**1440**	**(66,95)**
	Completed	353	(16,40)	350	(16,27)
	Compliance (% in those expected to complete questionnaires)[e]	353	(24,34)	350	(24,31)
	Not Completed	1097	(50,98)	1090	(50,67)
	Participant did not complete due to disease under study	0	(0,00)	2	(0,09)
	Not completed due to site staff error	20	(0,93)	18	(0,84)
	Participant in hospital or hospice	2	(0,09)	0	(0,00)
	Participant was physically unable to complete	4	(0,19)	1	(0,05)
	Participant lost to follow-up/unable to contact	4	(0,19)	3	(0,14)
	Participant did not complete due to side effect of treatment	0	(0,00)	0	(0,00)
	Participant refused for other reasons	8	(0,37)	8	(0,37)
	Other	23	(1,07)	25	(1,16)
	With visit, no record	1036	(48,14)	1033	(48,02)
	Missing by design[f]	**293**	**(13,62)**	**312**	**(14,50)**
	Translation not available in participant's language	0	(0,00)	0	(0,00)
	Participant died	293	(13,62)	312	(14,50)

Completion and Compliance of KCCQ Questionnaire by Visit and by Treatment Group
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]		Vericiguat N[b]= 2152		Placebo N[b]= 2151	
	Category	**n**	**(%)[c]**	**n**	**(%)[c]**
Week 144	**Expected to complete questionnaires[d]**	**1611**	**(74,86)**	**1629**	**(75,73)**
	Completed	1	(0,05)	3	(0,14)
	Compliance (% in those expected to complete questionnaires)[e]	1	(0,06)	3	(0,18)
	Not Completed	1610	(74,81)	1626	(75,59)
	Participant did not complete due to disease under study	0	(0,00)	0	(0,00)
	Not completed due to site staff error	0	(0,00)	1	(0,05)
	Participant in hospital or hospice	0	(0,00)	0	(0,00)
	Participant was physically unable to complete	0	(0,00)	0	(0,00)
	Participant lost to follow-up/unable to contact	0	(0,00)	0	(0,00)
	Participant did not complete due to side effect of treatment	0	(0,00)	0	(0,00)
	Participant refused for other reasons	1	(0,05)	0	(0,00)
	Other	0	(0,00)	0	(0,00)
	With visit, no record	1609	(74,77)	1625	(75,55)
	Missing by design[f]	**307**	**(14,27)**	**319**	**(14,83)**
	Translation not available in participant's language	0	(0,00)	0	(0,00)
	Participant died	307	(14,27)	319	(14,83)

a: Database Cut-off Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Calculated as n/N for all categories except compliance rate

d: Expected to complete questionnaire includes all participants who do not have missing data because of missing by design

e: Compliance is the proportion of participants who completed the questionnaire among those who are expected to complete the questionnaire at this time point

f: Reasons for data missing by design includes: death and translation not available in participant's language

Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

KCCQ: Kansas City Cardiomyopathy Questionnaire

3.1.3 Summary of Imputation with LOCF method

Table 3.1-3
Summary of Available and Imputed Week 32 data
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study:MK-1242-001[a]		Vericiguat N[b]=2152		Placebo N[b]=2151	
	Category	**n**	**(%)**	**n**	**(%)**
EQ-5D-5L VAS Score	**Participants with available baseline value**	**2035**	**94,6**	**2020**	**93,9**
	Participants with available Week 32 value[c]	1441	70,8	1409	69,8
	Participants with imputed Week 32 value[c]	312	15,3	330	16,3
	Participants with Day 28 value used for imputation[d]	150	48,1	122	37,0
	Participants with Week 16 value used for imputation[d]	162	51,9	208	63,0
Overall Summary Score	**Participants with available baseline value**	**1932**	**89,8**	**1920**	**89,3**
	Participants with available Week 32 value[c]	1312	67,9	1263	65,8
	Participants with imputed Week 32 value[c]	343	17,8	365	19,0
	Participants with Day 28 value used for imputation[d]	150	43,7	129	35,3
	Participants with Week 16 value used for imputation[d]	193	56,3	236	64,7
Total Symptom Score	**Participants with available baseline value**	**2039**	**94,7**	**2032**	**94,5**
	Participants with available Week 32 value[c]	1452	71,2	1424	70,1
	Participants with imputed Week 32 value[c]	308	15,1	327	16,1
	Participants with Day 28 value used for imputation[d]	149	48,4	125	38,2
	Participants with Week 16 value used for imputation[d]	159	51,6	202	61,8
Clinical Summary Score	**Participants with available baseline value**	**2008**	**93,3**	**2005**	**93,2**
	Participants with available Week 32 value[c]	1410	70,2	1384	69,0
	Participants with imputed Week 32 value[c]	316	15,7	334	16,7
	Participants with Day 28 value used for imputation[d]	151	47,8	125	37,4

Summary of Available and Imputed Week 32 data
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study:MK-1242-001[a]		**Vericiguat N[b]=2152**		**Placebo N[b]=2151**	
	Category	**n**	**(%)**	**n**	**(%)**
	Participants with Week 16 value used for imputation[d]	165	52,2	209	62,6
Physical Limitation Score	**Participants with available baseline value**	**2008**	**93,3**	**2005**	**93,2**
	Participants with available Week 32 value[c]	1410	70,2	1384	69,0
	Participants with imputed Week 32 value[c]	316	15,7	334	16,7
	Participants with Day 28 value used for imputation[d]	151	47,8	125	37,4
	Participants with Week 16 value used for imputation[d]	165	52,2	209	62,6
Quality of Life Score	**Participants with available baseline value**	**2039**	**94,7**	**2032**	**94,5**
	Participants with available Week 32 value[c]	1452	71,2	1424	70,1
	Participants with imputed Week 32 value[c]	308	15,1	327	16,1
	Participants with Day 28 value used for imputation[d]	149	48,4	125	38,2
	Participants with Week 16 value used for imputation[d]	159	51,6	202	61,8
Symptom Burden Score	**Participants with available baseline value**	**2039**	**94,7**	**2032**	**94,5**
	Participants with available Week 32 value[c]	1452	71,2	1424	70,1
	Participants with imputed Week 32 value[c]	308	15,1	327	16,1
	Participants with Day 28 value used for imputation[d]	149	48,4	125	38,2
	Participants with Week 16 value used for imputation[d]	159	51,6	202	61,8
Self-Efficacy Score	**Participants with available baseline value**	**2039**	**94,7**	**2032**	**94,5**
	Participants with available Week 32 value[c]	1452	71,2	1424	70,1

Summary of Available and Imputed Week 32 data
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study:MK-1242-001[a]		**Vericiguat N[b]=2152**		**Placebo N[b]=2151**	
	Category	**n**	**(%)**	**n**	**(%)**
	Participants with imputed Week 32 value[c]	308	15,1	327	16,1
	Participants with Day 28 value used for imputation[d]	149	48,4	125	38,2
	Participants with Week 16 value used for imputation[d]	159	51,6	202	61,8
Symptom Frequency Score	**Participants with available baseline value**	**2039**	**94,7**	**2032**	**94,5**
	Participants with available Week 32 value[c]	1452	71,2	1424	70,1
	Participants with imputed Week 32 value[c]	308	15,1	327	16,1
	Participants with Day 28 value used for imputation[d]	149	48,4	125	38,2
	Participants with Week 16 value used for imputation[d]	159	51,6	202	61,8
Social Limitation Score	**Participants with available baseline value**	**1944**	**90,3**	**1933**	**89,9**
	Participants with available Week 32 value[c]	1326	68,2	1275	66,0
	Participants with imputed Week 32 value[c]	343	17,6	367	19,0
	Participants with Day 28 value used for imputation[d]	150	43,7	130	35,4
	Participants with Week 16 value used for imputation[d]	193	56,3	237	64,6
Symptom Stability Score	**Participants with available baseline value**	**2039**	**94,7**	**2032**	**94,5**
	Participants with available Week 32 value[c]	1452	71,2	1424	70,1
	Participants with imputed Week 32 value[c]	308	15,1	327	16,1
	Participants with Day 28 value used for imputation[d]	149	48,4	125	38,2
	Participants with Week 16 value used for imputation[d]	159	51,6	202	61,8

a: Database Cut-off Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Percentages are calculated based on number of participants with available baseline value
d: Percentage are calculated based on number of participants with imputed Week 32 value

3.2 Descriptive Analysis and Change from Baseline

3.2.1 EQ-5D-5L VAS

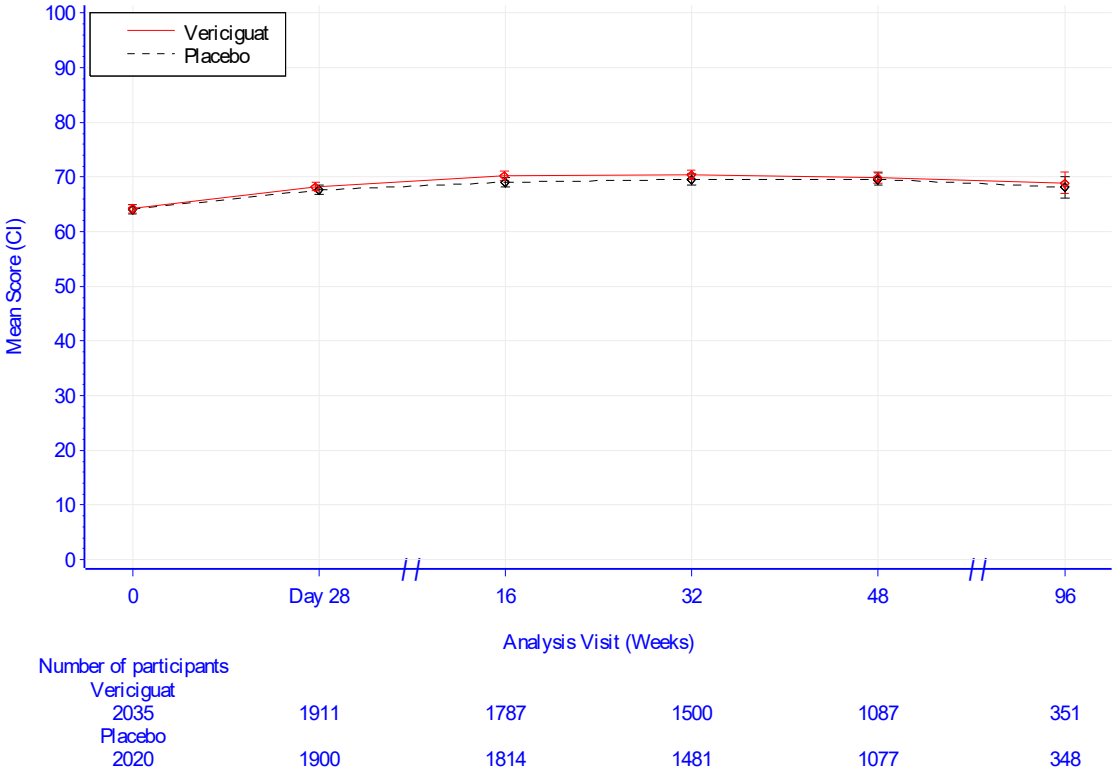
3.2.1.1 Descriptive summary over time

Table 3.2.1-1
Summary Statistics of EQ-5D VAS Score Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

EQ-5D VAS	Study: MK-1242-001[a]	
	Vericiguat N[b]=2152	**Placebo N[b]=2151**
Baseline		
N[c]	2035	2020
Mean (SD)	64,2 (18,8)	64,1 (18,5)
Median (Q1;Q3)	65,0 (50,0;80,0)	65,0 (50,0;80,0)
Min; Max	0,00;100,00	0,00;100,00
Day 28		
N[c]	1911	1900
Mean (SD)	68,2 (17,9)	67,6 (18,5)
Median (Q1;Q3)	70,0 (58,0;80,0)	70,0 (55,0;80,0)
Min; Max	9,00;100,00	0,00;100,00
Week 16		
N[c]	1787	1814
Mean (SD)	70,2 (17,9)	69,1 (18,5)
Median (Q1;Q3)	70,0 (60,0;81,0)	70,0 (58,0;81,0)
Min; Max	3,00;100,00	0,00;100,00
Week 32		
N[c]	1500	1481
Mean (SD)	70,5 (17,7)	69,6 (18,8)
Median (Q1;Q3)	71,0 (60,0;82,0)	70,0 (59,0;82,0)
Min; Max	0,00;100,00	0,00;100,00
Week 48		
N[c]	1087	1077
Mean (SD)	70,0 (17,1)	69,6 (18,6)
Median (Q1;Q3)	71,0 (60,0;81,0)	71,0 (59,0;80,0)
Min; Max	3,00;100,00	0,00;100,00
Week 96		
N[c]	351	348
Mean (SD)	69,0 (18,3)	68,1 (19,3)
Median (Q1;Q3)	70,0 (56,0;82,0)	70,0 (55,0;81,0)
Min; Max	0,00;100,00	1,00;100,00
Week 144		
N[c]	1	3
Mean (SD)	84,0 (.)	82,0 (9,8)
Median (Q1;Q3)	84,0 (84,0;84,0)	85,0 (71,0;90,0)
Min; Max	84,00;84,00	71,00;90,00

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Number of participants with data at each time point
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; Max: Maximum; Min: Minimum;
Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

Figure 3.2-1
Mean and 95% Confidence Interval Over Time: EQ-5D VAS Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%



Number of participants					
Vericiguat					
2035	1911	1787	1500	1087	351
Placebo					
2020	1900	1814	1481	1077	348

Based on data up to primary completion date (18JUN2019)
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

3.2.1.2 Change from baseline at Week 32

Table 3.2.1-2
Analysis of Change From Baseline in EQ-5D VAS Score at Week 32
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					**Vericiguat vs. Placebo**	
EQ-5D VAS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**
Vericiguat	2035	1948	64,2 (18,84)	4,83 (0,41)	0,70	-
Placebo	2020	1933	64,1 (18,47)	4,13 (0,42)	[-0,45; 1,85]	-

a: Database Cutoff Date: 18JUN2019

b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline

c: Number of participants with data available for analysis

d: Sample Mean and SD calculated for participants with data available for analysis

e: cLDA with change from baseline as the dependent variable, factors for treatment, analysis visit, stratification factor (defined by region and race) and treatment-by-visit interaction term, baseline value as covariate; including all post-baseline timepoints through week 96

Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment

f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero

Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

CI: confidence interval; cLDA: constrained Longitudinal Data Analysis; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; SD: Standard Deviation; SE: Standard Error

3.2.2 KCCQ: Overall Summary Score

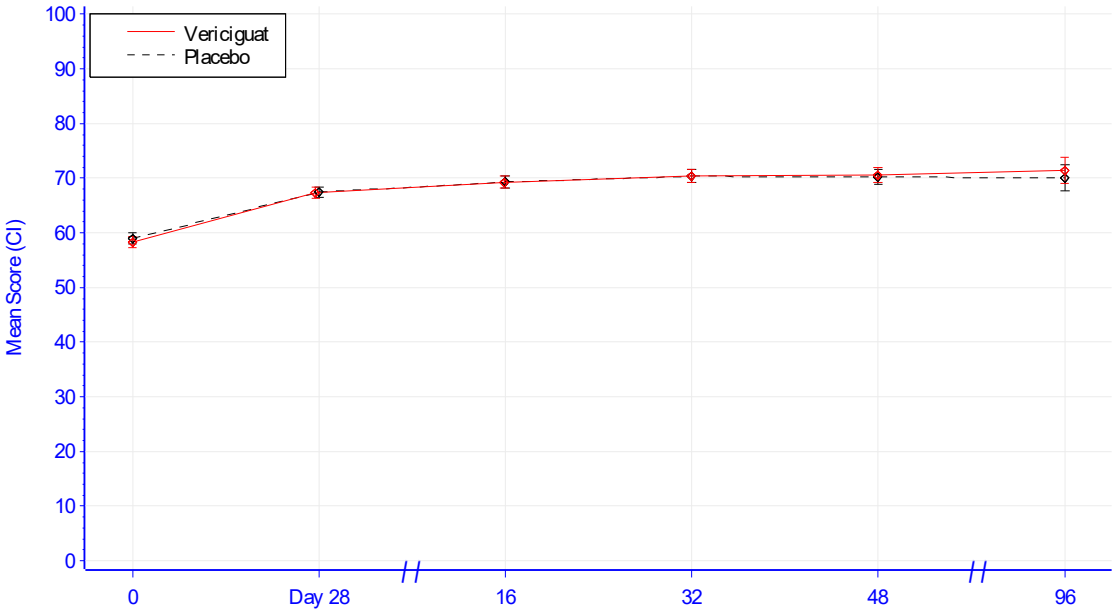
3.2.2.1 Descriptive summary over time

Table 3.2.2-1
Summary Statistics of KCCQ Overall Summary Score Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

KCCQ OSS	Study: MK-1242-001[a]	
	Vericiguat N[b]=2152	**Placebo N[b]=2151**
Baseline		
N[c]	1932	1920
Mean (SD)	58,3 (23,0)	59,0 (22,5)
Median (Q1;Q3)	59,4 (41,4;76,7)	60,7 (42,4;77,1)
Min; Max	0,00;100,00	0,00;100,00
Day 28		
N[c]	1816	1805
Mean (SD)	67,4 (21,9)	67,4 (21,9)
Median (Q1;Q3)	70,8 (52,3;85,4)	71,1 (53,1;85,4)
Min; Max	0,00;100,00	2,60;100,00
Week 16		
N[c]	1679	1702
Mean (SD)	69,3 (22,1)	69,3 (22,2)
Median (Q1;Q3)	73,4 (54,2;87,7)	73,7 (55,2;87,2)
Min; Max	0,00;100,00	2,08;100,00
Week 32		
N[c]	1411	1382
Mean (SD)	70,4 (21,8)	70,4 (22,2)
Median (Q1;Q3)	74,4 (56,7;88,9)	74,5 (55,5;89,1)
Min; Max	3,39;100,00	0,00;100,00
Week 48		
N[c]	1012	1004
Mean (SD)	70,5 (22,1)	70,2 (21,9)
Median (Q1;Q3)	74,8 (56,3;88,5)	74,5 (55,5;88,8)
Min; Max	0,00;100,00	3,13;100,00
Week 96		
N[c]	321	323
Mean (SD)	71,5 (21,7)	70,0 (21,7)
Median (Q1;Q3)	76,4 (56,3;89,6)	72,4 (56,5;88,0)
Min; Max	7,24;100,00	5,21;100,00
Week 144		
N[c]	1	3
Mean (SD)	63,8 (.)	87,6 (5,3)
Median (Q1;Q3)	63,8 (63,8;63,8)	90,1 (81,5;91,1)
Min; Max	63,80;63,80	81,51;91,15

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Number of participants with data at each time point
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
KCCQ: Kansas City Cardiomyopathy Questionnaire; Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

Figure 3.2-2
Mean and 95% Confidence Interval Over Time: KCCQ Overall Summary Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%



Number of participants					
Vericiguat					
1932	1816	1679	1411	1012	321
Placebo					
1920	1805	1702	1382	1004	323

Based on data up to primary completion date (18JUN2019)
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

3.2.2.2 Change from baseline at Week 32

Table 3.2.2-2
Analysis of Change From Baseline in KCCQ at Week 32: Overall Summary Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					**Vericiguat vs. Placebo**	
KCCQ OSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**
Vericiguat	1932	1833	58,3 (22,99)	9,35 (0,49)	0,69	-
Placebo	1920	1808	59,0 (22,50)	8,66 (0,50)	[-0,68; 2,07]	-

a: Database Cutoff Date: 18JUN2019
b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline
c: Number of participants with data available for analysis
d: Sample Mean and SD calculated for participants with data available for analysis
e: cLDA with change from baseline as the dependent variable, factors for treatment, analysis visit, stratification factor (defined by region and race) and treatment-by-visit interaction term, baseline value as covariate; including all post-baseline timepoints through week 96
Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment
f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
CI: confidence interval; cLDA: constrained Longitudinal Data Analysis; KCCQ: Kansas City Cardiomyopathy Questionnaire; SD: Standard Deviation; SE: Standard Error

3.2.3 KCCQ: Total Symptom Score

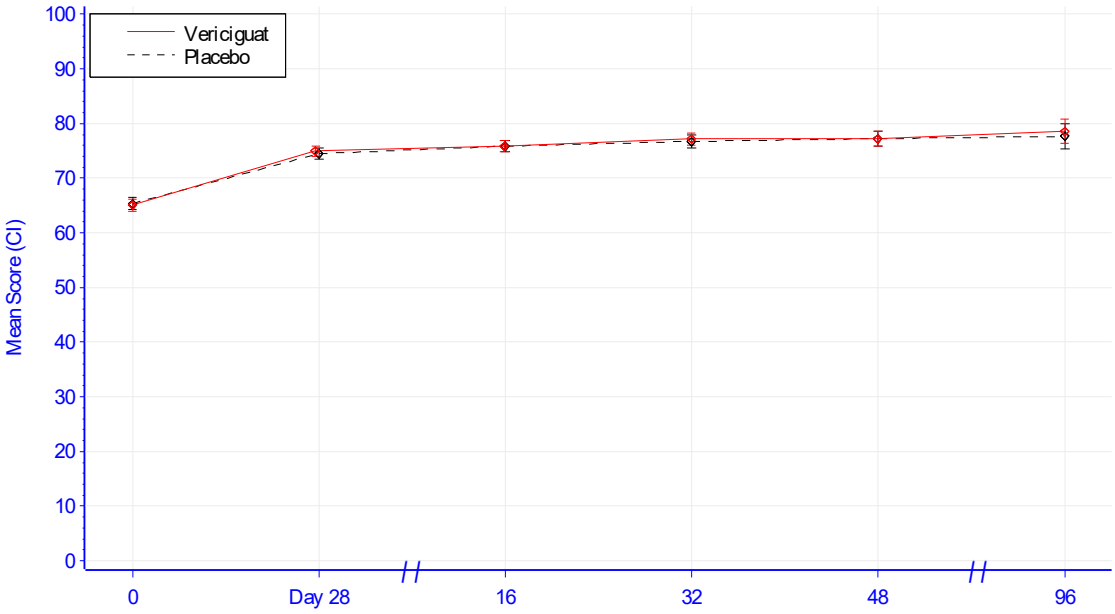
3.2.3.1 Descriptive summary over time

Table 3.2.3-1
Summary Statistics of KCCQ Total Symptom Score Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

KCCQ TSS	Study: MK-1242-001[a]	
	Vericiguat N[b]=2152	**Placebo N[b]=2151**
Baseline		
N[c]	2039	2032
Mean (SD)	65,1 (25,3)	65,4 (24,8)
Median (Q1;Q3)	68,8 (47,9;85,4)	68,8 (49,0;85,4)
Min; Max	0,00;100,00	0,00;100,00
Day 28		
N[c]	1922	1909
Mean (SD)	74,9 (22,5)	74,5 (22,8)
Median (Q1;Q3)	80,2 (61,5;93,8)	79,2 (60,4;93,8)
Min; Max	0,00;100,00	0,00;100,00
Week 16		
N[c]	1802	1822
Mean (SD)	75,9 (22,8)	75,9 (22,8)
Median (Q1;Q3)	81,3 (62,5;95,8)	81,3 (62,5;95,8)
Min; Max	0,00;100,00	0,00;100,00
Week 32		
N[c]	1506	1490
Mean (SD)	77,2 (22,4)	76,7 (22,5)
Median (Q1;Q3)	83,3 (64,6;95,8)	83,3 (64,6;95,8)
Min; Max	0,00;100,00	0,00;100,00
Week 48		
N[c]	1093	1085
Mean (SD)	77,2 (22,2)	77,2 (22,0)
Median (Q1;Q3)	83,3 (64,6;96,9)	83,3 (64,6;95,8)
Min; Max	0,00;100,00	0,00;100,00
Week 96		
N[c]	353	350
Mean (SD)	78,6 (21,3)	77,7 (21,6)
Median (Q1;Q3)	84,4 (66,7;95,8)	82,3 (66,7;95,8)
Min; Max	3,13;100,00	0,00;100,00
Week 144		
N[c]	1	3
Mean (SD)	80,2 (.)	87,8 (3,0)
Median (Q1;Q3)	80,2 (80,2;80,2)	89,6 (84,4;89,6)
Min; Max	80,21;80,21	84,38;89,58

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Number of participants with data at each time point
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
KCCQ: Kansas City Cardiomyopathy Questionnaire; Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

Figure 3.2-3
Mean and 95% Confidence Interval Over Time: KCCQ Total Summary Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%



Number of participants					
Vericiguat					
2039	1922	1802	1506	1093	353
Placebo					
2032	1909	1822	1490	1085	350

Based on data up to primary completion date (18JUN2019)
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

3.2.3.2 Change from baseline at Week 32

Table 3.2.3-2
Analysis of Change From Baseline in KCCQ at Week 32: Total Symptom Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					**Vericiguat vs. Placebo**	
KCCQ TSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**
Vericiguat	2039	1953	65,1 (25,34)	8,97 (0,52)	-0,10	-
Placebo	2032	1944	65,4 (24,77)	9,07 (0,52)	[-1,54; 1,33]	-

a: Database Cutoff Date: 18JUN2019
b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline
c: Number of participants with data available for analysis
d: Sample Mean and SD calculated for participants with data available for analysis
e: cLDA with change from baseline as the dependent variable, factors for treatment, analysis visit, stratification factor (defined by region and race) and treatment-by-visit interaction term, baseline value as covariate; including all post-baseline timepoints through week 96
Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment
f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
CI: confidence interval; cLDA: constrained Longitudinal Data Analysis; KCCQ: Kansas City Cardiomyopathy Questionnaire; SD: Standard Deviation; SE: Standard Error

3.2.4 KCCQ: Clinical Summary Score

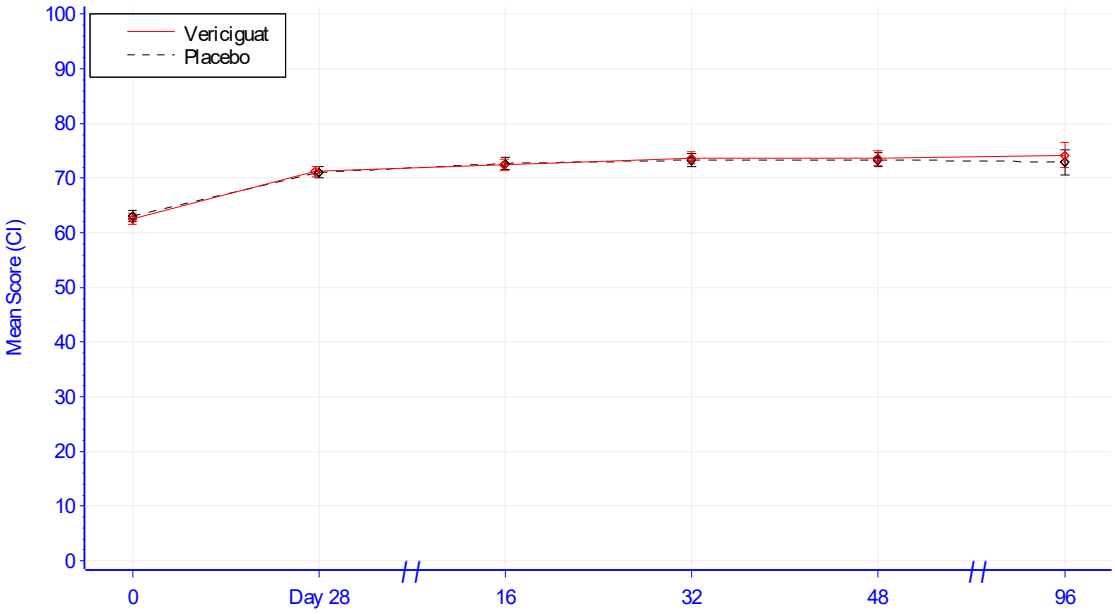
3.2.4.1 Descriptive summary over time

Table 3.2.4-1
Summary Statistics of KCCQ Clinical Summary Score Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

KCCQ CSS	Study: MK-1242-001[a]	
	Vericiguat N[b]=2152	**Placebo N[b]=2151**
Baseline		
N[c]	2008	2005
Mean (SD)	62,7 (23,4)	63,1 (23,3)
Median (Q1;Q3)	65,1 (46,4;81,3)	65,6 (45,8;82,3)
Min; Max	0,00;100,00	0,00;100,00
Day 28		
N[c]	1892	1875
Mean (SD)	71,2 (22,0)	71,1 (22,3)
Median (Q1;Q3)	75,0 (56,5;89,6)	75,2 (56,3;89,6)
Min; Max	0,00;100,00	1,04;100,00
Week 16		
N[c]	1761	1785
Mean (SD)	72,5 (22,4)	72,7 (22,4)
Median (Q1;Q3)	76,6 (57,7;91,7)	77,1 (58,3;91,7)
Min; Max	0,00;100,00	1,04;100,00
Week 32		
N[c]	1479	1463
Mean (SD)	73,7 (21,8)	73,3 (22,4)
Median (Q1;Q3)	78,1 (60,4;91,7)	78,1 (58,9;92,5)
Min; Max	3,13;100,00	0,00;100,00
Week 48		
N[c]	1066	1065
Mean (SD)	73,6 (22,1)	73,4 (22,0)
Median (Q1;Q3)	78,9 (60,4;91,7)	79,2 (58,5;91,7)
Min; Max	0,00;100,00	0,00;100,00
Week 96		
N[c]	340	340
Mean (SD)	74,2 (21,1)	73,0 (21,5)
Median (Q1;Q3)	77,6 (61,4;91,7)	77,1 (61,5;90,6)
Min; Max	10,31;100,00	2,08;100,00
Week 144		
N[c]	1	3
Mean (SD)	69,3 (.)	89,8 (4,6)
Median (Q1;Q3)	69,3 (69,3;69,3)	88,5 (85,9;94,8)
Min; Max	69,27;69,27	85,94;94,79

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Number of participants with data at each time point
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
KCCQ: Kansas City Cardiomyopathy Questionnaire; Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

Figure 3.2-4
Mean and 95% Confidence Interval Over Time: KCCQ Clinical Summary Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%



Number of participants					
Vericiguat					
2008	1892	1761	1479	1066	340
Placebo					
2005	1875	1785	1463	1065	340

Based on data up to primary completion date (18JUN2019)
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

3.2.4.2 Change from baseline at Week 32

Table 3.2.4-2
Analysis of Change From Baseline in KCCQ at Week 32: Clinical Summary Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					**Vericiguat vs. Placebo**	
KCCQ CSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**
Vericiguat	2008	1919	62,7 (23,41)	8,03 (0,48)	0,22	-
Placebo	2005	1911	63,1 (23,31)	7,81 (0,49)	[-1,13; 1,57]	-

a: Database Cutoff Date: 18JUN2019

b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline

c: Number of participants with data available for analysis

d: Sample Mean and SD calculated for participants with data available for analysis

e: cLDA with change from baseline as the dependent variable, factors for treatment, analysis visit, stratification factor (defined by region and race) and treatment-by-visit interaction term, baseline value as covariate; including all post-baseline timepoints through week 96

Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment

f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero

Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

CI: confidence interval; cLDA: constrained Longitudinal Data Analysis; KCCQ: Kansas City Cardiomyopathy Questionnaire; SD: Standard Deviation; SE: Standard Error

3.2.5 KCCQ: Physical Limitation Score

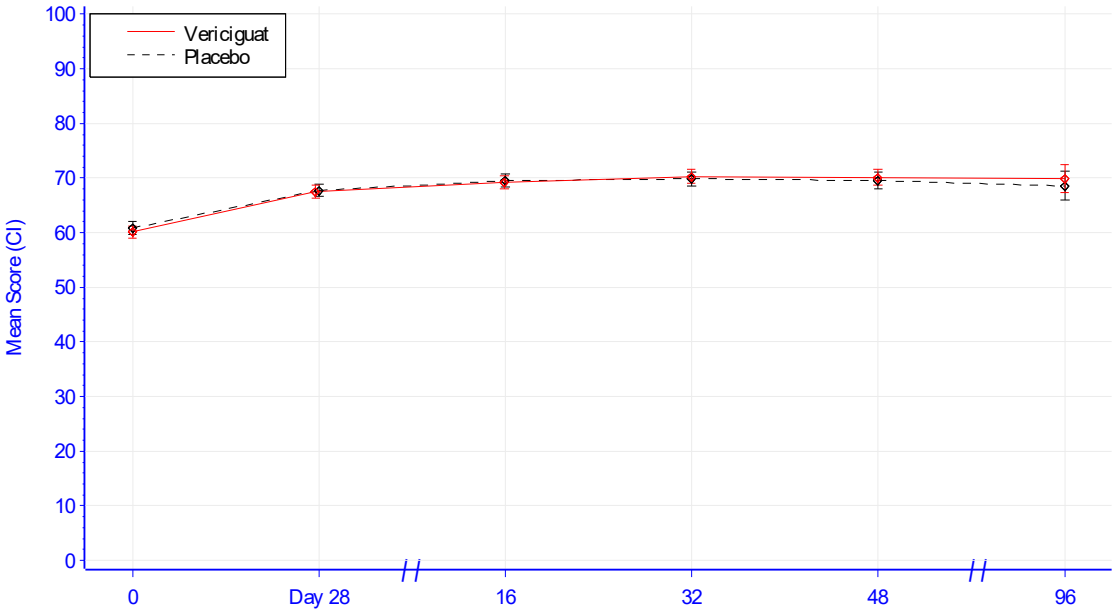
3.2.5.1 Descriptive summary over time

Table 3.2.5-1
Summary Statistics of KCCQ Physical Limitation Score Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

KCCQ PLS	Study: MK-1242-001[a]	
	Vericiguat N[b]=2152	**Placebo N[b]=2151**
Baseline		
N[c]	2008	2005
Mean (SD)	60,1 (25,5)	60,9 (25,6)
Median (Q1;Q3)	62,5 (41,7;79,6)	62,5 (41,7;83,3)
Min; Max	0,00;100,00	0,00;100,00
Day 28		
N[c]	1892	1875
Mean (SD)	67,5 (25,0)	67,7 (25,1)
Median (Q1;Q3)	70,8 (50,0;87,5)	70,8 (50,0;87,5)
Min; Max	0,00;100,00	0,00;100,00
Week 16		
N[c]	1761	1785
Mean (SD)	69,2 (25,1)	69,5 (25,3)
Median (Q1;Q3)	75,0 (50,0;91,7)	75,0 (54,2;91,7)
Min; Max	0,00;100,00	0,00;100,00
Week 32		
N[c]	1479	1463
Mean (SD)	70,3 (24,7)	69,9 (25,5)
Median (Q1;Q3)	75,0 (54,2;91,7)	75,0 (50,0;91,7)
Min; Max	0,00;100,00	0,00;100,00
Week 48		
N[c]	1066	1065
Mean (SD)	70,1 (24,9)	69,5 (25,2)
Median (Q1;Q3)	75,0 (54,2;91,7)	75,0 (50,0;91,7)
Min; Max	0,00;100,00	0,00;100,00
Week 96		
N[c]	340	340
Mean (SD)	69,9 (24,1)	68,6 (24,6)
Median (Q1;Q3)	75,0 (52,1;91,7)	75,0 (54,2;87,5)
Min; Max	5,00;100,00	0,00;100,00
Week 144		
N[c]	1	3
Mean (SD)	58,3 (.)	91,7 (7,2)
Median (Q1;Q3)	58,3 (58,3;58,3)	87,5 (87,5;100,0)
Min; Max	58,33;58,33	87,50;100,00

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Number of participants with data at each time point
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
KCCQ: Kansas City Cardiomyopathy Questionnaire; Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

Figure 3.2-5
Mean and 95% Confidence Interval Over Time: KCCQ Physical Limitation Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%



Number of participants					
Vericiguat					
2008	1892	1761	1479	1066	340
Placebo					
2005	1875	1785	1463	1065	340

Based on data up to primary completion date (18JUN2019)
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

3.2.5.2 Change from baseline at Week 32

Table 3.2.5-2
Analysis of Change From Baseline in KCCQ at Week 32: Physical Limitation Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					**Vericiguat vs. Placebo**	
KCCQ PLS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**
Vericiguat	2008	1919	60,1 (25,48)	7,21 (0,55)	0,56	-
Placebo	2005	1911	60,9 (25,63)	6,65 (0,55)	[-0,96; 2,07]	-

a: Database Cutoff Date: 18JUN2019
b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline
c: Number of participants with data available for analysis
d: Sample Mean and SD calculated for participants with data available for analysis
e: cLDA with change from baseline as the dependent variable, factors for treatment, analysis visit, stratification factor (defined by region and race) and treatment-by-visit interaction term, baseline value as covariate; including all post-baseline timepoints through week 96
Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment
f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
CI: confidence interval; cLDA: constrained Longitudinal Data Analysis; KCCQ: Kansas City Cardiomyopathy Questionnaire; SD: Standard Deviation; SE: Standard Error

3.2.6 KCCQ: Quality of Life Score

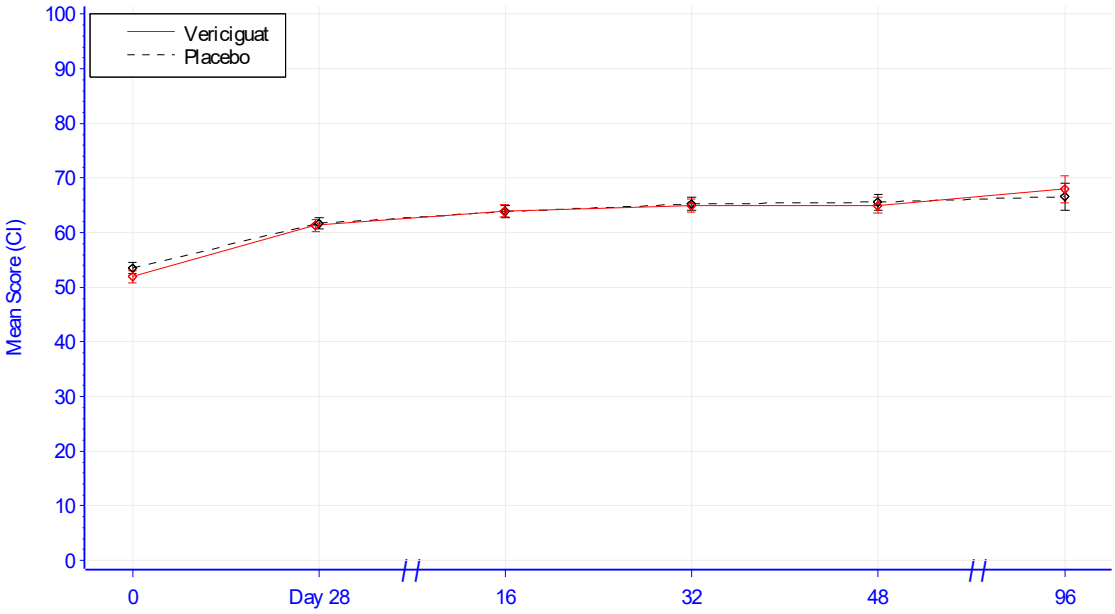
3.2.6.1 Descriptive summary over time

Table 3.2.6-1
Summary Statistics of KCCQ Quality of Life Score Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

KCCQ QoL	Study: MK-1242-001[a]	
	Vericiguat N[b]=2152	Placebo N[b]=2151
Baseline		
N[c]	2039	2032
Mean (SD)	52,0 (25,0)	53,6 (24,5)
Median (Q1;Q3)	50,0 (33,3;75,0)	50,0 (33,3;75,0)
Min; Max	0,00;100,00	0,00;100,00
Day 28		
N[c]	1922	1909
Mean (SD)	61,3 (24,1)	61,7 (24,0)
Median (Q1;Q3)	64,6 (41,7;83,3)	66,7 (41,7;83,3)
Min; Max	0,00;100,00	0,00;100,00
Week 16		
N[c]	1802	1822
Mean (SD)	64,0 (24,0)	63,9 (24,3)
Median (Q1;Q3)	66,7 (50,0;83,3)	66,7 (50,0;83,3)
Min; Max	0,00;100,00	0,00;100,00
Week 32		
N[c]	1506	1490
Mean (SD)	65,0 (24,0)	65,3 (24,2)
Median (Q1;Q3)	66,7 (50,0;83,3)	66,7 (50,0;83,3)
Min; Max	0,00;100,00	0,00;100,00
Week 48		
N[c]	1093	1085
Mean (SD)	65,0 (24,5)	65,6 (23,7)
Median (Q1;Q3)	66,7 (50,0;83,3)	66,7 (50,0;83,3)
Min; Max	0,00;100,00	0,00;100,00
Week 96		
N[c]	353	350
Mean (SD)	68,0 (24,0)	66,6 (23,2)
Median (Q1;Q3)	75,0 (50,0;87,5)	70,8 (50,0;83,3)
Min; Max	0,00;100,00	0,00;100,00
Week 144		
N[c]	1	3
Mean (SD)	50,0 (.)	75,0 (8,3)
Median (Q1;Q3)	50,0 (50,0;50,0)	75,0 (66,7;83,3)
Min; Max	50,00;50,00	66,67;83,33

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Number of participants with data at each time point
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
KCCQ: Kansas City Cardiomyopathy Questionnaire; Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

Figure 3.2-6
Mean and 95% Confidence Interval Over Time: KCCQ Quality of Life Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%



Number of participants					
Vericiguat					
2039	1922	1802	1506	1093	353
Placebo					
2032	1909	1822	1490	1085	350

Based on data up to primary completion date (18JUN2019)
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

3.2.6.2 Change from baseline at Week 32

Table 3.2.6-2
Analysis of Change From Baseline in KCCQ at Week 32: Quality of Life Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					**Vericiguat vs. Placebo**	
KCCQ QoL	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**
Vericiguat	2039	1953	52,0 (24,98)	10,03 (0,55)	0,32	-
Placebo	2032	1944	53,6 (24,53)	9,71 (0,55)	[-1,20; 1,84]	-

a: Database Cutoff Date: 18JUN2019
b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline
c: Number of participants with data available for analysis
d: Sample Mean and SD calculated for participants with data available for analysis
e: cLDA with change from baseline as the dependent variable, factors for treatment, analysis visit, stratification factor (defined by region and race) and treatment-by-visit interaction term, baseline value as covariate; including all post-baseline timepoints through week 96
Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment
f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
CI: confidence interval; cLDA: constrained Longitudinal Data Analysis; KCCQ: Kansas City Cardiomyopathy Questionnaire; SD: Standard Deviation; SE: Standard Error

3.2.7 KCCQ: Symptom Burden Score

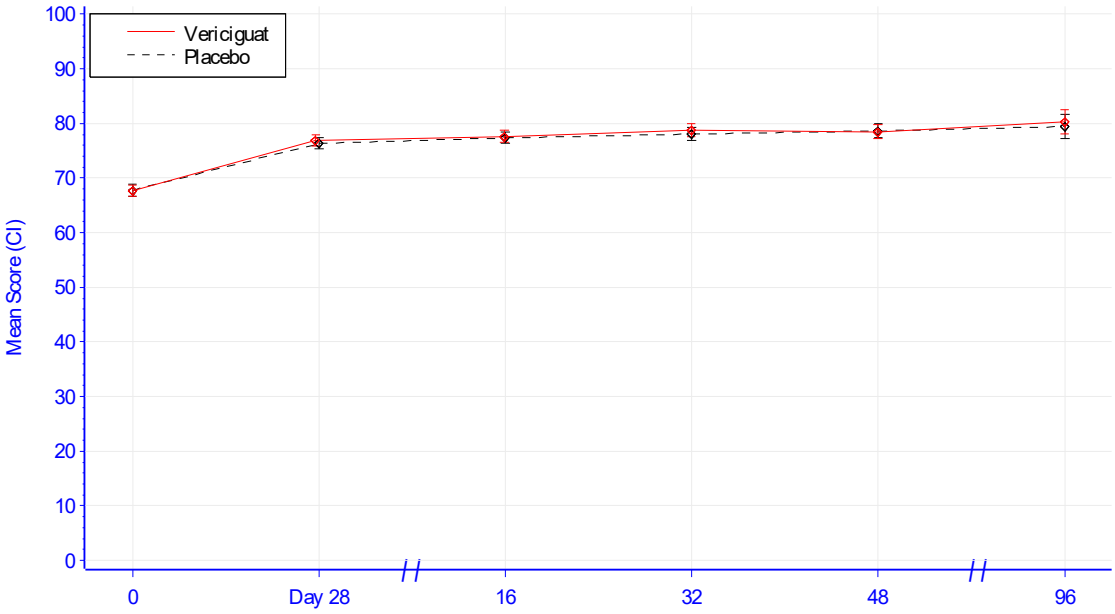
3.2.7.1 Descriptive summary over time

Table 3.2.7-1
Summary Statistics of KCCQ Symptom Burden Score Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

KCCQ SBS	Study: MK-1242-001[a]	
	Vericiguat N[b]=2152	**Placebo N[b]=2151**
Baseline		
N[c]	2039	2032
Mean (SD)	67,7 (25,3)	67,8 (24,9)
Median (Q1;Q3)	75,0 (50,0;91,7)	75,0 (50,0;83,3)
Min; Max	0,00;100,00	0,00;100,00
Day 28		
N[c]	1922	1909
Mean (SD)	77,0 (22,3)	76,3 (22,7)
Median (Q1;Q3)	83,3 (66,7;100,0)	83,3 (66,7;100,0)
Min; Max	0,00;100,00	0,00;100,00
Week 16		
N[c]	1802	1822
Mean (SD)	77,6 (22,7)	77,4 (22,9)
Median (Q1;Q3)	83,3 (66,7;100,0)	83,3 (66,7;100,0)
Min; Max	0,00;100,00	0,00;100,00
Week 32		
N[c]	1506	1490
Mean (SD)	78,8 (22,5)	78,1 (22,6)
Median (Q1;Q3)	83,3 (66,7;100,0)	83,3 (66,7;100,0)
Min; Max	0,00;100,00	0,00;100,00
Week 48		
N[c]	1093	1085
Mean (SD)	78,5 (22,3)	78,6 (22,0)
Median (Q1;Q3)	83,3 (66,7;100,0)	83,3 (66,7;100,0)
Min; Max	0,00;100,00	0,00;100,00
Week 96		
N[c]	353	350
Mean (SD)	80,3 (21,7)	79,4 (21,5)
Median (Q1;Q3)	83,3 (66,7;100,0)	83,3 (66,7;100,0)
Min; Max	0,00;100,00	0,00;100,00
Week 144		
N[c]	1	3
Mean (SD)	83,3 (.)	94,4 (9,6)
Median (Q1;Q3)	83,3 (83,3;83,3)	100,0 (83,3;100,0)
Min; Max	83,33;83,33	83,33;100,00

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Number of participants with data at each time point
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
KCCQ: Kansas City Cardiomyopathy Questionnaire; Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

Figure 3.2-7
Mean and 95% Confidence Interval Over Time: KCCQ Symptom Burden Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%



Number of participants					
Vericiguat					
2039	1922	1802	1506	1093	353
Placebo					
2032	1909	1822	1490	1085	350

Based on data up to primary completion date (18JUN2019)
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

3.2.7.2 Change from baseline at Week 32

Table 3.2.7-2
Analysis of Change From Baseline in KCCQ at Week 32: Symptom Burden Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					**Vericiguat vs. Placebo**	
KCCQ SBS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**
Vericiguat	2039	1953	67,7 (25,33)	8,07 (0,52)	-0,03	-
Placebo	2032	1944	67,8 (24,88)	8,10 (0,53)	[-1,48; 1,42]	-

a: Database Cutoff Date: 18JUN2019
b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline
c: Number of participants with data available for analysis
d: Sample Mean and SD calculated for participants with data available for analysis
e: cLDA with change from baseline as the dependent variable, factors for treatment, analysis visit, stratification factor (defined by region and race) and treatment-by-visit interaction term, baseline value as covariate; including all post-baseline timepoints through week 96
Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment
f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
CI: confidence interval; cLDA: constrained Longitudinal Data Analysis; KCCQ: Kansas City Cardiomyopathy Questionnaire; SD: Standard Deviation; SE: Standard Error

3.2.8 KCCQ: Self-Efficacy Score

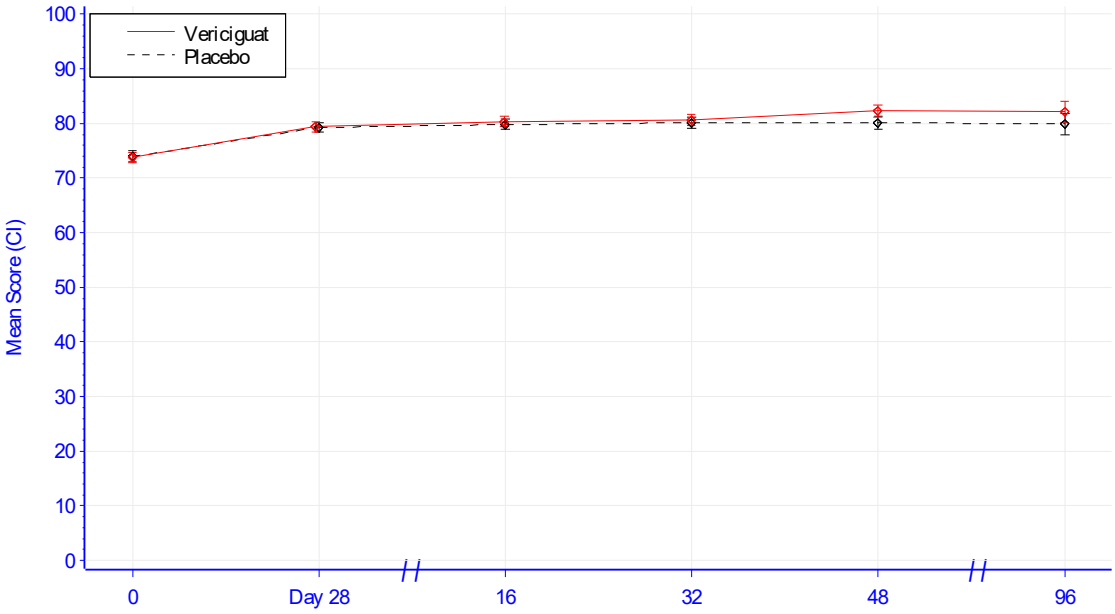
3.2.8.1 Descriptive summary over time

Table 3.2.8-1
Summary Statistics of KCCQ Self-Efficacy Score Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

KCCQ SES	Study: MK-1242-001[a]	
	Vericiguat N[b]=2152	Placebo N[b]=2151
Baseline		
N[c]	2039	2032
Mean (SD)	73,7 (23,3)	73,9 (23,2)
Median (Q1;Q3)	75,0 (50,0;100,0)	75,0 (62,5;100,0)
Min; Max	0,00;100,00	0,00;100,00
Day 28		
N[c]	1922	1909
Mean (SD)	79,4 (20,7)	79,3 (20,4)
Median (Q1;Q3)	75,0 (62,5;100,0)	75,0 (75,0;100,0)
Min; Max	0,00;100,00	0,00;100,00
Week 16		
N[c]	1802	1822
Mean (SD)	80,4 (20,3)	79,8 (20,4)
Median (Q1;Q3)	87,5 (75,0;100,0)	75,0 (75,0;100,0)
Min; Max	0,00;100,00	0,00;100,00
Week 32		
N[c]	1506	1490
Mean (SD)	80,7 (20,2)	80,2 (20,7)
Median (Q1;Q3)	87,5 (75,0;100,0)	87,5 (75,0;100,0)
Min; Max	0,00;100,00	0,00;100,00
Week 48		
N[c]	1093	1085
Mean (SD)	82,3 (19,1)	80,1 (20,0)
Median (Q1;Q3)	87,5 (75,0;100,0)	87,5 (75,0;100,0)
Min; Max	0,00;100,00	0,00;100,00
Week 96		
N[c]	353	350
Mean (SD)	82,1 (18,5)	79,9 (18,9)
Median (Q1;Q3)	87,5 (75,0;100,0)	75,0 (75,0;100,0)
Min; Max	0,00;100,00	0,00;100,00
Week 144		
N[c]	1	3
Mean (SD)	100,0 (.)	79,2 (19,1)
Median (Q1;Q3)	100,0 (100,0;100,0)	75,0 (62,5;100,0)
Min; Max	100,00;100,00	62,50;100,00

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Number of participants with data at each time point
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
KCCQ: Kansas City Cardiomyopathy Questionnaire; Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

Figure 3.2-8
Mean and 95% Confidence Interval Over Time: KCCQ Self-Efficacy Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%



Number of participants					
Vericiguat					
2039	1922	1802	1506	1093	353
Placebo					
2032	1909	1822	1490	1085	350

Based on data up to primary completion date (18JUN2019)
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

3.2.8.2 Change from baseline at Week 32

Table 3.2.8-2
Analysis of Change From Baseline in KCCQ at Week 32: Self-efficacy Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					**Vericiguat vs. Placebo**	
KCCQ SES	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**
Vericiguat	2039	1953	73,7 (23,33)	6,17 (0,47)	-0,10	-
Placebo	2032	1944	73,9 (23,23)	6,27 (0,48)	[-1,42; 1,22]	-

a: Database Cutoff Date: 18JUN2019

b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline

c: Number of participants with data available for analysis

d: Sample Mean and SD calculated for participants with data available for analysis

e: cLDA with change from baseline as the dependent variable, factors for treatment, analysis visit, stratification factor (defined by region and race) and treatment-by-visit interaction term, baseline value as covariate; including all post-baseline timepoints through week 96

Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment

f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero

Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

CI: confidence interval; cLDA: constrained Longitudinal Data Analysis; KCCQ: Kansas City Cardiomyopathy Questionnaire; SD: Standard Deviation; SE: Standard Error

3.2.9 KCCQ: Symptoms Frequency Score

3.2.9.1 Descriptive summary over time

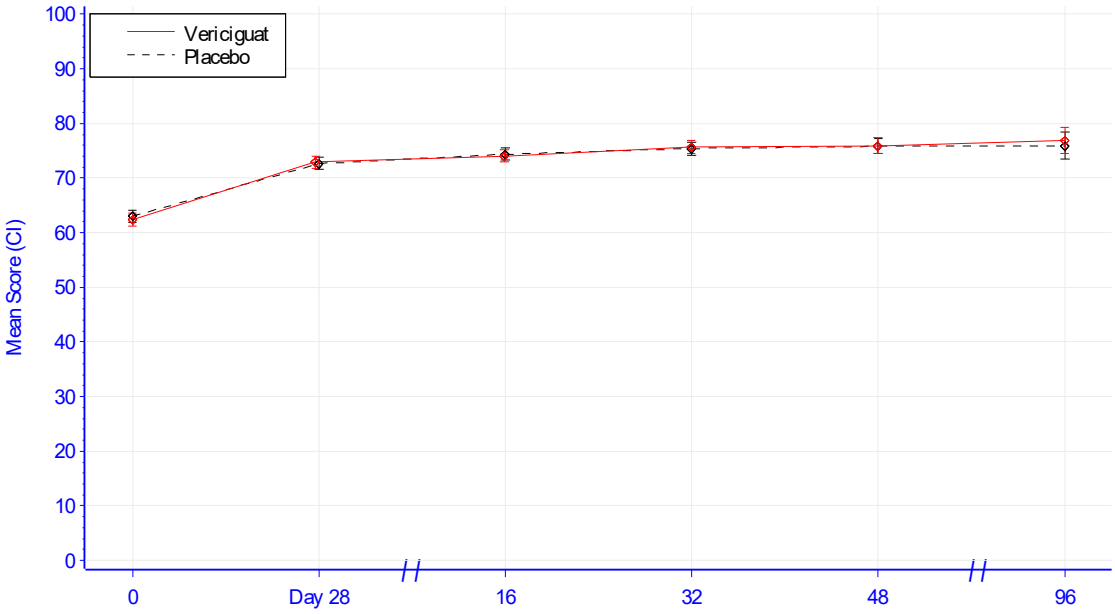
Table 3.2.9-1

Summary Statistics of KCCQ Symptoms Frequency Score Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

KCCQ SFS	Study: MK-1242-001[a]	
	Vericiguat N[b]=2152	Placebo N[b]=2151
Baseline		
N[c]	2039	2032
Mean (SD)	62,5 (27,3)	63,0 (26,6)
Median (Q1;Q3)	66,7 (43,8;85,4)	66,7 (43,8;83,3)
Min; Max	0,00;100,00	0,00;100,00
Day 28		
N[c]	1922	1909
Mean (SD)	72,9 (24,4)	72,7 (24,4)
Median (Q1;Q3)	79,2 (58,3;91,7)	79,2 (58,3;91,7)
Min; Max	0,00;100,00	0,00;100,00
Week 16		
N[c]	1802	1822
Mean (SD)	74,1 (24,4)	74,4 (24,4)
Median (Q1;Q3)	79,2 (60,4;95,8)	81,3 (60,4;95,8)
Min; Max	0,00;100,00	0,00;100,00
Week 32		
N[c]	1506	1490
Mean (SD)	75,6 (23,8)	75,4 (23,7)
Median (Q1;Q3)	83,3 (62,5;95,8)	81,3 (62,5;95,8)
Min; Max	0,00;100,00	0,00;100,00
Week 48		
N[c]	1093	1085
Mean (SD)	75,9 (23,4)	75,8 (23,4)
Median (Q1;Q3)	81,3 (62,5;95,8)	83,3 (62,5;95,8)
Min; Max	0,00;100,00	0,00;100,00
Week 96		
N[c]	353	350
Mean (SD)	76,9 (22,6)	75,9 (23,1)
Median (Q1;Q3)	83,3 (66,7;95,8)	81,3 (62,5;95,8)
Min; Max	4,17;100,00	0,00;100,00
Week 144		
N[c]	1	3
Mean (SD)	77,1 (.)	81,3 (3,6)
Median (Q1;Q3)	77,1 (77,1;77,1)	79,2 (79,2;85,4)
Min; Max	77,08;77,08	79,17;85,42

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Number of participants with data at each time point
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
KCCQ: Kansas City Cardiomyopathy Questionnaire; Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

Figure 3.2-9
Mean and 95% Confidence Interval Over Time: KCCQ Symptoms Frequency Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%



Number of participants					
Vericiguat					
2039	1922	1802	1506	1093	353
Placebo					
2032	1909	1822	1490	1085	350

Based on data up to primary completion date (18JUN2019)
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

3.2.9.2 Change from baseline at Week 32

Table 3.2.9-2
Analysis of Change From Baseline in KCCQ at Week 32: Symptoms Frequency Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					**Vericiguat vs. Placebo**	
KCCQ SFS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**
Vericiguat	2039	1953	62,5 (27,33)	9,93 (0,55)	-0,16	-
Placebo	2032	1944	63,0 (26,62)	10,09 (0,56)	[-1,70; 1,38]	-

a: Database Cutoff Date: 18JUN2019
b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline
c: Number of participants with data available for analysis
d: Sample Mean and SD calculated for participants with data available for analysis
e: cLDA with change from baseline as the dependent variable, factors for treatment, analysis visit, stratification factor (defined by region and race) and treatment-by-visit interaction term, baseline value as covariate; including all post-baseline timepoints through week 96
Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment
f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
CI: confidence interval; cLDA: constrained Longitudinal Data Analysis; KCCQ: Kansas City Cardiomyopathy Questionnaire; SD: Standard Deviation; SE: Standard Error

3.2.10 KCCQ: Social Limitation Score

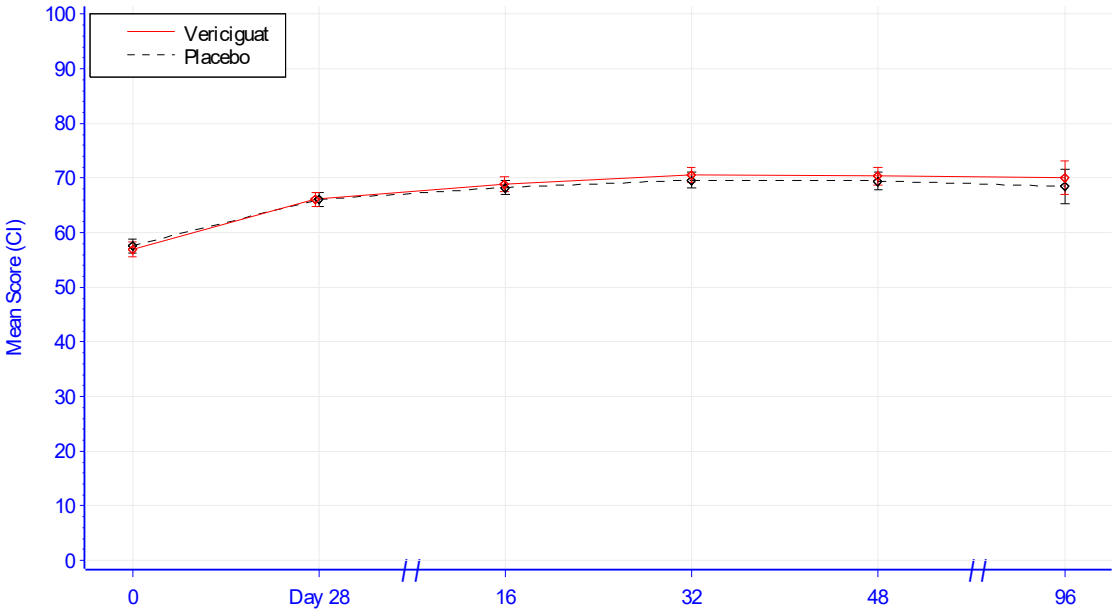
3.2.10.1 Descriptive summary over time

Table 3.2.10-1
Summary Statistics of KCCQ Social Limitation Score Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

KCCQ SLS	Study: MK-1242-001[a]	
	Vericiguat N[b]=2152	Placebo N[b]=2151
Baseline		
N[c]	1944	1933
Mean (SD)	56,9 (29,6)	57,6 (28,6)
Median (Q1;Q3)	58,3 (33,3;81,3)	58,3 (37,5;81,3)
Min; Max	0,00;100,00	0,00;100,00
Day 28		
N[c]	1829	1820
Mean (SD)	66,1 (27,8)	66,1 (27,9)
Median (Q1;Q3)	75,0 (50,0;91,7)	75,0 (50,0;91,7)
Min; Max	0,00;100,00	0,00;100,00
Week 16		
N[c]	1697	1714
Mean (SD)	68,9 (27,6)	68,3 (27,9)
Median (Q1;Q3)	75,0 (50,0;93,8)	75,0 (50,0;93,8)
Min; Max	0,00;100,00	0,00;100,00
Week 32		
N[c]	1420	1389
Mean (SD)	70,6 (27,3)	69,6 (27,7)
Median (Q1;Q3)	75,0 (50,0;93,8)	75,0 (50,0;93,8)
Min; Max	0,00;100,00	0,00;100,00
Week 48		
N[c]	1023	1013
Mean (SD)	70,4 (27,1)	69,5 (27,2)
Median (Q1;Q3)	75,0 (50,0;93,8)	75,0 (50,0;93,8)
Min; Max	0,00;100,00	0,00;100,00
Week 96		
N[c]	326	327
Mean (SD)	70,0 (27,8)	68,5 (28,8)
Median (Q1;Q3)	75,0 (50,0;93,8)	75,0 (50,0;100,0)
Min; Max	0,00;100,00	0,00;100,00
Week 144		
N[c]	1	3
Mean (SD)	66,7 (.)	95,8 (7,2)
Median (Q1;Q3)	66,7 (66,7;66,7)	100,0 (87,5;100,0)
Min; Max	66,67;66,67	87,50;100,00

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Number of participants with data at each time point
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
KCCQ: Kansas City Cardiomyopathy Questionnaire; Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

Figure 3.2-10
Mean and 95% Confidence Interval Over Time: KCCQ Social Limitation Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%



Number of participants					
Vericiguat					
1944	1829	1697	1420	1023	326
Placebo					
1933	1820	1714	1389	1013	327

Based on data up to primary completion date (18JUN2019)
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

3.2.10.2 Change from baseline at Week 32

Table 3.2.10-2
Analysis of Change From Baseline in KCCQ at Week 32: Social Limitation Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					**Vericiguat vs. Placebo**	
KCCQ SLS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**
Vericiguat	1944	1847	56,9 (29,63)	10,51 (0,63)	1,60	-
Placebo	1933	1823	57,6 (28,64)	8,91 (0,64)	[-0,17; 3,38]	-

a: Database Cutoff Date: 18JUN2019
b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline
c: Number of participants with data available for analysis
d: Sample Mean and SD calculated for participants with data available for analysis
e: cLDA with change from baseline as the dependent variable, factors for treatment, analysis visit, stratification factor (defined by region and race) and treatment-by-visit interaction term, baseline value as covariate; including all post-baseline timepoints through week 96
Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment
f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
CI: confidence interval; cLDA: constrained Longitudinal Data Analysis; KCCQ: Kansas City Cardiomyopathy Questionnaire; SD: Standard Deviation; SE: Standard Error

3.2.11 KCCQ: Symptom Stability Score

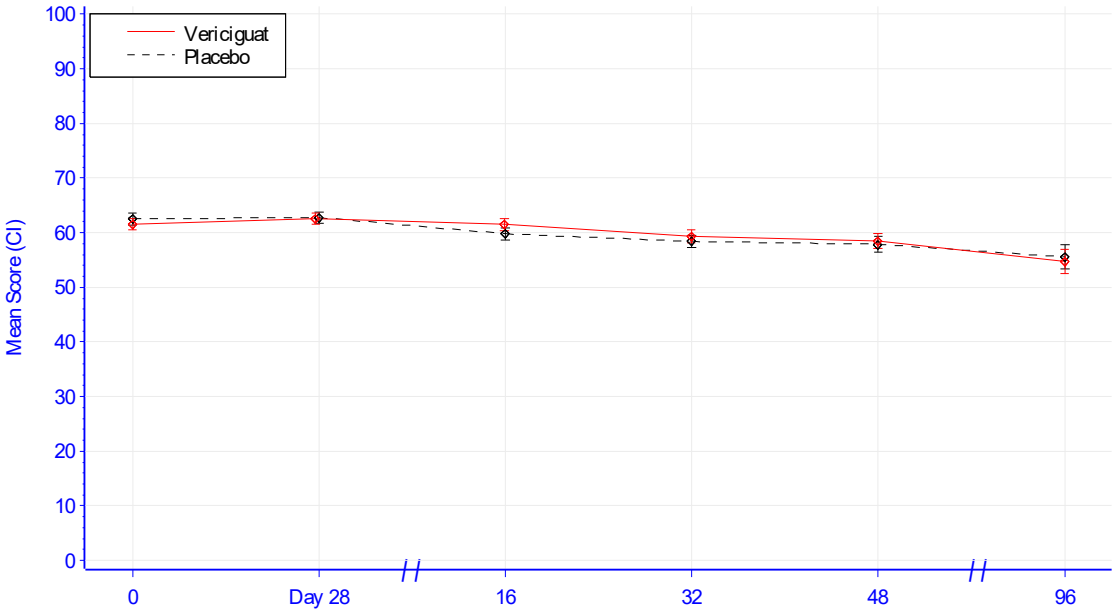
3.2.11.1 Descriptive summary over time

Table 3.2.11-1
Summary Statistics of KCCQ Symptom Stability Score Over Time
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

KCCQ SSS	Study: MK-1242-001[a]	
	Vericiguat N[b]=2152	**Placebo N[b]=2151**
Baseline		
N[c]	2039	2032
Mean (SD)	61,5 (24,6)	62,5 (24,7)
Median (Q1;Q3)	50,0 (50,0;75,0)	50,0 (50,0;75,0)
Min; Max	0,00;100,00	0,00;100,00
Day 28		
N[c]	1922	1909
Mean (SD)	62,6 (22,9)	62,8 (23,1)
Median (Q1;Q3)	50,0 (50,0;75,0)	50,0 (50,0;75,0)
Min; Max	0,00;100,00	0,00;100,00
Week 16		
N[c]	1802	1822
Mean (SD)	61,5 (23,6)	59,8 (23,7)
Median (Q1;Q3)	50,0 (50,0;75,0)	50,0 (50,0;75,0)
Min; Max	0,00;100,00	0,00;100,00
Week 32		
N[c]	1506	1490
Mean (SD)	59,3 (23,2)	58,4 (23,3)
Median (Q1;Q3)	50,0 (50,0;75,0)	50,0 (50,0;75,0)
Min; Max	0,00;100,00	0,00;100,00
Week 48		
N[c]	1093	1085
Mean (SD)	58,5 (22,7)	57,9 (23,7)
Median (Q1;Q3)	50,0 (50,0;75,0)	50,0 (50,0;75,0)
Min; Max	0,00;100,00	0,00;100,00
Week 96		
N[c]	353	350
Mean (SD)	54,7 (21,1)	55,6 (20,8)
Median (Q1;Q3)	50,0 (50,0;50,0)	50,0 (50,0;75,0)
Min; Max	0,00;100,00	0,00;100,00
Week 144		
N[c]	1	3
Mean (SD)	75,0 (.)	83,3 (14,4)
Median (Q1;Q3)	75,0 (75,0;75,0)	75,0 (75,0;100,0)
Min; Max	75,00;75,00	75,00;100,00

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Number of participants with data at each time point
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
KCCQ: Kansas City Cardiomyopathy Questionnaire; Max: Maximum; Min: Minimum; Q1: First Quartile; Q3: Third Quartile; SD: Standard Deviation

Figure 3.2-11
Mean and 95% Confidence Interval Over Time: KCCQ Symptom Stability Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%



Number of participants					
Vericiguat					
2039	1922	1802	1506	1093	353
Placebo					
2032	1909	1822	1490	1085	350

Based on data up to primary completion date (18JUN2019)
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

3.2.11.2 Change from baseline at Week 32

Table 3.2.11-2
Analysis of Change From Baseline in KCCQ at Week 32: Symptom Stability Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					**Vericiguat vs. Placebo**	
KCCQ SSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**
Vericiguat	2039	1953	61,5 (24,60)	-3,98 (0,60)	0,64	-
Placebo	2032	1944	62,5 (24,68)	-4,62 (0,60)	[-1,02; 2,30]	-

a: Database Cutoff Date: 18JUN2019

b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline

c: Number of participants with data available for analysis

d: Sample Mean and SD calculated for participants with data available for analysis

e: cLDA with change from baseline as the dependent variable, factors for treatment, analysis visit, stratification factor (defined by region and race) and treatment-by-visit interaction term, baseline value as covariate; including all post-baseline timepoints through week 48

Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment

f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero

Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start

CI: confidence interval; cLDA: constrained Longitudinal Data Analysis; KCCQ: Kansas City Cardiomyopathy Questionnaire; SD: Standard Deviation; SE: Standard Error

3.3 Subgroup Analyses: Change from Baseline

3.3.1 EQ-5D-5L VAS – Change from Baseline at Week 32

3.3.1.1 Consistency of Treatment Effect – Summary.

Table 3.3.1-1
Overview of Subgroup Analyses for Change From Baseline at Week 32 as Measured by EQ-5D VAS Score,
Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
EQ-5D VAS						
EQ-5D-5L VAS Score	0,424	0,535	0,480	0,945	0,218	0,250

Overview of Subgroup Analyses for Change From Baseline at Week 32 as Measured by EQ-5D VAS Score,
Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
EQ-5D VAS							
EQ-5D-5L VAS Score	**0,032[b]**	0,422	0,282	0,474	0,739	0,836	0,076

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.3.1.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.3.1-2
Subgroup Analysis of Change From Baseline at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
EQ-5D VAS	N[b]	N[c]	Mean at Baseline (SD)[d]	Mean Change from Baseline (SE)[e]	Mean Difference[e] [95 %-CI]	Standardized Mean Difference[f] [95 %-CI]	p-Value for Interaction Test[g]
Age category 1							
<65							
Vericiguat	786	757	64,5 (19,86)	6,38 (0,65)	1,28	0,08	0,424
Placebo	805	781	66,0 (18,56)	5,10 (0,65)	[-0,52; 3,07]	[-0,03; 0,19]	
≥65							
Vericiguat	1249	1191	64,1 (18,17)	3,79 (0,53)	0,33	0,02	
Placebo	1215	1151	62,9 (18,32)	3,46 (0,54)	[-1,16; 1,82]	[-0,07; 0,11]	
Age category 2							
<75							
Vericiguat	1448	1390	64,3 (19,12)	5,47 (0,48)	0,47	0,03	0,535
Placebo	1444	1387	65,0 (18,43)	5,00 (0,49)	[-0,88; 1,81]	[-0,05; 0,11]	
≥75							
Vericiguat	587	558	63,9 (18,14)	3,19 (0,78)	1,27	0,08	
Placebo	576	545	62,1 (18,44)	1,91 (0,79)	[-0,90; 3,44]	[-0,06; 0,21]	
Gender							
Male							
Vericiguat	1564	1498	64,1 (18,72)	4,77 (0,47)	0,46	0,03	0,480
Placebo	1557	1490	64,4 (18,42)	4,31 (0,47)	[-0,84; 1,77]	[-0,05; 0,11]	
Female							
Vericiguat	471	450	64,5 (19,24)	5,00 (0,87)	1,45	0,09	
Placebo	463	442	63,3 (18,66)	3,55 (0,87)	[-0,96; 3,86]	[-0,06; 0,24]	
Geographic Region							

Subgroup Analysis of Change From Baseline at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
EQ-5D VAS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
Asia Pacific							
Vericiguat	498	482	70,4 (17,17)	6,58 (0,83)	1,21	0,07	0,945
Placebo	482	468	69,6 (17,60)	5,37 (0,83)	[-1,09; 3,51]	[-0,07; 0,22]	
Eastern Europe							
Vericiguat	684	649	59,5 (18,41)	2,87 (0,72)	0,28	0,02	
Placebo	673	646	59,9 (18,12)	2,59 (0,73)	[-1,73; 2,28]	[-0,11; 0,14]	
Latin and South America							
Vericiguat	290	283	69,5 (17,54)	9,22 (1,05)	1,33	0,08	
Placebo	305	286	68,2 (16,78)	7,89 (1,07)	[-1,60; 4,27]	[-0,10; 0,26]	
North America							
Vericiguat	226	215	63,0 (19,35)	3,70 (1,26)	0,67	0,04	
Placebo	224	220	64,0 (19,64)	3,02 (1,24)	[-2,79; 4,13]	[-0,17; 0,25]	
Western Europe							
Vericiguat	337	319	60,9 (19,21)	2,67 (1,02)	0,02	0,00	
Placebo	336	312	61,3 (18,42)	2,65 (1,06)	[-2,87; 2,91]	[-0,18; 0,18]	
Index Event							
HF Hospitalization 3-6 Months							
Vericiguat	372	359	64,6 (18,78)	4,57 (0,95)	2,86	0,18	0,218
Placebo	335	324	64,4 (20,24)	1,71 (0,99)	[0,17; 5,54]	[0,01; 0,34]	
HF Hospitalization within 3 Months							
Vericiguat	1352	1289	64,1 (18,87)	5,07 (0,51)	0,16	0,01	
Placebo	1382	1315	63,9 (18,07)	4,91 (0,51)	[-1,25; 1,57]	[-0,08; 0,10]	

Subgroup Analysis of Change From Baseline at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
EQ-5D VAS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
IV diuretic for HF (without hospitalization) within 3 Months							
Vericiguat	311	300	64,0 (18,83)	4,13 (1,03)	0,54	0,03	
Placebo	303	293	65,1 (18,28)	3,59 (1,06)	[-2,35; 3,43]	[-0,14; 0,21]	
eGFR (mL/min/1.73 m²) Category							
≤30							
Vericiguat	203	182	61,8 (17,29)	4,57 (1,40)	3,66	0,23	0,250
Placebo	187	173	60,6 (17,90)	0,91 (1,49)	[-0,35; 7,67]	[-0,02; 0,47]	
>30 to ≤60							
Vericiguat	832	802	63,6 (18,94)	3,96 (0,64)	0,75	0,05	
Placebo	839	798	63,0 (18,80)	3,21 (0,65)	[-1,03; 2,53]	[-0,06; 0,16]	
>60							
Vericiguat	969	936	65,2 (19,01)	5,67 (0,59)	0,01	0,00	
Placebo	964	932	65,8 (18,14)	5,66 (0,59)	[-1,62; 1,64]	[-0,10; 0,10]	
Use of Sacubitril /Valsartan at Baseline							
Yes							
Vericiguat	315	299	64,2 (19,43)	3,45 (1,08)	1,85	0,11	0,422
Placebo	315	299	64,2 (19,09)	1,60 (1,09)	[-1,15; 4,84]	[-0,07; 0,30]	
No							
Vericiguat	1720	1649	64,2 (18,73)	5,06 (0,45)	0,52	0,03	
Placebo	1704	1632	64,1 (18,37)	4,54 (0,45)	[-0,72; 1,76]	[-0,04; 0,11]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab							
Q1 (≤1556)							

Subgroup Analysis of Change From Baseline at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					**Vericiguat vs. Placebo**		
EQ-5D VAS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
Vericiguat	467	456	66,5 (18,39)	4,91 (0,82)	-0,40	-0,02	0,282
Placebo	476	467	67,4 (17,34)	5,30 (0,82)	[-2,66; 1,87]	[-0,17; 0,12]	
Q2 (1556 - 2816)							
Vericiguat	497	484	65,6 (18,96)	5,12 (0,79)	-0,41	-0,03	
Placebo	452	439	65,9 (17,62)	5,53 (0,84)	[-2,67; 1,84]	[-0,17; 0,11]	
Q3 (2816 - 5314)							
Vericiguat	489	469	64,8 (18,71)	5,31 (0,85)	2,09	0,13	
Placebo	498	482	63,6 (18,75)	3,23 (0,83)	[-0,24; 4,41]	[-0,01; 0,27]	
Q4 (>5314)							
Vericiguat	505	466	60,4 (18,73)	4,46 (0,90)	1,71	0,11	
Placebo	490	445	60,8 (19,17)	2,75 (0,92)	[-0,81; 4,23]	[-0,05; 0,26]	
Baseline Ejection Fraction Group 2							
<35							
Vericiguat	1619	1546	64,1 (18,72)	4,81 (0,46)	0,47	0,03	0,474
Placebo	1623	1553	63,9 (18,67)	4,34 (0,47)	[-0,82; 1,76]	[-0,05; 0,11]	
≥35							
Vericiguat	416	402	64,6 (19,29)	4,89 (0,90)	1,50	0,09	
Placebo	397	379	65,0 (17,66)	3,38 (0,91)	[-1,01; 4,02]	[-0,06; 0,25]	
Race group							
White							
Vericiguat	1262	1199	61,4 (19,12)	3,19 (0,52)	0,73	0,05	0,739
Placebo	1260	1198	61,2 (18,37)	2,46 (0,53)	[-0,73; 2,19]	[-0,05; 0,14]	

Subgroup Analysis of Change From Baseline at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
EQ-5D VAS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
Asian							
Vericiguat	489	473	70,5 (16,56)	7,00 (0,84)	0,78	0,05	
Placebo	458	443	70,0 (17,16)	6,22 (0,86)	[-1,57; 3,14]	[-0,10; 0,19]	
Black							
Vericiguat	104	98	63,6 (19,24)	7,05 (1,94)	2,62	0,16	
Placebo	110	106	67,0 (20,66)	4,44 (1,74)	[-2,49; 7,72]	[-0,15; 0,47]	
Other							
Vericiguat	179	177	67,1 (18,05)	8,62 (1,37)	-0,91	-0,06	
Placebo	192	185	68,2 (16,56)	9,53 (1,33)	[-4,65; 2,83]	[-0,28; 0,17]	
CCSA class at Randomization							
No Angina							
Vericiguat	1739	1668	64,8 (18,85)	5,05 (0,45)	0,57	0,04	0,836
Placebo	1738	1661	64,8 (18,50)	4,47 (0,45)	[-0,67; 1,81]	[-0,04; 0,11]	
Angina Class 1 or 2							
Vericiguat	252	240	62,6 (18,00)	3,99 (1,16)	1,26	0,08	
Placebo	244	234	61,3 (17,58)	2,73 (1,20)	[-2,00; 4,52]	[-0,12; 0,28]	
Angina Class 3 or 4							
Vericiguat	44	40	52,2 (19,05)	0,47 (2,95)	2,58	0,15	
Placebo	38	37	51,8 (17,05)	-2,12 (2,97)	[-5,60; 10,77]	[-0,33; 0,64]	
Medical History of Diabetes Mellitus							
Yes							
Vericiguat	988	942	63,2 (19,49)	3,43 (0,60)	-0,40	-0,02	0,076

Subgroup Analysis of Change From Baseline at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
EQ-5D VAS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
Placebo	921	879	62,4 (18,93)	3,83 (0,62)	[-2,10; 1,30]	[-0,13; 0,08]	
No							
Vericiguat	1047	1006	65,2 (18,15)	6,07 (0,57)	1,69	0,10	
Placebo	1099	1053	65,6 (17,96)	4,39 (0,56)	[0,13; 3,24]	[0,01; 0,20]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline
c: Number of participants with data available for analysis
d: Sample Mean and SD calculated for participants with data available for analysis
e: cLDA model with change from baseline as the dependent variable, factors for treatment, analysis visit, subgroup, treatment-by-subgroup-by visit interaction and all second order interactions; stratification factor (defined by region and race) and baseline value as covariate; including all post-baseline timepoints through week 48
Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment
f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero
g: P-value computed with F-Test for the null-hypothesis that the mean differences for all levels of subgroup variable are equal
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
CI: Confidence Interval; cLDA: constrained Longitudinal Data Analysis; CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.3.1.3 Results for Subgroups With Interaction P-value < 0.05

Table 3.3.1-3
Subgroup Analysis of Change From Baseline at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test < 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
EQ-5D VAS	N[b]	N[c]	Mean at Baseline (SD)[d]	Mean Change from Baseline (SE)[e]	Mean Difference[e] [95 %-CI]	Standardized Mean Difference[f] [95 %-CI]	p-Value for Interaction Test[g]
NYHA Group at Baseline							
Class I or II							
Vericiguat	1181	1146	67,9 (17,86)	5,33 (0,53)	-0,24	-0,02	0,032
Placebo	1202	1163	68,2 (17,02)	5,58 (0,52)	[-1,70; 1,21]	[-0,11; 0,07]	
Class III or IV							
Vericiguat	852	800	59,1 (19,00)	4,13 (0,66)	2,35	0,15	
Placebo	818	769	58,2 (18,95)	1,78 (0,69)	[0,48; 4,21]	[0,03; 0,26]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline
c: Number of participants with data available for analysis
d: Sample Mean and SD calculated for participants with data available for analysis
e: cLDA model with change from baseline as the dependent variable, factors for treatment, analysis visit, subgroup, treatment-by-subgroup-by visit interaction and all second order interactions; stratification factor (defined by region and race) and baseline value as covariate; including all post-baseline timepoints through week 48
Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment
f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero
g: P-value computed with F-Test for the null-hypothesis that the mean differences for all levels of subgroup variable are equal
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
CI: Confidence Interval; cLDA: constrained Longitudinal Data Analysis; CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.3.2 KCCQ: Overall Summary Score – Change from Baseline at Week 32

3.3.2.1 Consistency of Treatment Effect – Summary

Table 3.3.2-1
Overview of Subgroup Analyses for Change From Baseline at Week 32 as Measured by KCCQ: Overall Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ OSS						
Overall Summary Score	0,987	0,951	0,977	0,967	0,312	0,810

Overview of Subgroup Analyses for Change From Baseline at Week 32 as Measured by KCCQ: Overall Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ OSS							
Overall Summary Score	0,406	0,244	0,869	0,938	0,938	0,963	0,995

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.3.2.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.3.2-2
Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ OSS	N[b]	N[c]	Mean at Baseline (SD)[d]	Mean Change from Baseline (SE)[e]	Mean Difference[e] [95 %-CI]	Standardized Mean Difference[f] [95 %-CI]	p-Value for Interaction Test[g]
Age category 1							
<65							
Vericiguat	760	728	57,0 (23,17)	10,52 (0,77)	0,74	0,04	0,987
Placebo	784	753	59,6 (22,03)	9,77 (0,76)	[-1,38; 2,87]	[-0,07; 0,15]	
≥65							
Vericiguat	1172	1105	59,2 (22,83)	8,55 (0,64)	0,72	0,04	
Placebo	1136	1054	58,5 (22,82)	7,83 (0,66)	[-1,08; 2,53]	[-0,06; 0,13]	
Age category 2							
<75							
Vericiguat	1393	1328	58,1 (22,98)	10,11 (0,58)	0,72	0,04	0,951
Placebo	1393	1320	59,0 (22,52)	9,40 (0,58)	[-0,89; 2,32]	[-0,05; 0,12]	
≥75							
Vericiguat	539	505	58,9 (23,02)	7,30 (0,96)	0,62	0,03	
Placebo	527	487	58,7 (22,48)	6,68 (0,97)	[-2,04; 3,28]	[-0,11; 0,17]	
Gender							
Male							
Vericiguat	1498	1421	59,0 (22,72)	9,61 (0,56)	0,72	0,04	0,977
Placebo	1487	1406	60,2 (22,18)	8,90 (0,57)	[-0,84; 2,28]	[-0,04; 0,12]	
Female							
Vericiguat	434	412	56,2 (23,77)	8,47 (1,05)	0,67	0,04	
Placebo	433	401	54,8 (23,12)	7,81 (1,07)	[-2,26; 3,60]	[-0,12; 0,19]	
Geographic Region							

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ OSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
Asia Pacific							
Vericiguat	456	437	64,3 (21,23)	11,19 (1,01)	1,14	0,06	0,967
Placebo	447	427	65,8 (21,06)	10,05 (1,02)	[-1,67; 3,95]	[-0,09; 0,21]	
Eastern Europe							
Vericiguat	653	614	54,1 (22,23)	8,72 (0,86)	0,36	0,02	
Placebo	643	607	55,3 (21,76)	8,36 (0,86)	[-2,02; 2,74]	[-0,11; 0,14]	
Latin and South America							
Vericiguat	273	264	59,1 (24,33)	13,35 (1,28)	0,59	0,03	
Placebo	287	264	59,6 (23,64)	12,76 (1,33)	[-3,02; 4,20]	[-0,16; 0,22]	
North America							
Vericiguat	221	209	60,3 (23,23)	5,28 (1,48)	1,81	0,09	
Placebo	220	214	56,6 (23,88)	3,46 (1,45)	[-2,24; 5,87]	[-0,12; 0,31]	
Western Europe							
Vericiguat	329	309	56,6 (23,64)	7,29 (1,20)	0,16	0,01	
Placebo	323	295	57,7 (21,88)	7,13 (1,26)	[-3,26; 3,57]	[-0,17; 0,19]	
Index Event							
HF Hospitalization 3-6 Months							
Vericiguat	358	343	61,6 (21,87)	6,97 (1,14)	2,97	0,16	0,312
Placebo	321	310	60,7 (22,70)	4,00 (1,17)	[-0,22; 6,17]	[-0,01; 0,33]	
HF Hospitalization within 3 Months							
Vericiguat	1272	1201	56,9 (23,08)	10,37 (0,61)	0,23	0,01	
Placebo	1305	1214	57,6 (22,25)	10,14 (0,62)	[-1,47; 1,93]	[-0,08; 0,10]	

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ OSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
IV diuretic for HF (without hospitalization) within 3 Months							
Vericiguat	302	289	60,7 (23,35)	8,09 (1,21)	0,16	0,01	
Placebo	294	283	62,9 (22,87)	7,93 (1,23)	[-3,23; 3,54]	[-0,17; 0,19]	
eGFR (mL/min/1.73 m²) Category							
≤30							
Vericiguat	181	160	54,7 (24,50)	7,71 (1,72)	1,93	0,10	0,810
Placebo	168	147	54,3 (22,19)	5,78 (1,90)	[-3,08; 6,95]	[-0,16; 0,36]	
>30 to ≤60							
Vericiguat	793	756	58,6 (23,17)	8,27 (0,77)	0,24	0,01	
Placebo	790	741	57,5 (22,97)	8,03 (0,78)	[-1,91; 2,39]	[-0,10; 0,13]	
>60							
Vericiguat	929	891	58,8 (22,49)	10,59 (0,70)	0,82	0,04	
Placebo	931	889	61,3 (21,83)	9,77 (0,70)	[-1,12; 2,75]	[-0,06; 0,15]	
NYHA Group at Baseline							
Class I or II							
Vericiguat	1129	1091	64,7 (21,42)	10,54 (0,63)	0,25	0,01	0,406
Placebo	1145	1094	65,4 (20,45)	10,29 (0,63)	[-1,49; 1,98]	[-0,08; 0,11]	
Class III or IV							
Vericiguat	801	740	49,3 (22,07)	7,60 (0,80)	1,45	0,08	
Placebo	775	713	49,4 (22,01)	6,15 (0,83)	[-0,79; 3,68]	[-0,04; 0,20]	
Use of Sacubitril /Valsartan at Baseline							
Yes							

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ OSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
Vericiguat	307	292	58,1 (23,84)	8,11 (1,27)	2,64	0,14	0,244
Placebo	302	280	57,6 (22,72)	5,46 (1,30)	[-0,90; 6,18]	[-0,05; 0,32]	
No							
Vericiguat	1625	1541	58,4 (22,83)	9,59 (0,54)	0,36	0,02	
Placebo	1617	1526	59,2 (22,45)	9,23 (0,54)	[-1,14; 1,85]	[-0,06; 0,10]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab							
Q1 (≤1556)							
Vericiguat	451	436	62,2 (23,49)	10,77 (0,98)	0,75	0,04	0,869
Placebo	460	447	63,5 (22,24)	10,01 (0,97)	[-1,95; 3,46]	[-0,10; 0,18]	
Q2 (1556 - 2816)							
Vericiguat	483	470	61,7 (21,83)	9,35 (0,93)	-0,01	-0,00	
Placebo	437	422	61,8 (21,58)	9,35 (0,99)	[-2,68; 2,67]	[-0,14; 0,14]	
Q3 (2816 - 5314)							
Vericiguat	452	427	59,9 (21,78)	9,01 (1,03)	1,55	0,08	
Placebo	468	450	59,6 (20,98)	7,46 (1,00)	[-1,26; 4,36]	[-0,07; 0,23]	
Q4 (>5314)							
Vericiguat	475	432	50,1 (22,83)	8,24 (1,07)	0,19	0,01	
Placebo	458	398	52,6 (23,71)	8,05 (1,13)	[-2,86; 3,24]	[-0,15; 0,17]	
Baseline Ejection Fraction Group 2							
<35							
Vericiguat	1535	1452	57,6 (23,09)	9,71 (0,55)	0,72	0,04	0,938
Placebo	1542	1451	58,6 (22,84)	8,99 (0,56)	[-0,83; 2,27]	[-0,04; 0,12]	

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ OSS	N[b]	N[c]	Mean at Baseline (SD)[d]	Mean Change from Baseline (SE)[e]	Mean Difference[e] [95 %-CI]	Standardized Mean Difference[f] [95 %-CI]	p-Value for Interaction Test[g]
≥35							
Vericiguat	397	381	61,1 (22,38)	8,03 (1,08)	0,58	0,03	
Placebo	378	356	60,4 (21,03)	7,45 (1,10)	[-2,43; 3,59]	[-0,13; 0,19]	
Race group							
White							
Vericiguat	1221	1151	56,8 (22,87)	7,79 (0,62)	0,52	0,03	0,938
Placebo	1213	1140	56,5 (22,32)	7,26 (0,63)	[-1,21; 2,26]	[-0,06; 0,12]	
Asian							
Vericiguat	443	424	65,3 (21,29)	11,91 (1,03)	1,16	0,06	
Placebo	421	398	66,4 (21,02)	10,75 (1,06)	[-1,74; 4,06]	[-0,09; 0,21]	
Black							
Vericiguat	100	93	53,1 (24,22)	8,41 (2,28)	1,87	0,10	
Placebo	105	101	55,6 (24,23)	6,53 (2,12)	[-4,23; 7,97]	[-0,22; 0,41]	
Other							
Vericiguat	167	164	54,5 (23,67)	14,26 (1,66)	-0,16	-0,01	
Placebo	181	168	59,9 (22,25)	14,42 (1,68)	[-4,80; 4,47]	[-0,25; 0,23]	
CCSA class at Randomization							
No Angina							
Vericiguat	1648	1568	58,5 (23,18)	9,65 (0,54)	0,63	0,03	0,963
Placebo	1637	1542	59,5 (22,52)	9,02 (0,54)	[-0,86; 2,12]	[-0,05; 0,11]	
Angina Class 1 or 2							
Vericiguat	241	226	58,5 (21,89)	9,05 (1,36)	1,16	0,06	

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ OSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
Placebo	243	227	57,5 (21,77)	7,89 (1,40)	[-2,65; 4,96]	[-0,14; 0,26]	
Angina Class 3 or 4							
Vericiguat	43	39	50,0 (20,39)	-0,17 (3,38)	0,18	0,01	
Placebo	40	38	45,6 (22,22)	-0,36 (3,45)	[-9,27; 9,63]	[-0,47; 0,49]	
Medical History of Diabetes Mellitus							
Yes							
Vericiguat	943	890	57,2 (23,21)	8,70 (0,72)	0,73	0,04	0,995
Placebo	869	821	56,4 (23,67)	7,97 (0,75)	[-1,31; 2,77]	[-0,07; 0,15]	
No							
Vericiguat	989	943	59,5 (22,72)	9,98 (0,68)	0,72	0,04	
Placebo	1051	986	61,0 (21,28)	9,26 (0,67)	[-1,15; 2,59]	[-0,06; 0,14]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline
c: Number of participants with data available for analysis
d: Sample Mean and SD calculated for participants with data available for analysis
e: cLDA model with change from baseline as the dependent variable, factors for treatment, analysis visit, subgroup, treatment-by-subgroup-by visit interaction and all second order interactions; stratification factor (defined by region and race) and baseline value as covariate; including all post-baseline timepoints through week 48
Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment
f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero
g: P-value computed with F-Test for the null-hypothesis that the mean differences for all levels of subgroup variable are equal
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
CI: Confidence Interval; cLDA: constrained Longitudinal Data Analysis; CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.3.3 KCCQ: Total Symptom Score – Change from Baseline at Week 32

3.3.3.1 Consistency of Treatment Effect – Summary

Table 3.3.3-1
Overview of Subgroup Analyses for Change From Baseline at Week 32 as Measured by KCCQ: Total Symptom Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ TSS						
Total Symptom Score	0,745	0,653	0,363	0,401	0,680	0,827

Overview of Subgroup Analyses for Change From Baseline at Week 32 as Measured by KCCQ: Total Symptom Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ TSS							
Total Symptom Score	0,304	0,507	0,644	0,928	0,560	0,867	0,972

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.3.3.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.3.3-2
Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ TSS	N[b]	N[c]	Mean at Baseline (SD)[d]	Mean Change from Baseline (SE)[e]	Mean Difference[e] [95 %-CI]	Standardized Mean Difference[f] [95 %-CI]	p-Value for Interaction Test[g]
Age category 1							
<65							
Vericiguat	786	757	64,2 (25,62)	9,41 (0,82)	0,20	0,01	0,745
Placebo	805	780	66,0 (24,58)	9,21 (0,81)	[-2,06; 2,46]	[-0,10; 0,12]	
≥65							
Vericiguat	1253	1196	65,6 (25,15)	8,76 (0,67)	-0,29	-0,01	
Placebo	1227	1163	65,0 (24,90)	9,05 (0,68)	[-2,15; 1,58]	[-0,11; 0,08]	
Age category 2							
<75							
Vericiguat	1449	1392	64,7 (25,67)	9,10 (0,61)	-0,30	-0,01	0,653
Placebo	1454	1396	65,4 (25,03)	9,40 (0,61)	[-2,00; 1,39]	[-0,10; 0,07]	
≥75							
Vericiguat	590	561	66,0 (24,50)	8,82 (0,98)	0,43	0,02	
Placebo	578	547	65,3 (24,13)	8,39 (0,99)	[-2,28; 3,15]	[-0,11; 0,15]	
Gender							
Male							
Vericiguat	1572	1506	65,7 (25,22)	8,98 (0,59)	-0,45	-0,02	0,363
Placebo	1567	1500	66,5 (24,54)	9,42 (0,59)	[-2,08; 1,18]	[-0,10; 0,06]	
Female							
Vericiguat	467	447	62,9 (25,65)	9,19 (1,09)	1,15	0,06	
Placebo	465	443	61,8 (25,24)	8,04 (1,10)	[-1,88; 4,18]	[-0,09; 0,20]	
Geographic Region							

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ TSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
Asia Pacific							
Vericiguat	500	484	73,8 (22,25)	10,72 (1,04)	-0,42	-0,02	0,401
Placebo	484	470	73,7 (23,36)	11,14 (1,04)	[-3,29; 2,46]	[-0,16; 0,12]	
Eastern Europe							
Vericiguat	682	647	59,0 (25,20)	8,56 (0,91)	-0,10	-0,00	
Placebo	674	645	60,6 (23,98)	8,66 (0,91)	[-2,62; 2,41]	[-0,13; 0,12]	
Latin and South America							
Vericiguat	289	282	66,5 (26,83)	13,49 (1,32)	2,59	0,13	
Placebo	306	287	67,2 (24,84)	10,90 (1,33)	[-1,10; 6,28]	[-0,05; 0,31]	
North America							
Vericiguat	227	217	67,4 (24,18)	4,48 (1,56)	0,65	0,03	
Placebo	228	225	64,2 (25,42)	3,83 (1,53)	[-3,64; 4,94]	[-0,18; 0,24]	
Western Europe							
Vericiguat	341	323	61,8 (25,48)	6,35 (1,27)	-2,57	-0,13	
Placebo	340	316	62,4 (24,74)	8,92 (1,32)	[-6,16; 1,01]	[-0,30; 0,05]	
Index Event							
HF Hospitalization 3-6 Months							
Vericiguat	373	361	69,4 (22,96)	6,98 (1,19)	1,12	0,05	0,680
Placebo	338	327	68,5 (23,60)	5,86 (1,23)	[-2,23; 4,48]	[-0,11; 0,22]	
HF Hospitalization within 3 Months							
Vericiguat	1354	1291	63,6 (25,96)	9,72 (0,64)	-0,49	-0,02	
Placebo	1389	1320	64,0 (25,04)	10,22 (0,64)	[-2,26; 1,28]	[-0,11; 0,06]	

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ TSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
IV diuretic for HF (without hospitalization) within 3 Months							
Vericiguat	312	301	66,3 (24,73)	8,53 (1,28)	0,41	0,02	
Placebo	305	296	68,2 (24,31)	8,13 (1,32)	[-3,20; 4,01]	[-0,16; 0,20]	
eGFR (mL/min/1.73 m²) Category							
≤30							
Vericiguat	202	182	59,7 (27,39)	8,07 (1,77)	1,32	0,06	0,827
Placebo	188	173	62,2 (26,67)	6,75 (1,87)	[-3,71; 6,35]	[-0,18; 0,31]	
>30 to ≤60							
Vericiguat	836	806	65,7 (25,64)	8,29 (0,80)	-0,37	-0,02	
Placebo	849	808	64,0 (25,48)	8,66 (0,81)	[-2,60; 1,85]	[-0,13; 0,09]	
>60							
Vericiguat	971	938	65,7 (24,61)	9,77 (0,74)	-0,28	-0,01	
Placebo	964	932	67,6 (23,42)	10,05 (0,74)	[-2,32; 1,77]	[-0,11; 0,09]	
NYHA Group at Baseline							
Class I or II							
Vericiguat	1183	1149	71,3 (23,34)	10,10 (0,66)	-0,65	-0,03	0,304
Placebo	1209	1169	71,8 (22,78)	10,74 (0,65)	[-2,46; 1,17]	[-0,12; 0,06]	
Class III or IV							
Vericiguat	854	802	56,5 (25,51)	7,48 (0,83)	0,90	0,04	
Placebo	823	774	56,0 (24,60)	6,58 (0,86)	[-1,42; 3,23]	[-0,07; 0,16]	
Use of Sacubitril /Valsartan at Baseline							
Yes							

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ TSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
Vericiguat	319	303	65,6 (25,31)	7,03 (1,34)	1,08	0,05	0,507
Placebo	317	301	65,6 (24,87)	5,95 (1,36)	[-2,64; 4,80]	[-0,13; 0,23]	
No							
Vericiguat	1720	1650	65,0 (25,35)	9,38 (0,56)	-0,28	-0,01	
Placebo	1714	1641	65,3 (24,76)	9,66 (0,56)	[-1,84; 1,27]	[-0,09; 0,06]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab							
Q1 (≤1556)							
Vericiguat	469	457	68,5 (24,78)	9,58 (1,03)	-0,98	-0,05	0,644
Placebo	478	469	69,8 (23,84)	10,56 (1,03)	[-3,83; 1,87]	[-0,19; 0,09]	
Q2 (1556 - 2816)							
Vericiguat	502	490	69,6 (23,59)	8,96 (0,99)	-0,68	-0,03	
Placebo	459	445	68,4 (22,96)	9,64 (1,04)	[-3,51; 2,14]	[-0,17; 0,10]	
Q3 (2816 - 5314)							
Vericiguat	488	468	66,6 (23,82)	9,13 (1,06)	1,49	0,07	
Placebo	499	484	66,9 (23,26)	7,65 (1,04)	[-1,43; 4,40]	[-0,07; 0,22]	
Q4 (>5314)							
Vericiguat	505	467	56,6 (26,69)	7,79 (1,13)	-0,20	-0,01	
Placebo	494	448	58,5 (26,75)	7,99 (1,15)	[-3,36; 2,95]	[-0,16; 0,14]	
Baseline Ejection Fraction Group 2							
<35							
Vericiguat	1622	1549	64,6 (25,63)	9,26 (0,58)	-0,07	-0,00	0,928
Placebo	1630	1559	65,1 (25,14)	9,33 (0,59)	[-1,69; 1,55]	[-0,08; 0,08]	

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ TSS	N[b]	N[c]	Mean at Baseline (SD)[d]	Mean Change from Baseline (SE)[e]	Mean Difference[e] [95 %-CI]	Standardized Mean Difference[f] [95 %-CI]	p-Value for Interaction Test[g]
≥35							
Vericiguat	417	404	67,1 (24,11)	8,11 (1,13)	-0,23	-0,01	
Placebo	402	384	66,6 (23,19)	8,35 (1,14)	[-3,37; 2,90]	[-0,16; 0,14]	
Race group							
White							
Vericiguat	1268	1206	62,8 (25,30)	7,49 (0,66)	-0,45	-0,02	0,560
Placebo	1274	1212	62,4 (24,42)	7,95 (0,66)	[-2,28; 1,37]	[-0,11; 0,07]	
Asian							
Vericiguat	490	474	74,5 (22,21)	11,38 (1,05)	-0,20	-0,01	
Placebo	459	444	73,9 (23,32)	11,58 (1,08)	[-3,16; 2,75]	[-0,15; 0,13]	
Black							
Vericiguat	103	97	59,3 (26,72)	5,83 (2,43)	-1,08	-0,05	
Placebo	105	101	62,8 (27,04)	6,92 (2,26)	[-7,58; 5,41]	[-0,36; 0,26]	
Other							
Vericiguat	177	175	59,0 (26,46)	14,57 (1,73)	3,15	0,15	
Placebo	194	186	66,5 (24,54)	11,42 (1,67)	[-1,56; 7,86]	[-0,08; 0,38]	
CCSA class at Randomization							
No Angina							
Vericiguat	1742	1672	65,2 (25,64)	9,16 (0,56)	-0,26	-0,01	0,867
Placebo	1744	1669	66,0 (24,85)	9,41 (0,56)	[-1,81; 1,29]	[-0,09; 0,06]	
Angina Class 1 or 2							
Vericiguat	253	241	65,6 (23,80)	9,87 (1,45)	0,93	0,05	

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ TSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
Placebo	248	236	63,3 (24,00)	8,94 (1,49)	[-3,14; 4,99]	[-0,15; 0,24]	
Angina Class 3 or 4							
Vericiguat	44	40	57,7 (21,01)	-2,30 (3,69)	0,04	0,00	
Placebo	40	38	50,5 (20,73)	-2,34 (3,72)	[-10,22; 10,29]	[-0,48; 0,48]	
Medical History of Diabetes Mellitus							
Yes							
Vericiguat	994	949	64,1 (25,90)	8,28 (0,75)	-0,03	-0,00	0,972
Placebo	933	893	62,7 (26,10)	8,31 (0,77)	[-2,15; 2,09]	[-0,10; 0,10]	
No							
Vericiguat	1045	1004	66,1 (24,77)	9,70 (0,71)	-0,08	-0,00	
Placebo	1099	1050	67,7 (23,35)	9,79 (0,70)	[-2,04; 1,88]	[-0,10; 0,09]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline
c: Number of participants with data available for analysis
d: Sample Mean and SD calculated for participants with data available for analysis
e: cLDA model with change from baseline as the dependent variable, factors for treatment, analysis visit, subgroup, treatment-by-subgroup-by visit interaction and all second order interactions; stratification factor (defined by region and race) and baseline value as covariate; including all post-baseline timepoints through week 48
Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment
f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero
g: P-value computed with F-Test for the null-hypothesis that the mean differences for all levels of subgroup variable are equal
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
CI: Confidence Interval; cLDA: constrained Longitudinal Data Analysis; CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.3.4 KCCQ: Clinical Summary Score – Change from Baseline at Week 32

3.3.4.1 Consistency of Treatment Effect – Summary

Table 3.3.4-1
Overview of Subgroup Analyses for Change From Baseline at Week 32 as Measured by KCCQ: Clinical Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ CSS						
Clinical Summary Score	0,657	0,913	0,427	0,736	0,228	0,496

Overview of Subgroup Analyses for Change From Baseline at Week 32 as Measured by KCCQ: Clinical Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ CSS							
Clinical Summary Score	0,533	0,449	0,753	0,552	0,920	0,666	0,934

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.3.4.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.3.4-2
Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ CSS	N[b]	N[c]	Mean at Baseline (SD)[d]	Mean Change from Baseline (SE)[e]	Mean Difference[e] [95 %-CI]	Standardized Mean Difference[f] [95 %-CI]	p-Value for Interaction Test[g]
Age category 1							
<65							
Vericiguat	780	750	63,0 (23,76)	9,35 (0,77)	0,62	0,03	0,657
Placebo	797	770	64,9 (22,88)	8,73 (0,76)	[-1,49; 2,73]	[-0,08; 0,14]	
≥65							
Vericiguat	1228	1169	62,4 (23,19)	7,17 (0,63)	-0,00	-0,00	
Placebo	1208	1140	61,8 (23,52)	7,17 (0,64)	[-1,76; 1,75]	[-0,09; 0,09]	
Age category 2							
<75							
Vericiguat	1434	1375	63,0 (23,57)	8,71 (0,57)	0,27	0,01	0,913
Placebo	1436	1374	63,7 (23,34)	8,45 (0,57)	[-1,32; 1,85]	[-0,07; 0,10]	
≥75							
Vericiguat	574	544	61,8 (23,00)	6,31 (0,92)	0,10	0,01	
Placebo	569	536	61,4 (23,17)	6,21 (0,92)	[-2,45; 2,65]	[-0,13; 0,14]	
Gender							
Male							
Vericiguat	1555	1487	63,6 (23,20)	8,05 (0,55)	-0,06	-0,00	0,427
Placebo	1551	1481	64,5 (22,98)	8,11 (0,55)	[-1,59; 1,47]	[-0,08; 0,08]	
Female							
Vericiguat	453	432	59,4 (23,85)	8,02 (1,03)	1,25	0,07	
Placebo	454	429	58,0 (23,75)	6,77 (1,04)	[-1,61; 4,11]	[-0,08; 0,21]	
Geographic Region							

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ CSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
Asia Pacific							
Vericiguat	490	473	71,7 (20,48)	10,18 (0,98)	0,40	0,02	0,736
Placebo	480	465	72,9 (21,08)	9,78 (0,98)	[-2,30; 3,10]	[-0,12; 0,16]	
Eastern Europe							
Vericiguat	672	635	57,4 (22,96)	7,79 (0,85)	0,51	0,03	
Placebo	666	633	58,6 (22,14)	7,28 (0,85)	[-1,85; 2,86]	[-0,10; 0,15]	
Latin and South America							
Vericiguat	283	275	64,4 (24,56)	12,22 (1,26)	1,86	0,10	
Placebo	297	278	64,4 (23,88)	10,35 (1,27)	[-1,64; 5,37]	[-0,09; 0,28]	
North America							
Vericiguat	226	216	62,9 (22,57)	3,20 (1,46)	-0,55	-0,03	
Placebo	226	222	58,9 (24,28)	3,75 (1,44)	[-4,57; 3,47]	[-0,24; 0,18]	
Western Europe							
Vericiguat	337	320	58,3 (23,77)	4,89 (1,19)	-1,44	-0,07	
Placebo	336	312	59,5 (23,23)	6,33 (1,23)	[-4,79; 1,92]	[-0,25; 0,10]	
Index Event							
HF Hospitalization 3-6 Months							
Vericiguat	371	359	66,1 (21,56)	6,40 (1,12)	2,73	0,14	0,228
Placebo	334	323	65,0 (22,97)	3,67 (1,15)	[-0,42; 5,87]	[-0,02; 0,31]	
HF Hospitalization within 3 Months							
Vericiguat	1326	1260	61,2 (23,82)	8,79 (0,60)	-0,39	-0,02	
Placebo	1372	1297	62,0 (23,29)	9,18 (0,60)	[-2,05; 1,27]	[-0,11; 0,07]	

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ CSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
IV diuretic for HF (without hospitalization) within 3 Months							
Vericiguat	311	300	64,6 (23,26)	6,99 (1,19)	0,20	0,01	
Placebo	299	290	65,8 (23,52)	6,79 (1,23)	[-3,16; 3,55]	[-0,16; 0,19]	
eGFR (mL/min/1.73 m²) Category							
≤30							
Vericiguat	199	178	57,8 (24,75)	5,68 (1,66)	0,71	0,04	0,496
Placebo	184	168	58,1 (24,90)	4,97 (1,76)	[-4,03; 5,45]	[-0,21; 0,28]	
>30 to ≤60							
Vericiguat	816	786	62,3 (23,48)	6,93 (0,75)	-0,81	-0,04	
Placebo	835	791	61,2 (23,75)	7,74 (0,76)	[-2,90; 1,28]	[-0,15; 0,07]	
>60							
Vericiguat	964	929	63,9 (22,98)	9,35 (0,69)	0,87	0,05	
Placebo	955	921	66,0 (22,14)	8,48 (0,69)	[-1,04; 2,78]	[-0,05; 0,15]	
NYHA Group at Baseline							
Class I or II							
Vericiguat	1173	1137	68,9 (21,56)	9,10 (0,62)	-0,08	-0,00	0,533
Placebo	1194	1153	69,8 (21,24)	9,18 (0,62)	[-1,78; 1,62]	[-0,09; 0,09]	
Class III or IV							
Vericiguat	833	780	53,8 (23,09)	6,52 (0,78)	0,80	0,04	
Placebo	811	757	53,1 (22,69)	5,72 (0,81)	[-1,39; 2,99]	[-0,07; 0,16]	
Use of Sacubitril /Valsartan at Baseline							
Yes							

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ CSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
Vericiguat	318	302	62,6 (23,69)	6,72 (1,25)	1,48	0,08	0,449
Placebo	317	300	63,0 (23,56)	5,25 (1,27)	[-1,99; 4,95]	[-0,10; 0,26]	
No							
Vericiguat	1690	1617	62,7 (23,36)	8,28 (0,53)	0,02	0,00	
Placebo	1687	1609	63,0 (23,27)	8,26 (0,53)	[-1,44; 1,49]	[-0,08; 0,08]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab							
Q1 (≤1556)							
Vericiguat	466	453	65,8 (23,74)	9,36 (0,96)	0,03	0,00	0,753
Placebo	472	463	67,3 (23,09)	9,33 (0,96)	[-2,63; 2,70]	[-0,14; 0,14]	
Q2 (1556 - 2816)							
Vericiguat	496	484	66,3 (22,61)	8,28 (0,93)	-0,32	-0,02	
Placebo	453	438	66,1 (22,06)	8,61 (0,98)	[-2,97; 2,32]	[-0,16; 0,12]	
Q3 (2816 - 5314)							
Vericiguat	478	457	64,6 (21,73)	7,76 (1,00)	1,54	0,08	
Placebo	493	478	64,0 (21,84)	6,23 (0,97)	[-1,19; 4,27]	[-0,06; 0,22]	
Q4 (>5314)							
Vericiguat	494	455	54,5 (23,73)	6,43 (1,06)	-0,32	-0,02	
Placebo	486	435	56,8 (24,85)	6,75 (1,08)	[-3,28; 2,64]	[-0,17; 0,14]	
Baseline Ejection Fraction Group 2							
<35							
Vericiguat	1596	1521	62,2 (23,70)	8,56 (0,55)	0,43	0,02	0,552
Placebo	1610	1533	62,8 (23,66)	8,13 (0,55)	[-1,08; 1,95]	[-0,06; 0,10]	

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ CSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
≥35							
Vericiguat	412	398	64,4 (22,17)	6,09 (1,06)	-0,57	-0,03	
Placebo	395	377	63,9 (21,83)	6,66 (1,07)	[-3,52; 2,38]	[-0,18; 0,12]	
Race group							
White							
Vericiguat	1253	1189	59,9 (23,27)	6,21 (0,62)	-0,08	-0,00	0,920
Placebo	1260	1196	59,5 (22,83)	6,29 (0,62)	[-1,79; 1,63]	[-0,09; 0,09]	
Asian							
Vericiguat	479	462	72,7 (20,19)	10,81 (1,00)	0,37	0,02	
Placebo	451	433	73,4 (20,94)	10,44 (1,02)	[-2,41; 3,15]	[-0,13; 0,16]	
Black							
Vericiguat	102	96	56,4 (24,55)	8,20 (2,27)	1,20	0,06	
Placebo	105	101	59,5 (25,17)	7,00 (2,10)	[-4,86; 7,25]	[-0,25; 0,37]	
Other							
Vericiguat	173	171	58,9 (24,13)	12,96 (1,63)	1,40	0,07	
Placebo	189	180	64,2 (23,47)	11,56 (1,59)	[-3,08; 5,87]	[-0,16; 0,30]	
CCSA class at Randomization							
No Angina							
Vericiguat	1712	1640	63,0 (23,62)	8,32 (0,53)	0,13	0,01	0,666
Placebo	1718	1639	63,8 (23,38)	8,19 (0,53)	[-1,32; 1,59]	[-0,07; 0,08]	
Angina Class 1 or 2							
Vericiguat	252	239	62,1 (22,46)	8,15 (1,35)	1,38	0,07	

Subgroup Analysis of Change From Baseline at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]					Vericiguat vs. Placebo		
KCCQ CSS	**N[b]**	**N[c]**	**Mean at Baseline (SD)[d]**	**Mean Change from Baseline (SE)[e]**	**Mean Difference[e] [95 %-CI]**	**Standardized Mean Difference[f] [95 %-CI]**	**p-Value for Interaction Test[g]**
Placebo	247	233	60,6 (22,23)	6,77 (1,40)	[-2,41; 5,18]	[-0,13; 0,27]	
Angina Class 3 or 4							
Vericiguat	44	40	54,2 (18,70)	-4,51 (3,42)	-2,99	-0,15	
Placebo	40	38	47,3 (20,46)	-1,52 (3,45)	[-12,49; 6,51]	[-0,63; 0,33]	
Medical History of Diabetes Mellitus							
Yes							
Vericiguat	977	930	61,3 (23,58)	7,38 (0,71)	0,19	0,01	0,934
Placebo	917	874	60,1 (24,67)	7,18 (0,73)	[-1,80; 2,19]	[-0,09; 0,11]	
No							
Vericiguat	1031	989	63,9 (23,18)	8,66 (0,67)	0,31	0,02	
Placebo	1088	1036	65,5 (21,82)	8,36 (0,66)	[-1,53; 2,14]	[-0,08; 0,11]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants in all-subjects-as-treated (ASaT) population with screening ejection fraction < 40% and questionnaire assesment available at baseline
c: Number of participants with data available for analysis
d: Sample Mean and SD calculated for participants with data available for analysis
e: cLDA model with change from baseline as the dependent variable, factors for treatment, analysis visit, subgroup, treatment-by-subgroup-by visit interaction and all second order interactions; stratification factor (defined by region and race) and baseline value as covariate; including all post-baseline timepoints through week 48
Mean change from baseline and mean difference (Vericiguat-Placebo) are estimated via REML method with Kenward-Roger adjustment
f: Standardized mean difference (Hedges's g) is only calculated if confidence interval for mean difference does not include zero
g: P-value computed with F-Test for the null-hypothesis that the mean differences for all levels of subgroup variable are equal
Baseline is defined as last observation before treatment start; analysis visit (timepoint) is calculated relatively to treatment start
CI: Confidence Interval; cLDA: constrained Longitudinal Data Analysis; CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.4 Analysis of Improvement and Deterioration Rates

3.4.1 EQ-5D-5L VAS

3.4.1.1 LOCF Analyses of Improvement and Deterioration Rates at Week 32

Table 3.4.1-1
LOCF Analysis of Improvement and Deterioration Rates at Week 32 as Measured by EQ-5D VAS Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 7 points	1753	777 (44,3)	1739	743 (42,7)	1,04 [0,96; 1,12]	0,331	1,07 [0,93; 1,22]	1,63 [-1,66; 4,91]
Increase from Baseline by at least 10 points	1753	700 (39,9)	1739	681 (39,2)	1,02 [0,94; 1,11]	0,638	1,03 [0,90; 1,18]	0,78 [-2,47; 4,02]
Increase from Baseline by at least 15 points	1753	483 (27,6)	1739	460 (26,5)	1,04 [0,93; 1,16]	0,457	1,06 [0,91; 1,23]	1,12 [-1,83; 4,06]
Decrease from Baseline by at least 7 points	1753	422 (24,1)	1739	456 (26,2)	0,92 [0,82; 1,03]	0,133	0,89 [0,76; 1,04]	-2,20 [-5,08; 0,67]
Decrease from Baseline by at least 10 points	1753	368 (21,0)	1739	404 (23,2)	0,90 [0,80; 1,02]	0,101	0,87 [0,75; 1,03]	-2,30 [-5,05; 0,45]
Decrease from Baseline by at least 15 points	1753	216 (12,3)	1739	259 (14,9)	0,82 [0,70; 0,98]	0,024	0,80 [0,66; 0,97]	-2,61 [-4,89; -0,34]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; LOCF: Last Observation Carried Forward

3.4.1.2 Analyses of Improvement and Deterioration Rates at Week 32 Without Imputation

Table 3.4.1-2
Analysis of Improvement and Deterioration Rates at Week 32 as Measured by EQ-5D VAS Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 7 points	1441	654 (45,4)	1409	606 (43,0)	1,05 [0,97; 1,15]	0,204	1,10 [0,95; 1,28]	2,36 [-1,28; 6,00]
Increase from Baseline by at least 10 points	1441	590 (40,9)	1409	557 (39,5)	1,04 [0,95; 1,13]	0,449	1,06 [0,91; 1,23]	1,39 [-2,21; 4,99]
Increase from Baseline by at least 15 points	1441	403 (28,0)	1409	378 (26,8)	1,04 [0,93; 1,18]	0,478	1,06 [0,90; 1,25]	1,19 [-2,09; 4,46]
Decrease from Baseline by at least 7 points	1441	329 (22,8)	1409	355 (25,2)	0,90 [0,79; 1,03]	0,128	0,87 [0,74; 1,04]	-2,44 [-5,58; 0,70]
Decrease from Baseline by at least 10 points	1441	289 (20,1)	1409	312 (22,1)	0,90 [0,78; 1,04]	0,152	0,88 [0,73; 1,05]	-2,19 [-5,19; 0,80]
Decrease from Baseline by at least 15 points	1441	168 (11,7)	1409	196 (13,9)	0,83 [0,69; 1,01]	0,060	0,81 [0,65; 1,01]	-2,35 [-4,82; 0,10]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at both baseline and Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X ; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score

3.4.2 KCCQ: Total Symptom Score

3.4.2.1 LOCF Analyses of Improvement Rate at Week 32

Table 3.4.2-1
LOCF Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Total Symptom Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ TSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1760	939 (53,4)	1751	926 (52,9)	1,01 [0,95; 1,07]	0,788	1,02 [0,89; 1,16]	0,45 [-2,84; 3,74]
Increase from Baseline by at least 15 points	1760	581 (33,0)	1751	613 (35,0)	0,94 [0,86; 1,03]	0,207	0,91 [0,79; 1,05]	-2,01 [-5,13; 1,11]
Decrease from Baseline by at least 5 points	1760	434 (24,7)	1751	452 (25,8)	0,96 [0,85; 1,07]	0,446	0,94 [0,81; 1,10]	-1,12 [-3,99; 1,76]
Decrease from Baseline by at least 15 points	1760	220 (12,5)	1751	237 (13,5)	0,92 [0,78; 1,10]	0,369	0,91 [0,75; 1,11]	-1,02 [-3,25; 1,21]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward

3.4.2.2 Analyses of Improvement Rate at Week 32

Table 3.4.2-2
Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Overall Summary Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1312	780 (59,5)	1263	691 (54,7)	1,08 [1,01; 1,16]	0,018	1,21 [1,03; 1,42]	4,59 [0,79; 8,39]
Increase from Baseline by at least 15 points	1312	460 (35,1)	1263	454 (35,9)	0,97 [0,88; 1,08]	0,583	0,96 [0,81; 1,12]	-1,03 [-4,72; 2,66]
Decrease from Baseline by at least 5 points	1312	249 (19,0)	1263	289 (22,9)	0,83 [0,71; 0,96]	0,014	0,79 [0,65; 0,95]	-3,93 [-7,08; -0,79]
Decrease from Baseline by at least 15 points	1312	111 (8,5)	1263	132 (10,5)	0,81 [0,64; 1,03]	0,085	0,79 [0,61; 1,03]	-1,99 [-4,28; 0,27]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at both baseline and Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X ; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire

3.4.3 KCCQ: Overall Summary Score

3.4.3.1 LOCF Analyses of Improvement Rate at Week 32

Table 3.4.3-1
LOCF Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Overall Summary Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1655	953 (57,6)	1628	865 (53,1)	1,08 [1,02; 1,15]	0,010	1,20 [1,05; 1,38]	4,47 [1,09; 7,85]
Increase from Baseline by at least 15 points	1655	558 (33,7)	1628	563 (34,6)	0,98 [0,89; 1,07]	0,606	0,96 [0,83; 1,11]	-0,85 [-4,09; 2,38]
Decrease from Baseline by at least 5 points	1655	341 (20,6)	1628	404 (24,8)	0,83 [0,73; 0,94]	0,004	0,79 [0,67; 0,93]	-4,23 [-7,09; -1,36]
Decrease from Baseline by at least 15 points	1655	161 (9,7)	1628	192 (11,8)	0,82 [0,68; 1,00]	0,056	0,81 [0,65; 1,01]	-2,07 [-4,21; 0,05]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward

3.4.3.2 Analyses of Improvement Rate at Week 32 without imputation

Table 3.4.3-2
Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Overall Summary Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1312	780 (59,5)	1263	691 (54,7)	1,08 [1,01; 1,16]	0,018	1,21 [1,03; 1,42]	4,59 [0,79; 8,39]
Increase from Baseline by at least 15 points	1312	460 (35,1)	1263	454 (35,9)	0,97 [0,88; 1,08]	0,583	0,96 [0,81; 1,12]	-1,03 [-4,72; 2,66]
Decrease from Baseline by at least 5 points	1312	249 (19,0)	1263	289 (22,9)	0,83 [0,71; 0,96]	0,014	0,79 [0,65; 0,95]	-3,93 [-7,08; -0,79]
Decrease from Baseline by at least 15 points	1312	111 (8,5)	1263	132 (10,5)	0,81 [0,64; 1,03]	0,085	0,79 [0,61; 1,03]	-1,99 [-4,28; 0,27]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at both baseline and Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X ; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire

3.4.4 KCCQ: Clinical Summary Score

3.4.4.1 LOCF Analyses of Improvement Rate at Week 32

Table 3.4.4-1
LOCF Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Clinical Summary Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1726	919 (53,2)	1718	922 (53,7)	0,99 [0,93; 1,06]	0,792	0,98 [0,86; 1,12]	-0,45 [-3,77; 2,88]
Increase from Baseline by at least 15 points	1726	550 (31,9)	1718	563 (32,8)	0,97 [0,88; 1,07]	0,568	0,96 [0,83; 1,11]	-0,91 [-4,02; 2,21]
Decrease from Baseline by at least 5 points	1726	414 (24,0)	1718	452 (26,3)	0,91 [0,81; 1,02]	0,120	0,88 [0,76; 1,03]	-2,30 [-5,20; 0,60]
Decrease from Baseline by at least 15 points	1726	204 (11,8)	1718	223 (13,0)	0,91 [0,76; 1,09]	0,301	0,90 [0,73; 1,10]	-1,16 [-3,37; 1,04]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward

3.4.4.2 Analyses of Improvement Rate at Week 32

Table 3.4.4-2
Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Clinical Summary Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1410	775 (55,0)	1384	761 (55,0)	1,00 [0,94; 1,07]	0,989	1,00 [0,86; 1,16]	-0,03 [-3,70; 3,65]
Increase from Baseline by at least 15 points	1410	456 (32,3)	1384	473 (34,2)	0,94 [0,85; 1,05]	0,287	0,92 [0,78; 1,07]	-1,89 [-5,37; 1,59]
Decrease from Baseline by at least 5 points	1410	307 (21,8)	1384	344 (24,9)	0,88 [0,77; 1,00]	0,055	0,84 [0,71; 1,00]	-3,08 [-6,22; 0,06]
Decrease from Baseline by at least 15 points	1410	142 (10,1)	1384	169 (12,2)	0,82 [0,66; 1,01]	0,065	0,80 [0,63; 1,01]	-2,20 [-4,55; 0,13]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at both baseline and Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X ; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire

3.4.5 KCCQ: Physical Limitation Score

3.4.5.1 LOCF Analyses of Improvement Rate at Week 32

Table 3.4.5-1
LOCF Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Physical Limitation Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	Vericiguat		Placebo		Vericiguat vs. Placebo			
KCCQ PLS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1726	867 (50,2)	1718	869 (50,6)	0,99 [0,93; 1,06]	0,845	0,99 [0,86; 1,13]	-0,33 [-3,67; 3,00]
Increase from Baseline by at least 15 points	1726	588 (34,1)	1718	576 (33,5)	1,02 [0,93; 1,12]	0,737	1,02 [0,89; 1,18]	0,54 [-2,61; 3,70]
Decrease from Baseline by at least 5 points	1726	431 (25,0)	1718	486 (28,3)	0,88 [0,79; 0,99]	0,028	0,84 [0,72; 0,98]	-3,32 [-6,27; -0,37]
Decrease from Baseline by at least 15 points	1726	259 (15,0)	1718	281 (16,4)	0,92 [0,79; 1,07]	0,275	0,90 [0,75; 1,08]	-1,35 [-3,79; 1,08]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward

3.4.5.2 Analyses of Improvement Rate at Week 32

Table 3.4.5-2
Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Physical Limitation Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ PLS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1410	734 (52,1)	1384	718 (51,9)	1,00 [0,94; 1,08]	0,902	1,01 [0,87; 1,17]	0,23 [-3,47; 3,94]
Increase from Baseline by at least 15 points	1410	485 (34,4)	1384	473 (34,2)	1,01 [0,91; 1,11]	0,910	1,01 [0,86; 1,18]	0,20 [-3,32; 3,72]
Decrease from Baseline by at least 5 points	1410	323 (22,9)	1384	374 (27,0)	0,85 [0,74; 0,96]	0,011	0,80 [0,67; 0,95]	-4,17 [-7,37; -0,96]
Decrease from Baseline by at least 15 points	1410	191 (13,5)	1384	216 (15,6)	0,87 [0,72; 1,04]	0,123	0,85 [0,69; 1,05]	-2,06 [-4,69; 0,56]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at both baseline and Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X ; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire

3.4.6 KCCQ: Quality of Life Score

3.4.6.1 LOCF Analyses of Improvement Rate at Week 32

Table 3.4.6-1
LOCF Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Quality of Life Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ QoL	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1760	1020 (58,0)	1751	977 (55,8)	1,04 [0,98; 1,10]	0,198	1,09 [0,96; 1,25]	2,15 [-1,12; 5,42]
Increase from Baseline by at least 15 points	1760	755 (42,9)	1751	738 (42,1)	1,02 [0,94; 1,10]	0,652	1,03 [0,90; 1,18]	0,75 [-2,51; 4,01]
Decrease from Baseline by at least 5 points	1760	457 (26,0)	1751	509 (29,1)	0,89 [0,80; 1,00]	0,041	0,86 [0,74; 0,99]	-3,08 [-6,03; -0,13]
Decrease from Baseline by at least 15 points	1760	266 (15,1)	1751	312 (17,8)	0,85 [0,73; 0,99]	0,032	0,82 [0,69; 0,98]	-2,68 [-5,14; -0,23]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward

3.4.6.2 Analyses of Improvement Rate at Week 32

Table 3.4.6-2
Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Quality of Life Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ QoL	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1452	872 (60,1)	1424	819 (57,5)	1,04 [0,98; 1,11]	0,173	1,11 [0,96; 1,29]	2,50 [-1,09; 6,09]
Increase from Baseline by at least 15 points	1452	646 (44,5)	1424	618 (43,4)	1,02 [0,94; 1,11]	0,599	1,04 [0,90; 1,21]	0,97 [-2,65; 4,59]
Decrease from Baseline by at least 5 points	1452	354 (24,4)	1424	389 (27,3)	0,89 [0,79; 1,01]	0,077	0,86 [0,73; 1,02]	-2,88 [-6,08; 0,32]
Decrease from Baseline by at least 15 points	1452	197 (13,6)	1424	231 (16,2)	0,84 [0,70; 1,00]	0,049	0,81 [0,66; 1,00]	-2,62 [-5,23; -0,02]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at both baseline and Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X ; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire

3.4.7 KCCQ: Symptom Burden Score

3.4.7.1 LOCF Analyses of Improvement Rate at Week 32

Table 3.4.7-1
LOCF Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Symptom Burden Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ SBS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1760	918 (52,2)	1751	906 (51,7)	1,01 [0,95; 1,07]	0,828	1,01 [0,89; 1,16]	0,37 [-2,93; 3,66]
Increase from Baseline by at least 15 points	1760	652 (37,0)	1751	673 (38,4)	0,96 [0,89; 1,05]	0,389	0,94 [0,82; 1,08]	-1,41 [-4,60; 1,79]
Decrease from Baseline by at least 5 points	1760	459 (26,1)	1751	476 (27,2)	0,96 [0,86; 1,07]	0,473	0,95 [0,81; 1,10]	-1,07 [-3,99; 1,85]
Decrease from Baseline by at least 15 points	1760	286 (16,3)	1751	313 (17,9)	0,91 [0,79; 1,05]	0,207	0,89 [0,75; 1,06]	-1,60 [-4,09; 0,89]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward

3.4.7.2 Analyses of Improvement Rate at Week 32

Table 3.4.7-2
Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Symptom Burden Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ SBS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1452	764 (52,6)	1424	746 (52,4)	1,00 [0,94; 1,07]	0,929	1,01 [0,87; 1,17]	0,16 [-3,47; 3,80]
Increase from Baseline by at least 15 points	1452	545 (37,5)	1424	557 (39,1)	0,96 [0,87; 1,05]	0,362	0,93 [0,80; 1,08]	-1,64 [-5,17; 1,89]
Decrease from Baseline by at least 5 points	1452	354 (24,4)	1424	362 (25,4)	0,96 [0,85; 1,09]	0,536	0,95 [0,80; 1,12]	-1,00 [-4,15; 2,16]
Decrease from Baseline by at least 15 points	1452	214 (14,7)	1424	229 (16,1)	0,92 [0,77; 1,09]	0,312	0,90 [0,74; 1,10]	-1,36 [-4,00; 1,28]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at both baseline and Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X ; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire

3.4.8 KCCQ: Self-Efficacy Score

3.4.8.1 LOCF Analyses of Improvement Rate at Week 32

Table 3.4.8-1
LOCF Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Self-efficacy Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ SES	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1760	716 (40,7)	1751	743 (42,4)	0,96 [0,89; 1,04]	0,274	0,93 [0,81; 1,06]	-1,82 [-5,06; 1,44]
Increase from Baseline by at least 15 points	1760	440 (25,0)	1751	479 (27,4)	0,91 [0,82; 1,02]	0,103	0,88 [0,76; 1,03]	-2,41 [-5,31; 0,49]
Decrease from Baseline by at least 5 points	1760	407 (23,1)	1751	412 (23,5)	0,98 [0,87; 1,11]	0,757	0,98 [0,83; 1,14]	-0,44 [-3,24; 2,36]
Decrease from Baseline by at least 15 points	1760	210 (11,9)	1751	218 (12,5)	0,96 [0,80; 1,14]	0,627	0,95 [0,78; 1,16]	-0,54 [-2,71; 1,63]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward

3.4.8.2 Analyses of Improvement Rate at Week 32

Table 3.4.8-2
Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Self-efficacy Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ SES	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1452	592 (40,8)	1424	615 (43,2)	0,94 [0,87; 1,03]	0,178	0,90 [0,78; 1,05]	-2,47 [-6,06; 1,12]
Increase from Baseline by at least 15 points	1452	374 (25,8)	1424	392 (27,5)	0,93 [0,83; 1,05]	0,268	0,91 [0,77; 1,07]	-1,82 [-5,04; 1,40]
Decrease from Baseline by at least 5 points	1452	320 (22,0)	1424	326 (22,9)	0,96 [0,84; 1,10]	0,566	0,95 [0,80; 1,13]	-0,89 [-3,95; 2,16]
Decrease from Baseline by at least 15 points	1452	163 (11,2)	1424	175 (12,3)	0,91 [0,74; 1,11]	0,352	0,90 [0,72; 1,13]	-1,12 [-3,48; 1,24]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at both baseline and Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X ; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire

3.4.9 KCCQ: Symptoms Frequency Score

3.4.9.1 LOCF Analyses of Improvement Rate at Week 32

Table 3.4.9-1
LOCF Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Symptoms Frequency Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ SFS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1760	927 (52,7)	1751	933 (53,3)	0,99 [0,93; 1,05]	0,718	0,98 [0,85; 1,11]	-0,60 [-3,89; 2,68]
Increase from Baseline by at least 15 points	1760	629 (35,7)	1751	659 (37,6)	0,95 [0,87; 1,04]	0,242	0,92 [0,80; 1,06]	-1,90 [-5,07; 1,28]
Decrease from Baseline by at least 5 points	1760	435 (24,7)	1751	457 (26,1)	0,95 [0,85; 1,06]	0,360	0,93 [0,80; 1,08]	-1,34 [-4,22; 1,53]
Decrease from Baseline by at least 15 points	1760	256 (14,5)	1751	262 (15,0)	0,97 [0,83; 1,14]	0,729	0,97 [0,80; 1,17]	-0,42 [-2,76; 1,93]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward

3.4.9.2 Analyses of Improvement Rate at Week 32

Table 3.4.9-2
Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Symptoms Frequency Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ SFS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1452	779 (53,7)	1424	782 (54,9)	0,98 [0,91; 1,04]	0,466	0,95 [0,82; 1,10]	-1,35 [-4,96; 2,28]
Increase from Baseline by at least 15 points	1452	531 (36,6)	1424	558 (39,2)	0,93 [0,85; 1,02]	0,132	0,89 [0,76; 1,04]	-2,71 [-6,24; 0,82]
Decrease from Baseline by at least 5 points	1452	331 (22,8)	1424	347 (24,4)	0,94 [0,82; 1,07]	0,337	0,92 [0,77; 1,09]	-1,52 [-4,62; 1,58]
Decrease from Baseline by at least 15 points	1452	186 (12,8)	1424	196 (13,8)	0,93 [0,77; 1,12]	0,458	0,92 [0,74; 1,14]	-0,94 [-3,43; 1,54]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at both baseline and Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X ; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire

3.4.10 KCCQ: Social Limitation Score

3.4.10.1 LOCF Analyses of Improvement Rate at Week 32

Table 3.4.10-1
LOCF Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Social Limitation Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ SLS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1669	928 (55,6)	1642	882 (53,7)	1,04 [0,97; 1,10]	0,275	1,08 [0,94; 1,24]	1,88 [-1,50; 5,26]
Increase from Baseline by at least 15 points	1669	656 (39,3)	1642	610 (37,1)	1,06 [0,97; 1,15]	0,202	1,10 [0,95; 1,26]	2,15 [-1,15; 5,45]
Decrease from Baseline by at least 5 points	1669	447 (26,8)	1642	484 (29,5)	0,91 [0,81; 1,01]	0,083	0,87 [0,75; 1,02]	-2,70 [-5,75; 0,36]
Decrease from Baseline by at least 15 points	1669	232 (13,9)	1642	317 (19,3)	0,72 [0,62; 0,84]	< 0,001	0,67 [0,56; 0,81]	-5,43 [-7,97; -2,91]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward

3.4.10.2 Analyses of Improvement Rate at Week 32

Table 3.4.10-2
Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Social Limitation Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ SLS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1326	767 (57,8)	1275	700 (54,9)	1,05 [0,98; 1,12]	0,148	1,12 [0,96; 1,31]	2,81 [-1,00; 6,60]
Increase from Baseline by at least 15 points	1326	541 (40,8)	1275	490 (38,4)	1,06 [0,96; 1,16]	0,248	1,10 [0,94; 1,29]	2,22 [-1,54; 5,96]
Decrease from Baseline by at least 5 points	1326	327 (24,7)	1275	356 (27,9)	0,88 [0,78; 1,01]	0,061	0,85 [0,71; 1,01]	-3,22 [-6,60; 0,16]
Decrease from Baseline by at least 15 points	1326	166 (12,5)	1275	221 (17,3)	0,72 [0,60; 0,87]	< 0,001	0,68 [0,55; 0,85]	-4,86 [-7,61; -2,12]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at both baseline and Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X ; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire

3.4.11 KCCQ: Symptom Stability Score

3.4.11.1 LOCF Analyses of Deterioration Rate at Week 32

Table 3.4.11-1
LOCF Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Symptom Stability Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ SSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1760	475 (27,0)	1751	437 (25,0)	1,08 [0,97; 1,21]	0,171	1,11 [0,96; 1,29]	2,03 [-0,87; 4,93]
Increase from Baseline by at least 15 points	1760	475 (27,0)	1751	437 (25,0)	1,08 [0,97; 1,21]	0,171	1,11 [0,96; 1,29]	2,03 [-0,87; 4,93]
Decrease from Baseline by at least 5 points	1760	621 (35,3)	1751	653 (37,3)	0,95 [0,87; 1,03]	0,217	0,92 [0,80; 1,05]	-2,00 [-5,18; 1,18]
Decrease from Baseline by at least 15 points	1760	621 (35,3)	1751	653 (37,3)	0,95 [0,87; 1,03]	0,217	0,92 [0,80; 1,05]	-2,00 [-5,18; 1,18]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward

3.4.11.2 Analyses of Improvement Rate at Week 32

Table 3.4.11-2
Analysis of Improvement and Deterioration Rates at Week 32 as Measured by KCCQ: Symptom Stability Score
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**			
KCCQ SSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**
Increase from Baseline by at least 5 points	1452	390 (26,9)	1424	340 (23,9)	1,13 [0,99; 1,28]	0,063	1,17 [0,99; 1,39]	3,02 [-0,16; 6,20]
Increase from Baseline by at least 15 points	1452	390 (26,9)	1424	340 (23,9)	1,13 [0,99; 1,28]	0,063	1,17 [0,99; 1,39]	3,02 [-0,16; 6,20]
Decrease from Baseline by at least 5 points	1452	510 (35,1)	1424	523 (36,7)	0,95 [0,86; 1,05]	0,330	0,93 [0,80; 1,08]	-1,74 [-5,24; 1,76]
Decrease from Baseline by at least 15 points	1452	510 (35,1)	1424	523 (36,7)	0,95 [0,86; 1,05]	0,330	0,93 [0,80; 1,08]	-1,74 [-5,24; 1,76]

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at both baseline and Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
Increase by at least X points is defined as change from baseline ≥ X ; Decrease by at least X points is defined as change from baseline ≤ - X
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CI: Confidence Interval; KCCQ: Kansas City Cardiomyopathy Questionnaire

3.5 Subgroup Analyses: Analysis for Improvement and Deterioration Rates for EQ-5D-5L VAS

3.5.1 Improvement by at least 7 points at Week 32

3.5.1.1 Consistency of Treatment Effect – Summary

Table 3.5.1-1
Overview of LOCF Subgroup Analyses for Improvement Rate by at least 7 points at Week 32 as Measured by EQ-5D VAS Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
EQ-5D VAS						
EQ-5D-5L VAS Score	0,443	0,713	0,557	0,782	0,056	0,457

Overview of LOCF Subgroup Analyses for Improvement Rate by at least 7 points at Week 32 as Measured by EQ-5D VAS Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
EQ-5D VAS							
EQ-5D-5L VAS Score	**0,043[b]**	0,672	0,185	0,713	0,364	0,984	0,055

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.5.1.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.5.1-2
LOCF Analysis of Improvement Rate by at least 7 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N**[b]	**Participants with Event n (%)**	**N**[b]	**Participants with Event n (%)**	**Relative Risk**[c] **[95 %-CI]**	**p-Value**[d]	**Odds Ratio**[e] **[95 %-CI]**	**Risk Difference**[f] **[95 %-CI]**	**p-Value for Interaction**[g] **Test**
Age category 1									
<65	685	320 (46,7)	699	304 (43,5)	1,07 [0,95; 1,20]	0,253	1,13 [0,92; 1,40]	3,07 [-2,18; 8,30]	0,443
≥65	1068	457 (42,8)	1040	439 (42,2)	1,01 [0,92; 1,12]	0,789	1,02 [0,86; 1,22]	0,57 [-3,64; 4,78]	
Age category 2									
<75	1246	558 (44,8)	1240	541 (43,6)	1,03 [0,94; 1,12]	0,520	1,05 [0,90; 1,23]	1,28 [-2,62; 5,18]	0,713
≥75	507	219 (43,2)	499	202 (40,5)	1,06 [0,92; 1,23]	0,432	1,11 [0,86; 1,42]	2,46 [-3,65; 8,55]	
Gender									
Male	1351	606 (44,9)	1343	574 (42,7)	1,05 [0,96; 1,14]	0,262	1,09 [0,94; 1,27]	2,14 [-1,60; 5,88]	0,557
Female	402	171 (42,5)	396	169 (42,7)	0,99 [0,85; 1,17]	0,950	0,99 [0,75; 1,31]	-0,22 [-7,07; 6,63]	
Geographic Region									
Asia Pacific	423	173 (40,9)	411	170 (41,4)	0,99 [0,84; 1,16]	0,892	0,98 [0,74; 1,29]	-0,46 [-7,14; 6,21]	0,782
Eastern Europe	578	252 (43,6)	575	240 (41,7)	1,04 [0,91; 1,19]	0,523	1,08 [0,85; 1,36]	1,86 [-3,85; 7,56]	
Latin and South America	258	137 (53,1)	262	122 (46,6)	1,14 [0,96; 1,36]	0,137	1,30 [0,92; 1,83]	6,54 [-2,07; 15,04]	
North America	195	86 (44,1)	202	85 (42,1)	1,05 [0,84; 1,31]	0,684	1,09 [0,73; 1,62]	2,02 [-7,70; 11,72]	
Western Europe	299	129 (43,1)	289	126 (43,6)	0,99 [0,82; 1,19]	0,911	0,98 [0,71; 1,36]	-0,45 [-8,45; 7,54]	
Index Event									
HF Hospitalization 3-6 Months	328	143 (43,6)	301	113 (37,5)	1,16 [0,96; 1,40]	0,132	1,28 [0,93; 1,76]	5,92 [-1,75; 13,51]	0,056
HF Hospitalization within 3 Months	1162	507 (43,6)	1171	524 (44,7)	0,97 [0,89; 1,07]	0,584	0,96 [0,81; 1,12]	-1,13 [-5,15; 2,90]	

LOCF Analysis of Improvement Rate by at least 7 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	263	127 (48,3)	267	106 (39,7)	1,22 [1,01; 1,49]	0,039	1,44 [1,02; 2,03]	8,90 [0,42; 17,26]	
eGFR (mL/min/1.73 m^2) Category									
≤30	162	75 (46,3)	157	60 (38,2)	1,20 [0,92; 1,56]	0,174	1,36 [0,87; 2,13]	7,61 [-3,30; 18,34]	0,457
>30 to ≤60	728	315 (43,3)	723	303 (41,9)	1,04 [0,92; 1,17]	0,545	1,07 [0,87; 1,31]	1,57 [-3,52; 6,64]	
>60	838	376 (44,9)	833	370 (44,4)	1,01 [0,91; 1,12]	0,875	1,02 [0,84; 1,23]	0,38 [-4,39; 5,15]	
Use of Sacubitril /Valsartan at Baseline									
Yes	254	108 (42,5)	253	99 (39,1)	1,09 [0,88; 1,35]	0,442	1,15 [0,81; 1,64]	3,40 [-5,19; 11,92]	0,672
No	1499	669 (44,6)	1485	643 (43,3)	1,03 [0,95; 1,12]	0,437	1,06 [0,92; 1,22]	1,41 [-2,14; 4,97]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	415	159 (38,3)	419	174 (41,5)	0,93 [0,79; 1,10]	0,405	0,89 [0,67; 1,17]	-2,82 [-9,46; 3,84]	0,185
Q2 (1556 - 2816)	447	192 (43,0)	398	176 (44,2)	0,97 [0,83; 1,13]	0,702	0,95 [0,72; 1,25]	-1,31 [-8,02; 5,40]	
Q3 (2816 - 5314)	412	197 (47,8)	439	184 (41,9)	1,14 [0,98; 1,32]	0,080	1,27 [0,97; 1,67]	5,94 [-0,73; 12,57]	
Q4 (>5314)	417	203 (48,7)	395	175 (44,3)	1,10 [0,95; 1,28]	0,191	1,20 [0,91; 1,59]	4,59 [-2,29; 11,43]	
Baseline Ejection Fraction Group 2									
<35	1398	621 (44,4)	1391	599 (43,1)	1,03 [0,95; 1,12]	0,475	1,06 [0,91; 1,23]	1,34 [-2,34; 5,02]	0,713
≥35	355	156 (43,9)	348	144 (41,4)	1,06 [0,90; 1,26]	0,468	1,12 [0,83; 1,51]	2,69 [-4,59; 9,94]	
Race group									
White	1094	477 (43,6)	1094	455 (41,6)	1,05 [0,95; 1,16]	0,342	1,09 [0,92; 1,29]	2,01 [-2,13; 6,15]	0,364

LOCF Analysis of Improvement Rate by at least 7 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Asian	418	171 (40,9)	385	164 (42,6)	0,96 [0,82; 1,13]	0,628	0,93 [0,70; 1,24]	-1,69 [-8,50; 5,13]	
Black	85	45 (52,9)	95	38 (40,0)	1,32 [0,96; 1,82]	0,084	1,69 [0,93; 3,05]	12,94 [-1,68; 27,05]	
Other	156	84 (53,8)	165	86 (52,1)	1,03 [0,84; 1,27]	0,757	1,07 [0,69; 1,66]	1,72 [-9,17; 12,58]	
CCSA class at Randomization									
No Angina	1493	665 (44,5)	1493	643 (43,1)	1,03 [0,95; 1,12]	0,407	1,06 [0,92; 1,23]	1,50 [-2,05; 5,06]	0,984
Angina Class 1 or 2	224	95 (42,4)	210	84 (40,0)	1,06 [0,84; 1,33]	0,627	1,10 [0,75; 1,62]	2,32 [-7,01; 11,60]	
Angina Class 3 or 4	36	17 (47,2)	36	16 (44,4)	0,98 [0,59; 1,61]	0,922	0,95 [0,36; 2,52]	-1,14 [-23,35; 22,53]	
Medical History of Diabetes Mellitus									
Yes	847	349 (41,2)	784	336 (42,9)	0,96 [0,85; 1,07]	0,442	0,93 [0,76; 1,13]	-1,88 [-6,65; 2,90]	0,055
No	906	428 (47,2)	955	407 (42,6)	1,11 [1,00; 1,23]	0,046	1,20 [1,00; 1,45]	4,60 [0,08; 9,12]	

a: Database Cut-off Date: 18JUN2019

b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32

c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)

d: Two-sided p-value for Relative Risk based on Wald test

e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)

f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)

g: P-value from the likelihood ration test for treatment by subgroup interaction

Increase by at least 7 points is defined as change from baseline ≥ 7

Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.5.1.3 Results for Subgroups With Interaction P-value < 0.05

Table 3.5.1-3
LOCF Analysis of Improvement Rate by at least 7 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test < 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
NYHA Group at Baseline									
Class I or II	1034	430 (41,6)	1052	451 (42,9)	0,97 [0,88; 1,08]	0,592	0,95 [0,80; 1,13]	-1,16 [-5,39; 3,08]	0,043
Class III or IV	717	346 (48,3)	687	292 (42,5)	1,14 [1,01; 1,27]	0,032	1,26 [1,02; 1,56]	5,75 [0,53; 10,94]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Increase by at least 7 points is defined as change from baseline ≥ 7
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.5.2 Improvement by at least 10 points at Week 32

3.5.2.1 Consistency of Treatment Effect – Summary

Table 3.5.2-1
Overview of LOCF Subgroup Analyses for Improvement Rate by at least 10 points at Week 32 as Measured by EQ-5D VAS Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
EQ-5D VAS						
EQ-5D-5L VAS Score	0,504	0,575	0,984	0,948	**0,011[b]**	0,202

Overview of LOCF Subgroup Analyses for Improvement Rate by at least 10 points at Week 32 as Measured by EQ-5D VAS Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
EQ-5D VAS							
EQ-5D-5L VAS Score	**0,017[b]**	0,804	0,315	0,975	0,605	0,673	0,080

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.5.2.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.5.2-2
LOCF Analysis of Improvement Rate by at least 10 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Age category 1									
<65	685	286 (41,8)	699	277 (39,6)	1,05 [0,92; 1,19]	0,466	1,08 [0,87; 1,34]	1,93 [-3,25; 7,10]	0,504
≥65	1068	414 (38,8)	1040	404 (38,8)	1,00 [0,90; 1,11]	0,967	1,00 [0,84; 1,19]	-0,09 [-4,24; 4,07]	
Age category 2									
<75	1246	498 (40,0)	1240	494 (39,8)	1,00 [0,91; 1,11]	0,928	1,01 [0,86; 1,18]	0,18 [-3,67; 4,03]	0,575
≥75	507	202 (39,8)	499	187 (37,5)	1,06 [0,90; 1,24]	0,482	1,10 [0,85; 1,41]	2,17 [-3,86; 8,18]	
Gender									
Male	1351	541 (40,0)	1343	527 (39,2)	1,02 [0,93; 1,12]	0,670	1,03 [0,89; 1,21]	0,80 [-2,89; 4,49]	0,984
Female	402	159 (39,6)	396	154 (38,9)	1,02 [0,86; 1,21]	0,837	1,03 [0,78; 1,37]	0,71 [-6,07; 7,49]	
Geographic Region									
Asia Pacific	423	162 (38,3)	411	161 (39,2)	0,98 [0,82; 1,16]	0,795	0,96 [0,73; 1,27]	-0,87 [-7,48; 5,73]	0,948
Eastern Europe	578	225 (38,9)	575	219 (38,1)	1,02 [0,88; 1,18]	0,769	1,04 [0,82; 1,31]	0,84 [-4,78; 6,45]	
Latin and South America	258	118 (45,7)	262	110 (42,0)	1,09 [0,90; 1,32]	0,389	1,16 [0,82; 1,65]	3,75 [-4,78; 12,23]	
North America	195	76 (39,0)	202	76 (37,6)	1,04 [0,81; 1,33]	0,782	1,06 [0,71; 1,59]	1,35 [-8,19; 10,89]	
Western Europe	299	119 (39,8)	289	115 (39,8)	1,00 [0,82; 1,22]	0,999	1,00 [0,72; 1,39]	0,01 [-7,90; 7,90]	
eGFR (mL/min/1.73 m^2) Category									
≤30	162	69 (42,6)	157	53 (33,8)	1,25 [0,94; 1,67]	0,127	1,43 [0,91; 2,25]	8,43 [-2,29; 18,95]	0,202
>30 to ≤60	728	291 (40,0)	723	276 (38,2)	1,05 [0,93; 1,20]	0,433	1,09 [0,88; 1,34]	2,01 [-3,01; 7,02]	

LOCF Analysis of Improvement Rate by at least 10 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
>60	838	331 (39,5)	833	342 (41,1)	0,96 [0,85; 1,08]	0,495	0,93 [0,77; 1,14]	-1,64 [-6,34; 3,06]	
Use of Sacubitril /Valsartan at Baseline									
Yes	254	94 (37,0)	253	89 (35,2)	1,06 [0,83; 1,34]	0,649	1,09 [0,76; 1,57]	1,96 [-6,41; 10,29]	0,804
No	1499	606 (40,4)	1485	591 (39,8)	1,02 [0,93; 1,11]	0,705	1,03 [0,89; 1,19]	0,68 [-2,84; 4,19]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	415	143 (34,5)	419	161 (38,4)	0,90 [0,75; 1,08]	0,257	0,85 [0,64; 1,13]	-3,79 [-10,32; 2,77]	0,315
Q2 (1556 - 2816)	447	174 (38,9)	398	157 (39,4)	0,98 [0,83; 1,17]	0,853	0,97 [0,74; 1,28]	-0,62 [-7,23; 5,97]	
Q3 (2816 - 5314)	412	177 (43,0)	439	171 (39,0)	1,10 [0,94; 1,30]	0,230	1,18 [0,90; 1,56]	4,04 [-2,56; 10,62]	
Q4 (>5314)	417	184 (44,1)	395	161 (40,8)	1,08 [0,92; 1,27]	0,323	1,15 [0,87; 1,52]	3,44 [-3,40; 10,24]	
Baseline Ejection Fraction Group 2									
<35	1398	563 (40,3)	1391	549 (39,5)	1,02 [0,93; 1,12]	0,678	1,03 [0,89; 1,20]	0,77 [-2,87; 4,40]	0,975
≥35	355	137 (38,6)	348	132 (37,9)	1,02 [0,85; 1,23]	0,803	1,04 [0,77; 1,41]	0,91 [-6,27; 8,08]	
Race group									
White	1094	429 (39,2)	1094	412 (37,7)	1,04 [0,94; 1,16]	0,455	1,07 [0,90; 1,27]	1,55 [-2,52; 5,63]	0,605
Asian	418	160 (38,3)	385	155 (40,3)	0,95 [0,80; 1,13]	0,565	0,92 [0,69; 1,22]	-1,98 [-8,73; 4,77]	
Black	85	38 (44,7)	95	35 (36,8)	1,21 [0,85; 1,73]	0,284	1,39 [0,76; 2,52]	7,86 [-6,50; 22,00]	
Other	156	73 (46,8)	165	79 (47,9)	0,98 [0,78; 1,23]	0,846	0,96 [0,62; 1,48]	-1,08 [-11,95; 9,81]	
CCSA class at Randomization									

LOCF Analysis of Improvement Rate by at least 10 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
No Angina	1493	598 (40,1)	1493	595 (39,9)	1,00 [0,92; 1,10]	0,915	1,01 [0,87; 1,17]	0,19 [-3,32; 3,71]	0,673
Angina Class 1 or 2	224	87 (38,8)	210	73 (34,8)	1,11 [0,86; 1,43]	0,414	1,18 [0,80; 1,74]	3,83 [-5,34; 12,92]	
Angina Class 3 or 4	36	15 (41,7)	36	13 (36,1)	1,00 [0,57; 1,76]	0,996	1,00 [0,38; 2,65]	-0,06 [-22,42; 23,41]	
Medical History of Diabetes Mellitus									
Yes	847	315 (37,2)	784	309 (39,4)	0,94 [0,83; 1,06]	0,317	0,90 [0,74; 1,10]	-2,41 [-7,12; 2,31]	0,080
No	906	385 (42,5)	955	372 (39,0)	1,09 [0,98; 1,22]	0,125	1,16 [0,96; 1,39]	3,50 [-0,97; 7,97]	

a: Database Cut-off Date: 18JUN2019

b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32

c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)

d: Two-sided p-value for Relative Risk based on Wald test

e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)

f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)

g: P-value from the likelihood ration test for treatment by subgroup interaction

Increase by at least 10 points is defined as change from baseline ≥ 10

Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start

Validity of the model fit is questionable for Geographic Region-Western Europe

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.5.2.3 Results for Subgroups With Interaction P-value < 0.05

Table 3.5.2-3
LOCF Analysis of Improvement Rate by at least 10 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test < 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Index Event									
HF Hospitalization 3-6 Months	328	132 (40,2)	301	101 (33,6)	1,20 [0,97; 1,47]	0,090	1,33 [0,96; 1,83]	6,57 [-1,00; 14,05]	0,011
HF Hospitalization within 3 Months	1162	450 (38,7)	1171	484 (41,3)	0,94 [0,85; 1,03]	0,193	0,90 [0,76; 1,06]	-2,64 [-6,61; 1,33]	
IV diuretic for HF (without hospitalization) within 3 Months	263	118 (44,9)	267	96 (36,0)	1,25 [1,01; 1,54]	0,037	1,45 [1,02; 2,06]	8,93 [0,55; 17,21]	
NYHA Group at Baseline									
Class I or II	1034	381 (36,8)	1052	415 (39,4)	0,94 [0,84; 1,04]	0,240	0,90 [0,75; 1,07]	-2,50 [-6,66; 1,67]	0,017
Class III or IV	717	318 (44,4)	687	266 (38,7)	1,14 [1,01; 1,30]	0,036	1,26 [1,02; 1,56]	5,56 [0,39; 10,70]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Increase by at least 10 points is defined as change from baseline ≥ 10
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
Validity of the model fit is questionable for Geographic Region-Western Europe
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.5.3 Improvement by at least 15 points at Week 32

3.5.3.1 Consistency of Treatment Effect – Summary

Table 3.5.3-1
Overview of LOCF Subgroup Analyses for Improvement Rate by at least 15 points at Week 32 as Measured by EQ-5D VAS Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
EQ-5D VAS						
EQ-5D-5L VAS Score	0,439	0,763	0,377	0,774	0,061	0,331

Overview of LOCF Subgroup Analyses for Improvement Rate by at least 15 points at Week 32 as Measured by EQ-5D VAS Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
EQ-5D VAS							
EQ-5D-5L VAS Score	0,126	0,922	0,556	0,121	0,433	0,927	0,598

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.5.3.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.5.3-2
LOCF Analysis of Improvement Rate by at least 15 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Age category 1									
<65	685	204 (29,8)	699	190 (27,2)	1,09 [0,92; 1,29]	0,305	1,13 [0,89; 1,43]	2,50 [-2,27; 7,26]	0,439
≥65	1068	279 (26,1)	1040	270 (26,0)	1,01 [0,87; 1,16]	0,929	1,01 [0,83; 1,23]	0,17 [-3,58; 3,92]	
Age category 2									
<75	1246	356 (28,6)	1240	337 (27,2)	1,05 [0,93; 1,20]	0,420	1,07 [0,90; 1,28]	1,45 [-2,08; 4,98]	0,763
≥75	507	127 (25,0)	499	123 (24,6)	1,01 [0,82; 1,26]	0,896	1,02 [0,77; 1,36]	0,35 [-5,01; 5,71]	
Gender									
Male	1351	368 (27,2)	1343	361 (26,9)	1,01 [0,90; 1,15]	0,817	1,02 [0,86; 1,21]	0,40 [-2,96; 3,75]	0,377
Female	402	115 (28,6)	396	99 (25,0)	1,14 [0,91; 1,44]	0,255	1,20 [0,88; 1,64]	3,59 [-2,59; 9,75]	
Geographic Region									
Asia Pacific	423	109 (25,8)	411	109 (26,5)	0,97 [0,77; 1,22]	0,805	0,96 [0,71; 1,31]	-0,75 [-6,73; 5,21]	0,774
Eastern Europe	578	154 (26,6)	575	155 (27,0)	0,99 [0,82; 1,20]	0,905	0,98 [0,76; 1,28]	-0,31 [-5,43; 4,80]	
Latin and South America	258	80 (31,0)	262	72 (27,5)	1,13 [0,86; 1,48]	0,377	1,19 [0,81; 1,73]	3,53 [-4,30; 11,33]	
North America	195	57 (29,2)	202	49 (24,3)	1,21 [0,87; 1,67]	0,264	1,29 [0,83; 2,01]	4,97 [-3,75; 13,68]	
Western Europe	299	83 (27,8)	289	75 (26,0)	1,07 [0,82; 1,40]	0,621	1,10 [0,76; 1,58]	1,81 [-5,38; 8,96]	
Index Event									
HF Hospitalization 3-6 Months	328	90 (27,4)	301	68 (22,6)	1,21 [0,92; 1,59]	0,168	1,29 [0,90; 1,86]	4,78 [-2,02; 11,51]	0,061
HF Hospitalization within 3 Months	1162	316 (27,2)	1171	333 (28,4)	0,96 [0,84; 1,09]	0,493	0,94 [0,78; 1,13]	-1,27 [-4,91; 2,37]	

LOCF Analysis of Improvement Rate by at least 15 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	263	77 (29,3)	267	59 (22,1)	1,30 [0,97; 1,75]	0,079	1,43 [0,96; 2,12]	6,75 [-0,71; 14,19]	
eGFR (mL/min/1.73 m^2) Category									
≤30	162	51 (31,5)	157	37 (23,6)	1,32 [0,91; 1,90]	0,144	1,46 [0,89; 2,40]	7,42 [-2,37; 17,10]	0,331
>30 to ≤60	728	195 (26,8)	723	185 (25,6)	1,05 [0,88; 1,25]	0,579	1,07 [0,85; 1,35]	1,28 [-3,26; 5,81]	
>60	838	232 (27,7)	833	232 (27,9)	0,99 [0,85; 1,16]	0,949	0,99 [0,80; 1,23]	-0,14 [-4,44; 4,16]	
NYHA Group at Baseline									
Class I or II	1034	257 (24,9)	1052	271 (25,8)	0,97 [0,83; 1,12]	0,651	0,96 [0,78; 1,16]	-0,86 [-4,59; 2,88]	0,126
Class III or IV	717	226 (31,5)	687	189 (27,5)	1,15 [0,98; 1,35]	0,098	1,21 [0,97; 1,53]	4,05 [-0,74; 8,82]	
Use of Sacubitril /Valsartan at Baseline									
Yes	254	68 (26,8)	253	64 (25,3)	1,07 [0,79; 1,44]	0,666	1,09 [0,73; 1,62]	1,70 [-6,00; 9,35]	0,922
No	1499	415 (27,7)	1485	395 (26,6)	1,04 [0,93; 1,17]	0,489	1,06 [0,90; 1,24]	1,13 [-2,07; 4,32]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	415	102 (24,6)	419	97 (23,2)	1,08 [0,85; 1,38]	0,536	1,11 [0,80; 1,52]	1,83 [-3,99; 7,64]	0,556
Q2 (1556 - 2816)	447	111 (24,8)	398	109 (27,4)	0,90 [0,72; 1,14]	0,386	0,87 [0,64; 1,19]	-2,64 [-8,61; 3,30]	
Q3 (2816 - 5314)	412	124 (30,1)	439	117 (26,7)	1,12 [0,91; 1,39]	0,280	1,18 [0,87; 1,59]	3,33 [-2,72; 9,41]	
Q4 (>5314)	417	129 (30,9)	395	115 (29,1)	1,07 [0,87; 1,32]	0,536	1,10 [0,81; 1,49]	2,00 [-4,35; 8,32]	
Baseline Ejection Fraction Group 2									
<35	1398	387 (27,7)	1391	385 (27,7)	1,00 [0,89; 1,13]	0,996	1,00 [0,85; 1,18]	-0,01 [-3,33; 3,32]	0,121

LOCF Analysis of Improvement Rate by at least 15 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
≥35	355	96 (27,0)	348	75 (21,6)	1,26 [0,97; 1,64]	0,085	1,36 [0,96; 1,93]	5,60 [-0,75; 11,92]	
Race group									
White	1094	295 (27,0)	1094	280 (25,6)	1,05 [0,92; 1,21]	0,466	1,07 [0,89; 1,30]	1,37 [-2,32; 5,06]	0,433
Asian	418	107 (25,6)	385	103 (26,8)	0,96 [0,76; 1,21]	0,710	0,94 [0,69; 1,29]	-1,16 [-7,26; 4,92]	
Black	85	28 (32,9)	95	21 (22,1)	1,49 [0,92; 2,42]	0,106	1,73 [0,89; 3,36]	10,84 [-2,23; 23,84]	
Other	156	53 (34,0)	165	56 (33,9)	1,00 [0,74; 1,36]	0,995	1,00 [0,63; 1,59]	0,03 [-10,29; 10,40]	
CCSA class at Randomization									
No Angina	1493	415 (27,8)	1493	396 (26,5)	1,05 [0,93; 1,18]	0,429	1,07 [0,91; 1,25]	1,29 [-1,91; 4,48]	0,927
Angina Class 1 or 2	224	59 (26,3)	210	56 (26,7)	0,98 [0,71; 1,35]	0,902	0,97 [0,63; 1,50]	-0,53 [-8,90; 7,81]	
Angina Class 3 or 4	36	9 (25,0)	36	8 (22,2)	0,95 [0,44; 2,05]	0,903	0,93 [0,30; 2,92]	-1,20 [-21,82; 19,67]	
Medical History of Diabetes Mellitus									
Yes	847	227 (26,8)	784	208 (26,5)	1,01 [0,86; 1,18]	0,930	1,01 [0,81; 1,26]	0,19 [-4,11; 4,48]	0,598
No	906	256 (28,3)	955	252 (26,4)	1,07 [0,92; 1,24]	0,362	1,10 [0,90; 1,35]	1,89 [-2,17; 5,95]	

a: Database Cut-off Date: 18JUN2019

b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32

c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)

d: Two-sided p-value for Relative Risk based on Wald test

e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)

f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)

g: P-value from the likelihood ration test for treatment by subgroup interaction

Increase by at least 15 points is defined as change from baseline ≥ 15

Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.5.4 Deterioration by at least 7 points at Week 32

3.5.4.1 Consistency of Treatment Effect – Summary.

Table 3.5.4-1
Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 7 points at Week 32 as Measured by EQ-5D VAS Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
EQ-5D VAS						
EQ-5D-5L VAS Score	0,762	0,504	0,508	0,854	0,956	0,269

Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 7 points at Week 32 as Measured by EQ-5D VAS Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
EQ-5D VAS							
EQ-5D-5L VAS Score	0,145	0,803	0,405	0,979	0,308	0,834	**0,002[b]**

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.5.4.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.5.4-2
LOCF Analysis of Deterioration Rate by at least 7 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N**[b]	**Participants with Event n (%)**	**N**[b]	**Participants with Event n (%)**	**Relative Risk**[c] **[95 %-CI]**	**p-Value**[d]	**Odds Ratio**[e] **[95 %-CI]**	**Risk Difference**[f] **[95 %-CI]**	**p-Value for Interaction**[g] **Test**
Age category 1									
<65	685	155 (22,6)	699	175 (25,0)	0,90 [0,75; 1,09]	0,297	0,88 [0,68; 1,12]	-2,39 [-6,89; 2,11]	0,762
≥65	1068	267 (25,0)	1040	281 (27,0)	0,93 [0,80; 1,07]	0,294	0,90 [0,74; 1,09]	-2,00 [-5,74; 1,74]	
Age category 2									
<75	1246	292 (23,4)	1240	307 (24,8)	0,94 [0,82; 1,08]	0,411	0,93 [0,77; 1,11]	-1,41 [-4,77; 1,96]	0,504
≥75	507	130 (25,6)	499	149 (29,9)	0,87 [0,71; 1,06]	0,166	0,82 [0,62; 1,08]	-3,92 [-9,45; 1,62]	
Gender									
Male	1351	328 (24,3)	1343	362 (27,0)	0,90 [0,79; 1,02]	0,100	0,86 [0,73; 1,03]	-2,77 [-6,06; 0,52]	0,508
Female	402	94 (23,4)	396	94 (23,7)	0,99 [0,77; 1,27]	0,945	0,99 [0,71; 1,37]	-0,21 [-6,12; 5,70]	
Geographic Region									
Asia Pacific	423	112 (26,5)	411	115 (28,0)	0,95 [0,76; 1,18]	0,626	0,93 [0,68; 1,26]	-1,50 [-7,55; 4,54]	0,854
Eastern Europe	578	134 (23,2)	575	154 (26,8)	0,87 [0,71; 1,06]	0,159	0,83 [0,63; 1,08]	-3,60 [-8,59; 1,40]	
Latin and South America	258	47 (18,2)	262	58 (22,1)	0,82 [0,58; 1,16]	0,267	0,78 [0,51; 1,20]	-3,92 [-10,84; 3,01]	
North America	195	48 (24,6)	202	51 (25,2)	0,97 [0,69; 1,37]	0,884	0,97 [0,61; 1,52]	-0,63 [-9,15; 7,92]	
Western Europe	299	81 (27,1)	289	78 (27,0)	1,00 [0,77; 1,31]	0,978	1,01 [0,70; 1,45]	0,10 [-7,10; 7,28]	
Index Event									
HF Hospitalization 3-6 Months	328	83 (25,3)	301	86 (28,6)	0,89 [0,69; 1,15]	0,368	0,85 [0,60; 1,21]	-3,18 [-10,15; 3,75]	0,956
HF Hospitalization within 3 Months	1162	279 (24,0)	1171	304 (26,0)	0,92 [0,80; 1,06]	0,268	0,90 [0,75; 1,09]	-1,98 [-5,49; 1,53]	

LOCF Analysis of Deterioration Rate by at least 7 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	263	60 (22,8)	267	66 (24,7)	0,93 [0,68; 1,26]	0,639	0,91 [0,61; 1,36]	-1,74 [-9,05; 5,57]	
eGFR (mL/min/1.73 m^2) Category									
≤30	162	38 (23,5)	157	52 (33,1)	0,72 [0,51; 1,02]	0,067	0,63 [0,38; 1,03]	-9,25 [-19,04; 0,62]	0,269
>30 to ≤60	728	198 (27,2)	723	198 (27,4)	0,98 [0,83; 1,16]	0,853	0,98 [0,78; 1,23]	-0,43 [-5,02; 4,16]	
>60	838	180 (21,5)	833	194 (23,3)	0,92 [0,77; 1,10]	0,366	0,90 [0,71; 1,13]	-1,84 [-5,85; 2,16]	
NYHA Group at Baseline									
Class I or II	1034	252 (24,4)	1052	261 (24,8)	0,98 [0,84; 1,14]	0,803	0,97 [0,80; 1,19]	-0,47 [-4,16; 3,23]	0,145
Class III or IV	717	169 (23,6)	687	195 (28,4)	0,83 [0,69; 0,99]	0,035	0,77 [0,61; 0,98]	-4,94 [-9,53; -0,34]	
Use of Sacubitril /Valsartan at Baseline									
Yes	254	69 (27,2)	253	78 (30,8)	0,88 [0,67; 1,16]	0,360	0,84 [0,57; 1,23]	-3,69 [-11,58; 4,23]	0,803
No	1499	353 (23,5)	1485	378 (25,5)	0,92 [0,81; 1,05]	0,205	0,90 [0,76; 1,06]	-1,99 [-5,08; 1,09]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	415	91 (21,9)	419	100 (23,9)	0,90 [0,70; 1,16]	0,432	0,88 [0,63; 1,21]	-2,29 [-8,01; 3,44]	0,405
Q2 (1556 - 2816)	447	112 (25,1)	398	93 (23,4)	1,07 [0,84; 1,35]	0,603	1,09 [0,79; 1,49]	1,54 [-4,30; 7,32]	
Q3 (2816 - 5314)	412	91 (22,1)	439	119 (27,1)	0,82 [0,64; 1,03]	0,092	0,76 [0,56; 1,04]	-5,00 [-10,75; 0,80]	
Q4 (>5314)	417	106 (25,4)	395	122 (30,9)	0,83 [0,67; 1,03]	0,095	0,77 [0,57; 1,05]	-5,27 [-11,47; 0,93]	
Baseline Ejection Fraction Group 2									
<35	1398	334 (23,9)	1391	362 (26,0)	0,91 [0,80; 1,04]	0,176	0,89 [0,75; 1,05]	-2,22 [-5,42; 1,00]	0,979

LOCF Analysis of Deterioration Rate by at least 7 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
≥35	355	88 (24,8)	348	94 (27,0)	0,90 [0,70; 1,15]	0,398	0,86 [0,61; 1,21]	-2,78 [-9,24; 3,69]	
Race group									
White	1094	275 (25,1)	1094	294 (26,9)	0,94 [0,81; 1,08]	0,355	0,91 [0,75; 1,11]	-1,74 [-5,41; 1,94]	0,308
Asian	418	105 (25,1)	385	98 (25,5)	0,99 [0,78; 1,25]	0,913	0,98 [0,71; 1,35]	-0,33 [-6,38; 5,67]	
Black	85	13 (15,3)	95	26 (27,4)	0,56 [0,31; 1,02]	0,056	0,48 [0,23; 1,01]	-12,07 [-23,85; 0,02]	
Other	156	29 (18,6)	165	38 (23,0)	0,81 [0,52; 1,24]	0,330	0,76 [0,44; 1,31]	-4,44 [-13,33; 4,53]	
CCSA class at Randomization									
No Angina	1493	352 (23,6)	1493	385 (25,8)	0,91 [0,80; 1,03]	0,145	0,88 [0,75; 1,04]	-2,30 [-5,39; 0,79]	0,834
Angina Class 1 or 2	224	58 (25,9)	210	60 (28,6)	0,90 [0,66; 1,22]	0,499	0,86 [0,57; 1,32]	-2,90 [-11,37; 5,54]	
Angina Class 3 or 4	36	12 (33,3)	36	11 (30,6)	1,16 [0,58; 2,30]	0,672	1,24 [0,45; 3,42]	4,86 [-18,17; 26,20]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Decrease by at least 7 points is defined as change from baseline ≤ -7
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.5.4.3 Results for Subgroups With Interaction P-value < 0.05

Table 3.5.4-3
LOCF Analysis of Deterioration Rate by at least 7 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test < 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Medical History of Diabetes Mellitus									
Yes	847	232 (27,4)	784	195 (24,9)	1,11 [0,94; 1,30]	0,230	1,15 [0,92; 1,43]	2,61 [-1,65; 6,86]	0,002
No	906	190 (21,0)	955	261 (27,3)	0,77 [0,65; 0,91]	0,002	0,71 [0,57; 0,88]	-6,32 [-10,19; -2,43]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Decrease by at least 7 points is defined as change from baseline ≤ -7
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.5.5 Deterioration by at least 10 points at Week 32

3.5.5.1 Consistency of Treatment Effect – Summary

Table 3.5.5-1
Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 10 points at Week 32 as Measured by EQ-5D VAS Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
EQ-5D VAS						
EQ-5D-5L VAS Score	0,802	0,295	0,657	0,667	0,898	0,515

Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 10 points at Week 32 as Measured by EQ-5D VAS Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
EQ-5D VAS							
EQ-5D-5L VAS Score	0,102	0,761	0,176	0,578	0,377	0,933	**0,005[b]**

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.5.5.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.5.5-2
LOCF Analysis of Deterioration Rate by at least 10 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N**[b]	**Participants with Event n (%)**	**N**[b]	**Participants with Event n (%)**	**Relative Risk**[c] **[95 %-CI]**	**p-Value**[d]	**Odds Ratio**[e] **[95 %-CI]**	**Risk Difference**[f] **[95 %-CI]**	**p-Value for Interaction**[g] **Test**
Age category 1									
<65	685	135 (19,7)	699	148 (21,2)	0,93 [0,76; 1,14]	0,496	0,91 [0,70; 1,19]	-1,48 [-5,73; 2,79]	0,802
≥65	1068	233 (21,8)	1040	256 (24,6)	0,89 [0,76; 1,04]	0,130	0,85 [0,70; 1,05]	-2,79 [-6,38; 0,81]	
Age category 2									
<75	1246	254 (20,4)	1240	266 (21,5)	0,95 [0,81; 1,10]	0,474	0,93 [0,77; 1,13]	-1,17 [-4,36; 2,03]	0,295
≥75	507	114 (22,5)	499	138 (27,7)	0,82 [0,66; 1,02]	0,076	0,77 [0,58; 1,03]	-4,88 [-10,23; 0,49]	
Gender									
Male	1351	287 (21,2)	1343	320 (23,8)	0,89 [0,77; 1,02]	0,095	0,86 [0,71; 1,03]	-2,69 [-5,84; 0,46]	0,657
Female	402	81 (20,1)	396	84 (21,2)	0,96 [0,73; 1,26]	0,769	0,95 [0,67; 1,34]	-0,84 [-6,49; 4,79]	
Geographic Region									
Asia Pacific	423	106 (25,1)	411	104 (25,3)	0,99 [0,78; 1,25]	0,935	0,99 [0,72; 1,35]	-0,25 [-6,15; 5,65]	0,667
Eastern Europe	578	110 (19,0)	575	132 (23,0)	0,83 [0,66; 1,04]	0,103	0,79 [0,59; 1,05]	-3,93 [-8,63; 0,78]	
Latin and South America	258	39 (15,1)	262	52 (19,8)	0,76 [0,52; 1,11]	0,158	0,72 [0,46; 1,14]	-4,73 [-11,30; 1,83]	
North America	195	43 (22,1)	202	44 (21,8)	1,01 [0,70; 1,47]	0,948	1,02 [0,63; 1,63]	0,27 [-7,89; 8,47]	
Western Europe	299	70 (23,4)	289	72 (24,9)	0,94 [0,71; 1,25]	0,671	0,92 [0,63; 1,34]	-1,50 [-8,45; 5,43]	
Index Event									
HF Hospitalization 3-6 Months	328	74 (22,6)	301	71 (23,6)	0,96 [0,72; 1,27]	0,761	0,94 [0,65; 1,37]	-1,02 [-7,66; 5,57]	0,898
HF Hospitalization within 3 Months	1162	241 (20,7)	1171	274 (23,4)	0,88 [0,76; 1,03]	0,115	0,85 [0,70; 1,04]	-2,71 [-6,06; 0,66]	

LOCF Analysis of Deterioration Rate by at least 10 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	263	53 (20,2)	267	59 (22,1)	0,93 [0,67; 1,29]	0,656	0,91 [0,60; 1,38]	-1,59 [-8,61; 5,41]	
eGFR (mL/min/1.73 m^2) Category									
≤30	162	36 (22,2)	157	47 (29,9)	0,75 [0,52; 1,09]	0,135	0,68 [0,41; 1,13]	-7,34 [-16,94; 2,29]	0,515
>30 to ≤60	728	166 (22,8)	723	180 (24,9)	0,91 [0,76; 1,09]	0,307	0,88 [0,69; 1,12]	-2,28 [-6,67; 2,11]	
>60	838	160 (19,1)	833	166 (19,9)	0,95 [0,78; 1,16]	0,632	0,94 [0,74; 1,20]	-0,93 [-4,73; 2,88]	
NYHA Group at Baseline									
Class I or II	1034	217 (21,0)	1052	225 (21,4)	0,98 [0,83; 1,16]	0,816	0,98 [0,79; 1,20]	-0,42 [-3,92; 3,09]	0,102
Class III or IV	717	150 (20,9)	687	179 (26,1)	0,80 [0,66; 0,97]	0,021	0,75 [0,58; 0,96]	-5,25 [-9,69; -0,81]	
Use of Sacubitril /Valsartan at Baseline									
Yes	254	62 (24,4)	253	72 (28,5)	0,85 [0,64; 1,14]	0,276	0,80 [0,54; 1,19]	-4,27 [-11,90; 3,43]	0,761
No	1499	306 (20,4)	1485	332 (22,4)	0,91 [0,79; 1,04]	0,176	0,89 [0,74; 1,06]	-2,03 [-4,97; 0,91]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	415	84 (20,2)	419	88 (21,0)	0,95 [0,73; 1,24]	0,691	0,93 [0,67; 1,31]	-1,12 [-6,63; 4,41]	0,176
Q2 (1556 - 2816)	447	99 (22,1)	398	80 (20,1)	1,09 [0,84; 1,42]	0,497	1,12 [0,80; 1,56]	1,91 [-3,65; 7,40]	
Q3 (2816 - 5314)	412	77 (18,7)	439	104 (23,7)	0,79 [0,61; 1,02]	0,074	0,74 [0,53; 1,03]	-5,03 [-10,49; 0,47]	
Q4 (>5314)	417	89 (21,3)	395	112 (28,4)	0,76 [0,60; 0,96]	0,024	0,69 [0,50; 0,95]	-6,87 [-12,83; -0,91]	
Baseline Ejection Fraction Group 2									
<35	1398	288 (20,6)	1391	323 (23,2)	0,88 [0,77; 1,02]	0,083	0,85 [0,71; 1,02]	-2,72 [-5,78; 0,35]	0,578

LOCF Analysis of Deterioration Rate by at least 10 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
≥35	355	80 (22,5)	348	81 (23,3)	0,95 [0,72; 1,24]	0,687	0,93 [0,65; 1,33]	-1,27 [-7,48; 4,94]	
Race group									
White	1094	233 (21,3)	1094	261 (23,9)	0,89 [0,76; 1,04]	0,153	0,86 [0,71; 1,06]	-2,56 [-6,06; 0,95]	0,377
Asian	418	99 (23,7)	385	90 (23,4)	1,01 [0,79; 1,30]	0,918	1,02 [0,73; 1,41]	0,31 [-5,60; 6,17]	
Black	85	9 (10,6)	95	19 (20,0)	0,53 [0,25; 1,11]	0,091	0,47 [0,20; 1,11]	-9,41 [-20,05; 1,29]	
Other	156	27 (17,3)	165	34 (20,6)	0,84 [0,53; 1,32]	0,453	0,81 [0,46; 1,41]	-3,30 [-11,91; 5,39]	
CCSA class at Randomization									
No Angina	1493	313 (21,0)	1493	343 (23,0)	0,91 [0,79; 1,04]	0,164	0,88 [0,74; 1,05]	-2,11 [-5,07; 0,86]	0,933
Angina Class 1 or 2	224	48 (21,4)	210	53 (25,2)	0,83 [0,59; 1,18]	0,301	0,79 [0,51; 1,24]	-4,22 [-12,27; 3,81]	
Angina Class 3 or 4	36	7 (19,4)	36	8 (22,2)	0,87 [0,34; 2,20]	0,763	0,84 [0,26; 2,67]	-3,00 [-23,53; 17,02]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Decrease by at least 10 points is defined as change from baseline ≤ -10
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.5.5.3 Results for Subgroups With Interaction P-value < 0.05

Table 3.5.5-3
LOCF Analysis of Deterioration Rate by at least 10 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test < 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Medical History of Diabetes Mellitus									
Yes	847	203 (24,0)	784	174 (22,2)	1,08 [0,91; 1,29]	0,368	1,11 [0,88; 1,40]	1,88 [-2,22; 5,95]	0,005
No	906	165 (18,2)	955	230 (24,1)	0,76 [0,64; 0,91]	0,002	0,70 [0,56; 0,88]	-5,80 [-9,49; -2,09]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Decrease by at least 10 points is defined as change from baseline ≤ -10
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.5.6 Deterioration by at least 15 points at Week 32

3.5.6.1 Consistency of Treatment Effect – Summary

Table 3.5.6-1
Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 15 points at Week 32 as Measured by EQ-5D VAS Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
EQ-5D VAS						
EQ-5D-5L VAS Score	0,782	0,794	0,384	0,807	0,862	0,729

Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 15 points at Week 32 as Measured by EQ-5D VAS Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
EQ-5D VAS							
EQ-5D-5L VAS Score	0,525	0,398	0,645	0,455	0,442	0,937	**0,002[b]**

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.5.6.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.5.6-2
LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Age category 1									
<65	685	76 (11,1)	699	96 (13,7)	0,81 [0,61; 1,07]	0,131	0,78 [0,57; 1,08]	-2,68 [-6,19; 0,80]	0,782
≥65	1068	140 (13,1)	1040	163 (15,7)	0,84 [0,68; 1,03]	0,095	0,81 [0,64; 1,04]	-2,55 [-5,55; 0,44]	
Age category 2									
<75	1246	144 (11,6)	1240	175 (14,1)	0,81 [0,66; 1,00]	0,050	0,79 [0,62; 1,00]	-2,63 [-5,27; -0,00]	0,794
≥75	507	72 (14,2)	499	84 (16,8)	0,85 [0,64; 1,13]	0,266	0,82 [0,58; 1,16]	-2,54 [-7,05; 1,95]	
Gender									
Male	1351	172 (12,7)	1343	198 (14,7)	0,86 [0,71; 1,04]	0,113	0,84 [0,67; 1,04]	-2,10 [-4,70; 0,50]	0,384
Female	402	44 (10,9)	396	61 (15,4)	0,72 [0,50; 1,04]	0,076	0,69 [0,45; 1,04]	-4,27 [-9,05; 0,43]	
Geographic Region									
Asia Pacific	423	58 (13,7)	411	69 (16,8)	0,82 [0,59; 1,13]	0,217	0,79 [0,54; 1,15]	-3,08 [-8,01; 1,81]	0,807
Eastern Europe	578	67 (11,6)	575	76 (13,2)	0,88 [0,64; 1,19]	0,403	0,86 [0,61; 1,22]	-1,63 [-5,47; 2,20]	
Latin and South America	258	20 (7,8)	262	33 (12,6)	0,62 [0,36; 1,04]	0,072	0,58 [0,33; 1,05]	-4,84 [-10,20; 0,37]	
North America	195	26 (13,3)	202	33 (16,3)	0,82 [0,51; 1,31]	0,402	0,79 [0,45; 1,37]	-3,00 [-10,09; 4,08]	
Western Europe	299	45 (15,1)	289	48 (16,6)	0,91 [0,62; 1,32]	0,605	0,89 [0,57; 1,39]	-1,56 [-7,53; 4,37]	
Index Event									
HF Hospitalization 3-6 Months	328	43 (13,1)	301	48 (15,9)	0,82 [0,56; 1,20]	0,302	0,79 [0,51; 1,24]	-2,90 [-8,45; 2,62]	0,862
HF Hospitalization within 3 Months	1162	138 (11,9)	1171	172 (14,7)	0,81 [0,65; 0,99]	0,043	0,78 [0,61; 0,99]	-2,85 [-5,61; -0,10]	

LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	263	35 (13,3)	267	39 (14,6)	0,93 [0,61; 1,44]	0,754	0,92 [0,56; 1,51]	-0,95 [-6,96; 5,02]	
eGFR (mL/min/1.73 m^2) Category									
≤30	162	23 (14,2)	157	26 (16,6)	0,87 [0,52; 1,45]	0,586	0,84 [0,46; 1,56]	-2,20 [-10,22; 5,88]	0,729
>30 to ≤60	728	105 (14,4)	723	115 (15,9)	0,90 [0,71; 1,15]	0,410	0,89 [0,66; 1,18]	-1,55 [-5,26; 2,15]	
>60	838	86 (10,3)	833	109 (13,1)	0,78 [0,60; 1,02]	0,068	0,76 [0,56; 1,02]	-2,88 [-5,98; 0,21]	
NYHA Group at Baseline									
Class I or II	1034	123 (11,9)	1052	145 (13,8)	0,86 [0,69; 1,08]	0,196	0,84 [0,65; 1,09]	-1,90 [-4,76; 0,98]	0,525
Class III or IV	717	93 (13,0)	687	114 (16,6)	0,78 [0,61; 1,00]	0,054	0,75 [0,55; 1,00]	-3,66 [-7,42; 0,05]	
Use of Sacubitril /Valsartan at Baseline									
Yes	254	38 (15,0)	253	53 (20,9)	0,71 [0,49; 1,02]	0,066	0,65 [0,41; 1,03]	-6,25 [-12,92; 0,39]	0,398
No	1499	178 (11,9)	1485	206 (13,9)	0,85 [0,71; 1,03]	0,094	0,83 [0,67; 1,03]	-2,05 [-4,47; 0,35]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	415	49 (11,8)	419	56 (13,4)	0,87 [0,61; 1,25]	0,448	0,85 [0,57; 1,29]	-1,75 [-6,32; 2,80]	0,645
Q2 (1556 - 2816)	447	52 (11,6)	398	55 (13,8)	0,83 [0,58; 1,18]	0,303	0,81 [0,54; 1,21]	-2,36 [-6,97; 2,15]	
Q3 (2816 - 5314)	412	51 (12,4)	439	59 (13,4)	0,92 [0,65; 1,30]	0,624	0,90 [0,60; 1,35]	-1,13 [-5,65; 3,43]	
Q4 (>5314)	417	52 (12,5)	395	73 (18,5)	0,68 [0,49; 0,94]	0,019	0,63 [0,43; 0,93]	-6,00 [-11,07; -1,01]	
Baseline Ejection Fraction Group 2									
<35	1398	168 (12,0)	1391	209 (15,0)	0,80 [0,66; 0,96]	0,018	0,77 [0,62; 0,96]	-3,06 [-5,61; -0,53]	0,455

LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
≥35	355	48 (13,5)	348	50 (14,4)	0,91 [0,63; 1,32]	0,632	0,90 [0,59; 1,38]	-1,25 [-6,43; 3,92]	
Race group									
White	1094	143 (13,1)	1094	161 (14,7)	0,89 [0,72; 1,09]	0,266	0,87 [0,68; 1,11]	-1,65 [-4,56; 1,26]	0,442
Asian	418	53 (12,7)	385	60 (15,6)	0,81 [0,58; 1,15]	0,238	0,79 [0,53; 1,17]	-2,90 [-7,81; 1,92]	
Black	85	6 (7,1)	95	13 (13,7)	0,52 [0,21; 1,30]	0,159	0,48 [0,17; 1,32]	-6,63 [-16,00; 2,61]	
Other	156	14 (9,0)	165	25 (15,2)	0,59 [0,32; 1,10]	0,096	0,55 [0,28; 1,11]	-6,18 [-13,49; 1,02]	
CCSA class at Randomization									
No Angina	1493	180 (12,1)	1493	220 (14,7)	0,81 [0,68; 0,98]	0,028	0,79 [0,64; 0,97]	-2,74 [-5,19; -0,30]	0,937
Angina Class 1 or 2	224	33 (14,7)	210	36 (17,1)	0,84 [0,54; 1,30]	0,437	0,81 [0,49; 1,37]	-2,73 [-9,80; 4,20]	
Angina Class 3 or 4	36	3 (8,3)	36	3 (8,3)	1,07 [0,14; 8,40]	0,951	1,06 [0,18; 6,19]	0,42 [-15,63; 16,00]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Decrease by at least 15 points is defined as change from baseline ≤ -15
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.5.6.3 Results for Subgroups With Interaction P-value < 0.05

Table 3.5.6-3
LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by EQ-5D VAS Score
For Subgroups with P-value for Interaction test < 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
EQ-5D VAS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Medical History of Diabetes Mellitus									
Yes	847	125 (14,8)	784	107 (13,6)	1,08 [0,85; 1,37]	0,518	1,10 [0,83; 1,45]	1,12 [-2,29; 4,51]	0,002
No	906	91 (10,0)	955	152 (15,9)	0,63 [0,50; 0,81]	< 0,001	0,59 [0,45; 0,78]	-5,81 [-8,87; -2,77]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Decrease by at least 15 points is defined as change from baseline ≤ -15
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; EQ-5D VAS: EuroQol 5 Dimensions Visual Analogue Score; HF: Heart failure; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.6 Subgroup Analyses: Analysis for Improvement and Deterioration Rates for KCCQ Overall Summary Score

3.6.1 Improvement by at least 5 points at Week 32

3.6.1.1 Consistency of Treatment Effect – Summary

Table 3.6.1-1
Overview of LOCF Subgroup Analyses for Improvement Rate by at least 5 points at Week 32 as Measured by KCCQ: Overall Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ OSS						
Overall Summary Score	0,737	0,838	0,559	0,703	0,509	0,575

Overview of LOCF Subgroup Analyses for Improvement Rate by at least 5 points at Week 32 as Measured by KCCQ: Overall Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ OSS							
Overall Summary Score	0,934	0,847	0,956	0,547	0,810	0,970	0,214

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.6.1.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.6.1-2
LOCF Analysis of Improvement Rate by at least 5 points at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Age category 1									
<65	656	395 (60,2)	676	379 (56,1)	1,07 [0,98; 1,17]	0,139	1,18 [0,95; 1,47]	4,00 [-1,30; 9,27]	0,737
≥65	999	558 (55,9)	952	486 (51,1)	1,09 [1,01; 1,19]	0,032	1,22 [1,02; 1,46]	4,81 [0,42; 9,19]	
Age category 2									
<75	1192	702 (58,9)	1185	646 (54,5)	1,08 [1,01; 1,16]	0,028	1,20 [1,02; 1,41]	4,45 [0,48; 8,41]	0,838
≥75	463	251 (54,2)	443	219 (49,4)	1,08 [0,96; 1,23]	0,203	1,19 [0,91; 1,55]	4,19 [-2,25; 10,61]	
Gender									
Male	1285	747 (58,1)	1271	674 (53,0)	1,10 [1,02; 1,18]	0,009	1,24 [1,06; 1,45]	5,15 [1,32; 8,97]	0,559
Female	370	206 (55,7)	357	191 (53,5)	1,04 [0,91; 1,19]	0,590	1,08 [0,81; 1,45]	1,99 [-5,24; 9,21]	
Geographic Region									
Asia Pacific	386	215 (55,7)	375	189 (50,4)	1,11 [0,97; 1,26]	0,144	1,24 [0,93; 1,65]	5,30 [-1,80; 12,34]	0,703
Eastern Europe	547	327 (59,8)	543	303 (55,8)	1,07 [0,97; 1,19]	0,184	1,18 [0,93; 1,50]	3,98 [-1,89; 9,82]	
Latin and South America	240	166 (69,2)	240	144 (60,0)	1,15 [1,01; 1,32]	0,037	1,50 [1,03; 2,18]	9,17 [0,60; 17,61]	
North America	191	94 (49,2)	198	87 (43,9)	1,12 [0,90; 1,39]	0,298	1,24 [0,83; 1,84]	5,28 [-4,64; 15,09]	
Western Europe	291	151 (51,9)	272	142 (52,2)	0,99 [0,85; 1,16]	0,940	0,99 [0,71; 1,37]	-0,32 [-8,55; 7,93]	
Index Event									
HF Hospitalization 3-6 Months	314	158 (50,3)	287	126 (43,9)	1,16 [0,97; 1,37]	0,096	1,32 [0,95; 1,82]	6,79 [-1,18; 14,67]	0,509
HF Hospitalization within 3 Months	1085	661 (60,9)	1082	605 (55,9)	1,09 [1,02; 1,17]	0,017	1,23 [1,04; 1,46]	5,03 [0,89; 9,15]	

LOCF Analysis of Improvement Rate by at least 5 points at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	256	134 (52,3)	259	134 (51,7)	1,01 [0,86; 1,19]	0,926	1,02 [0,72; 1,44]	0,41 [-8,22; 9,04]	
eGFR (mL/min/1.73 m^2) Category									
≤30	144	76 (52,8)	132	60 (45,5)	1,15 [0,90; 1,46]	0,259	1,31 [0,82; 2,10]	6,82 [-5,06; 18,54]	0,575
>30 to ≤60	689	378 (54,9)	673	356 (52,9)	1,04 [0,94; 1,14]	0,479	1,08 [0,87; 1,34]	1,91 [-3,36; 7,16]	
>60	799	486 (60,8)	796	437 (54,9)	1,11 [1,02; 1,20]	0,017	1,28 [1,05; 1,56]	5,90 [1,07; 10,71]	
NYHA Group at Baseline									
Class I or II	989	553 (55,9)	991	515 (52,0)	1,08 [0,99; 1,17]	0,069	1,18 [0,99; 1,41]	4,06 [-0,31; 8,42]	0,934
Class III or IV	664	399 (60,1)	637	350 (54,9)	1,09 [0,99; 1,20]	0,077	1,22 [0,98; 1,52]	4,85 [-0,52; 10,20]	
Use of Sacubitril /Valsartan at Baseline									
Yes	248	129 (52,0)	241	114 (47,3)	1,09 [0,91; 1,31]	0,331	1,19 [0,84; 1,71]	4,39 [-4,46; 13,18]	0,847
No	1407	824 (58,6)	1386	751 (54,2)	1,08 [1,01; 1,15]	0,020	1,20 [1,03; 1,39]	4,35 [0,68; 8,00]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	397	218 (54,9)	404	209 (51,7)	1,06 [0,93; 1,21]	0,352	1,14 [0,86; 1,51]	3,28 [-3,63; 10,16]	0,956
Q2 (1556 - 2816)	437	254 (58,1)	381	197 (51,7)	1,14 [1,00; 1,29]	0,042	1,34 [1,01; 1,77]	7,09 [0,30; 13,83]	
Q3 (2816 - 5314)	378	222 (58,7)	409	223 (54,5)	1,08 [0,96; 1,22]	0,221	1,19 [0,90; 1,58]	4,31 [-2,61; 11,18]	
Q4 (>5314)	385	228 (59,2)	355	193 (54,4)	1,09 [0,96; 1,24]	0,171	1,23 [0,92; 1,65]	5,01 [-2,13; 12,11]	
Baseline Ejection Fraction Group 2									
<35	1313	775 (59,0)	1302	700 (53,8)	1,10 [1,02; 1,17]	0,007	1,24 [1,06; 1,45]	5,18 [1,39; 8,95]	0,547

LOCF Analysis of Improvement Rate by at least 5 points at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
≥35	342	178 (52,0)	326	165 (50,6)	1,03 [0,89; 1,20]	0,677	1,07 [0,79; 1,45]	1,61 [-5,97; 9,17]	
Race group									
White	1053	590 (56,0)	1045	549 (52,5)	1,07 [0,99; 1,15]	0,108	1,15 [0,97; 1,37]	3,49 [-0,77; 7,75]	0,810
Asian	377	213 (56,5)	345	179 (51,9)	1,09 [0,95; 1,25]	0,215	1,20 [0,90; 1,62]	4,61 [-2,66; 11,85]	
Black	81	51 (63,0)	90	48 (53,3)	1,18 [0,91; 1,52]	0,203	1,49 [0,81; 2,74]	9,63 [-5,23; 24,01]	
Other	144	99 (68,8)	148	89 (60,1)	1,14 [0,96; 1,36]	0,125	1,46 [0,90; 2,36]	8,61 [-2,39; 19,42]	
CCSA class at Randomization									
No Angina	1404	812 (57,8)	1386	738 (53,2)	1,09 [1,02; 1,16]	0,015	1,21 [1,04; 1,40]	4,58 [0,91; 8,23]	0,970
Angina Class 1 or 2	215	123 (57,2)	205	111 (54,1)	1,06 [0,89; 1,25]	0,512	1,14 [0,77; 1,68]	3,16 [-6,33; 12,59]	
Angina Class 3 or 4	36	18 (50,0)	37	16 (43,2)	1,16 [0,68; 1,98]	0,580	1,30 [0,51; 3,30]	6,92 [-17,07; 30,16]	
Medical History of Diabetes Mellitus									
Yes	806	444 (55,1)	735	388 (52,8)	1,04 [0,95; 1,14]	0,364	1,10 [0,90; 1,34]	2,30 [-2,67; 7,25]	0,214
No	849	509 (60,0)	893	477 (53,4)	1,12 [1,03; 1,22]	0,007	1,30 [1,08; 1,58]	6,44 [1,79; 11,05]	

a: Database Cut-off Date: 18JUN2019

b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32

c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)

d: Two-sided p-value for Relative Risk based on Wald test

e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)

f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)

g: P-value from the likelihood ration test for treatment by subgroup interaction

Increase by at least 5 points is defined as change from baseline ≥ 5

Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.6.2 Improvement by at least 15 points at Week 32

3.6.2.1 Consistency of Treatment Effect – Summary

Table 3.6.2-1
Overview of LOCF Subgroup Analyses for Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Overall Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ OSS						
Overall Summary Score	0,641	0,611	0,418	0,668	0,861	0,930

Overview of LOCF Subgroup Analyses for Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Overall Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ OSS							
Overall Summary Score	0,741	0,412	0,959	0,927	0,141	0,483	0,051

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.6.2.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.6.2-2
LOCF Analysis of Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Age category 1									
<65	656	241 (36,7)	676	248 (36,7)	1,00 [0,87; 1,15]	0,973	1,00 [0,80; 1,25]	0,09 [-5,09; 5,27]	0,641
≥65	999	317 (31,7)	952	315 (33,1)	0,96 [0,85; 1,09]	0,529	0,94 [0,78; 1,14]	-1,32 [-5,45; 2,80]	
Age category 2									
<75	1192	427 (35,8)	1185	429 (36,2)	0,99 [0,89; 1,10]	0,879	0,99 [0,83; 1,17]	-0,30 [-4,16; 3,55]	0,611
≥75	463	131 (28,3)	443	134 (30,2)	0,92 [0,75; 1,12]	0,412	0,89 [0,66; 1,18]	-2,47 [-8,37; 3,43]	
Gender									
Male	1285	426 (33,2)	1271	442 (34,8)	0,95 [0,86; 1,06]	0,392	0,93 [0,79; 1,10]	-1,60 [-5,26; 2,07]	0,418
Female	370	132 (35,7)	357	121 (33,9)	1,05 [0,86; 1,28]	0,646	1,07 [0,79; 1,46]	1,62 [-5,30; 8,50]	
Geographic Region									
Asia Pacific	386	125 (32,4)	375	115 (30,7)	1,06 [0,86; 1,30]	0,611	1,08 [0,80; 1,47]	1,72 [-4,89; 8,30]	0,668
Eastern Europe	547	190 (34,7)	543	209 (38,5)	0,90 [0,77; 1,06]	0,199	0,85 [0,66; 1,09]	-3,75 [-9,46; 1,97]	
Latin and South America	240	100 (41,7)	240	94 (39,2)	1,06 [0,86; 1,32]	0,577	1,11 [0,77; 1,60]	2,50 [-6,28; 11,24]	
North America	191	52 (27,2)	198	53 (26,8)	1,02 [0,73; 1,41]	0,919	1,02 [0,65; 1,60]	0,46 [-8,37; 9,31]	
Western Europe	291	91 (31,3)	272	92 (33,8)	0,92 [0,73; 1,17]	0,518	0,89 [0,63; 1,27]	-2,55 [-10,29; 5,18]	
Index Event									
HF Hospitalization 3-6 Months	314	80 (25,5)	287	70 (24,4)	1,06 [0,80; 1,40]	0,681	1,08 [0,74; 1,57]	1,44 [-5,49; 8,31]	0,861
HF Hospitalization within 3 Months	1085	400 (36,9)	1082	410 (37,9)	0,97 [0,87; 1,08]	0,620	0,96 [0,80; 1,14]	-1,03 [-5,10; 3,04]	

LOCF Analysis of Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	256	78 (30,5)	259	83 (32,0)	0,95 [0,74; 1,22]	0,683	0,92 [0,63; 1,35]	-1,66 [-9,64; 6,33]	
eGFR (mL/min/1.73 m^2) Category									
≤30	144	46 (31,9)	132	41 (31,1)	1,02 [0,72; 1,45]	0,890	1,04 [0,62; 1,72]	0,77 [-10,31; 11,77]	0,930
>30 to ≤60	689	224 (32,5)	673	229 (34,0)	0,96 [0,82; 1,11]	0,562	0,94 [0,75; 1,17]	-1,48 [-6,47; 3,52]	
>60	799	280 (35,0)	796	285 (35,8)	0,98 [0,86; 1,12]	0,787	0,97 [0,79; 1,19]	-0,65 [-5,33; 4,04]	
NYHA Group at Baseline									
Class I or II	989	306 (30,9)	991	321 (32,4)	0,96 [0,84; 1,09]	0,497	0,94 [0,77; 1,13]	-1,42 [-5,50; 2,67]	0,741
Class III or IV	664	252 (38,0)	637	242 (38,0)	0,99 [0,86; 1,13]	0,866	0,98 [0,78; 1,23]	-0,45 [-5,71; 4,81]	
Use of Sacubitril /Valsartan at Baseline									
Yes	248	74 (29,8)	241	66 (27,4)	1,09 [0,83; 1,45]	0,526	1,14 [0,76; 1,69]	2,58 [-5,44; 10,57]	0,412
No	1407	484 (34,4)	1386	497 (35,9)	0,96 [0,87; 1,06]	0,411	0,94 [0,80; 1,09]	-1,48 [-5,01; 2,05]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	397	127 (32,0)	404	131 (32,4)	0,99 [0,81; 1,21]	0,914	0,98 [0,73; 1,32]	-0,36 [-6,83; 6,12]	0,959
Q2 (1556 - 2816)	437	137 (31,4)	381	126 (33,1)	0,96 [0,79; 1,18]	0,722	0,95 [0,70; 1,27]	-1,16 [-7,57; 5,20]	
Q3 (2816 - 5314)	378	124 (32,8)	409	141 (34,5)	0,95 [0,78; 1,16]	0,609	0,93 [0,69; 1,24]	-1,73 [-8,31; 4,90]	
Q4 (>5314)	385	150 (39,0)	355	136 (38,3)	1,02 [0,85; 1,22]	0,851	1,03 [0,76; 1,39]	0,68 [-6,36; 7,69]	
Baseline Ejection Fraction Group 2									
<35	1313	459 (35,0)	1302	465 (35,7)	0,98 [0,88; 1,08]	0,667	0,97 [0,82; 1,13]	-0,80 [-4,46; 2,85]	0,927

LOCF Analysis of Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
≥35	342	99 (28,9)	326	98 (30,1)	0,97 [0,77; 1,23]	0,799	0,96 [0,69; 1,34]	-0,90 [-7,85; 6,03]	
Race group									
White	1053	332 (31,5)	1045	363 (34,7)	0,91 [0,80; 1,03]	0,119	0,87 [0,72; 1,04]	-3,21 [-7,23; 0,82]	0,141
Asian	377	122 (32,4)	345	108 (31,3)	1,03 [0,83; 1,28]	0,761	1,05 [0,77; 1,44]	1,06 [-5,76; 7,83]	
Black	81	36 (44,4)	90	30 (33,3)	1,33 [0,91; 1,95]	0,138	1,60 [0,86; 2,97]	11,11 [-3,53; 25,40]	
Other	144	68 (47,2)	148	62 (41,9)	1,13 [0,87; 1,46]	0,360	1,24 [0,78; 1,97]	5,33 [-6,07; 16,60]	
CCSA class at Randomization									
No Angina	1404	477 (34,0)	1386	490 (35,4)	0,96 [0,87; 1,06]	0,438	0,94 [0,80; 1,10]	-1,40 [-4,92; 2,13]	0,483
Angina Class 1 or 2	215	74 (34,4)	205	64 (31,2)	1,11 [0,84; 1,46]	0,454	1,17 [0,78; 1,77]	3,44 [-5,58; 12,38]	
Angina Class 3 or 4	36	7 (19,4)	37	9 (24,3)	0,67 [0,28; 1,56]	0,352	0,58 [0,18; 1,86]	-9,28 [-29,08; 11,04]	
Medical History of Diabetes Mellitus									
Yes	806	258 (32,0)	735	267 (36,3)	0,88 [0,76; 1,01]	0,068	0,82 [0,66; 1,01]	-4,42 [-9,15; 0,31]	0,051
No	849	300 (35,3)	893	296 (33,1)	1,06 [0,93; 1,21]	0,359	1,10 [0,90; 1,34]	2,08 [-2,36; 6,53]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Increase by at least 15 points is defined as change from baseline ≥ 15
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.6.3 Deterioration by at least 5 points at Week 32

3.6.3.1 Consistency of Treatment Effect – Summary

Table 3.6.3-1
Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Overall Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ OSS						
Overall Summary Score	0,977	0,859	0,573	0,810	0,324	0,569

Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Overall Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ OSS							
Overall Summary Score	0,636	0,670	0,877	0,722	0,638	0,360	0,530

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.6.3.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.6.3-2
LOCF Analysis of Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Age category 1									
<65	656	122 (18,6)	676	152 (22,5)	0,83 [0,67; 1,03]	0,084	0,79 [0,61; 1,03]	-3,84 [-8,19; 0,51]	0,977
≥65	999	219 (21,9)	952	252 (26,5)	0,83 [0,71; 0,97]	0,019	0,78 [0,63; 0,96]	-4,54 [-8,34; -0,74]	
Age category 2									
<75	1192	236 (19,8)	1185	284 (24,0)	0,83 [0,71; 0,96]	0,014	0,78 [0,64; 0,95]	-4,18 [-7,50; -0,85]	0,859
≥75	463	105 (22,7)	443	120 (27,1)	0,85 [0,67; 1,06]	0,151	0,80 [0,59; 1,08]	-4,13 [-9,77; 1,51]	
Gender									
Male	1285	259 (20,2)	1271	314 (24,7)	0,81 [0,70; 0,94]	0,006	0,77 [0,64; 0,93]	-4,57 [-7,80; -1,34]	0,573
Female	370	82 (22,2)	357	90 (25,2)	0,88 [0,68; 1,14]	0,345	0,85 [0,60; 1,19]	-2,98 [-9,18; 3,20]	
Geographic Region									
Asia Pacific	386	75 (19,4)	375	89 (23,7)	0,82 [0,62; 1,07]	0,150	0,77 [0,55; 1,10]	-4,30 [-10,17; 1,55]	0,810
Eastern Europe	547	103 (18,8)	543	129 (23,8)	0,79 [0,63; 1,00]	0,048	0,74 [0,56; 1,00]	-4,93 [-9,79; -0,06]	
Latin and South America	240	41 (17,1)	240	56 (23,3)	0,73 [0,51; 1,05]	0,090	0,68 [0,43; 1,06]	-6,25 [-13,45; 0,95]	
North America	191	49 (25,7)	198	58 (29,3)	0,88 [0,63; 1,21]	0,423	0,83 [0,53; 1,30]	-3,64 [-12,48; 5,27]	
Western Europe	291	73 (25,1)	272	72 (26,5)	0,95 [0,72; 1,25]	0,707	0,93 [0,64; 1,36]	-1,38 [-8,65; 5,84]	
Index Event									
HF Hospitalization 3-6 Months	314	87 (27,7)	287	82 (28,6)	0,97 [0,75; 1,25]	0,787	0,95 [0,67; 1,36]	-0,99 [-8,22; 6,20]	0,324
HF Hospitalization within 3 Months	1085	198 (18,2)	1082	257 (23,8)	0,77 [0,65; 0,90]	0,002	0,71 [0,58; 0,88]	-5,55 [-8,97; -2,12]	

LOCF Analysis of Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	256	56 (21,9)	259	65 (25,1)	0,87 [0,64; 1,20]	0,404	0,84 [0,56; 1,27]	-3,14 [-10,48; 4,22]	
eGFR (mL/min/1.73 m^2) Category									
≤30	144	36 (25,0)	132	36 (27,3)	0,92 [0,62; 1,37]	0,676	0,89 [0,52; 1,52]	-2,21 [-12,74; 8,22]	0,569
>30 to ≤60	689	167 (24,2)	673	189 (28,1)	0,87 [0,72; 1,04]	0,115	0,82 [0,65; 1,05]	-3,75 [-8,41; 0,92]	
>60	799	133 (16,6)	796	173 (21,7)	0,77 [0,63; 0,94]	0,011	0,72 [0,56; 0,93]	-5,07 [-8,95; -1,20]	
NYHA Group at Baseline									
Class I or II	989	196 (19,8)	991	242 (24,4)	0,81 [0,69; 0,96]	0,013	0,76 [0,62; 0,94]	-4,65 [-8,30; -1,00]	0,636
Class III or IV	664	144 (21,7)	637	162 (25,4)	0,86 [0,71; 1,05]	0,131	0,82 [0,63; 1,06]	-3,55 [-8,18; 1,07]	
Use of Sacubitril /Valsartan at Baseline									
Yes	248	65 (26,2)	241	71 (29,5)	0,88 [0,66; 1,18]	0,394	0,84 [0,57; 1,25]	-3,47 [-11,46; 4,53]	0,670
No	1407	276 (19,6)	1386	333 (24,0)	0,82 [0,71; 0,94]	0,005	0,77 [0,65; 0,93]	-4,38 [-7,44; -1,32]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	397	69 (17,4)	404	85 (21,0)	0,83 [0,62; 1,10]	0,200	0,79 [0,56; 1,13]	-3,59 [-9,08; 1,90]	0,877
Q2 (1556 - 2816)	437	89 (20,4)	381	94 (24,7)	0,80 [0,62; 1,03]	0,079	0,74 [0,53; 1,04]	-5,07 [-10,80; 0,60]	
Q3 (2816 - 5314)	378	77 (20,4)	409	110 (26,9)	0,76 [0,59; 0,98]	0,035	0,70 [0,50; 0,98]	-6,44 [-12,35; -0,47]	
Q4 (>5314)	385	89 (23,1)	355	94 (26,5)	0,87 [0,67; 1,11]	0,264	0,83 [0,59; 1,16]	-3,56 [-9,84; 2,70]	
Baseline Ejection Fraction Group 2									
<35	1313	263 (20,0)	1302	319 (24,5)	0,82 [0,71; 0,95]	0,006	0,77 [0,64; 0,93]	-4,44 [-7,63; -1,26]	0,722

LOCF Analysis of Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
≥35	342	78 (22,8)	326	85 (26,1)	0,87 [0,66; 1,13]	0,295	0,83 [0,58; 1,18]	-3,49 [-10,05; 3,05]	
Race group									
White	1053	235 (22,3)	1045	268 (25,6)	0,87 [0,75; 1,01]	0,075	0,83 [0,68; 1,02]	-3,33 [-6,98; 0,33]	0,638
Asian	377	70 (18,6)	345	79 (22,9)	0,81 [0,61; 1,08]	0,152	0,77 [0,53; 1,10]	-4,33 [-10,30; 1,58]	
Black	81	14 (17,3)	90	24 (26,7)	0,65 [0,36; 1,17]	0,148	0,57 [0,27; 1,21]	-9,38 [-21,66; 3,22]	
Other	144	22 (15,3)	148	33 (22,3)	0,69 [0,42; 1,12]	0,129	0,63 [0,35; 1,14]	-7,02 [-16,03; 2,00]	
CCSA class at Randomization									
No Angina	1404	290 (20,7)	1386	338 (24,4)	0,85 [0,74; 0,97]	0,018	0,81 [0,67; 0,96]	-3,74 [-6,83; -0,64]	0,360
Angina Class 1 or 2	215	42 (19,5)	205	47 (22,9)	0,84 [0,58; 1,22]	0,370	0,81 [0,50; 1,29]	-3,59 [-11,51; 4,29]	
Angina Class 3 or 4	36	9 (25,0)	37	19 (51,4)	0,50 [0,27; 0,93]	0,030	0,32 [0,12; 0,86]	-27,53 [-48,47; -3,98]	
Medical History of Diabetes Mellitus									
Yes	806	178 (22,1)	735	187 (25,4)	0,87 [0,73; 1,04]	0,125	0,83 [0,66; 1,05]	-3,33 [-7,61; 0,92]	0,530
No	849	163 (19,2)	893	217 (24,3)	0,80 [0,67; 0,95]	0,012	0,75 [0,59; 0,94]	-4,95 [-8,80; -1,08]	

a: Database Cut-off Date: 18JUN2019

b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32

c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)

d: Two-sided p-value for Relative Risk based on Wald test

e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)

f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)

g: P-value from the likelihood ration test for treatment by subgroup interaction

Decrease by at least 5 points is defined as change from baseline ≤ -5

Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.6.4 Deterioration by at least 15 points at Week 32

3.6.4.1 Consistency of Treatment Effect – Summary

Table 3.6.4-1
Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Overall Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ OSS						
Overall Summary Score	0,840	0,729	0,969	0,512	0,872	**0,006[b]**

Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Overall Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ OSS							
Overall Summary Score	0,995	0,637	0,641	0,990	0,758	0,548	0,603

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.6.4.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.6.4-2
LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Age category 1									
<65	656	59 (9,0)	676	76 (11,2)	0,80 [0,58; 1,11]	0,181	0,78 [0,55; 1,12]	-2,22 [-5,51; 1,04]	0,840
≥65	999	102 (10,2)	952	116 (12,2)	0,84 [0,65; 1,08]	0,167	0,82 [0,62; 1,09]	-1,97 [-4,80; 0,82]	
Age category 2									
<75	1192	117 (9,8)	1185	138 (11,6)	0,84 [0,67; 1,06]	0,151	0,83 [0,64; 1,07]	-1,82 [-4,33; 0,67]	0,729
≥75	463	44 (9,5)	443	54 (12,2)	0,78 [0,54; 1,13]	0,193	0,76 [0,50; 1,15]	-2,70 [-6,84; 1,37]	
Gender									
Male	1285	123 (9,6)	1271	147 (11,6)	0,83 [0,66; 1,04]	0,102	0,81 [0,63; 1,04]	-2,00 [-4,40; 0,39]	0,969
Female	370	38 (10,3)	357	45 (12,6)	0,82 [0,54; 1,23]	0,334	0,80 [0,50; 1,26]	-2,29 [-7,03; 2,36]	
Geographic Region									
Asia Pacific	386	39 (10,1)	375	37 (9,9)	1,02 [0,67; 1,57]	0,913	1,03 [0,64; 1,65]	0,24 [-4,10; 4,56]	0,512
Eastern Europe	547	46 (8,4)	543	66 (12,2)	0,69 [0,48; 0,99]	0,043	0,66 [0,45; 0,99]	-3,75 [-7,41; -0,14]	
Latin and South America	240	21 (8,8)	240	27 (11,3)	0,78 [0,45; 1,34]	0,363	0,76 [0,41; 1,38]	-2,50 [-8,04; 2,95]	
North America	191	26 (13,6)	198	25 (12,6)	1,08 [0,65; 1,80]	0,773	1,09 [0,61; 1,97]	0,99 [-5,82; 7,86]	
Western Europe	291	29 (10,0)	272	37 (13,6)	0,73 [0,46; 1,16]	0,182	0,70 [0,42; 1,18]	-3,64 [-9,13; 1,70]	
Index Event									
HF Hospitalization 3-6 Months	314	35 (11,1)	287	40 (13,9)	0,81 [0,53; 1,23]	0,319	0,78 [0,48; 1,27]	-2,72 [-8,15; 2,62]	0,872
HF Hospitalization within 3 Months	1085	102 (9,4)	1082	119 (11,0)	0,85 [0,66; 1,10]	0,213	0,84 [0,63; 1,11]	-1,62 [-4,19; 0,93]	

LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	256	24 (9,4)	259	33 (12,7)	0,75 [0,46; 1,23]	0,259	0,73 [0,42; 1,27]	-3,14 [-8,71; 2,37]	
NYHA Group at Baseline									
Class I or II	989	91 (9,2)	991	111 (11,2)	0,82 [0,63; 1,07]	0,141	0,80 [0,60; 1,08]	-2,01 [-4,71; 0,66]	0,995
Class III or IV	664	69 (10,4)	637	81 (12,7)	0,82 [0,61; 1,11]	0,204	0,80 [0,57; 1,13]	-2,25 [-5,78; 1,23]	
Use of Sacubitril /Valsartan at Baseline									
Yes	248	28 (11,3)	241	36 (14,9)	0,74 [0,47; 1,16]	0,187	0,70 [0,41; 1,19]	-4,04 [-10,24; 1,95]	0,637
No	1407	133 (9,5)	1386	156 (11,3)	0,84 [0,68; 1,05]	0,122	0,82 [0,65; 1,05]	-1,79 [-4,06; 0,48]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	397	30 (7,6)	404	38 (9,4)	0,82 [0,51; 1,29]	0,388	0,80 [0,49; 1,32]	-1,71 [-5,67; 2,21]	0,641
Q2 (1556 - 2816)	437	33 (7,6)	381	44 (11,5)	0,64 [0,42; 0,98]	0,042	0,61 [0,38; 0,98]	-4,19 [-8,44; -0,18]	
Q3 (2816 - 5314)	378	40 (10,6)	409	48 (11,7)	0,91 [0,61; 1,35]	0,641	0,90 [0,58; 1,40]	-1,05 [-5,50; 3,43]	
Q4 (>5314)	385	49 (12,7)	355	52 (14,6)	0,86 [0,60; 1,24]	0,426	0,84 [0,55; 1,28]	-2,03 [-7,12; 2,96]	
Baseline Ejection Fraction Group 2									
<35	1313	127 (9,7)	1302	153 (11,8)	0,82 [0,66; 1,03]	0,086	0,80 [0,63; 1,03]	-2,08 [-4,47; 0,29]	0,990
≥35	342	34 (9,9)	326	39 (12,0)	0,81 [0,53; 1,26]	0,355	0,79 [0,49; 1,29]	-2,24 [-7,11; 2,53]	
Race group									
White	1053	109 (10,4)	1045	132 (12,6)	0,82 [0,65; 1,04]	0,102	0,80 [0,61; 1,05]	-2,28 [-5,03; 0,45]	0,758
Asian	377	34 (9,0)	345	32 (9,3)	0,97 [0,61; 1,54]	0,905	0,97 [0,58; 1,61]	-0,26 [-4,59; 3,99]	

LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Black	81	8 (9,9)	90	11 (12,2)	0,81 [0,34; 1,91]	0,627	0,79 [0,30; 2,07]	-2,35 [-12,15; 7,65]	
Other	144	10 (6,9)	148	17 (11,5)	0,60 [0,29; 1,28]	0,187	0,58 [0,25; 1,30]	-4,54 [-11,55; 2,23]	
CCSA class at Randomization									
No Angina	1404	132 (9,4)	1386	163 (11,8)	0,80 [0,64; 0,99]	0,043	0,78 [0,61; 0,99]	-2,37 [-4,67; -0,08]	0,548
Angina Class 1 or 2	215	25 (11,6)	205	22 (10,7)	1,05 [0,60; 1,84]	0,853	1,06 [0,58; 1,95]	0,58 [-5,63; 6,79]	
Angina Class 3 or 4	36	4 (11,1)	37	7 (18,9)	0,58 [0,19; 1,81]	0,349	0,52 [0,14; 2,01]	-8,46 [-26,64; 9,85]	
Medical History of Diabetes Mellitus									
Yes	806	86 (10,7)	735	90 (12,2)	0,87 [0,66; 1,15]	0,316	0,85 [0,62; 1,17]	-1,63 [-4,86; 1,56]	0,603
No	849	75 (8,8)	893	102 (11,4)	0,77 [0,58; 1,02]	0,072	0,75 [0,55; 1,03]	-2,62 [-5,48; 0,22]	

a: Database Cut-off Date: 18JUN2019

b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32

c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)

d: Two-sided p-value for Relative Risk based on Wald test

e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)

f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)

g: P-value from the likelihood ration test for treatment by subgroup interaction

Decrease by at least 15 points is defined as change from baseline ≤ -15

Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.6.4.3 Results for Subgroups With Interaction P-value < 0.05

Table 3.6.4-3
LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Overall Summary Score
For Subgroups with P-value for Interaction test < 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ OSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
eGFR (mL/min/1.73 m^2) Category									
≤30	144	12 (8,3)	132	15 (11,4)	0,71 [0,34; 1,50]	0,372	0,70 [0,31; 1,55]	-3,22 [-10,81; 3,96]	0,006
>30 to ≤60	689	92 (13,4)	673	79 (11,7)	1,14 [0,86; 1,50]	0,374	1,16 [0,84; 1,60]	1,60 [-1,94; 5,14]	
>60	799	55 (6,9)	796	95 (11,9)	0,58 [0,42; 0,79]	< 0,001	0,55 [0,39; 0,78]	-5,03 [-7,95; -2,18]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Decrease by at least 15 points is defined as change from baseline ≤ -15
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.7 Subgroup Analyses: Analysis for Improvement and Deterioration Rates for KCCQ Total Symptom Score

3.7.1 Improvement by at least 5 Points at Week 32

3.7.1.1 Consistency of Treatment Effect – Summary

Table 3.7.1-1
Overview of LOCF Subgroup Analyses for Improvement Rate by at least 5 points at Week 32 as Measured by KCCQ: Total Symptom Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ TSS						
Total Symptom Score	0,434	0,403	0,862	0,736	0,290	0,138

Overview of LOCF Subgroup Analyses for Improvement Rate by at least 5 points at Week 32 as Measured by KCCQ: Total Symptom Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ TSS							
Total Symptom Score	0,671	0,536	0,220	0,780	**0,019[b]**	0,449	0,190

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.7.1.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.7.1-2
LOCF Analysis of Improvement Rate by at least 5 points at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ TSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Age category 1									
<65	685	375 (54,7)	698	390 (55,9)	0,98 [0,89; 1,08]	0,678	0,96 [0,77; 1,18]	-1,11 [-6,36; 4,14]	0,434
≥65	1075	564 (52,5)	1053	536 (50,9)	1,03 [0,95; 1,12]	0,461	1,07 [0,90; 1,27]	1,59 [-2,63; 5,80]	
Age category 2									
<75	1249	678 (54,3)	1250	684 (54,7)	0,99 [0,92; 1,07]	0,842	0,98 [0,84; 1,15]	-0,40 [-4,29; 3,50]	0,403
≥75	511	261 (51,1)	501	242 (48,3)	1,04 [0,92; 1,18]	0,493	1,09 [0,85; 1,40]	2,16 [-3,97; 8,28]	
Gender									
Male	1361	721 (53,0)	1354	713 (52,7)	1,01 [0,94; 1,08]	0,853	1,01 [0,87; 1,18]	0,35 [-3,39; 4,10]	0,862
Female	399	218 (54,6)	397	213 (53,7)	1,02 [0,89; 1,15]	0,803	1,04 [0,78; 1,37]	0,88 [-6,01; 7,77]	
Geographic Region									
Asia Pacific	425	216 (50,8)	413	204 (49,4)	1,03 [0,90; 1,18]	0,679	1,06 [0,81; 1,39]	1,43 [-5,34; 8,18]	0,736
Eastern Europe	576	324 (56,3)	574	325 (56,6)	0,99 [0,90; 1,10]	0,899	0,99 [0,78; 1,24]	-0,37 [-6,09; 5,36]	
Latin and South America	258	157 (60,9)	263	146 (55,5)	1,10 [0,95; 1,27]	0,217	1,25 [0,88; 1,77]	5,34 [-3,14; 13,74]	
North America	198	86 (43,4)	208	94 (45,2)	0,96 [0,77; 1,20]	0,722	0,93 [0,63; 1,38]	-1,76 [-11,37; 7,90]	
Western Europe	303	156 (51,5)	293	157 (53,6)	0,96 [0,82; 1,12]	0,608	0,92 [0,67; 1,27]	-2,10 [-10,08; 5,91]	
Index Event									
HF Hospitalization 3-6 Months	330	160 (48,5)	304	129 (42,4)	1,15 [0,97; 1,36]	0,110	1,30 [0,94; 1,78]	6,35 [-1,39; 14,00]	0,290
HF Hospitalization within 3 Months	1164	640 (55,0)	1177	653 (55,5)	0,99 [0,92; 1,07]	0,811	0,98 [0,83; 1,15]	-0,49 [-4,51; 3,53]	

LOCF Analysis of Improvement Rate by at least 5 points at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ TSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	266	139 (52,3)	270	144 (53,3)	0,98 [0,84; 1,15]	0,839	0,97 [0,69; 1,36]	-0,87 [-9,31; 7,57]	
eGFR (mL/min/1.73 m^2) Category									
≤30	162	89 (54,9)	157	71 (45,2)	1,22 [0,98; 1,52]	0,076	1,49 [0,96; 2,32]	9,98 [-1,03; 20,74]	0,138
>30 to ≤60	733	365 (49,8)	733	378 (51,6)	0,96 [0,87; 1,07]	0,486	0,93 [0,76; 1,14]	-1,82 [-6,93; 3,30]	
>60	841	472 (56,1)	834	461 (55,3)	1,02 [0,93; 1,11]	0,702	1,04 [0,86; 1,26]	0,93 [-3,81; 5,65]	
NYHA Group at Baseline									
Class I or II	1038	526 (50,7)	1059	528 (49,9)	1,02 [0,94; 1,11]	0,654	1,04 [0,88; 1,24]	0,97 [-3,29; 5,23]	0,671
Class III or IV	720	412 (57,2)	692	398 (57,5)	0,99 [0,90; 1,08]	0,799	0,97 [0,79; 1,20]	-0,67 [-5,82; 4,49]	
Use of Sacubitril /Valsartan at Baseline									
Yes	258	128 (49,6)	256	119 (46,5)	1,07 [0,89; 1,28]	0,484	1,13 [0,80; 1,60]	3,09 [-5,56; 11,70]	0,536
No	1502	811 (54,0)	1494	807 (54,0)	1,00 [0,93; 1,07]	0,963	1,00 [0,86; 1,15]	-0,08 [-3,64; 3,48]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	416	219 (52,6)	422	219 (51,9)	1,01 [0,89; 1,15]	0,872	1,02 [0,78; 1,34]	0,55 [-6,18; 7,28]	0,220
Q2 (1556 - 2816)	454	231 (50,9)	404	224 (55,4)	0,93 [0,82; 1,06]	0,269	0,86 [0,65; 1,13]	-3,74 [-10,36; 2,90]	
Q3 (2816 - 5314)	412	215 (52,2)	441	228 (51,7)	1,01 [0,89; 1,15]	0,880	1,02 [0,78; 1,34]	0,52 [-6,18; 7,21]	
Q4 (>5314)	418	239 (57,2)	398	203 (51,0)	1,12 [0,99; 1,27]	0,078	1,28 [0,97; 1,69]	6,19 [-0,67; 13,00]	
Baseline Ejection Fraction Group 2									
<35	1402	748 (53,4)	1398	734 (52,5)	1,01 [0,95; 1,09]	0,688	1,03 [0,89; 1,20]	0,76 [-2,93; 4,44]	0,780

LOCF Analysis of Improvement Rate by at least 5 points at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ TSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
≥35	358	191 (53,4)	353	192 (54,4)	0,99 [0,86; 1,13]	0,858	0,97 [0,72; 1,31]	-0,66 [-7,95; 6,63]	
CCSA class at Randomization									
No Angina	1499	796 (53,1)	1502	799 (53,2)	1,00 [0,93; 1,07]	0,934	0,99 [0,86; 1,15]	-0,15 [-3,71; 3,41]	0,449
Angina Class 1 or 2	225	128 (56,9)	212	110 (51,9)	1,12 [0,95; 1,33]	0,186	1,30 [0,88; 1,91]	6,25 [-3,01; 15,37]	
Angina Class 3 or 4	36	15 (41,7)	37	17 (45,9)	1,01 [0,58; 1,76]	0,977	1,01 [0,39; 2,63]	0,36 [-22,87; 23,39]	
Medical History of Diabetes Mellitus									
Yes	855	453 (53,0)	799	440 (55,1)	0,96 [0,88; 1,05]	0,406	0,92 [0,76; 1,12]	-2,03 [-6,81; 2,76]	0,190
No	905	486 (53,7)	952	486 (51,1)	1,05 [0,96; 1,14]	0,283	1,11 [0,92; 1,33]	2,49 [-2,05; 7,02]	

a: Database Cut-off Date: 18JUN2019

b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32

c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)

d: Two-sided p-value for Relative Risk based on Wald test

e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)

f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)

g: P-value from the likelihood ration test for treatment by subgroup interaction

Increase by at least 5 points is defined as change from baseline ≥ 5

Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.7.1.3 Results for Subgroups With Interaction P-value < 0.05

Table 3.7.1-3
LOCF Analysis of Improvement Rate by at least 5 points at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test < 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ TSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Race group									
White	1102	576 (52,3)	1109	599 (54,0)	0,97 [0,89; 1,05]	0,411	0,93 [0,79; 1,10]	-1,74 [-5,90; 2,42]	0,019
Asian	419	213 (50,8)	386	193 (50,0)	1,02 [0,89; 1,17]	0,813	1,03 [0,78; 1,36]	0,84 [-6,07; 7,73]	
Black	84	42 (50,0)	90	46 (51,1)	0,98 [0,73; 1,31]	0,884	0,96 [0,53; 1,73]	-1,11 [-15,83; 13,66]	
Other	155	108 (69,7)	166	88 (53,0)	1,31 [1,10; 1,57]	0,002	2,04 [1,29; 3,22]	16,67 [6,01; 26,93]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Increase by at least 5 points is defined as change from baseline ≥ 5
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.7.2 Improvement by at least 15 Points at Week 32

3.7.2.1 Consistency of Treatment Effect – Summary

Table 3.7.2-1
Overview of LOCF Subgroup Analyses for Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Total Symptom Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ TSS						
Total Symptom Score	0,804	0,499	0,824	0,922	0,892	0,796

Overview of LOCF Subgroup Analyses for Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Total Symptom Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ TSS							
Total Symptom Score	0,957	0,720	0,204	0,346	0,057	0,342	0,132

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.7.2.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.7.2-2
LOCF Analysis of Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ TSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Age category 1									
<65	685	231 (33,7)	698	245 (35,1)	0,96 [0,83; 1,11]	0,573	0,94 [0,75; 1,17]	-1,44 [-6,44; 3,57]	0,804
≥65	1075	350 (32,6)	1053	368 (34,9)	0,93 [0,83; 1,05]	0,248	0,90 [0,75; 1,08]	-2,36 [-6,35; 1,64]	
Age category 2									
<75	1249	425 (34,0)	1250	442 (35,4)	0,96 [0,87; 1,07]	0,494	0,94 [0,80; 1,11]	-1,30 [-5,02; 2,42]	0,499
≥75	511	156 (30,5)	501	171 (34,1)	0,88 [0,74; 1,06]	0,179	0,83 [0,64; 1,09]	-3,95 [-9,68; 1,79]	
Gender									
Male	1361	441 (32,4)	1354	468 (34,6)	0,94 [0,84; 1,04]	0,231	0,91 [0,77; 1,06]	-2,16 [-5,70; 1,38]	0,824
Female	399	140 (35,1)	397	145 (36,5)	0,96 [0,80; 1,16]	0,660	0,94 [0,70; 1,25]	-1,49 [-8,12; 5,16]	
Geographic Region									
Asia Pacific	425	128 (30,1)	413	128 (31,0)	0,97 [0,79; 1,19]	0,783	0,96 [0,72; 1,29]	-0,88 [-7,12; 5,36]	0,922
Eastern Europe	576	208 (36,1)	574	221 (38,5)	0,94 [0,81; 1,09]	0,402	0,90 [0,71; 1,15]	-2,39 [-7,97; 3,20]	
Latin and South America	258	98 (38,0)	263	99 (37,6)	1,01 [0,81; 1,26]	0,936	1,01 [0,71; 1,45]	0,34 [-7,97; 8,66]	
North America	198	47 (23,7)	208	57 (27,4)	0,87 [0,62; 1,21]	0,399	0,82 [0,53; 1,29]	-3,67 [-12,13; 4,87]	
Western Europe	303	100 (33,0)	293	108 (36,9)	0,90 [0,72; 1,12]	0,324	0,84 [0,60; 1,18]	-3,86 [-11,49; 3,80]	
Index Event									
HF Hospitalization 3-6 Months	330	91 (27,6)	304	84 (27,6)	1,01 [0,79; 1,30]	0,940	1,01 [0,71; 1,44]	0,27 [-6,69; 7,17]	0,892
HF Hospitalization within 3 Months	1164	405 (34,8)	1177	439 (37,3)	0,93 [0,84; 1,04]	0,199	0,89 [0,76; 1,06]	-2,54 [-6,41; 1,34]	

LOCF Analysis of Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ TSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	266	85 (32,0)	270	90 (33,3)	0,97 [0,76; 1,23]	0,806	0,96 [0,66; 1,38]	-0,99 [-8,91; 6,91]	
eGFR (mL/min/1.73 m^2) Category									
≤30	162	51 (31,5)	157	48 (30,6)	1,04 [0,75; 1,45]	0,820	1,06 [0,66; 1,70]	1,19 [-9,05; 11,35]	0,796
>30 to ≤60	733	236 (32,2)	733	256 (34,9)	0,92 [0,80; 1,06]	0,270	0,88 [0,71; 1,10]	-2,72 [-7,54; 2,12]	
>60	841	285 (33,9)	834	301 (36,1)	0,94 [0,83; 1,07]	0,355	0,91 [0,74; 1,11]	-2,15 [-6,69; 2,40]	
NYHA Group at Baseline									
Class I or II	1038	315 (30,3)	1059	341 (32,2)	0,94 [0,83; 1,07]	0,380	0,92 [0,76; 1,11]	-1,77 [-5,72; 2,18]	0,957
Class III or IV	720	266 (36,9)	692	272 (39,3)	0,93 [0,82; 1,07]	0,314	0,90 [0,72; 1,11]	-2,60 [-7,66; 2,47]	
Use of Sacubitril /Valsartan at Baseline									
Yes	258	70 (27,1)	256	70 (27,3)	0,99 [0,75; 1,31]	0,950	0,99 [0,67; 1,46]	-0,25 [-8,00; 7,50]	0,720
No	1502	511 (34,0)	1494	543 (36,3)	0,93 [0,85; 1,03]	0,173	0,90 [0,77; 1,05]	-2,37 [-5,78; 1,04]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	416	127 (30,5)	422	138 (32,7)	0,93 [0,77; 1,14]	0,489	0,90 [0,67; 1,21]	-2,21 [-8,47; 4,07]	0,204
Q2 (1556 - 2816)	454	125 (27,5)	404	137 (33,9)	0,83 [0,68; 1,01]	0,069	0,76 [0,57; 1,02]	-5,71 [-11,89; 0,44]	
Q3 (2816 - 5314)	412	138 (33,5)	441	160 (36,3)	0,93 [0,77; 1,11]	0,412	0,89 [0,67; 1,18]	-2,68 [-9,05; 3,73]	
Q4 (>5314)	418	168 (40,2)	398	146 (36,7)	1,10 [0,92; 1,31]	0,304	1,16 [0,88; 1,54]	3,55 [-3,16; 10,22]	
Baseline Ejection Fraction Group 2									
<35	1402	476 (34,0)	1398	492 (35,2)	0,96 [0,87; 1,07]	0,456	0,94 [0,81; 1,10]	-1,34 [-4,85; 2,18]	0,346

LOCF Analysis of Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ TSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
≥35	358	105 (29,3)	353	121 (34,3)	0,87 [0,70; 1,08]	0,195	0,81 [0,59; 1,11]	-4,53 [-11,33; 2,30]	
Race group									
White	1102	349 (31,7)	1109	400 (36,1)	0,88 [0,78; 0,99]	0,029	0,82 [0,69; 0,98]	-4,40 [-8,33; -0,45]	0,057
Asian	419	127 (30,3)	386	122 (31,6)	0,96 [0,78; 1,18]	0,691	0,94 [0,70; 1,27]	-1,30 [-7,70; 5,09]	
Black	84	34 (40,5)	90	31 (34,4)	1,18 [0,80; 1,73]	0,412	1,29 [0,70; 2,40]	6,03 [-8,34; 20,25]	
Other	155	71 (45,8)	166	60 (36,1)	1,27 [0,97; 1,65]	0,080	1,49 [0,95; 2,34]	9,66 [-1,11; 20,25]	
CCSA class at Randomization									
No Angina	1499	503 (33,6)	1502	525 (35,0)	0,96 [0,87; 1,06]	0,398	0,94 [0,81; 1,09]	-1,46 [-4,84; 1,93]	0,342
Angina Class 1 or 2	225	70 (31,1)	212	74 (34,9)	0,91 [0,70; 1,19]	0,512	0,87 [0,59; 1,31]	-2,95 [-11,79; 5,86]	
Angina Class 3 or 4	36	8 (22,2)	37	14 (37,8)	0,59 [0,26; 1,32]	0,198	0,49 [0,17; 1,41]	-14,93 [-35,70; 6,98]	
Medical History of Diabetes Mellitus									
Yes	855	281 (32,9)	799	301 (37,7)	0,87 [0,77; 0,99]	0,040	0,81 [0,66; 0,99]	-4,81 [-9,39; -0,22]	0,132
No	905	300 (33,1)	952	312 (32,8)	1,01 [0,88; 1,15]	0,910	1,01 [0,83; 1,23]	0,25 [-4,02; 4,52]	

a: Database Cut-off Date: 18JUN2019

b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32

c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)

d: Two-sided p-value for Relative Risk based on Wald test

e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)

f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)

g: P-value from the likelihood ration test for treatment by subgroup interaction

Increase by at least 15 points is defined as change from baseline ≥ 15

Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.7.3 Deterioration by at least 5 Points at Week 32

3.7.3.1 Consistency of Treatment Effect – Summary

Table 3.7.3-1
Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Total Symptom Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ TSS						
Total Symptom Score	0,296	0,606	0,627	0,411	0,237	0,222

Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Total Symptom Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ TSS							
Total Symptom Score	0,734	0,321	0,740	0,861	0,350	0,755	0,063

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.7.3.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.7.3-2
LOCF Analysis of Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ TSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Age category 1									
<65	685	172 (25,1)	698	171 (24,5)	1,03 [0,86; 1,24]	0,767	1,04 [0,81; 1,32]	0,69 [-3,87; 5,25]	0,296
≥65	1075	262 (24,4)	1053	281 (26,7)	0,91 [0,79; 1,06]	0,224	0,89 [0,73; 1,08]	-2,30 [-6,00; 1,40]	
Age category 2									
<75	1249	308 (24,7)	1250	316 (25,3)	0,98 [0,85; 1,12]	0,726	0,97 [0,81; 1,16]	-0,61 [-4,00; 2,79]	0,606
≥75	511	126 (24,7)	501	136 (27,1)	0,92 [0,75; 1,13]	0,444	0,90 [0,68; 1,19]	-2,10 [-7,50; 3,29]	
Gender									
Male	1361	337 (24,8)	1354	356 (26,3)	0,94 [0,83; 1,07]	0,368	0,92 [0,78; 1,10]	-1,50 [-4,78; 1,77]	0,627
Female	399	97 (24,3)	397	96 (24,2)	1,01 [0,79; 1,29]	0,959	1,01 [0,73; 1,40]	0,16 [-5,81; 6,12]	
Geographic Region									
Asia Pacific	425	110 (25,9)	413	101 (24,5)	1,06 [0,84; 1,34]	0,634	1,08 [0,79; 1,47]	1,43 [-4,46; 7,30]	0,411
Eastern Europe	576	134 (23,3)	574	135 (23,5)	0,99 [0,80; 1,22]	0,919	0,99 [0,75; 1,30]	-0,26 [-5,16; 4,64]	
Latin and South America	258	51 (19,8)	263	72 (27,4)	0,72 [0,53; 0,99]	0,043	0,65 [0,43; 0,98]	-7,61 [-14,86; -0,31]	
North America	198	63 (31,8)	208	68 (32,7)	0,97 [0,73; 1,29]	0,851	0,96 [0,63; 1,46]	-0,87 [-9,94; 8,24]	
Western Europe	303	76 (25,1)	293	76 (25,9)	0,97 [0,73; 1,27]	0,811	0,96 [0,66; 1,38]	-0,86 [-7,88; 6,15]	
Index Event									
HF Hospitalization 3-6 Months	330	101 (30,6)	304	90 (29,6)	1,03 [0,81; 1,31]	0,797	1,05 [0,74; 1,47]	0,94 [-6,25; 8,08]	0,237
HF Hospitalization within 3 Months	1164	276 (23,7)	1177	285 (24,2)	0,98 [0,85; 1,13]	0,785	0,97 [0,81; 1,18]	-0,48 [-3,94; 2,98]	

LOCF Analysis of Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ TSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	266	57 (21,4)	270	77 (28,5)	0,76 [0,56; 1,02]	0,070	0,69 [0,47; 1,03]	-6,85 [-14,20; 0,50]	
eGFR (mL/min/1.73 m^2) Category									
≤30	162	43 (26,5)	157	44 (28,0)	0,93 [0,65; 1,34]	0,710	0,91 [0,56; 1,49]	-1,88 [-11,73; 7,95]	0,222
>30 to ≤60	733	208 (28,4)	733	196 (26,7)	1,06 [0,90; 1,26]	0,469	1,09 [0,87; 1,37]	1,69 [-2,89; 6,27]	
>60	841	178 (21,2)	834	205 (24,6)	0,86 [0,72; 1,03]	0,097	0,82 [0,66; 1,04]	-3,40 [-7,42; 0,62]	
NYHA Group at Baseline									
Class I or II	1038	252 (24,3)	1059	272 (25,7)	0,94 [0,81; 1,09]	0,429	0,92 [0,76; 1,13]	-1,49 [-5,20; 2,21]	0,734
Class III or IV	720	181 (25,1)	692	180 (26,0)	0,98 [0,82; 1,17]	0,809	0,97 [0,76; 1,23]	-0,56 [-5,12; 3,99]	
Use of Sacubitril /Valsartan at Baseline									
Yes	258	70 (27,1)	256	81 (31,6)	0,85 [0,65; 1,12]	0,247	0,80 [0,55; 1,17]	-4,68 [-12,57; 3,25]	0,321
No	1502	364 (24,2)	1494	371 (24,8)	0,98 [0,86; 1,11]	0,748	0,97 [0,82; 1,15]	-0,51 [-3,59; 2,57]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	416	91 (21,9)	422	104 (24,6)	0,91 [0,71; 1,16]	0,447	0,88 [0,64; 1,22]	-2,22 [-7,94; 3,50]	0,740
Q2 (1556 - 2816)	454	105 (23,1)	404	102 (25,2)	0,88 [0,70; 1,12]	0,305	0,85 [0,62; 1,16]	-2,96 [-8,68; 2,72]	
Q3 (2816 - 5314)	412	106 (25,7)	441	119 (27,0)	0,95 [0,76; 1,19]	0,664	0,93 [0,69; 1,27]	-1,31 [-7,18; 4,62]	
Q4 (>5314)	418	116 (27,8)	398	107 (26,9)	1,03 [0,82; 1,28]	0,826	1,04 [0,76; 1,41]	0,69 [-5,47; 6,82]	
Baseline Ejection Fraction Group 2									
<35	1402	344 (24,5)	1398	358 (25,6)	0,96 [0,85; 1,09]	0,539	0,95 [0,80; 1,12]	-1,00 [-4,22; 2,21]	0,861

LOCF Analysis of Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ TSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
≥35	358	90 (25,1)	353	94 (26,6)	0,92 [0,72; 1,19]	0,537	0,90 [0,64; 1,26]	-2,01 [-8,41; 4,39]	
Race group									
White	1102	273 (24,8)	1109	291 (26,2)	0,94 [0,82; 1,09]	0,429	0,93 [0,76; 1,12]	-1,47 [-5,10; 2,17]	0,350
Asian	419	106 (25,3)	386	92 (23,8)	1,06 [0,83; 1,35]	0,630	1,08 [0,78; 1,49]	1,46 [-4,52; 7,40]	
Black	84	26 (31,0)	90	25 (27,8)	1,11 [0,70; 1,77]	0,646	1,17 [0,61; 2,24]	3,17 [-10,36; 16,73]	
Other	155	29 (18,7)	166	44 (26,5)	0,71 [0,47; 1,07]	0,100	0,64 [0,38; 1,09]	-7,80 [-16,88; 1,41]	
CCSA class at Randomization									
No Angina	1499	371 (24,7)	1502	388 (25,8)	0,96 [0,85; 1,09]	0,530	0,95 [0,80; 1,12]	-1,00 [-4,10; 2,11]	0,755
Angina Class 1 or 2	225	48 (21,3)	212	50 (23,6)	0,87 [0,62; 1,24]	0,455	0,84 [0,54; 1,32]	-2,98 [-10,88; 4,88]	
Angina Class 3 or 4	36	15 (41,7)	37	14 (37,8)	0,96 [0,52; 1,77]	0,899	0,94 [0,36; 2,45]	-1,58 [-24,07; 21,67]	
Medical History of Diabetes Mellitus									
Yes	855	235 (27,5)	799	205 (25,7)	1,07 [0,91; 1,25]	0,413	1,10 [0,88; 1,36]	1,78 [-2,48; 6,02]	0,063
No	905	199 (22,0)	952	247 (25,9)	0,85 [0,72; 1,00]	0,052	0,81 [0,65; 1,00]	-3,86 [-7,74; 0,03]	

a: Database Cut-off Date: 18JUN2019

b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32

c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)

d: Two-sided p-value for Relative Risk based on Wald test

e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)

f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)

g: P-value from the likelihood ration test for treatment by subgroup interaction

Decrease by at least 5 points is defined as change from baseline ≤ -5

Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.7.4 Deterioration by at least 15 Points at Week 32

3.7.4.1 Consistency of Treatment Effect – Summary

Table 3.7.4-1
Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Total Symptom Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ TSS						
Total Symptom Score	0,909	0,969	0,985	0,440	0,345	0,257

Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Total Symptom Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ TSS							
Total Symptom Score	0,760	0,736	0,137	0,780	0,242	0,969	0,840

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.7.4.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.7.4-2
LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ TSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Age category 1									
<65	685	84 (12,3)	698	94 (13,5)	0,91 [0,69; 1,20]	0,515	0,90 [0,66; 1,23]	-1,17 [-4,73; 2,38]	0,909
≥65	1075	136 (12,7)	1053	143 (13,6)	0,93 [0,75; 1,16]	0,524	0,92 [0,72; 1,19]	-0,93 [-3,81; 1,94]	
Age category 2									
<75	1249	158 (12,7)	1250	171 (13,7)	0,93 [0,76; 1,13]	0,456	0,92 [0,73; 1,15]	-1,01 [-3,67; 1,65]	0,969
≥75	511	62 (12,1)	501	66 (13,2)	0,93 [0,67; 1,28]	0,639	0,92 [0,63; 1,33]	-0,98 [-5,12; 3,15]	
Gender									
Male	1361	172 (12,6)	1354	185 (13,7)	0,93 [0,76; 1,12]	0,438	0,92 [0,73; 1,14]	-1,01 [-3,56; 1,54]	0,985
Female	399	48 (12,0)	397	52 (13,1)	0,92 [0,64; 1,33]	0,662	0,91 [0,60; 1,39]	-1,03 [-5,69; 3,60]	
Geographic Region									
Asia Pacific	425	60 (14,1)	413	54 (13,1)	1,08 [0,77; 1,52]	0,660	1,09 [0,74; 1,62]	1,04 [-3,64; 5,72]	0,440
Eastern Europe	576	62 (10,8)	574	71 (12,4)	0,87 [0,63; 1,20]	0,395	0,85 [0,59; 1,23]	-1,61 [-5,34; 2,11]	
Latin and South America	258	26 (10,1)	263	41 (15,6)	0,65 [0,41; 1,02]	0,063	0,61 [0,36; 1,03]	-5,51 [-11,36; 0,25]	
North America	198	34 (17,2)	208	34 (16,3)	1,05 [0,68; 1,62]	0,824	1,06 [0,63; 1,79]	0,83 [-6,49; 8,21]	
Western Europe	303	38 (12,5)	293	37 (12,6)	0,99 [0,65; 1,52]	0,975	0,99 [0,61; 1,61]	-0,09 [-5,50; 5,30]	
Index Event									
HF Hospitalization 3-6 Months	330	52 (15,8)	304	40 (13,2)	1,20 [0,82; 1,75]	0,349	1,24 [0,79; 1,93]	2,62 [-2,92; 8,12]	0,345
HF Hospitalization within 3 Months	1164	133 (11,4)	1177	157 (13,3)	0,86 [0,69; 1,07]	0,165	0,84 [0,66; 1,07]	-1,90 [-4,58; 0,77]	

LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ TSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	266	35 (13,2)	270	40 (14,8)	0,91 [0,59; 1,38]	0,645	0,89 [0,54; 1,46]	-1,38 [-7,38; 4,55]	
eGFR (mL/min/1.73 m^2) Category									
≤30	162	22 (13,6)	157	26 (16,6)	0,80 [0,47; 1,36]	0,407	0,77 [0,42; 1,43]	-3,33 [-11,43; 4,61]	0,257
>30 to ≤60	733	107 (14,6)	733	99 (13,5)	1,08 [0,84; 1,39]	0,548	1,09 [0,81; 1,47]	1,09 [-2,48; 4,67]	
>60	841	87 (10,3)	834	107 (12,8)	0,81 [0,62; 1,05]	0,110	0,78 [0,58; 1,06]	-2,51 [-5,61; 0,57]	
NYHA Group at Baseline									
Class I or II	1038	132 (12,7)	1059	143 (13,5)	0,94 [0,76; 1,17]	0,593	0,93 [0,72; 1,20]	-0,79 [-3,69; 2,11]	0,760
Class III or IV	720	87 (12,1)	692	94 (13,6)	0,89 [0,68; 1,17]	0,402	0,87 [0,64; 1,20]	-1,49 [-5,02; 2,01]	
Use of Sacubitril /Valsartan at Baseline									
Yes	258	39 (15,1)	256	39 (15,2)	0,97 [0,65; 1,46]	0,888	0,97 [0,60; 1,56]	-0,45 [-6,75; 5,84]	0,736
No	1502	181 (12,1)	1494	198 (13,3)	0,91 [0,75; 1,10]	0,334	0,90 [0,72; 1,12]	-1,17 [-3,56; 1,21]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	416	42 (10,1)	422	51 (12,1)	0,85 [0,58; 1,25]	0,403	0,83 [0,54; 1,28]	-1,82 [-6,13; 2,48]	0,137
Q2 (1556 - 2816)	454	46 (10,1)	404	60 (14,9)	0,66 [0,46; 0,95]	0,025	0,62 [0,41; 0,94]	-5,07 [-9,62; -0,67]	
Q3 (2816 - 5314)	412	54 (13,1)	441	63 (14,3)	0,92 [0,66; 1,30]	0,644	0,91 [0,62; 1,35]	-1,09 [-5,70; 3,57]	
Q4 (>5314)	418	66 (15,8)	398	54 (13,6)	1,15 [0,83; 1,60]	0,399	1,18 [0,80; 1,74]	2,10 [-2,82; 7,01]	
Baseline Ejection Fraction Group 2									
<35	1402	174 (12,4)	1398	186 (13,3)	0,93 [0,77; 1,13]	0,488	0,92 [0,74; 1,15]	-0,88 [-3,37; 1,61]	0,780

LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Total Symptom Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ TSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
≥35	358	46 (12,8)	353	51 (14,4)	0,87 [0,60; 1,25]	0,447	0,85 [0,55; 1,30]	-1,94 [-7,03; 3,11]	
Race group									
White	1102	134 (12,2)	1109	153 (13,8)	0,88 [0,71; 1,09]	0,253	0,86 [0,67; 1,11]	-1,64 [-4,45; 1,17]	0,242
Asian	419	62 (14,8)	386	48 (12,4)	1,19 [0,84; 1,69]	0,331	1,22 [0,82; 1,83]	2,36 [-2,43; 7,12]	
Black	84	10 (11,9)	90	11 (12,2)	0,97 [0,44; 2,17]	0,949	0,97 [0,39; 2,42]	-0,32 [-10,35; 9,91]	
Other	155	14 (9,0)	166	25 (15,1)	0,60 [0,32; 1,11]	0,104	0,56 [0,28; 1,12]	-6,03 [-13,33; 1,18]	
CCSA class at Randomization									
No Angina	1499	191 (12,7)	1502	207 (13,8)	0,93 [0,77; 1,11]	0,414	0,92 [0,74; 1,13]	-1,01 [-3,44; 1,42]	0,969
Angina Class 1 or 2	225	22 (9,8)	212	21 (9,9)	0,95 [0,53; 1,71]	0,873	0,95 [0,51; 1,78]	-0,46 [-6,26; 5,30]	
Angina Class 3 or 4	36	7 (19,4)	37	9 (24,3)	0,70 [0,28; 1,74]	0,442	0,63 [0,20; 1,99]	-8,10 [-27,69; 12,62]	
Medical History of Diabetes Mellitus									
Yes	855	124 (14,5)	799	124 (15,5)	0,93 [0,74; 1,17]	0,557	0,92 [0,70; 1,21]	-1,03 [-4,50; 2,41]	0,840
No	905	96 (10,6)	952	113 (11,9)	0,90 [0,69; 1,16]	0,405	0,88 [0,66; 1,18]	-1,22 [-4,11; 1,67]	

a: Database Cut-off Date: 18JUN2019

b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32

c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)

d: Two-sided p-value for Relative Risk based on Wald test

e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)

f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)

g: P-value from the likelihood ration test for treatment by subgroup interaction

Decrease by at least 15 points is defined as change from baseline ≤ -15

Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.8 Subgroup Analyses: Analysis for Improvement and Deterioration Rates for KCCQ Clincal Summary Score

3.8.1 Improvement by at least 5 Points at Week 32

3.8.1.1 Consistency of Treatment Effect – Summary

Table 3.8.1-1
Overview of LOCF Subgroup Analyses for Improvement Rate by at least 5 points at Week 32 at Week 32 as Measured by KCCQ: Clinical Summary Score,
Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ CSS						
Clinical Summary Score	0,713	0,413	0,360	0,873	0,735	0,615

Overview of LOCF Subgroup Analyses for Improvement Rate by at least 5 points at Week 32 at Week 32 as Measured by KCCQ: Clinical Summary Score,
Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ CSS							
Clinical Summary Score	0,804	0,977	0,469	0,070	0,137	0,622	0,241

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.8.1.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.8.1-2
LOCF Analysis of Improvement Rate by at least 5 points at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Age category 1									
<65	678	369 (54,4)	688	382 (55,5)	0,98 [0,89; 1,08]	0,668	0,95 [0,77; 1,18]	-1,15 [-6,43; 4,13]	0,713
≥65	1048	550 (52,5)	1030	540 (52,4)	1,00 [0,92; 1,09]	0,989	1,00 [0,84; 1,19]	0,03 [-4,24; 4,30]	
Age category 2									
<75	1233	662 (53,7)	1228	675 (55,0)	0,98 [0,91; 1,05]	0,545	0,95 [0,81; 1,12]	-1,21 [-5,14; 2,71]	0,413
≥75	493	257 (52,1)	490	247 (50,4)	1,03 [0,91; 1,16]	0,678	1,05 [0,82; 1,36]	1,32 [-4,91; 7,55]	
Gender									
Male	1341	705 (52,6)	1335	718 (53,8)	0,98 [0,91; 1,05]	0,538	0,95 [0,82; 1,11]	-1,18 [-4,95; 2,59]	0,360
Female	385	214 (55,6)	383	204 (53,3)	1,04 [0,92; 1,19]	0,524	1,10 [0,83; 1,46]	2,30 [-4,75; 9,32]	
Geographic Region									
Asia Pacific	414	211 (51,0)	408	202 (49,5)	1,03 [0,90; 1,18]	0,676	1,06 [0,81; 1,39]	1,46 [-5,37; 8,27]	0,873
Eastern Europe	565	320 (56,6)	563	319 (56,7)	1,00 [0,90; 1,11]	0,994	1,00 [0,79; 1,26]	-0,02 [-5,80; 5,75]	
Latin and South America	251	148 (59,0)	253	147 (58,1)	1,01 [0,88; 1,18]	0,844	1,04 [0,73; 1,48]	0,86 [-7,73; 9,44]	
North America	197	86 (43,7)	205	94 (45,9)	0,95 [0,77; 1,18]	0,658	0,91 [0,62; 1,36]	-2,20 [-11,86; 7,51]	
Western Europe	299	154 (51,5)	289	160 (55,4)	0,93 [0,80; 1,08]	0,349	0,86 [0,62; 1,18]	-3,86 [-11,87; 4,21]	
Index Event									
HF Hospitalization 3-6 Months	328	152 (46,3)	300	135 (45,0)	1,03 [0,87; 1,23]	0,699	1,06 [0,78; 1,46]	1,54 [-6,26; 9,32]	0,735
HF Hospitalization within 3 Months	1133	633 (55,9)	1153	646 (56,0)	1,00 [0,93; 1,07]	0,938	0,99 [0,84; 1,17]	-0,16 [-4,22; 3,90]	

LOCF Analysis of Improvement Rate by at least 5 points at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	265	134 (50,6)	265	141 (53,2)	0,95 [0,81; 1,12]	0,536	0,90 [0,63; 1,27]	-2,65 [-11,07; 5,80]	
eGFR (mL/min/1.73 m^2) Category									
≤30	158	83 (52,5)	152	77 (50,7)	1,04 [0,84; 1,29]	0,701	1,09 [0,70; 1,71]	2,17 [-8,95; 13,21]	0,615
>30 to ≤60	713	367 (51,5)	715	385 (53,8)	0,95 [0,86; 1,05]	0,349	0,91 [0,74; 1,12]	-2,47 [-7,63; 2,71]	
>60	832	459 (55,2)	824	447 (54,2)	1,02 [0,93; 1,11]	0,723	1,04 [0,85; 1,26]	0,86 [-3,91; 5,64]	
NYHA Group at Baseline									
Class I or II	1027	527 (51,3)	1042	537 (51,5)	1,00 [0,92; 1,08]	0,953	0,99 [0,84; 1,18]	-0,13 [-4,42; 4,16]	0,804
Class III or IV	697	392 (56,2)	676	385 (57,0)	0,98 [0,89; 1,08]	0,675	0,96 [0,77; 1,18]	-1,12 [-6,33; 4,11]	
Use of Sacubitril /Valsartan at Baseline									
Yes	257	125 (48,6)	256	126 (49,2)	0,99 [0,83; 1,18]	0,892	0,98 [0,69; 1,38]	-0,60 [-9,23; 8,05]	0,977
No	1469	794 (54,1)	1461	795 (54,4)	0,99 [0,93; 1,06]	0,820	0,98 [0,85; 1,14]	-0,42 [-4,01; 3,18]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	412	208 (50,5)	416	218 (52,4)	0,96 [0,84; 1,10]	0,567	0,92 [0,70; 1,21]	-1,98 [-8,77; 4,82]	0,469
Q2 (1556 - 2816)	448	230 (51,3)	397	216 (54,4)	0,96 [0,84; 1,09]	0,492	0,91 [0,69; 1,19]	-2,37 [-9,08; 4,35]	
Q3 (2816 - 5314)	400	220 (55,0)	434	223 (51,4)	1,07 [0,94; 1,22]	0,296	1,16 [0,88; 1,52]	3,60 [-3,17; 10,34]	
Q4 (>5314)	406	230 (56,7)	386	217 (56,2)	1,00 [0,89; 1,13]	0,986	1,00 [0,76; 1,33]	0,06 [-6,84; 6,98]	
Baseline Ejection Fraction Group 2									
<35	1375	750 (54,5)	1373	732 (53,3)	1,02 [0,95; 1,09]	0,553	1,05 [0,90; 1,22]	1,13 [-2,59; 4,84]	0,070

LOCF Analysis of Improvement Rate by at least 5 points at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
≥35	351	169 (48,1)	345	190 (55,1)	0,88 [0,76; 1,01]	0,076	0,76 [0,57; 1,03]	-6,74 [-14,10; 0,69]	
Race group									
White	1085	562 (51,8)	1094	593 (54,2)	0,96 [0,88; 1,03]	0,260	0,91 [0,77; 1,07]	-2,41 [-6,59; 1,78]	0,137
Asian	407	208 (51,1)	375	193 (51,5)	0,99 [0,87; 1,14]	0,920	0,99 [0,74; 1,31]	-0,36 [-7,36; 6,64]	
Black	83	48 (57,8)	90	46 (51,1)	1,13 [0,86; 1,49]	0,375	1,31 [0,72; 2,39]	6,72 [-8,14; 21,26]	
Other	151	101 (66,9)	159	90 (56,6)	1,18 [0,99; 1,41]	0,064	1,55 [0,98; 2,46]	10,28 [-0,57; 20,88]	
CCSA class at Randomization									
No Angina	1467	792 (54,0)	1472	797 (54,1)	1,00 [0,93; 1,06]	0,899	0,99 [0,86; 1,15]	-0,23 [-3,82; 3,36]	0,622
Angina Class 1 or 2	223	117 (52,5)	209	111 (53,1)	1,00 [0,84; 1,19]	0,988	1,00 [0,68; 1,46]	-0,07 [-9,41; 9,24]	
Angina Class 3 or 4	36	10 (27,8)	37	14 (37,8)	0,74 [0,35; 1,55]	0,428	0,66 [0,24; 1,81]	-9,38 [-30,84; 13,09]	
Medical History of Diabetes Mellitus									
Yes	837	437 (52,2)	779	426 (54,7)	0,96 [0,87; 1,05]	0,320	0,91 [0,74; 1,10]	-2,46 [-7,29; 2,39]	0,241
No	889	482 (54,2)	939	496 (52,8)	1,02 [0,94; 1,12]	0,574	1,05 [0,88; 1,27]	1,31 [-3,26; 5,88]	

a: Database Cut-off Date: 18JUN2019

b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32

c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)

d: Two-sided p-value for Relative Risk based on Wald test

e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)

f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)

g: P-value from the likelihood ration test for treatment by subgroup interaction

Increase by at least 5 points is defined as change from baseline ≥ 5

Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.8.2 Improvement by at least 15 Points at Week 32

3.8.2.1 Consistency of Treatment Effect – Summary

Table 3.8.2-1
Overview of LOCF Subgroup Analyses for Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Clinical Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ CSS						
Clinical Summary Score	0,883	0,757	0,828	0,583	0,279	0,553

Overview of LOCF Subgroup Analyses for Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Clinical Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ CSS							
Clinical Summary Score	0,807	0,540	0,530	0,120	0,116	0,236	0,110

a: Database Cutoff Date: 18JUN2019

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.8.2.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.8.2-2
LOCF Analysis of Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Age category 1									
<65	678	227 (33,5)	688	235 (34,2)	0,98 [0,85; 1,14]	0,812	0,97 [0,78; 1,22]	-0,61 [-5,64; 4,42]	0,883
≥65	1048	323 (30,8)	1030	328 (31,8)	0,97 [0,85; 1,10]	0,607	0,95 [0,79; 1,15]	-1,04 [-5,00; 2,92]	
Age category 2									
<75	1233	405 (32,8)	1228	412 (33,6)	0,98 [0,88; 1,10]	0,739	0,97 [0,82; 1,15]	-0,63 [-4,35; 3,09]	0,757
≥75	493	145 (29,4)	490	151 (30,8)	0,94 [0,77; 1,13]	0,501	0,91 [0,69; 1,20]	-1,96 [-7,66; 3,75]	
Gender									
Male	1341	417 (31,1)	1335	430 (32,2)	0,97 [0,87; 1,08]	0,553	0,95 [0,81; 1,12]	-1,06 [-4,58; 2,45]	0,828
Female	385	133 (34,5)	383	133 (34,7)	0,99 [0,82; 1,20]	0,924	0,99 [0,73; 1,33]	-0,33 [-7,04; 6,39]	
Geographic Region									
Asia Pacific	414	120 (29,0)	408	110 (27,0)	1,08 [0,86; 1,34]	0,518	1,11 [0,82; 1,50]	2,02 [-4,12; 8,15]	0,583
Eastern Europe	565	188 (33,3)	563	207 (36,8)	0,90 [0,77; 1,06]	0,219	0,86 [0,67; 1,10]	-3,49 [-9,04; 2,08]	
Latin and South America	251	99 (39,4)	253	92 (36,4)	1,08 [0,87; 1,36]	0,477	1,14 [0,80; 1,63]	3,08 [-5,39; 11,51]	
North America	197	49 (24,9)	205	57 (27,8)	0,89 [0,64; 1,24]	0,505	0,86 [0,55; 1,34]	-2,93 [-11,52; 5,72]	
Western Europe	299	94 (31,4)	289	97 (33,6)	0,94 [0,74; 1,18]	0,582	0,91 [0,64; 1,28]	-2,13 [-9,69; 5,44]	
Index Event									
HF Hospitalization 3-6 Months	328	85 (25,9)	300	65 (21,7)	1,22 [0,92; 1,61]	0,175	1,29 [0,89; 1,88]	4,62 [-2,06; 11,22]	0,279
HF Hospitalization within 3 Months	1133	385 (34,0)	1153	419 (36,3)	0,93 [0,84; 1,04]	0,235	0,90 [0,76; 1,07]	-2,37 [-6,27; 1,54]	

LOCF Analysis of Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	265	80 (30,2)	265	79 (29,8)	1,03 [0,80; 1,33]	0,817	1,05 [0,72; 1,52]	0,92 [-6,90; 8,70]	
eGFR (mL/min/1.73 m^2) Category									
≤30	158	47 (29,7)	152	46 (30,3)	0,99 [0,71; 1,38]	0,940	0,98 [0,60; 1,60]	-0,39 [-10,59; 9,82]	0,553
>30 to ≤60	713	219 (30,7)	715	241 (33,7)	0,91 [0,79; 1,06]	0,239	0,87 [0,70; 1,09]	-2,91 [-7,74; 1,94]	
>60	832	276 (33,2)	824	267 (32,4)	1,03 [0,89; 1,18]	0,725	1,04 [0,84; 1,27]	0,81 [-3,70; 5,32]	
NYHA Group at Baseline									
Class I or II	1027	293 (28,5)	1042	311 (29,8)	0,96 [0,84; 1,10]	0,532	0,94 [0,78; 1,14]	-1,25 [-5,15; 2,66]	0,807
Class III or IV	697	257 (36,9)	676	252 (37,3)	0,98 [0,86; 1,13]	0,819	0,97 [0,78; 1,21]	-0,60 [-5,70; 4,51]	
Use of Sacubitril /Valsartan at Baseline									
Yes	257	72 (28,0)	256	68 (26,6)	1,05 [0,80; 1,40]	0,715	1,08 [0,73; 1,59]	1,43 [-6,29; 9,14]	0,540
No	1469	478 (32,5)	1461	495 (33,9)	0,96 [0,87; 1,06]	0,434	0,94 [0,81; 1,10]	-1,36 [-4,76; 2,05]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	412	121 (29,4)	416	124 (29,8)	0,99 [0,80; 1,22]	0,902	0,98 [0,73; 1,32]	-0,39 [-6,61; 5,82]	0,530
Q2 (1556 - 2816)	448	124 (27,7)	397	128 (32,2)	0,88 [0,71; 1,08]	0,207	0,83 [0,61; 1,11]	-3,97 [-10,17; 2,20]	
Q3 (2816 - 5314)	400	130 (32,5)	434	139 (32,0)	1,02 [0,84; 1,24]	0,872	1,02 [0,77; 1,37]	0,52 [-5,80; 6,86]	
Q4 (>5314)	406	154 (37,9)	386	138 (35,8)	1,05 [0,87; 1,26]	0,591	1,08 [0,81; 1,45]	1,85 [-4,89; 8,57]	
Baseline Ejection Fraction Group 2									
<35	1375	462 (33,6)	1373	457 (33,3)	1,01 [0,91; 1,12]	0,891	1,01 [0,86; 1,19]	0,25 [-3,27; 3,76]	0,120

LOCF Analysis of Improvement Rate by at least 15 points at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
≥35	351	88 (25,1)	345	106 (30,7)	0,82 [0,64; 1,04]	0,104	0,76 [0,54; 1,06]	-5,53 [-12,18; 1,15]	
Race group									
White	1085	327 (30,1)	1094	367 (33,5)	0,90 [0,79; 1,02]	0,088	0,85 [0,71; 1,02]	-3,41 [-7,31; 0,51]	0,116
Asian	407	118 (29,0)	375	103 (27,5)	1,06 [0,84; 1,32]	0,636	1,08 [0,79; 1,47]	1,53 [-4,81; 7,82]	
Black	83	33 (39,8)	90	31 (34,4)	1,15 [0,78; 1,70]	0,470	1,26 [0,68; 2,33]	5,31 [-9,06; 19,57]	
Other	151	72 (47,7)	159	62 (39,0)	1,22 [0,95; 1,58]	0,124	1,43 [0,91; 2,24]	8,69 [-2,36; 19,55]	
CCSA class at Randomization									
No Angina	1467	482 (32,9)	1472	484 (32,9)	1,00 [0,90; 1,11]	0,972	1,00 [0,85; 1,16]	-0,06 [-3,45; 3,33]	0,236
Angina Class 1 or 2	223	62 (27,8)	209	68 (32,5)	0,87 [0,65; 1,15]	0,327	0,81 [0,54; 1,23]	-4,34 [-13,04; 4,30]	
Angina Class 3 or 4	36	6 (16,7)	37	11 (29,7)	0,52 [0,21; 1,30]	0,160	0,43 [0,13; 1,39]	-14,71 [-34,34; 5,65]	
Medical History of Diabetes Mellitus									
Yes	837	261 (31,2)	779	271 (34,8)	0,89 [0,78; 1,03]	0,112	0,84 [0,68; 1,04]	-3,70 [-8,27; 0,86]	0,110
No	889	289 (32,5)	939	292 (31,1)	1,05 [0,91; 1,20]	0,520	1,07 [0,88; 1,30]	1,40 [-2,86; 5,67]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Increase by at least 15 points is defined as change from baseline ≥ 15
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.8.3 Deterioration by at least 5 Points at Week 32

3.8.3.1 Consistency of Treatment Effect – Summary

Table 3.8.3-1
Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Clinical Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ CSS						
Clinical Summary Score	0,523	0,620	0,793	0,201	0,709	**0,012[b]**

Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Clinical Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ CSS							
Clinical Summary Score	0,965	0,730	0,346	0,906	0,257	0,561	0,136

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.8.3.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.8.3-2
LOCF Analysis of Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction[g] Test**
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	
Age category 1									
<65	678	151 (22,3)	688	177 (25,7)	0,87 [0,72; 1,05]	0,152	0,83 [0,65; 1,07]	-3,32 [-7,85; 1,22]	0,523
≥65	1048	263 (25,1)	1030	275 (26,7)	0,94 [0,81; 1,09]	0,409	0,92 [0,76; 1,12]	-1,59 [-5,35; 2,18]	
Age category 2									
<75	1233	290 (23,5)	1228	322 (26,2)	0,90 [0,78; 1,03]	0,123	0,87 [0,72; 1,04]	-2,69 [-6,10; 0,73]	0,620
≥75	493	124 (25,2)	490	130 (26,5)	0,96 [0,78; 1,19]	0,726	0,95 [0,71; 1,27]	-0,98 [-6,44; 4,49]	
Gender									
Male	1341	325 (24,2)	1335	357 (26,7)	0,91 [0,80; 1,03]	0,138	0,88 [0,74; 1,04]	-2,50 [-5,81; 0,80]	0,793
Female	385	89 (23,1)	383	95 (24,8)	0,93 [0,73; 1,20]	0,599	0,91 [0,66; 1,27]	-1,63 [-7,68; 4,43]	
Geographic Region									
Asia Pacific	414	107 (25,8)	408	111 (27,2)	0,95 [0,76; 1,19]	0,659	0,93 [0,68; 1,27]	-1,36 [-7,40; 4,68]	0,201
Eastern Europe	565	120 (21,2)	563	143 (25,4)	0,84 [0,68; 1,03]	0,099	0,79 [0,60; 1,04]	-4,16 [-9,09; 0,78]	
Latin and South America	251	47 (18,7)	253	68 (26,9)	0,70 [0,50; 0,97]	0,031	0,63 [0,41; 0,96]	-8,15 [-15,45; -0,82]	
North America	197	62 (31,5)	205	61 (29,8)	1,06 [0,79; 1,42]	0,709	1,08 [0,71; 1,66]	1,72 [-7,29; 10,73]	
Western Europe	299	78 (26,1)	289	69 (23,9)	1,09 [0,83; 1,45]	0,536	1,13 [0,77; 1,64]	2,21 [-4,81; 9,20]	
Index Event									
HF Hospitalization 3-6 Months	328	88 (26,8)	300	95 (31,7)	0,85 [0,67; 1,09]	0,194	0,80 [0,56; 1,12]	-4,73 [-11,88; 2,40]	0,709
HF Hospitalization within 3 Months	1133	266 (23,5)	1153	287 (24,9)	0,94 [0,82; 1,09]	0,429	0,93 [0,76; 1,12]	-1,42 [-4,93; 2,09]	

LOCF Analysis of Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	265	60 (22,6)	265	70 (26,4)	0,86 [0,64; 1,16]	0,321	0,82 [0,55; 1,22]	-3,72 [-11,08; 3,64]	
NYHA Group at Baseline									
Class I or II	1027	249 (24,2)	1042	277 (26,6)	0,91 [0,79; 1,06]	0,218	0,88 [0,72; 1,08]	-2,36 [-6,11; 1,39]	0,965
Class III or IV	697	164 (23,5)	676	175 (25,9)	0,92 [0,77; 1,11]	0,388	0,90 [0,70; 1,15]	-2,00 [-6,57; 2,55]	
Use of Sacubitril /Valsartan at Baseline									
Yes	257	70 (27,2)	256	79 (30,9)	0,87 [0,67; 1,14]	0,323	0,83 [0,56; 1,21]	-3,97 [-11,84; 3,93]	0,730
No	1469	344 (23,4)	1461	373 (25,5)	0,92 [0,81; 1,04]	0,192	0,89 [0,75; 1,06]	-2,07 [-5,19; 1,04]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	412	88 (21,4)	416	97 (23,3)	0,93 [0,72; 1,20]	0,560	0,91 [0,65; 1,26]	-1,69 [-7,40; 4,01]	0,346
Q2 (1556 - 2816)	448	94 (21,0)	397	105 (26,4)	0,77 [0,60; 0,98]	0,034	0,71 [0,51; 0,97]	-6,17 [-11,90; -0,48]	
Q3 (2816 - 5314)	400	102 (25,5)	434	127 (29,3)	0,87 [0,70; 1,09]	0,221	0,83 [0,61; 1,12]	-3,80 [-9,82; 2,29]	
Q4 (>5314)	406	113 (27,8)	386	104 (26,9)	1,04 [0,83; 1,30]	0,742	1,05 [0,77; 1,44]	1,05 [-5,21; 7,27]	
Baseline Ejection Fraction Group 2									
<35	1375	326 (23,7)	1373	356 (25,9)	0,92 [0,80; 1,04]	0,190	0,89 [0,75; 1,06]	-2,16 [-5,38; 1,07]	0,906
≥35	351	88 (25,1)	345	96 (27,8)	0,89 [0,70; 1,15]	0,375	0,86 [0,61; 1,20]	-2,98 [-9,53; 3,58]	
Race group									
White	1085	266 (24,5)	1094	289 (26,4)	0,93 [0,80; 1,07]	0,309	0,90 [0,75; 1,10]	-1,90 [-5,56; 1,76]	0,257
Asian	407	103 (25,3)	375	94 (25,1)	1,01 [0,79; 1,29]	0,938	1,01 [0,73; 1,40]	0,24 [-5,88; 6,32]	

LOCF Analysis of Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction[g] Test**
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	
Black	83	19 (22,9)	90	25 (27,8)	0,82 [0,49; 1,38]	0,463	0,77 [0,39; 1,54]	-4,89 [-17,76; 8,25]	
Other	151	26 (17,2)	159	44 (27,7)	0,62 [0,40; 0,96]	0,031	0,54 [0,31; 0,94]	-10,45 [-19,65; -1,15]	
CCSA class at Randomization									
No Angina	1467	351 (23,9)	1472	379 (25,7)	0,93 [0,82; 1,06]	0,270	0,91 [0,77; 1,08]	-1,76 [-4,88; 1,37]	0,561
Angina Class 1 or 2	223	51 (22,9)	209	55 (26,3)	0,85 [0,61; 1,19]	0,354	0,81 [0,52; 1,26]	-3,85 [-12,04; 4,31]	
Angina Class 3 or 4	36	12 (33,3)	37	18 (48,6)	0,64 [0,34; 1,21]	0,170	0,49 [0,19; 1,29]	-17,80 [-39,80; 6,21]	
Medical History of Diabetes Mellitus									
Yes	837	218 (26,0)	779	203 (26,1)	1,00 [0,85; 1,18]	0,989	1,00 [0,80; 1,25]	-0,03 [-4,32; 4,24]	0,136
No	889	196 (22,0)	939	249 (26,5)	0,83 [0,71; 0,98]	0,028	0,79 [0,63; 0,97]	-4,44 [-8,36; -0,50]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Decrease by at least 5 points is defined as change from baseline ≤ -5
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.8.3.3 Results for Subgroups With Interaction P-value < 0.05

Table 3.8.3-3
LOCF Analysis of Deterioration Rate by at least 5 points at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test < 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
eGFR (mL/min/1.73 m^2) Category									
≤30	158	46 (29,1)	152	44 (28,9)	1,00 [0,70; 1,42]	0,991	1,00 [0,61; 1,63]	-0,06 [-10,21; 10,11]	0,012
>30 to ≤60	713	196 (27,5)	715	181 (25,3)	1,09 [0,92; 1,30]	0,317	1,13 [0,89; 1,43]	2,33 [-2,23; 6,90]	
>60	832	169 (20,3)	824	220 (26,7)	0,76 [0,64; 0,91]	0,002	0,70 [0,56; 0,88]	-6,35 [-10,43; -2,27]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Decrease by at least 5 points is defined as change from baseline ≤ -5
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.8.4 Deterioration by at least 15 Points at Week 32

3.8.4.1 Consistency of Treatment Effect – Summary

Table 3.8.4-1
Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Clinical Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**					
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 30 / >30 to ≤ 60 / >60)**
KCCQ CSS						
Clinical Summary Score	0,331	0,403	0,974	0,372	0,777	**< 0,001[b]**

Overview of LOCF Subgroup Analyses for Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Clinical Summary Score, Treatment by Subgroup Interactions
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests**						
	NYHA Group at Baseline (Class I or II / Class III or IV)	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**	**NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))**	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**
KCCQ CSS							
Clinical Summary Score	0,248	0,855	**0,047[b]**	0,548	0,232	0,660	0,166

a: Database Cutoff Date: 18JUN2019

b: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

3.8.4.2 Results for Subgroups With Interaction P-value ≥ 0.05

Table 3.8.4-2
LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Age category 1									
<65	678	74 (10,9)	688	92 (13,4)	0,82 [0,61; 1,09]	0,164	0,79 [0,57; 1,10]	-2,47 [-5,97; 1,01]	0,331
≥65	1048	130 (12,4)	1030	131 (12,7)	0,98 [0,78; 1,23]	0,841	0,97 [0,75; 1,26]	-0,29 [-3,15; 2,57]	
Age category 2									
<75	1233	142 (11,5)	1228	163 (13,3)	0,87 [0,70; 1,07]	0,191	0,85 [0,67; 1,08]	-1,74 [-4,36; 0,87]	0,403
≥75	493	62 (12,6)	490	60 (12,2)	1,03 [0,74; 1,43]	0,878	1,03 [0,70; 1,51]	0,32 [-3,84; 4,50]	
Gender									
Male	1341	160 (11,9)	1335	175 (13,1)	0,91 [0,74; 1,11]	0,353	0,90 [0,71; 1,13]	-1,19 [-3,71; 1,32]	0,974
Female	385	44 (11,4)	383	48 (12,5)	0,92 [0,62; 1,35]	0,660	0,91 [0,59; 1,40]	-1,03 [-5,71; 3,59]	
Geographic Region									
Asia Pacific	414	51 (12,3)	408	48 (11,8)	1,05 [0,72; 1,52]	0,807	1,05 [0,69; 1,60]	0,55 [-3,94; 5,05]	0,372
Eastern Europe	565	54 (9,6)	563	70 (12,4)	0,77 [0,55; 1,07]	0,124	0,74 [0,51; 1,08]	-2,88 [-6,58; 0,78]	
Latin and South America	251	25 (10,0)	253	37 (14,6)	0,68 [0,42; 1,10]	0,114	0,65 [0,38; 1,11]	-4,66 [-10,52; 1,10]	
North America	197	30 (15,2)	205	29 (14,1)	1,08 [0,67; 1,72]	0,759	1,09 [0,63; 1,89]	1,08 [-5,91; 8,14]	
Western Europe	299	44 (14,7)	289	39 (13,5)	1,09 [0,73; 1,63]	0,671	1,11 [0,69; 1,76]	1,22 [-4,47; 6,90]	
Index Event									
HF Hospitalization 3-6 Months	328	46 (14,0)	300	51 (17,0)	0,83 [0,58; 1,20]	0,322	0,80 [0,52; 1,24]	-2,87 [-8,66; 2,81]	0,777
HF Hospitalization within 3 Months	1133	128 (11,3)	1153	137 (11,9)	0,95 [0,76; 1,19]	0,645	0,94 [0,73; 1,22]	-0,62 [-3,25; 2,02]	

LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
IV diuretic for HF (without hospitalization) within 3 Months	265	30 (11,3)	265	35 (13,2)	0,88 [0,56; 1,39]	0,578	0,86 [0,51; 1,46]	-1,58 [-7,29; 4,09]	
NYHA Group at Baseline									
Class I or II	1027	114 (11,1)	1042	139 (13,3)	0,83 [0,66; 1,05]	0,119	0,81 [0,62; 1,06]	-2,25 [-5,09; 0,58]	0,248
Class III or IV	697	89 (12,8)	676	84 (12,4)	1,03 [0,78; 1,36]	0,844	1,03 [0,75; 1,42]	0,35 [-3,19; 3,89]	
Use of Sacubitril /Valsartan at Baseline									
Yes	257	33 (12,8)	256	37 (14,5)	0,87 [0,56; 1,34]	0,529	0,85 [0,51; 1,41]	-1,91 [-7,93; 4,11]	0,855
No	1469	171 (11,6)	1461	186 (12,7)	0,92 [0,75; 1,11]	0,378	0,91 [0,73; 1,13]	-1,07 [-3,45; 1,31]	
Baseline Ejection Fraction Group 2									
<35	1375	162 (11,8)	1373	173 (12,6)	0,94 [0,77; 1,14]	0,514	0,93 [0,74; 1,16]	-0,81 [-3,27; 1,64]	0,548
≥35	351	42 (12,0)	345	50 (14,5)	0,82 [0,56; 1,20]	0,302	0,79 [0,51; 1,23]	-2,65 [-7,77; 2,41]	
Race group									
White	1085	134 (12,4)	1094	146 (13,3)	0,93 [0,74; 1,15]	0,488	0,91 [0,71; 1,18]	-1,00 [-3,82; 1,82]	0,232
Asian	407	50 (12,3)	375	41 (10,9)	1,12 [0,76; 1,66]	0,556	1,14 [0,74; 1,77]	1,35 [-3,21; 5,88]	
Black	83	8 (9,6)	90	12 (13,3)	0,72 [0,31; 1,68]	0,451	0,69 [0,27; 1,79]	-3,69 [-13,63; 6,28]	
Other	151	12 (7,9)	159	24 (15,1)	0,53 [0,27; 1,01]	0,055	0,49 [0,23; 1,01]	-7,15 [-14,48; -0,00]	
CCSA class at Randomization									
No Angina	1467	178 (12,1)	1472	190 (12,9)	0,94 [0,78; 1,14]	0,526	0,93 [0,75; 1,16]	-0,77 [-3,17; 1,62]	0,660
Angina Class 1 or 2	223	22 (9,9)	209	28 (13,4)	0,71 [0,41; 1,23]	0,221	0,69 [0,38; 1,25]	-3,86 [-10,14; 2,28]	

LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test ≥ 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
Angina Class 3 or 4	36	4 (11,1)	37	5 (13,5)	0,84 [0,24; 2,89]	0,784	0,82 [0,19; 3,44]	-2,22 [-19,28; 15,33]	
Medical History of Diabetes Mellitus									
Yes	837	116 (13,9)	779	105 (13,5)	1,02 [0,80; 1,31]	0,855	1,03 [0,77; 1,36]	0,31 [-3,07; 3,67]	0,166
No	889	88 (9,9)	939	118 (12,6)	0,79 [0,61; 1,02]	0,073	0,76 [0,57; 1,03]	-2,66 [-5,57; 0,24]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Decrease by at least 15 points is defined as change from baseline ≤ -15
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

3.8.4.3 Results for Subgroups With Interaction P-value < 0.05

Table 3.8.4-3
LOCF Analysis of Deterioration Rate by at least 15 points at Week 32 as Measured by KCCQ: Clinical Summary Score
For Subgroups with P-value for Interaction test < 0.05
All Subjects as Treated Population
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
KCCQ CSS	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Relative Risk[c] [95 %-CI]**	**p-Value[d]**	**Odds Ratio[e] [95 %-CI]**	**Risk Difference[f] [95 %-CI]**	**p-Value for Interaction[g] Test**
eGFR (mL/min/1.73 m^2) Category									
≤30	158	23 (14,6)	152	20 (13,2)	1,09 [0,62; 1,92]	0,755	1,11 [0,58; 2,11]	1,23 [-6,72; 9,10]	0,001
>30 to ≤60	713	112 (15,7)	715	91 (12,7)	1,24 [0,96; 1,60]	0,098	1,29 [0,95; 1,74]	3,06 [-0,56; 6,72]	
>60	832	66 (7,9)	824	108 (13,1)	0,60 [0,45; 0,81]	< 0,001	0,57 [0,41; 0,79]	-5,22 [-8,22; -2,28]	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	412	34 (8,3)	416	44 (10,6)	0,80 [0,52; 1,22]	0,297	0,78 [0,49; 1,25]	-2,12 [-6,19; 1,90]	0,047
Q2 (1556 - 2816)	448	39 (8,7)	397	48 (12,1)	0,70 [0,47; 1,04]	0,078	0,67 [0,43; 1,05]	-3,70 [-7,96; 0,40]	
Q3 (2816 - 5314)	400	48 (12,0)	434	69 (15,9)	0,76 [0,54; 1,07]	0,117	0,73 [0,49; 1,08]	-3,79 [-8,50; 0,95]	
Q4 (>5314)	406	72 (17,7)	386	53 (13,7)	1,28 [0,92; 1,76]	0,141	1,34 [0,91; 1,97]	3,85 [-1,27; 8,94]	

a: Database Cut-off Date: 18JUN2019
b: Number of participants with non-missing assessment at baseline and at least one post-baseline assessment through Week 32
c: Mantel-Haenszel Relative Risk, stratified by stratification factor (defined by region and race)
d: Two-sided p-value for Relative Risk based on Wald test
e: Estimated from logistic regression model, stratified by stratification factor (defined by region and race)
f: Miettinen and Nurminen method stratified by stratification factor (defined by region and race)
g: P-value from the likelihood ration test for treatment by subgroup interaction
Decrease by at least 15 points is defined as change from baseline ≤ -15
Baseline is defined as last observation before treatment start; week 32 analysis visit is calculated relatively to treatment start
CCSA: Canadian Cardiovascular Society Functional Classification of Angina; CI: Confidence Interval; eGFR: Estimated glomerular filtration rate; HF: Heart failure; KCCQ: Kansas City Cardiomyopathy Questionnaire; LOCF: Last Observation Carried Forward; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association

SAFETY

1.1 Adverse Event Endpoints

Table 4
Overall Adverse Event Related Endpoints
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**			
	Vericiguat (N[b]=2152)	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**
AE	1726 (80.2)	1741 (80.9)	-0.73 [-3.10; 1.63]	0.95 [0.82; 1.11]	0.99 [0.96; 1.02]	0.543
Serious AE	702 (32.6)	743 (34.5)	-1.92 [-4.74; 0.90]	0.92 [0.81; 1.04]	0.94 [0.87; 1.03]	0.182
Mild AE	1441 (67.0)	1459 (67.8)	-0.87 [-3.67; 1.93]	0.96 [0.85; 1.09]	0.99 [0.95; 1.03]	0.544
Moderate AE	941 (43.7)	954 (44.4)	-0.62 [-3.59; 2.34]	0.97 [0.86; 1.10]	0.99 [0.92; 1.05]	0.680
Severe AE	701 (32.6)	728 (33.8)	-1.27 [-4.08; 1.54]	0.94 [0.83; 1.07]	0.96 [0.88; 1.05]	0.376
AE resulting to death	71 (3.3)	70 (3.3)	0.04 [-1.03; 1.12]	1.01 [0.73; 1.42]	1.01 [0.73; 1.40]	0.934
AE leading to treatment discontinuation	139 (6.5)	134 (6.2)	0.23 [-1.23; 1.70]	1.04 [0.81; 1.33]	1.04 [0.82; 1.30]	0.758

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

AE: Adverse Events; CI: Confidence Interval.

1.2 Adverse Event by SOC and PT Endpoints

1.2.1 Adverse Events by SOC and PT

Table 5
Adverse Events by System Organ Class and Preferred Term
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Blood and lymphatic system disorders	223 (10.4)	170 (7.9)	2.46 [0.74; 4.19]	1.35 [1.09; 1.66]	1.31 [1.08; 1.59]	0.005	0.116
Anaemia	156 (7.2)	112 (5.2)	2.04 [0.60; 3.50]	1.42 [1.11; 1.83]	1.39 [1.10; 1.76]	0.006	n.s.
Thrombocytopenia	20 (0.9)	25 (1.2)	-0.23 [-0.87; 0.39]	0.80 [0.44; 1.44]	0.80 [0.44; 1.44]	0.453	n.s.
Cardiac disorders	504 (23.4)	568 (26.4)	-2.99 [-5.57; -0.40]	0.85 [0.74; 0.98]	0.89 [0.80; 0.98]	0.024	0.177
Angina pectoris	23 (1.1)	22 (1.0)	0.05 [-0.58; 0.68]	1.05 [0.58; 1.88]	1.04 [0.58; 1.87]	0.882	n.s.
Atrial fibrillation	75 (3.5)	82 (3.8)	-0.33 [-1.46; 0.80]	0.91 [0.66; 1.25]	0.91 [0.67; 1.24]	0.567	n.s.
Atrial flutter	18 (0.8)	25 (1.2)	-0.33 [-0.96; 0.28]	0.72 [0.39; 1.31]	0.72 [0.39; 1.31]	0.283	n.s.
Bradycardia	17 (0.8)	24 (1.1)	-0.33 [-0.94; 0.27]	0.71 [0.38; 1.31]	0.71 [0.38; 1.31]	0.271	n.s.
Cardiac failure	192 (8.9)	231 (10.7)	-1.82 [-3.61; -0.04]	0.81 [0.67; 1.00]	0.83 [0.69; 1.00]	0.046	n.s.
Cardiac failure chronic	17 (0.8)	32 (1.5)	-0.70 [-1.38; -0.07]	0.54 [0.31; 0.95]	0.54 [0.31; 0.95]	0.031	n.s.
Cardiac failure congestive	30 (1.4)	42 (2.0)	-0.56 [-1.36; 0.21]	0.71 [0.44; 1.14]	0.71 [0.45; 1.14]	0.155	n.s.
Palpitations	29 (1.3)	23 (1.1)	0.28 [-0.39; 0.96]	1.26 [0.73; 2.19]	1.26 [0.73; 2.17]	0.405	n.s.
Ventricular extrasystoles	25 (1.2)	21 (1.0)	0.19 [-0.45; 0.83]	1.19 [0.67; 2.13]	1.19 [0.67; 2.13]	0.554	n.s.
Ventricular tachycardia	35 (1.6)	55 (2.6)	-0.93 [-1.82; -0.08]	0.63 [0.41; 0.97]	0.64 [0.42; 0.97]	0.035	n.s.
Ear and labyrinth disorders	60 (2.8)	46 (2.1)	0.65 [-0.28; 1.60]	1.31 [0.89; 1.94]	1.30 [0.89; 1.91]	0.171	0.541
Vertigo	32 (1.5)	36 (1.7)	-0.19 [-0.96; 0.57]	0.89 [0.55; 1.43]	0.89 [0.55; 1.43]	0.624	n.s.
Endocrine disorders	55 (2.6)	49 (2.3)	0.28 [-0.65; 1.21]	1.13 [0.76; 1.66]	1.12 [0.77; 1.64]	0.553	0.936

Adverse Events by System Organ Class and Preferred Term
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Hypothyroidism	30 (1.4)	29 (1.3)	0.05 [-0.67; 0.76]	1.03 [0.62; 1.73]	1.03 [0.62; 1.72]	0.897	n.s.
Eye disorders	74 (3.4)	84 (3.9)	-0.47 [-1.61; 0.66]	0.88 [0.64; 1.20]	0.88 [0.65; 1.20]	0.416	0.767
Gastrointestinal disorders	537 (25.0)	474 (22.0)	2.92 [0.38; 5.45]	1.18 [1.02; 1.35]	1.13 [1.02; 1.26]	0.024	0.177
Abdominal pain	30 (1.4)	27 (1.3)	0.14 [-0.56; 0.85]	1.11 [0.66; 1.88]	1.11 [0.66; 1.86]	0.691	n.s.
Abdominal pain upper	33 (1.5)	26 (1.2)	0.32 [-0.38; 1.05]	1.27 [0.76; 2.14]	1.27 [0.76; 2.11]	0.361	n.s.
Constipation	68 (3.2)	63 (2.9)	0.23 [-0.81; 1.27]	1.08 [0.76; 1.53]	1.08 [0.77; 1.51]	0.659	n.s.
Diarrhoea	107 (5.0)	116 (5.4)	-0.42 [-1.76; 0.91]	0.92 [0.70; 1.20]	0.92 [0.71; 1.19]	0.534	n.s.
Dyspepsia	55 (2.6)	25 (1.2)	1.39 [0.60; 2.24]	2.23 [1.38; 3.59]	2.20 [1.38; 3.51]	< 0.001	n.s.
Gastritis	20 (0.9)	25 (1.2)	-0.23 [-0.87; 0.39]	0.80 [0.44; 1.44]	0.80 [0.44; 1.44]	0.453	n.s.
Gastrooesophageal reflux disease	39 (1.8)	15 (0.7)	1.11 [0.47; 1.83]	2.46 [1.44; 4.20]	2.46 [1.44; 4.20]	0.001	n.s.
Nausea	82 (3.8)	60 (2.8)	1.02 [-0.05; 2.11]	1.38 [0.98; 1.94]	1.37 [0.98; 1.90]	0.062	n.s.
Vomiting	50 (2.3)	44 (2.0)	0.28 [-0.61; 1.17]	1.14 [0.76; 1.72]	1.14 [0.76; 1.70]	0.533	n.s.
General disorders and administration site conditions	321 (14.9)	340 (15.8)	-0.89 [-3.05; 1.27]	0.93 [0.79; 1.10]	0.94 [0.82; 1.09]	0.418	0.767
Asthenia	41 (1.9)	47 (2.2)	-0.28 [-1.15; 0.58]	0.87 [0.57; 1.33]	0.87 [0.58; 1.32]	0.517	n.s.
Chest pain	50 (2.3)	66 (3.1)	-0.74 [-1.74; 0.23]	0.75 [0.52; 1.09]	0.76 [0.53; 1.09]	0.133	n.s.
Fatigue	41 (1.9)	42 (2.0)	-0.05 [-0.89; 0.79]	0.98 [0.63; 1.51]	0.98 [0.64; 1.49]	0.910	n.s.
Oedema peripheral	82 (3.8)	80 (3.7)	0.09 [-1.06; 1.24]	1.03 [0.75; 1.40]	1.02 [0.76; 1.39]	0.875	n.s.
Peripheral swelling	25 (1.2)	18 (0.8)	0.32 [-0.28; 0.96]	1.39 [0.76; 2.53]	1.39 [0.76; 2.53]	0.284	n.s.

Adverse Events by System Organ Class and Preferred Term
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Pyrexia	29 (1.3)	30 (1.4)	-0.05 [-0.76; 0.67]	0.97 [0.58; 1.61]	0.97 [0.58; 1.60]	0.894	n.s.
Hepatobiliary disorders	110 (5.1)	103 (4.8)	0.32 [-0.98; 1.63]	1.07 [0.81; 1.41]	1.07 [0.82; 1.39]	0.625	0.958
Infections and infestations	745 (34.6)	743 (34.5)	0.08 [-2.77; 2.92]	1.00 [0.88; 1.14]	1.00 [0.92; 1.09]	0.958	0.958
Bronchitis	71 (3.3)	89 (4.1)	-0.84 [-1.99; 0.30]	0.79 [0.58; 1.09]	0.80 [0.59; 1.08]	0.147	n.s.
Cellulitis	45 (2.1)	39 (1.8)	0.28 [-0.56; 1.13]	1.16 [0.75; 1.78]	1.15 [0.75; 1.76]	0.510	n.s.
Gastroenteritis	36 (1.7)	31 (1.4)	0.23 [-0.52; 1.00]	1.16 [0.72; 1.89]	1.16 [0.72; 1.87]	0.540	n.s.
Influenza	65 (3.0)	49 (2.3)	0.74 [-0.22; 1.73]	1.34 [0.92; 1.95]	1.33 [0.92; 1.91]	0.131	n.s.
Lower respiratory tract infection	29 (1.3)	32 (1.5)	-0.14 [-0.87; 0.58]	0.90 [0.55; 1.50]	0.91 [0.55; 1.49]	0.698	n.s.
Nasopharyngitis	102 (4.7)	103 (4.8)	-0.05 [-1.33; 1.23]	0.99 [0.75; 1.31]	0.99 [0.76; 1.29]	0.940	n.s.
Pneumonia	135 (6.3)	157 (7.3)	-1.03 [-2.54; 0.48]	0.85 [0.67; 1.08]	0.86 [0.69; 1.07]	0.182	n.s.
Respiratory tract infection	27 (1.3)	32 (1.5)	-0.23 [-0.96; 0.48]	0.84 [0.50; 1.41]	0.84 [0.51; 1.40]	0.512	n.s.
Sepsis	19 (0.9)	26 (1.2)	-0.33 [-0.97; 0.29]	0.73 [0.41; 1.31]	0.73 [0.41; 1.31]	0.294	n.s.
Upper respiratory tract infection	108 (5.0)	100 (4.6)	0.37 [-0.92; 1.66]	1.08 [0.82; 1.43]	1.08 [0.83; 1.41]	0.572	n.s.
Urinary tract infection	79 (3.7)	81 (3.8)	-0.09 [-1.24; 1.05]	0.97 [0.71; 1.34]	0.97 [0.72; 1.32]	0.870	n.s.
Injury, poisoning and procedural complications	266 (12.4)	270 (12.6)	-0.19 [-2.17; 1.79]	0.98 [0.82; 1.18]	0.98 [0.84; 1.15]	0.849	0.958
Accidental overdose	58 (2.7)	40 (1.9)	0.84 [-0.06; 1.76]	1.46 [0.97; 2.20]	1.45 [0.97; 2.16]	0.068	n.s.
Contusion	18 (0.8)	27 (1.3)	-0.42 [-1.07; 0.20]	0.67 [0.37; 1.20]	0.67 [0.37; 1.20]	0.177	n.s.
Fall	51 (2.4)	51 (2.4)	-0.00 [-0.93; 0.92]	1.00 [0.67; 1.48]	1.00 [0.68; 1.47]	0.998	n.s.

Adverse Events by System Organ Class and Preferred Term
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(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Investigations	317 (14.7)	348 (16.2)	-1.45 [-3.61; 0.71]	0.90 [0.76; 1.06]	0.91 [0.79; 1.05]	0.189	0.541
Blood bilirubin increased	14 (0.7)	23 (1.1)	-0.42 [-1.02; 0.14]	0.61 [0.32; 1.17]	0.61 [0.32; 1.17]	0.137	n.s.
Blood creatinine increased	45 (2.1)	46 (2.1)	-0.05 [-0.92; 0.83]	0.98 [0.65; 1.48]	0.98 [0.65; 1.47]	0.914	n.s.
Blood potassium increased	20 (0.9)	22 (1.0)	-0.09 [-0.71; 0.52]	0.91 [0.49; 1.67]	0.91 [0.49; 1.67]	0.755	n.s.
Blood uric acid increased	26 (1.2)	32 (1.5)	-0.28 [-1.00; 0.42]	0.81 [0.48; 1.36]	0.81 [0.49; 1.36]	0.427	n.s.
Gamma-glutamyltransferase increased	42 (2.0)	58 (2.7)	-0.74 [-1.67; 0.16]	0.72 [0.48; 1.07]	0.72 [0.49; 1.07]	0.107	n.s.
Glycosylated haemoglobin increased	20 (0.9)	26 (1.2)	-0.28 [-0.93; 0.35]	0.77 [0.43; 1.37]	0.77 [0.43; 1.37]	0.373	n.s.
Weight decreased	27 (1.3)	22 (1.0)	0.23 [-0.42; 0.90]	1.23 [0.70; 2.17]	1.23 [0.70; 2.15]	0.474	n.s.
Weight increased	38 (1.8)	45 (2.1)	-0.33 [-1.17; 0.51]	0.84 [0.54; 1.30]	0.84 [0.55; 1.29]	0.437	n.s.
Metabolism and nutrition disorders	470 (21.8)	523 (24.3)	-2.47 [-4.99; 0.04]	0.87 [0.75; 1.00]	0.90 [0.81; 1.00]	0.054	0.239
Decreased appetite	34 (1.6)	29 (1.3)	0.23 [-0.50; 0.98]	1.17 [0.71; 1.93]	1.17 [0.72; 1.92]	0.527	n.s.
Dehydration	29 (1.3)	43 (2.0)	-0.65 [-1.45; 0.12]	0.67 [0.42; 1.08]	0.67 [0.42; 1.08]	0.098	n.s.
Diabetes mellitus	37 (1.7)	47 (2.2)	-0.47 [-1.32; 0.37]	0.78 [0.51; 1.21]	0.79 [0.51; 1.21]	0.271	n.s.
Gout	75 (3.5)	87 (4.0)	-0.56 [-1.71; 0.58]	0.86 [0.63; 1.17]	0.86 [0.64; 1.17]	0.336	n.s.
Hyperglycaemia	24 (1.1)	20 (0.9)	0.19 [-0.43; 0.82]	1.20 [0.66; 2.18]	1.20 [0.66; 2.18]	0.546	n.s.
Hyperkalaemia	95 (4.4)	118 (5.5)	-1.07 [-2.38; 0.23]	0.80 [0.60; 1.05]	0.80 [0.62; 1.05]	0.106	n.s.
Hyperuricaemia	66 (3.1)	56 (2.6)	0.46 [-0.54; 1.47]	1.18 [0.82; 1.70]	1.18 [0.83; 1.67]	0.360	n.s.
Hypoglycaemia	34 (1.6)	32 (1.5)	0.09 [-0.66; 0.85]	1.06 [0.65; 1.73]	1.06 [0.66; 1.71]	0.806	n.s.

Adverse Events by System Organ Class and Preferred Term
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Hypokalaemia	76 (3.5)	77 (3.6)	-0.05 [-1.17; 1.07]	0.99 [0.71; 1.36]	0.99 [0.72; 1.35]	0.932	n.s.
Hyponatraemia	23 (1.1)	42 (2.0)	-0.88 [-1.65; -0.16]	0.54 [0.33; 0.91]	0.55 [0.33; 0.91]	0.019	n.s.
Musculoskeletal and connective tissue disorders	271 (12.6)	295 (13.7)	-1.12 [-3.15; 0.90]	0.91 [0.76; 1.08]	0.92 [0.79; 1.07]	0.277	0.676
Arthralgia	43 (2.0)	46 (2.1)	-0.14 [-1.01; 0.72]	0.93 [0.61; 1.42]	0.93 [0.62; 1.41]	0.746	n.s.
Back pain	52 (2.4)	50 (2.3)	0.09 [-0.83; 1.02]	1.04 [0.70; 1.54]	1.04 [0.71; 1.53]	0.843	n.s.
Muscle spasms	27 (1.3)	25 (1.2)	0.09 [-0.58; 0.77]	1.08 [0.63; 1.87]	1.08 [0.63; 1.85]	0.782	n.s.
Musculoskeletal pain	22 (1.0)	29 (1.3)	-0.33 [-1.01; 0.33]	0.76 [0.43; 1.32]	0.76 [0.44; 1.32]	0.325	n.s.
Pain in extremity	41 (1.9)	44 (2.0)	-0.14 [-0.99; 0.71]	0.93 [0.61; 1.43]	0.93 [0.61; 1.42]	0.741	n.s.
Neoplasms benign, malignant and unspecified (incl cysts and	64 (3.0)	65 (3.0)	-0.05 [-1.08; 0.98]	0.98 [0.69; 1.40]	0.98 [0.70; 1.38]	0.927	0.958
Nervous system disorders	400 (18.6)	378 (17.6)	1.01 [-1.29; 3.32]	1.07 [0.92; 1.25]	1.06 [0.93; 1.20]	0.388	0.767
Dizziness	141 (6.6)	130 (6.0)	0.51 [-0.95; 1.97]	1.09 [0.85; 1.39]	1.08 [0.86; 1.37]	0.493	n.s.
Headache	74 (3.4)	55 (2.6)	0.88 [-0.14; 1.92]	1.36 [0.95; 1.93]	1.34 [0.95; 1.90]	0.091	n.s.
Syncope	89 (4.1)	80 (3.7)	0.42 [-0.75; 1.59]	1.12 [0.82; 1.52]	1.11 [0.83; 1.50]	0.482	n.s.
Psychiatric disorders	91 (4.2)	121 (5.6)	-1.40 [-2.71; -0.10]	0.74 [0.56; 0.98]	0.75 [0.58; 0.98]	0.035	0.193
Insomnia	30 (1.4)	46 (2.1)	-0.74 [-1.57; 0.04]	0.65 [0.41; 1.03]	0.65 [0.41; 1.03]	0.066	n.s.
Renal and urinary disorders	374 (17.4)	379 (17.6)	-0.24 [-2.51; 2.03]	0.98 [0.84; 1.15]	0.99 [0.87; 1.12]	0.836	0.958
Acute kidney injury	118 (5.5)	112 (5.2)	0.28 [-1.07; 1.63]	1.06 [0.81; 1.38]	1.05 [0.82; 1.35]	0.687	n.s.
Chronic kidney disease	77 (3.6)	77 (3.6)	-0.00 [-1.12; 1.12]	1.00 [0.72; 1.38]	1.00 [0.73; 1.36]	0.998	n.s.

Adverse Events by System Organ Class and Preferred Term
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Renal failure	77 (3.6)	72 (3.3)	0.23 [-0.87; 1.34]	1.07 [0.77; 1.49]	1.07 [0.78; 1.47]	0.679	n.s.
Renal impairment	56 (2.6)	59 (2.7)	-0.14 [-1.12; 0.84]	0.95 [0.65; 1.37]	0.95 [0.66; 1.36]	0.775	n.s.
Reproductive system and breast disorders	72 (3.3)	73 (3.4)	-0.05 [-1.14; 1.04]	0.99 [0.71; 1.37]	0.99 [0.72; 1.36]	0.930	0.958
Benign prostatic hyperplasia	18 (0.8)	22 (1.0)	-0.19 [-0.79; 0.40]	0.82 [0.44; 1.52]	0.82 [0.44; 1.52]	0.524	n.s.
Gynaecomastia	27 (1.3)	24 (1.1)	0.14 [-0.53; 0.81]	1.13 [0.65; 1.96]	1.12 [0.65; 1.94]	0.674	n.s.
Respiratory, thoracic and mediastinal disorders	426 (19.8)	434 (20.2)	-0.38 [-2.77; 2.01]	0.98 [0.84; 1.13]	0.98 [0.87; 1.11]	0.755	0.958
Chronic obstructive pulmonary disease	63 (2.9)	46 (2.1)	0.79 [-0.15; 1.75]	1.38 [0.94; 2.03]	1.37 [0.94; 1.99]	0.101	n.s.
Cough	103 (4.8)	91 (4.2)	0.56 [-0.69; 1.81]	1.14 [0.85; 1.52]	1.13 [0.86; 1.49]	0.380	n.s.
Dyspnoea	121 (5.6)	113 (5.3)	0.37 [-0.99; 1.74]	1.07 [0.83; 1.40]	1.07 [0.83; 1.37]	0.593	n.s.
Epistaxis	31 (1.4)	50 (2.3)	-0.88 [-1.73; -0.07]	0.61 [0.39; 0.97]	0.62 [0.40; 0.97]	0.035	n.s.
Pleural effusion	27 (1.3)	32 (1.5)	-0.23 [-0.96; 0.48]	0.84 [0.50; 1.41]	0.84 [0.51; 1.40]	0.512	n.s.
Skin and subcutaneous tissue disorders	187 (8.7)	193 (9.0)	-0.28 [-1.99; 1.42]	0.97 [0.78; 1.19]	0.97 [0.80; 1.17]	0.744	0.958
Pruritus	32 (1.5)	42 (2.0)	-0.47 [-1.27; 0.32]	0.76 [0.48; 1.21]	0.76 [0.48; 1.20]	0.242	n.s.
Rash	23 (1.1)	24 (1.1)	-0.05 [-0.69; 0.60]	0.96 [0.54; 1.70]	0.96 [0.54; 1.69]	0.882	n.s.
Skin ulcer	29 (1.3)	28 (1.3)	0.05 [-0.66; 0.75]	1.04 [0.61; 1.75]	1.04 [0.62; 1.73]	0.895	n.s.
Surgical and medical procedures	38 (1.8)	41 (1.9)	-0.14 [-0.96; 0.68]	0.93 [0.59; 1.44]	0.93 [0.60; 1.43]	0.732	0.958
Vascular disorders	479 (22.3)	444 (20.6)	1.62 [-0.84; 4.07]	1.10 [0.95; 1.27]	1.08 [0.96; 1.21]	0.197	0.541
Hypertension	42 (2.0)	54 (2.5)	-0.56 [-1.47; 0.33]	0.77 [0.51; 1.16]	0.78 [0.52; 1.16]	0.216	n.s.

Adverse Events by System Organ Class and Preferred Term
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Hypotension	339 (15.8)	311 (14.5)	1.29 [-0.85; 3.44]	1.11 [0.94; 1.31]	1.09 [0.95; 1.26]	0.236	n.s.
Orthostatic hypotension	23 (1.1)	24 (1.1)	-0.05 [-0.69; 0.60]	0.96 [0.54; 1.70]	0.96 [0.54; 1.69]	0.882	n.s.

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: A system organ class or specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more treatment groups

d: Based on Unstratified Miettinen & Nurminen method.

e: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

g: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

h: Adjusted p-values for treatment comparisons of adverse events at the SOC level were computed using the FDR procedure, and they were computed using the double FDR procedure (dFDR) for comparisons of adverse events at the PT level. Not significant (i.e. 'n.s.') is reported for PTs in a SOC when the SOC did not meet the threshold p-value criteria in the first step of the dFDR procedure. Adjusted p-values should be used for evaluating the results in order to reduce the number of false discoveries (i.e., statistical findings) when numerous statistical tests are performed

CI: Confidence Interval; FDR: False Discovery Rate; n.s.: Non-Significant (adjusted p-value ≥ 0.05); PT: Preferred Term; SOC: System Organ Class.

1.2.2 Serious Adverse Events by SOC and PT

Table 6
Serious Adverse Events by System Organ Class and Preferred Term
(Incidence ≥ 5% or (Incidence ≥ 1% and in at least 10 participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Serious Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Blood and lymphatic system disorders	39 (1.8)	20 (0.9)	0.88 [0.19; 1.62]	1.92 [1.15; 3.21]	1.92 [1.15; 3.21]	0.013	0.090
Anaemia	28 (1.3)	16 (0.7)	0.56 [-0.05; 1.20]	1.73 [0.96; 3.14]	1.73 [0.96; 3.14]	0.069	n.s.
Cardiac disorders	169 (7.9)	240 (11.2)	-3.30 [-5.07; -1.56]	0.68 [0.55; 0.83]	0.70 [0.58; 0.85]	< 0.001	0.003
Atrial fibrillation	9 (0.4)	26 (1.2)	-0.79 [-1.39; -0.27]	0.38 [0.19; 0.73]	0.38 [0.19; 0.73]	0.004	n.s.
Cardiac failure	67 (3.1)	99 (4.6)	-1.49 [-2.66; -0.34]	0.67 [0.49; 0.91]	0.68 [0.50; 0.92]	0.012	n.s.
Cardiac failure congestive	11 (0.5)	22 (1.0)	-0.51 [-1.09; 0.01]	0.51 [0.26; 1.01]	0.51 [0.26; 1.01]	0.054	n.s.
Ventricular tachycardia	12 (0.6)	23 (1.1)	-0.51 [-1.10; 0.03]	0.53 [0.27; 1.03]	0.53 [0.27; 1.03]	0.062	n.s.
Gastrointestinal disorders	85 (3.9)	78 (3.6)	0.32 [-0.83; 1.48]	1.09 [0.80; 1.50]	1.09 [0.81; 1.47]	0.578	0.998
General disorders and administration site conditions	37 (1.7)	37 (1.7)	-0.00 [-0.80; 0.79]	1.00 [0.63; 1.58]	1.00 [0.64; 1.57]	0.998	0.998
Hepatobiliary disorders	34 (1.6)	20 (0.9)	0.65 [-0.02; 1.36]	1.69 [0.99; 2.89]	1.69 [0.99; 2.89]	0.055	0.259
Infections and infestations	231 (10.7)	230 (10.7)	0.04 [-1.81; 1.89]	1.00 [0.83; 1.22]	1.00 [0.84; 1.19]	0.965	0.998
Cellulitis	23 (1.1)	17 (0.8)	0.28 [-0.31; 0.89]	1.35 [0.73; 2.52]	1.35 [0.73; 2.52]	0.341	n.s.
Pneumonia	81 (3.8)	100 (4.6)	-0.89 [-2.10; 0.32]	0.80 [0.59; 1.08]	0.81 [0.61; 1.08]	0.149	n.s.
Sepsis	13 (0.6)	22 (1.0)	-0.42 [-1.00; 0.12]	0.60 [0.31; 1.16]	0.60 [0.31; 1.16]	0.126	n.s.
Injury, poisoning and procedural complications	52 (2.4)	60 (2.8)	-0.37 [-1.34; 0.59]	0.86 [0.59; 1.26]	0.87 [0.60; 1.25]	0.443	0.998
Metabolism and nutrition disorders	67 (3.1)	80 (3.7)	-0.61 [-1.71; 0.49]	0.83 [0.60; 1.16]	0.84 [0.61; 1.15]	0.275	0.961
Musculoskeletal and connective tissue disorders	26 (1.2)	30 (1.4)	-0.19 [-0.89; 0.51]	0.86 [0.51; 1.47]	0.87 [0.51; 1.46]	0.590	0.998

Serious Adverse Events by System Organ Class and Preferred Term
(Incidence ≥ 5% or (Incidence ≥ 1% and in at least 10 participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Serious Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Neoplasms benign, malignant and unspecified (incl cysts and	40 (1.9)	38 (1.8)	0.09 [-0.72; 0.91]	1.05 [0.67; 1.65]	1.05 [0.68; 1.63]	0.821	0.998
Nervous system disorders	71 (3.3)	71 (3.3)	-0.00 [-1.08; 1.08]	1.00 [0.72; 1.40]	1.00 [0.72; 1.38]	0.998	0.998
Syncope	39 (1.8)	30 (1.4)	0.42 [-0.34; 1.20]	1.30 [0.81; 2.11]	1.30 [0.81; 2.08]	0.277	n.s.
Renal and urinary disorders	121 (5.6)	116 (5.4)	0.23 [-1.14; 1.60]	1.05 [0.80; 1.36]	1.04 [0.81; 1.34]	0.741	0.998
Acute kidney injury	58 (2.7)	47 (2.2)	0.51 [-0.42; 1.45]	1.24 [0.84; 1.83]	1.23 [0.84; 1.80]	0.279	n.s.
Chronic kidney disease	35 (1.6)	25 (1.2)	0.46 [-0.24; 1.20]	1.41 [0.84; 2.36]	1.40 [0.84; 2.33]	0.196	n.s.
Renal failure	18 (0.8)	25 (1.2)	-0.33 [-0.96; 0.28]	0.72 [0.39; 1.31]	0.72 [0.39; 1.31]	0.283	n.s.
Respiratory, thoracic and mediastinal disorders	78 (3.6)	79 (3.7)	-0.05 [-1.18; 1.08]	0.99 [0.72; 1.36]	0.99 [0.73; 1.34]	0.933	0.998
Chronic obstructive pulmonary disease	30 (1.4)	27 (1.3)	0.14 [-0.56; 0.85]	1.11 [0.66; 1.88]	1.11 [0.66; 1.86]	0.691	n.s.
Vascular disorders	72 (3.3)	74 (3.4)	-0.09 [-1.19; 1.00]	0.97 [0.70; 1.35]	0.97 [0.71; 1.34]	0.864	0.998
Hypotension	31 (1.4)	38 (1.8)	-0.33 [-1.10; 0.44]	0.81 [0.50; 1.31]	0.82 [0.51; 1.31]	0.395	n.s.

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: A system organ class or specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more treatment groups

d: Based on Unstratified Miettinen & Nurminen method.

e: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

g: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

h: Adjusted p-values for treatment comparisons of adverse events at the SOC level were computed using the FDR procedure, and they were computed using the double FDR procedure (dFDR) for comparisons of adverse events at the PT level. Not significant (i.e. 'n.s.') is reported for PTs in a SOC when the SOC did not meet the threshold p-value criteria in the first step of the dFDR procedure. Adjusted p-values should be used for evaluating the results in order to reduce the number of false discoveries (i.e., statistical findings) when numerous statistical tests are performed

CI: Confidence Interval; FDR: False Discovery Rate; n.s.: Non-Significant (adjusted p-value ≥ 0.05); PT: Preferred Term; SOC: System Organ Class.

1.2.3 Adverse Events by severity by SOC and PT

Table 7
Mild Adverse Events by System Organ Class and Preferred Term
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Mild Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Blood and lymphatic system disorders	128 (5.9)	104 (4.8)	1.11 [-0.24; 2.48]	1.24 [0.95; 1.62]	1.23 [0.96; 1.58]	0.107	0.380
Anaemia	88 (4.1)	64 (3.0)	1.11 [0.01; 2.24]	1.39 [1.00; 1.93]	1.37 [1.00; 1.89]	0.049	n.s.
Cardiac disorders	229 (10.6)	233 (10.8)	-0.19 [-2.05; 1.66]	0.98 [0.81; 1.19]	0.98 [0.83; 1.17]	0.840	0.966
Atrial fibrillation	33 (1.5)	24 (1.1)	0.42 [-0.27; 1.13]	1.38 [0.81; 2.34]	1.37 [0.82; 2.32]	0.233	n.s.
Cardiac failure	63 (2.9)	69 (3.2)	-0.28 [-1.33; 0.76]	0.91 [0.64; 1.29]	0.91 [0.65; 1.28]	0.594	n.s.
Palpitations	24 (1.1)	16 (0.7)	0.37 [-0.21; 0.99]	1.50 [0.80; 2.79]	1.50 [0.80; 2.79]	0.204	n.s.
Ear and labyrinth disorders	44 (2.0)	29 (1.3)	0.70 [-0.08; 1.50]	1.53 [0.95; 2.45]	1.52 [0.95; 2.41]	0.079	0.380
Vertigo	24 (1.1)	24 (1.1)	-0.00 [-0.65; 0.65]	1.00 [0.57; 1.77]	1.00 [0.57; 1.75]	0.999	n.s.
Endocrine disorders	36 (1.7)	37 (1.7)	-0.05 [-0.84; 0.74]	0.97 [0.61; 1.54]	0.97 [0.62; 1.53]	0.904	0.966
Hypothyroidism	22 (1.0)	22 (1.0)	-0.00 [-0.63; 0.63]	1.00 [0.55; 1.81]	1.00 [0.56; 1.80]	0.999	n.s.
Eye disorders	48 (2.2)	57 (2.6)	-0.42 [-1.36; 0.51]	0.84 [0.57; 1.24]	0.84 [0.58; 1.23]	0.373	0.784
Gastrointestinal disorders	386 (17.9)	334 (15.5)	2.41 [0.18; 4.64]	1.19 [1.01; 1.40]	1.16 [1.01; 1.32]	0.035	0.380
Abdominal pain upper	22 (1.0)	18 (0.8)	0.19 [-0.41; 0.79]	1.22 [0.66; 2.28]	1.22 [0.66; 2.28]	0.526	0.614
Constipation	49 (2.3)	46 (2.1)	0.14 [-0.75; 1.03]	1.07 [0.71; 1.60]	1.06 [0.72; 1.59]	0.757	0.757
Diarrhoea	73 (3.4)	82 (3.8)	-0.42 [-1.55; 0.70]	0.89 [0.64; 1.22]	0.89 [0.65; 1.21]	0.460	0.614
Dyspepsia	40 (1.9)	23 (1.1)	0.79 [0.07; 1.55]	1.75 [1.05; 2.94]	1.74 [1.04; 2.89]	0.033	0.117
Gastrooesophageal reflux disease	29 (1.3)	5 (0.2)	1.12 [0.63; 1.72]	4.15 [2.11; 8.14]	4.15 [2.11; 8.14]	< 0.001	< 0.001

Mild Adverse Events by System Organ Class and Preferred Term
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Mild Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Nausea	54 (2.5)	46 (2.1)	0.37 [-0.54; 1.29]	1.18 [0.79; 1.75]	1.17 [0.80; 1.73]	0.420	0.614
Vomiting	25 (1.2)	32 (1.5)	-0.33 [-1.04; 0.37]	0.78 [0.46; 1.32]	0.78 [0.46; 1.31]	0.351	0.614
General disorders and administration site conditions	217 (10.1)	217 (10.1)	-0.00 [-1.81; 1.80]	1.00 [0.82; 1.22]	1.00 [0.84; 1.19]	0.996	0.996
Asthenia	27 (1.3)	29 (1.3)	-0.09 [-0.80; 0.60]	0.93 [0.55; 1.58]	0.93 [0.55; 1.57]	0.787	n.s.
Chest pain	25 (1.2)	38 (1.8)	-0.60 [-1.36; 0.12]	0.65 [0.39; 1.09]	0.66 [0.40; 1.09]	0.101	n.s.
Fatigue	26 (1.2)	30 (1.4)	-0.19 [-0.89; 0.51]	0.86 [0.51; 1.47]	0.87 [0.51; 1.46]	0.590	n.s.
Oedema peripheral	62 (2.9)	55 (2.6)	0.32 [-0.66; 1.31]	1.13 [0.78; 1.63]	1.13 [0.79; 1.61]	0.514	n.s.
Hepatobiliary disorders	53 (2.5)	54 (2.5)	-0.05 [-0.99; 0.90]	0.98 [0.67; 1.44]	0.98 [0.67; 1.43]	0.920	0.966
Infections and infestations	437 (20.3)	428 (19.9)	0.41 [-1.99; 2.81]	1.03 [0.88; 1.19]	1.02 [0.91; 1.15]	0.738	0.966
Bronchitis	40 (1.9)	41 (1.9)	-0.05 [-0.88; 0.78]	0.97 [0.63; 1.51]	0.98 [0.63; 1.50]	0.909	n.s.
Influenza	50 (2.3)	32 (1.5)	0.84 [0.02; 1.69]	1.58 [1.01; 2.46]	1.56 [1.01; 2.42]	0.047	n.s.
Nasopharyngitis	88 (4.1)	88 (4.1)	-0.00 [-1.20; 1.19]	1.00 [0.74; 1.35]	1.00 [0.75; 1.33]	0.997	n.s.
Pneumonia	22 (1.0)	26 (1.2)	-0.19 [-0.84; 0.46]	0.84 [0.48; 1.49]	0.85 [0.48; 1.49]	0.561	n.s.
Upper respiratory tract infection	78 (3.6)	72 (3.3)	0.28 [-0.83; 1.39]	1.09 [0.78; 1.50]	1.08 [0.79; 1.48]	0.620	n.s.
Urinary tract infection	38 (1.8)	51 (2.4)	-0.61 [-1.48; 0.25]	0.74 [0.48; 1.13]	0.74 [0.49; 1.13]	0.165	n.s.
Injury, poisoning and procedural complications	159 (7.4)	132 (6.1)	1.25 [-0.25; 2.76]	1.22 [0.96; 1.55]	1.20 [0.96; 1.50]	0.103	0.380
Accidental overdose	31 (1.4)	21 (1.0)	0.46 [-0.20; 1.15]	1.48 [0.85; 2.55]	1.48 [0.85; 2.55]	0.164	n.s.
Fall	35 (1.6)	30 (1.4)	0.23 [-0.51; 0.99]	1.17 [0.72; 1.91]	1.17 [0.72; 1.89]	0.534	n.s.

Mild Adverse Events by System Organ Class and Preferred Term
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(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Mild Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Investigations	218 (10.1)	238 (11.1)	-0.93 [-2.78; 0.91]	0.91 [0.75; 1.10]	0.92 [0.77; 1.09]	0.320	0.746
Blood creatinine increased	28 (1.3)	30 (1.4)	-0.09 [-0.81; 0.61]	0.93 [0.55; 1.57]	0.93 [0.56; 1.56]	0.790	n.s.
Blood uric acid increased	23 (1.1)	23 (1.1)	-0.00 [-0.64; 0.64]	1.00 [0.56; 1.79]	1.00 [0.56; 1.78]	0.999	n.s.
Gamma-glutamyltransferase increased	29 (1.3)	41 (1.9)	-0.56 [-1.35; 0.20]	0.70 [0.44; 1.14]	0.71 [0.44; 1.13]	0.150	n.s.
Weight increased	29 (1.3)	28 (1.3)	0.05 [-0.66; 0.75]	1.04 [0.61; 1.75]	1.04 [0.62; 1.73]	0.895	n.s.
Metabolism and nutrition disorders	321 (14.9)	347 (16.1)	-1.22 [-3.38; 0.95]	0.91 [0.77; 1.08]	0.92 [0.80; 1.06]	0.271	0.746
Decreased appetite	27 (1.3)	24 (1.1)	0.14 [-0.53; 0.81]	1.13 [0.65; 1.96]	1.12 [0.65; 1.94]	0.674	n.s.
Diabetes mellitus	22 (1.0)	21 (1.0)	0.05 [-0.57; 0.67]	1.05 [0.57; 1.91]	1.05 [0.57; 1.91]	0.879	n.s.
Gout	42 (2.0)	42 (2.0)	-0.00 [-0.84; 0.84]	1.00 [0.65; 1.54]	1.00 [0.65; 1.53]	0.998	n.s.
Hyperkalaemia	70 (3.3)	82 (3.8)	-0.56 [-1.68; 0.55]	0.85 [0.61; 1.17]	0.85 [0.62; 1.17]	0.321	n.s.
Hyperuricaemia	56 (2.6)	48 (2.2)	0.37 [-0.56; 1.31]	1.17 [0.79; 1.73]	1.17 [0.80; 1.71]	0.429	n.s.
Hypokalaemia	53 (2.5)	58 (2.7)	-0.23 [-1.20; 0.72]	0.91 [0.62; 1.33]	0.91 [0.63; 1.32]	0.629	n.s.
Hyponatraemia	17 (0.8)	22 (1.0)	-0.23 [-0.83; 0.35]	0.77 [0.41; 1.45]	0.77 [0.41; 1.45]	0.420	n.s.
Musculoskeletal and connective tissue disorders	183 (8.5)	181 (8.4)	0.09 [-1.58; 1.76]	1.01 [0.82; 1.25]	1.01 [0.83; 1.23]	0.916	0.966
Arthralgia	24 (1.1)	30 (1.4)	-0.28 [-0.98; 0.40]	0.80 [0.46; 1.37]	0.80 [0.47; 1.36]	0.411	n.s.
Back pain	26 (1.2)	26 (1.2)	-0.00 [-0.68; 0.67]	1.00 [0.58; 1.73]	1.00 [0.58; 1.72]	0.999	n.s.
Muscle spasms	22 (1.0)	21 (1.0)	0.05 [-0.57; 0.67]	1.05 [0.57; 1.91]	1.05 [0.57; 1.91]	0.879	n.s.
Pain in extremity	32 (1.5)	28 (1.3)	0.19 [-0.53; 0.91]	1.14 [0.69; 1.91]	1.14 [0.69; 1.89]	0.605	n.s.

Mild Adverse Events by System Organ Class and Preferred Term
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Mild Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Neoplasms benign, malignant and unspecified (incl cysts and	20 (0.9)	25 (1.2)	-0.23 [-0.87; 0.39]	0.80 [0.44; 1.44]	0.80 [0.44; 1.44]	0.453	0.864
Nervous system disorders	258 (12.0)	236 (11.0)	1.02 [-0.89; 2.93]	1.11 [0.92; 1.33]	1.09 [0.93; 1.29]	0.296	0.746
Dizziness	114 (5.3)	106 (4.9)	0.37 [-0.95; 1.70]	1.08 [0.82; 1.42]	1.07 [0.83; 1.39]	0.582	n.s.
Headache	55 (2.6)	41 (1.9)	0.65 [-0.24; 1.56]	1.35 [0.90; 2.03]	1.34 [0.90; 2.00]	0.151	n.s.
Syncope	22 (1.0)	18 (0.8)	0.19 [-0.41; 0.79]	1.22 [0.66; 2.28]	1.22 [0.66; 2.28]	0.526	n.s.
Psychiatric disorders	55 (2.6)	74 (3.4)	-0.88 [-1.93; 0.14]	0.74 [0.52; 1.05]	0.74 [0.53; 1.05]	0.090	0.380
Insomnia	23 (1.1)	30 (1.4)	-0.33 [-1.02; 0.34]	0.76 [0.44; 1.32]	0.77 [0.45; 1.31]	0.334	n.s.
Renal and urinary disorders	151 (7.0)	162 (7.5)	-0.51 [-2.08; 1.04]	0.93 [0.74; 1.17]	0.93 [0.75; 1.15]	0.516	0.903
Acute kidney injury	26 (1.2)	37 (1.7)	-0.51 [-1.26; 0.21]	0.70 [0.42; 1.16]	0.70 [0.43; 1.16]	0.164	n.s.
Chronic kidney disease	25 (1.2)	24 (1.1)	0.05 [-0.61; 0.70]	1.04 [0.59; 1.83]	1.04 [0.60; 1.82]	0.887	n.s.
Renal failure	23 (1.1)	15 (0.7)	0.37 [-0.20; 0.97]	1.53 [0.81; 2.89]	1.53 [0.81; 2.89]	0.193	n.s.
Renal impairment	25 (1.2)	30 (1.4)	-0.23 [-0.93; 0.45]	0.83 [0.49; 1.42]	0.83 [0.49; 1.41]	0.497	n.s.
Reproductive system and breast disorders	55 (2.6)	51 (2.4)	0.18 [-0.75; 1.13]	1.08 [0.73; 1.59]	1.08 [0.74; 1.57]	0.696	0.966
Gynaecomastia	23 (1.1)	19 (0.9)	0.19 [-0.42; 0.81]	1.21 [0.66; 2.22]	1.21 [0.66; 2.22]	0.536	n.s.
Respiratory, thoracic and mediastinal disorders	263 (12.2)	270 (12.6)	-0.33 [-2.30; 1.64]	0.97 [0.81; 1.16]	0.97 [0.83; 1.14]	0.742	0.966
Cough	88 (4.1)	76 (3.5)	0.56 [-0.59; 1.72]	1.16 [0.85; 1.59]	1.16 [0.86; 1.56]	0.341	n.s.
Dyspnoea	62 (2.9)	54 (2.5)	0.37 [-0.61; 1.36]	1.15 [0.80; 1.67]	1.15 [0.80; 1.64]	0.453	n.s.
Epistaxis	20 (0.9)	39 (1.8)	-0.88 [-1.62; -0.19]	0.52 [0.31; 0.87]	0.52 [0.31; 0.87]	0.013	n.s.

Mild Adverse Events by System Organ Class and Preferred Term
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Mild Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Skin and subcutaneous tissue disorders	138 (6.4)	136 (6.3)	0.09 [-1.38; 1.56]	1.02 [0.79; 1.30]	1.01 [0.81; 1.28]	0.904	0.966
Pruritus	27 (1.3)	34 (1.6)	-0.33 [-1.06; 0.39]	0.79 [0.48; 1.32]	0.79 [0.48; 1.31]	0.367	n.s.
Vascular disorders	287 (13.3)	252 (11.7)	1.62 [-0.36; 3.60]	1.16 [0.97; 1.39]	1.14 [0.97; 1.33]	0.109	0.380
Hypertension	26 (1.2)	33 (1.5)	-0.33 [-1.05; 0.38]	0.78 [0.47; 1.32]	0.79 [0.47; 1.31]	0.359	n.s.
Hypotension	214 (9.9)	172 (8.0)	1.95 [0.24; 3.67]	1.27 [1.03; 1.57]	1.24 [1.03; 1.51]	0.026	n.s.

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: A system organ class or specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more treatment groups

d: Based on Unstratified Miettinen & Nurminen method.

e: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

g: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

h: Adjusted p-values for treatment comparisons of adverse events at the SOC level were computed using the FDR procedure, and they were computed using the double FDR procedure (dFDR) for comparisons of adverse events at the PT level. Not significant (i.e. 'n.s.') is reported for PTs in a SOC when the SOC did not meet the threshold p-value criteria in the first step of the dFDR procedure. Adjusted p-values should be used for evaluating the results in order to reduce the number of false discoveries (i.e., statistical findings) when numerous statistical tests are performed

CI: Confidence Interval; FDR: False Discovery Rate; n.s.: Non-Significant (adjusted p-value ≥ 0.05); PT: Preferred Term; SOC: System Organ Class.

Table 8
Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Moderate Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Blood and lymphatic system disorders	76 (3.5)	55 (2.6)	0.97 [-0.05; 2.03]	1.40 [0.98; 1.98]	1.38 [0.98; 1.94]	0.064	0.332
Anaemia	50 (2.3)	39 (1.8)	0.51 [-0.35; 1.39]	1.29 [0.84; 1.97]	1.28 [0.85; 1.94]	0.241	n.s.
Cardiac disorders	218 (10.1)	241 (11.2)	-1.07 [-2.93; 0.77]	0.89 [0.74; 1.08]	0.90 [0.76; 1.08]	0.254	0.617
Atrial fibrillation	32 (1.5)	39 (1.8)	-0.33 [-1.11; 0.45]	0.82 [0.51; 1.31]	0.82 [0.52; 1.30]	0.402	n.s.
Cardiac failure	89 (4.1)	99 (4.6)	-0.47 [-1.70; 0.76]	0.89 [0.67; 1.20]	0.90 [0.68; 1.19]	0.454	n.s.
Eye disorders	22 (1.0)	28 (1.3)	-0.28 [-0.95; 0.37]	0.78 [0.45; 1.37]	0.79 [0.45; 1.37]	0.394	0.744
Gastrointestinal disorders	175 (8.1)	153 (7.1)	1.02 [-0.57; 2.61]	1.16 [0.92; 1.45]	1.14 [0.93; 1.41]	0.208	0.590
Diarrhoea	33 (1.5)	34 (1.6)	-0.05 [-0.81; 0.71]	0.97 [0.60; 1.57]	0.97 [0.60; 1.56]	0.900	n.s.
Nausea	29 (1.3)	17 (0.8)	0.56 [-0.06; 1.21]	1.69 [0.95; 3.03]	1.69 [0.95; 3.03]	0.076	n.s.
Vomiting	24 (1.1)	10 (0.5)	0.65 [0.13; 1.24]	2.29 [1.17; 4.50]	2.29 [1.17; 4.50]	0.016	n.s.
General disorders and administration site conditions	102 (4.7)	128 (6.0)	-1.21 [-2.57; 0.13]	0.79 [0.60; 1.03]	0.80 [0.62; 1.03]	0.078	0.332
Chest pain	20 (0.9)	25 (1.2)	-0.23 [-0.87; 0.39]	0.80 [0.44; 1.44]	0.80 [0.44; 1.44]	0.453	n.s.
Oedema peripheral	23 (1.1)	21 (1.0)	0.09 [-0.53; 0.72]	1.10 [0.60; 1.98]	1.10 [0.60; 1.98]	0.763	n.s.
Hepatobiliary disorders	32 (1.5)	33 (1.5)	-0.05 [-0.80; 0.70]	0.97 [0.59; 1.58]	0.97 [0.60; 1.57]	0.899	0.997
Infections and infestations	259 (12.0)	274 (12.7)	-0.70 [-2.68; 1.27]	0.94 [0.78; 1.12]	0.94 [0.81; 1.11]	0.484	0.775
Bronchitis	26 (1.2)	43 (2.0)	-0.79 [-1.58; -0.04]	0.60 [0.37; 0.98]	0.60 [0.37; 0.98]	0.041	n.s.
Pneumonia	46 (2.1)	55 (2.6)	-0.42 [-1.35; 0.49]	0.83 [0.56; 1.24]	0.84 [0.57; 1.23]	0.364	n.s.

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Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Moderate Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Upper respiratory tract infection	28 (1.3)	23 (1.1)	0.23 [-0.43; 0.91]	1.22 [0.70; 2.12]	1.22 [0.70; 2.11]	0.483	n.s.
Urinary tract infection	33 (1.5)	25 (1.2)	0.37 [-0.33; 1.09]	1.32 [0.78; 2.23]	1.32 [0.79; 2.21]	0.293	n.s.
Injury, poisoning and procedural complications	65 (3.0)	92 (4.3)	-1.26 [-2.40; -0.14]	0.70 [0.50; 0.96]	0.71 [0.52; 0.96]	0.029	0.332
Investigations	115 (5.3)	124 (5.8)	-0.42 [-1.80; 0.95]	0.92 [0.71; 1.20]	0.93 [0.72; 1.19]	0.547	0.775
Metabolism and nutrition disorders	167 (7.8)	193 (9.0)	-1.21 [-2.88; 0.44]	0.85 [0.69; 1.06]	0.86 [0.71; 1.05]	0.151	0.515
Gout	30 (1.4)	36 (1.7)	-0.28 [-1.04; 0.47]	0.83 [0.51; 1.35]	0.83 [0.51; 1.35]	0.456	n.s.
Hyperkalaemia	23 (1.1)	38 (1.8)	-0.70 [-1.44; 0.01]	0.60 [0.36; 1.01]	0.60 [0.36; 1.01]	0.055	n.s.
Hypokalaemia	23 (1.1)	20 (0.9)	0.14 [-0.47; 0.76]	1.15 [0.63; 2.10]	1.15 [0.63; 2.10]	0.647	n.s.
Musculoskeletal and connective tissue disorders	91 (4.2)	117 (5.4)	-1.21 [-2.51; 0.07]	0.77 [0.58; 1.02]	0.78 [0.60; 1.02]	0.065	0.332
Back pain	24 (1.1)	23 (1.1)	0.05 [-0.60; 0.69]	1.04 [0.59; 1.85]	1.04 [0.59; 1.84]	0.885	n.s.
Nervous system disorders	120 (5.6)	121 (5.6)	-0.05 [-1.43; 1.33]	0.99 [0.76; 1.28]	0.99 [0.78; 1.27]	0.944	0.997
Dizziness	30 (1.4)	25 (1.2)	0.23 [-0.45; 0.93]	1.20 [0.70; 2.05]	1.20 [0.71; 2.03]	0.499	n.s.
Syncope	30 (1.4)	34 (1.6)	-0.19 [-0.93; 0.55]	0.88 [0.54; 1.44]	0.88 [0.54; 1.44]	0.613	n.s.
Psychiatric disorders	35 (1.6)	44 (2.0)	-0.42 [-1.25; 0.39]	0.79 [0.51; 1.24]	0.80 [0.51; 1.23]	0.307	0.652
Renal and urinary disorders	155 (7.2)	154 (7.2)	0.04 [-1.51; 1.59]	1.01 [0.80; 1.27]	1.01 [0.81; 1.25]	0.956	0.997
Acute kidney injury	44 (2.0)	38 (1.8)	0.28 [-0.55; 1.12]	1.16 [0.75; 1.80]	1.16 [0.75; 1.78]	0.505	n.s.
Chronic kidney disease	30 (1.4)	33 (1.5)	-0.14 [-0.88; 0.59]	0.91 [0.55; 1.49]	0.91 [0.56; 1.48]	0.702	n.s.
Renal failure	40 (1.9)	40 (1.9)	-0.00 [-0.83; 0.82]	1.00 [0.64; 1.56]	1.00 [0.65; 1.54]	0.998	n.s.

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Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Moderate Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Renal impairment	25 (1.2)	26 (1.2)	-0.05 [-0.72; 0.62]	0.96 [0.55; 1.67]	0.96 [0.56; 1.66]	0.887	n.s.
Respiratory, thoracic and mediastinal disorders	153 (7.1)	153 (7.1)	-0.00 [-1.55; 1.54]	1.00 [0.79; 1.26]	1.00 [0.81; 1.24]	0.997	0.997
Chronic obstructive pulmonary disease	25 (1.2)	12 (0.6)	0.60 [0.05; 1.21]	2.03 [1.06; 3.88]	2.03 [1.06; 3.88]	0.032	n.s.
Dyspnoea	60 (2.8)	55 (2.6)	0.23 [-0.74; 1.21]	1.09 [0.75; 1.58]	1.09 [0.76; 1.56]	0.638	n.s.
Skin and subcutaneous tissue disorders	47 (2.2)	51 (2.4)	-0.19 [-1.10; 0.72]	0.92 [0.62; 1.37]	0.92 [0.62; 1.36]	0.681	0.891
Vascular disorders	171 (7.9)	183 (8.5)	-0.56 [-2.21; 1.08]	0.93 [0.75; 1.15]	0.93 [0.76; 1.14]	0.503	0.775
Hypotension	117 (5.4)	129 (6.0)	-0.56 [-1.96; 0.83]	0.90 [0.70; 1.17]	0.91 [0.71; 1.16]	0.429	n.s.

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: A system organ class or specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more treatment groups

d: Based on Unstratified Miettinen & Nurminen method.

e: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

g: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

h: Adjusted p-values for treatment comparisons of adverse events at the SOC level were computed using the FDR procedure, and they were computed using the double FDR procedure (dFDR) for comparisons of adverse events at the PT level. Not significant (i.e. 'n.s.') is reported for PTs in a SOC when the SOC did not meet the threshold p-value criteria in the first step of the dFDR procedure. Adjusted p-values should be used for evaluating the results in order to reduce the number of false discoveries (i.e., statistical findings) when numerous statistical tests are performed

CI: Confidence Interval; FDR: False Discovery Rate; n.s.: Non-Significant (adjusted p-value ≥ 0.05); PT: Preferred Term; SOC: System Organ Class.

Table 9
Severe Adverse Events by System Organ Class and Preferred Term
(Incidence ≥ 5% or (Incidence ≥ 1% and in at least 10 participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Severe Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Blood and lymphatic system disorders	38 (1.8)	21 (1.0)	0.79 [0.10; 1.53]	1.79 [1.07; 3.00]	1.79 [1.07; 3.00]	0.026	0.186
Anaemia	28 (1.3)	15 (0.7)	0.60 [0.01; 1.24]	1.84 [1.01; 3.36]	1.84 [1.01; 3.36]	0.047	n.s.
Cardiac disorders	173 (8.0)	228 (10.6)	-2.56 [-4.31; -0.83]	0.74 [0.60; 0.91]	0.76 [0.63; 0.92]	0.004	0.060
Atrial fibrillation	11 (0.5)	27 (1.3)	-0.74 [-1.36; -0.19]	0.43 [0.23; 0.81]	0.43 [0.23; 0.81]	0.009	n.s.
Cardiac failure	65 (3.0)	88 (4.1)	-1.07 [-2.20; 0.04]	0.73 [0.53; 1.01]	0.74 [0.54; 1.01]	0.059	n.s.
Ventricular tachycardia	14 (0.7)	23 (1.1)	-0.42 [-1.02; 0.14]	0.61 [0.32; 1.17]	0.61 [0.32; 1.17]	0.137	n.s.
Gastrointestinal disorders	73 (3.4)	78 (3.6)	-0.23 [-1.35; 0.88]	0.93 [0.67; 1.29]	0.94 [0.68; 1.28]	0.677	0.895
General disorders and administration site conditions	34 (1.6)	32 (1.5)	0.09 [-0.66; 0.85]	1.06 [0.65; 1.73]	1.06 [0.66; 1.71]	0.806	0.895
Hepatobiliary disorders	33 (1.5)	23 (1.1)	0.46 [-0.22; 1.18]	1.44 [0.84; 2.46]	1.43 [0.84; 2.43]	0.182	0.545
Infections and infestations	214 (9.9)	218 (10.1)	-0.19 [-1.99; 1.61]	0.98 [0.80; 1.19]	0.98 [0.82; 1.17]	0.835	0.895
Pneumonia	77 (3.6)	92 (4.3)	-0.70 [-1.88; 0.47]	0.83 [0.61; 1.13]	0.84 [0.62; 1.13]	0.239	n.s.
Sepsis	11 (0.5)	22 (1.0)	-0.51 [-1.09; 0.01]	0.51 [0.26; 1.01]	0.51 [0.26; 1.01]	0.054	n.s.
Injury, poisoning and procedural complications	52 (2.4)	61 (2.8)	-0.42 [-1.40; 0.54]	0.85 [0.58; 1.23]	0.85 [0.59; 1.23]	0.390	0.692
Investigations	20 (0.9)	25 (1.2)	-0.23 [-0.87; 0.39]	0.80 [0.44; 1.44]	0.80 [0.44; 1.44]	0.453	0.692
Metabolism and nutrition disorders	65 (3.0)	89 (4.1)	-1.12 [-2.25; -0.01]	0.72 [0.52; 1.00]	0.73 [0.53; 1.00]	0.050	0.186
Musculoskeletal and connective tissue disorders	22 (1.0)	38 (1.8)	-0.74 [-1.49; -0.04]	0.57 [0.34; 0.97]	0.58 [0.34; 0.97]	0.040	0.186
Neoplasms benign, malignant and unspecified (incl cysts and	37 (1.7)	34 (1.6)	0.14 [-0.64; 0.92]	1.09 [0.68; 1.74]	1.09 [0.69; 1.73]	0.721	0.895

Severe Adverse Events by System Organ Class and Preferred Term
(Incidence ≥ 5% or (Incidence ≥ 1% and in at least 10 participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**				
Severe Adverse Events by SOC and PT[c]	**Vericiguat (N[b]=2152)**	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][d]**	**Odds Ratio [95 %-CI][e]**	**Relative Risk [95 %-CI][f]**	**p-Value[f,g]**	**Adjusted p-Value[h]**
Nervous system disorders	79 (3.7)	70 (3.3)	0.42 [-0.68; 1.53]	1.13 [0.82; 1.57]	1.13 [0.82; 1.55]	0.455	0.692
Syncope	41 (1.9)	30 (1.4)	0.51 [-0.26; 1.30]	1.37 [0.85; 2.21]	1.37 [0.86; 2.18]	0.191	n.s.
Renal and urinary disorders	122 (5.7)	111 (5.2)	0.51 [-0.85; 1.87]	1.10 [0.85; 1.44]	1.10 [0.86; 1.41]	0.461	0.692
Acute kidney injury	55 (2.6)	43 (2.0)	0.56 [-0.34; 1.47]	1.29 [0.86; 1.92]	1.28 [0.86; 1.90]	0.222	n.s.
Chronic kidney disease	29 (1.3)	25 (1.2)	0.19 [-0.50; 0.88]	1.16 [0.68; 1.99]	1.16 [0.68; 1.97]	0.585	n.s.
Renal failure	25 (1.2)	22 (1.0)	0.14 [-0.50; 0.79]	1.14 [0.64; 2.02]	1.14 [0.64; 2.01]	0.661	n.s.
Respiratory, thoracic and mediastinal disorders	84 (3.9)	84 (3.9)	-0.00 [-1.17; 1.17]	1.00 [0.73; 1.36]	1.00 [0.74; 1.34]	0.998	0.998
Chronic obstructive pulmonary disease	26 (1.2)	26 (1.2)	-0.00 [-0.68; 0.67]	1.00 [0.58; 1.73]	1.00 [0.58; 1.72]	0.999	n.s.
Vascular disorders	72 (3.3)	81 (3.8)	-0.42 [-1.54; 0.69]	0.88 [0.64; 1.22]	0.89 [0.65; 1.21]	0.457	0.692
Hypotension	34 (1.6)	42 (2.0)	-0.37 [-1.19; 0.42]	0.81 [0.51; 1.27]	0.81 [0.52; 1.27]	0.354	n.s.

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: A system organ class or specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more treatment groups

d: Based on Unstratified Miettinen & Nurminen method.

e: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

g: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

h: Adjusted p-values for treatment comparisons of adverse events at the SOC level were computed using the FDR procedure, and they were computed using the double FDR procedure (dFDR) for comparisons of adverse events at the PT level. Not significant (i.e. 'n.s.') is reported for PTs in a SOC when the SOC did not meet the threshold p-value criteria in the first step of the dFDR procedure. Adjusted p-values should be used for evaluating the results in order to reduce the number of false discoveries (i.e., statistical findings) when numerous statistical tests are performed

CI: Confidence Interval; FDR: False Discovery Rate; n.s.: Non-Significant (adjusted p-value ≥ 0.05); PT: Preferred Term; SOC: System Organ Class.

1.3 Incidences of Adverse Events by SOC and PT

1.3.1 Adverse Events by SOC and PT

Table 10
Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Participants with one or more adverse events	1726 (80.2)	1741 (80.9)
Blood and lymphatic system disorders	223 (10.4)	170 (7.9)
Anaemia	156 (7.2)	112 (5.2)
Anaemia macrocytic	1 (0.0)	2 (0.1)
Autoimmune haemolytic anaemia	1 (0.0)	0 (0.0)
Blood loss anaemia	2 (0.1)	2 (0.1)
Bone marrow oedema	1 (0.0)	0 (0.0)
Coagulopathy	4 (0.2)	1 (0.0)
Cytopenia	0 (0.0)	1 (0.0)
Disseminated intravascular coagulation	1 (0.0)	0 (0.0)
Eosinophilia	1 (0.0)	0 (0.0)
Haemolytic anaemia	0 (0.0)	1 (0.0)
Haemorrhagic diathesis	0 (0.0)	1 (0.0)
Hypercoagulation	0 (0.0)	1 (0.0)
Hypergammaglobulinaemia	1 (0.0)	0 (0.0)
Hypochromasia	1 (0.0)	0 (0.0)
Hypochromic anaemia	2 (0.1)	2 (0.1)
Hypocoagulable state	1 (0.0)	0 (0.0)
Immune thrombocytopenic purpura	1 (0.0)	0 (0.0)
Increased tendency to bruise	1 (0.0)	0 (0.0)
Iron deficiency anaemia	21 (1.0)	15 (0.7)
Leukocytosis	4 (0.2)	6 (0.3)
Leukopenia	2 (0.1)	3 (0.1)
Lymphadenitis	0 (0.0)	1 (0.0)
Lymphadenopathy	1 (0.0)	0 (0.0)
Lymphadenopathy mediastinal	0 (0.0)	1 (0.0)
Lymphatic insufficiency	0 (0.0)	1 (0.0)
Macrocytosis	1 (0.0)	1 (0.0)
Microcytic anaemia	5 (0.2)	0 (0.0)
Nephrogenic anaemia	1 (0.0)	2 (0.1)
Neutropenia	0 (0.0)	2 (0.1)
Normochromic normocytic anaemia	7 (0.3)	2 (0.1)
Normocytic anaemia	2 (0.1)	0 (0.0)
Pancytopenia	4 (0.2)	0 (0.0)
Pernicious anaemia	0 (0.0)	1 (0.0)
Polycythaemia	5 (0.2)	0 (0.0)
Splenic infarction	1 (0.0)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Splenomegaly	2 (0.1)	1 (0.0)
Spontaneous haematoma	1 (0.0)	2 (0.1)
Thrombocytopenia	20 (0.9)	25 (1.2)
Cardiac disorders	504 (23.4)	568 (26.4)
Acute coronary syndrome	1 (0.0)	5 (0.2)
Acute left ventricular failure	1 (0.0)	1 (0.0)
Acute myocardial infarction	6 (0.3)	7 (0.3)
Angina pectoris	23 (1.1)	22 (1.0)
Angina unstable	3 (0.1)	9 (0.4)
Aortic valve calcification	1 (0.0)	0 (0.0)
Aortic valve incompetence	1 (0.0)	4 (0.2)
Aortic valve stenosis	2 (0.1)	3 (0.1)
Arrhythmia	6 (0.3)	6 (0.3)
Arteriosclerosis coronary artery	2 (0.1)	1 (0.0)
Atrial fibrillation	75 (3.5)	82 (3.8)
Atrial flutter	18 (0.8)	25 (1.2)
Atrial tachycardia	1 (0.0)	7 (0.3)
Atrial thrombosis	4 (0.2)	4 (0.2)
Atrioventricular block	1 (0.0)	0 (0.0)
Atrioventricular block complete	0 (0.0)	1 (0.0)
Atrioventricular block first degree	11 (0.5)	8 (0.4)
Atrioventricular block second degree	0 (0.0)	5 (0.2)
Bifascicular block	1 (0.0)	0 (0.0)
Bradyarrhythmia	1 (0.0)	1 (0.0)
Bradycardia	17 (0.8)	24 (1.1)
Bundle branch block	0 (0.0)	1 (0.0)
Bundle branch block left	6 (0.3)	5 (0.2)
Bundle branch block right	3 (0.1)	1 (0.0)
Cardiac aneurysm	1 (0.0)	0 (0.0)
Cardiac arrest	3 (0.1)	1 (0.0)
Cardiac disorder	1 (0.0)	0 (0.0)
Cardiac failure	192 (8.9)	231 (10.7)
Cardiac failure acute	5 (0.2)	19 (0.9)
Cardiac failure chronic	17 (0.8)	32 (1.5)
Cardiac failure congestive	30 (1.4)	42 (2.0)
Cardiac perforation	0 (0.0)	1 (0.0)
Cardiac ventricular thrombosis	4 (0.2)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Cardio-respiratory arrest	4 (0.2)	1 (0.0)
Cardiogenic shock	5 (0.2)	5 (0.2)
Cardiomegaly	2 (0.1)	2 (0.1)
Cardiomyopathy	0 (0.0)	1 (0.0)
Cardiopulmonary failure	1 (0.0)	0 (0.0)
Cardiorenal syndrome	2 (0.1)	6 (0.3)
Cardiovascular disorder	1 (0.0)	0 (0.0)
Congestive cardiomyopathy	4 (0.2)	3 (0.1)
Coronary artery disease	9 (0.4)	4 (0.2)
Coronary artery occlusion	2 (0.1)	1 (0.0)
Coronary artery stenosis	2 (0.1)	2 (0.1)
Coronary ostial stenosis	1 (0.0)	0 (0.0)
Cyanosis	0 (0.0)	1 (0.0)
Defect conduction intraventricular	1 (0.0)	0 (0.0)
Extrasystoles	3 (0.1)	2 (0.1)
Hypertensive heart disease	1 (0.0)	0 (0.0)
Intracardiac thrombus	1 (0.0)	3 (0.1)
Ischaemic cardiomyopathy	2 (0.1)	3 (0.1)
Left atrial dilatation	1 (0.0)	1 (0.0)
Left ventricular dysfunction	4 (0.2)	3 (0.1)
Left ventricular failure	2 (0.1)	2 (0.1)
Mitral valve disease	1 (0.0)	0 (0.0)
Mitral valve incompetence	11 (0.5)	9 (0.4)
Myocardial infarction	6 (0.3)	4 (0.2)
Myocardial ischaemia	5 (0.2)	3 (0.1)
Myocarditis	0 (0.0)	1 (0.0)
Palpitations	29 (1.3)	23 (1.1)
Pericardial effusion	3 (0.1)	3 (0.1)
Pericarditis	0 (0.0)	1 (0.0)
Pulmonary valve incompetence	1 (0.0)	1 (0.0)
Pulseless electrical activity	0 (0.0)	1 (0.0)
Restrictive cardiomyopathy	1 (0.0)	0 (0.0)
Right ventricular failure	1 (0.0)	0 (0.0)
Sinus arrest	0 (0.0)	1 (0.0)
Sinus arrhythmia	0 (0.0)	1 (0.0)
Sinus bradycardia	9 (0.4)	6 (0.3)
Sinus node dysfunction	2 (0.1)	3 (0.1)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Sinus tachycardia	8 (0.4)	4 (0.2)
Supraventricular extrasystoles	6 (0.3)	4 (0.2)
Supraventricular tachycardia	3 (0.1)	5 (0.2)
Tachyarrhythmia	3 (0.1)	0 (0.0)
Tachycardia	20 (0.9)	20 (0.9)
Tricuspid valve incompetence	5 (0.2)	4 (0.2)
Ventricular arrhythmia	4 (0.2)	5 (0.2)
Ventricular dysfunction	0 (0.0)	1 (0.0)
Ventricular dyssynchrony	0 (0.0)	1 (0.0)
Ventricular extrasystoles	25 (1.2)	21 (1.0)
Ventricular fibrillation	12 (0.6)	11 (0.5)
Ventricular flutter	0 (0.0)	1 (0.0)
Ventricular tachycardia	35 (1.6)	55 (2.6)
Wolff-Parkinson-White syndrome	0 (0.0)	1 (0.0)
Congenital, familial and genetic disorders	12 (0.6)	8 (0.4)
Adenomatous polyposis coli	0 (0.0)	1 (0.0)
Bronchogenic cyst	1 (0.0)	0 (0.0)
Congenital inguinal hernia	0 (0.0)	1 (0.0)
Corneal dystrophy	1 (0.0)	0 (0.0)
Dermoid cyst	1 (0.0)	0 (0.0)
Dolichocolon	0 (0.0)	1 (0.0)
Epidermolysis	2 (0.1)	0 (0.0)
Gastrointestinal arteriovenous malformation	1 (0.0)	1 (0.0)
Hydrocele	4 (0.2)	2 (0.1)
Hypospadias	0 (0.0)	1 (0.0)
Phimosis	1 (0.0)	0 (0.0)
Renal dysplasia	0 (0.0)	1 (0.0)
Spine malformation	1 (0.0)	0 (0.0)
Ear and labyrinth disorders	60 (2.8)	46 (2.1)
Auditory disorder	1 (0.0)	0 (0.0)
Deafness bilateral	2 (0.1)	1 (0.0)
Deafness neurosensory	2 (0.1)	0 (0.0)
Ear congestion	1 (0.0)	0 (0.0)
Ear haemorrhage	1 (0.0)	0 (0.0)
Ear pain	2 (0.1)	1 (0.0)
Eustachian tube dysfunction	1 (0.0)	0 (0.0)
Excessive cerumen production	4 (0.2)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Hypoacusis	2 (0.1)	1 (0.0)
Meniere's disease	1 (0.0)	0 (0.0)
Middle ear effusion	1 (0.0)	0 (0.0)
Presbyacusis	1 (0.0)	0 (0.0)
Sudden hearing loss	1 (0.0)	0 (0.0)
Tinnitus	7 (0.3)	2 (0.1)
Vertigo	32 (1.5)	36 (1.7)
Vertigo positional	3 (0.1)	4 (0.2)
Vestibular disorder	1 (0.0)	1 (0.0)
Endocrine disorders	55 (2.6)	49 (2.3)
Adrenal insufficiency	1 (0.0)	0 (0.0)
Autoimmune thyroiditis	0 (0.0)	1 (0.0)
Basedow's disease	1 (0.0)	0 (0.0)
Carcinoid syndrome	1 (0.0)	0 (0.0)
Cushingoid	1 (0.0)	0 (0.0)
Empty sella syndrome	1 (0.0)	0 (0.0)
Euthyroid sick syndrome	0 (0.0)	1 (0.0)
Glucocorticoid deficiency	1 (0.0)	0 (0.0)
Goitre	2 (0.1)	6 (0.3)
Hyperaldosteronism	1 (0.0)	0 (0.0)
Hyperparathyroidism	0 (0.0)	1 (0.0)
Hyperparathyroidism secondary	1 (0.0)	1 (0.0)
Hyperplasia adrenal	1 (0.0)	0 (0.0)
Hyperthyroidism	14 (0.7)	8 (0.4)
Hypoparathyroidism secondary	0 (0.0)	1 (0.0)
Hypothyroidism	30 (1.4)	29 (1.3)
Thyroid disorder	1 (0.0)	0 (0.0)
Thyroid mass	2 (0.1)	2 (0.1)
Toxic goitre	0 (0.0)	1 (0.0)
Eye disorders	74 (3.4)	84 (3.9)
Age-related macular degeneration	0 (0.0)	2 (0.1)
Amaurosis fugax	1 (0.0)	0 (0.0)
Asthenopia	0 (0.0)	1 (0.0)
Astigmatism	0 (0.0)	1 (0.0)
Blepharitis	1 (0.0)	1 (0.0)
Blepharospasm	0 (0.0)	1 (0.0)
Cataract	21 (1.0)	21 (1.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Chalazion	0 (0.0)	1 (0.0)
Conjunctival haemorrhage	5 (0.2)	5 (0.2)
Conjunctival irritation	0 (0.0)	1 (0.0)
Conjunctivitis allergic	1 (0.0)	1 (0.0)
Corneal erosion	1 (0.0)	0 (0.0)
Corneal lesion	0 (0.0)	1 (0.0)
Diabetic retinopathy	8 (0.4)	5 (0.2)
Diplopia	1 (0.0)	0 (0.0)
Dry eye	5 (0.2)	4 (0.2)
Eye colour change	0 (0.0)	1 (0.0)
Eye haematoma	0 (0.0)	3 (0.1)
Eye haemorrhage	1 (0.0)	1 (0.0)
Eye inflammation	0 (0.0)	1 (0.0)
Eye oedema	0 (0.0)	1 (0.0)
Eye ulcer	1 (0.0)	0 (0.0)
Eyelid oedema	1 (0.0)	1 (0.0)
Eyelid ptosis	1 (0.0)	0 (0.0)
Flat anterior chamber of eye	0 (0.0)	1 (0.0)
Foreign body sensation in eyes	0 (0.0)	1 (0.0)
Glaucoma	4 (0.2)	1 (0.0)
Hypermetropia	0 (0.0)	1 (0.0)
Iritis	0 (0.0)	1 (0.0)
Keratitis	1 (0.0)	0 (0.0)
Lacrimation increased	1 (0.0)	1 (0.0)
Macular cyst	0 (0.0)	1 (0.0)
Macular degeneration	2 (0.1)	0 (0.0)
Maculopathy	1 (0.0)	0 (0.0)
Meibomian gland dysfunction	0 (0.0)	1 (0.0)
Myopia	0 (0.0)	1 (0.0)
Neovascular age-related macular degeneration	1 (0.0)	0 (0.0)
Ocular hyperaemia	2 (0.1)	5 (0.2)
Oculorespiratory syndrome	0 (0.0)	1 (0.0)
Optic neuropathy	1 (0.0)	0 (0.0)
Periorbital swelling	1 (0.0)	0 (0.0)
Posterior capsule opacification	0 (0.0)	1 (0.0)
Presbyopia	1 (0.0)	0 (0.0)
Retinal artery thrombosis	1 (0.0)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Retinal degeneration	1 (0.0)	0 (0.0)
Retinal detachment	1 (0.0)	1 (0.0)
Retinal haemorrhage	1 (0.0)	1 (0.0)
Retinal vascular disorder	1 (0.0)	1 (0.0)
Retinopathy	1 (0.0)	0 (0.0)
Retinopathy hypertensive	2 (0.1)	0 (0.0)
Swelling of eyelid	0 (0.0)	1 (0.0)
Tractional retinal detachment	1 (0.0)	1 (0.0)
Trichiasis	0 (0.0)	1 (0.0)
Ulcerative keratitis	1 (0.0)	0 (0.0)
Vision blurred	8 (0.4)	10 (0.5)
Visual acuity reduced	1 (0.0)	4 (0.2)
Visual impairment	4 (0.2)	4 (0.2)
Vitreous degeneration	1 (0.0)	0 (0.0)
Vitreous detachment	1 (0.0)	0 (0.0)
Vitreous floaters	0 (0.0)	1 (0.0)
Vitreous haemorrhage	5 (0.2)	3 (0.1)
Xanthopsia	0 (0.0)	1 (0.0)
Gastrointestinal disorders	537 (25.0)	474 (22.0)
Abdominal discomfort	14 (0.7)	7 (0.3)
Abdominal distension	16 (0.7)	20 (0.9)
Abdominal hernia	0 (0.0)	2 (0.1)
Abdominal mass	1 (0.0)	0 (0.0)
Abdominal pain	30 (1.4)	27 (1.3)
Abdominal pain lower	1 (0.0)	2 (0.1)
Abdominal pain upper	33 (1.5)	26 (1.2)
Abdominal rigidity	1 (0.0)	0 (0.0)
Abdominal tenderness	0 (0.0)	1 (0.0)
Abdominal wall haematoma	0 (0.0)	1 (0.0)
Abnormal faeces	0 (0.0)	1 (0.0)
Acid peptic disease	1 (0.0)	1 (0.0)
Alcoholic pancreatitis	1 (0.0)	0 (0.0)
Anal fissure	0 (0.0)	1 (0.0)
Anal fistula	1 (0.0)	0 (0.0)
Anal haemorrhage	0 (0.0)	1 (0.0)
Anal incontinence	2 (0.1)	2 (0.1)
Anal pruritus	0 (0.0)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Angular cheilitis	1 (0.0)	0 (0.0)
Anorectal disorder	1 (0.0)	0 (0.0)
Anorectal ulcer	1 (0.0)	0 (0.0)
Ascites	18 (0.8)	17 (0.8)
Barrett's oesophagus	1 (0.0)	2 (0.1)
Chronic gastritis	15 (0.7)	13 (0.6)
Coating in mouth	0 (0.0)	1 (0.0)
Colitis	2 (0.1)	5 (0.2)
Colitis ischaemic	2 (0.1)	1 (0.0)
Constipation	68 (3.2)	63 (2.9)
Dental caries	6 (0.3)	6 (0.3)
Diaphragmatic hernia	1 (0.0)	0 (0.0)
Diarrhoea	107 (5.0)	116 (5.4)
Diverticulum	6 (0.3)	3 (0.1)
Diverticulum intestinal	7 (0.3)	7 (0.3)
Dry mouth	4 (0.2)	9 (0.4)
Duodenal ulcer	2 (0.1)	3 (0.1)
Duodenitis	5 (0.2)	5 (0.2)
Duodenogastric reflux	1 (0.0)	1 (0.0)
Dyspepsia	55 (2.6)	25 (1.2)
Dysphagia	9 (0.4)	8 (0.4)
Enteritis	1 (0.0)	2 (0.1)
Enterocolitis	0 (0.0)	2 (0.1)
Epigastric discomfort	3 (0.1)	6 (0.3)
Erosive duodenitis	1 (0.0)	1 (0.0)
Erosive oesophagitis	3 (0.1)	0 (0.0)
Eructation	3 (0.1)	0 (0.0)
Faecaloma	1 (0.0)	3 (0.1)
Faeces discoloured	4 (0.2)	0 (0.0)
Faeces soft	2 (0.1)	0 (0.0)
Flatulence	4 (0.2)	3 (0.1)
Food poisoning	1 (0.0)	2 (0.1)
Frequent bowel movements	1 (0.0)	0 (0.0)
Functional gastrointestinal disorder	0 (0.0)	1 (0.0)
Gastric antral vascular ectasia	0 (0.0)	1 (0.0)
Gastric dilatation	1 (0.0)	0 (0.0)
Gastric disorder	2 (0.1)	6 (0.3)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Gastric haemorrhage	2 (0.1)	0 (0.0)
Gastric mucosa erythema	3 (0.1)	1 (0.0)
Gastric perforation	1 (0.0)	0 (0.0)
Gastric polyps	5 (0.2)	2 (0.1)
Gastric ulcer	6 (0.3)	6 (0.3)
Gastric ulcer haemorrhage	0 (0.0)	1 (0.0)
Gastritis	20 (0.9)	25 (1.2)
Gastritis erosive	13 (0.6)	7 (0.3)
Gastritis haemorrhagic	0 (0.0)	1 (0.0)
Gastritis hypertrophic	0 (0.0)	1 (0.0)
Gastroduodenal ulcer	0 (0.0)	1 (0.0)
Gastrointestinal angiodysplasia	1 (0.0)	4 (0.2)
Gastrointestinal disorder	3 (0.1)	1 (0.0)
Gastrointestinal erosion	1 (0.0)	0 (0.0)
Gastrointestinal haemorrhage	13 (0.6)	12 (0.6)
Gastrointestinal melanosis	1 (0.0)	0 (0.0)
Gastrointestinal motility disorder	0 (0.0)	1 (0.0)
Gastrointestinal polyp	0 (0.0)	1 (0.0)
Gastrointestinal toxicity	1 (0.0)	0 (0.0)
Gastrointestinal ulcer	1 (0.0)	0 (0.0)
Gastrooesophageal reflux disease	39 (1.8)	15 (0.7)
Gingival bleeding	2 (0.1)	3 (0.1)
Gingival pain	3 (0.1)	1 (0.0)
Gingival swelling	1 (0.0)	0 (0.0)
Haematemesis	3 (0.1)	3 (0.1)
Haematochezia	2 (0.1)	7 (0.3)
Haemorrhoidal haemorrhage	2 (0.1)	3 (0.1)
Haemorrhoids	17 (0.8)	14 (0.7)
Haemorrhoids thrombosed	0 (0.0)	1 (0.0)
Hiatus hernia	10 (0.5)	6 (0.3)
Ileus	2 (0.1)	2 (0.1)
Ileus paralytic	1 (0.0)	0 (0.0)
Impaired gastric emptying	4 (0.2)	0 (0.0)
Incarcerated inguinal hernia	0 (0.0)	3 (0.1)
Incarcerated umbilical hernia	1 (0.0)	0 (0.0)
Inguinal hernia	19 (0.9)	8 (0.4)
Inguinal hernia strangulated	1 (0.0)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Inguinal hernia, obstructive	1 (0.0)	0 (0.0)
Intestinal congestion	1 (0.0)	0 (0.0)
Intestinal haemorrhage	0 (0.0)	1 (0.0)
Intestinal infarction	0 (0.0)	1 (0.0)
Intestinal ischaemia	1 (0.0)	1 (0.0)
Intestinal obstruction	1 (0.0)	0 (0.0)
Intestinal polyp	0 (0.0)	2 (0.1)
Intra-abdominal fluid collection	0 (0.0)	2 (0.1)
Intra-abdominal haematoma	2 (0.1)	1 (0.0)
Irritable bowel syndrome	2 (0.1)	1 (0.0)
Ischaemic enteritis	0 (0.0)	1 (0.0)
Large intestinal haemorrhage	1 (0.0)	0 (0.0)
Large intestinal stenosis	0 (0.0)	1 (0.0)
Large intestinal ulcer	0 (0.0)	1 (0.0)
Large intestinal ulcer haemorrhage	0 (0.0)	1 (0.0)
Large intestinal ulcer perforation	1 (0.0)	0 (0.0)
Large intestine polyp	11 (0.5)	12 (0.6)
Lip dry	1 (0.0)	0 (0.0)
Lip ulceration	1 (0.0)	0 (0.0)
Loose tooth	0 (0.0)	1 (0.0)
Lower gastrointestinal haemorrhage	2 (0.1)	2 (0.1)
Melaena	3 (0.1)	4 (0.2)
Mouth haemorrhage	2 (0.1)	1 (0.0)
Mouth ulceration	4 (0.2)	2 (0.1)
Nausea	82 (3.8)	60 (2.8)
Oesophageal achalasia	0 (0.0)	2 (0.1)
Oesophageal disorder	1 (0.0)	0 (0.0)
Oesophageal irritation	1 (0.0)	0 (0.0)
Oesophageal stenosis	1 (0.0)	0 (0.0)
Oesophageal varices haemorrhage	0 (0.0)	1 (0.0)
Oesophagitis	8 (0.4)	1 (0.0)
Oesophagitis ulcerative	0 (0.0)	1 (0.0)
Oral contusion	1 (0.0)	0 (0.0)
Oral pain	0 (0.0)	1 (0.0)
Pancreatic cyst	1 (0.0)	0 (0.0)
Pancreatic disorder	1 (0.0)	1 (0.0)
Pancreatic enlargement	1 (0.0)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Pancreatic steatosis	1 (0.0)	1 (0.0)
Pancreatitis	1 (0.0)	3 (0.1)
Pancreatitis acute	2 (0.1)	1 (0.0)
Pancreatitis chronic	4 (0.2)	3 (0.1)
Pancreatolithiasis	1 (0.0)	0 (0.0)
Peptic ulcer	2 (0.1)	5 (0.2)
Periodontal disease	2 (0.1)	1 (0.0)
Peritoneal haemorrhage	0 (0.0)	1 (0.0)
Pharyngo-oesophageal diverticulum	0 (0.0)	1 (0.0)
Pneumatosis intestinalis	0 (0.0)	1 (0.0)
Portal hypertensive gastropathy	1 (0.0)	0 (0.0)
Rectal haemorrhage	12 (0.6)	5 (0.2)
Rectal polyp	0 (0.0)	5 (0.2)
Regurgitation	0 (0.0)	1 (0.0)
Small intestinal obstruction	1 (0.0)	0 (0.0)
Small intestine polyp	1 (0.0)	0 (0.0)
Subileus	0 (0.0)	1 (0.0)
Swollen tongue	1 (0.0)	1 (0.0)
Tongue dry	0 (0.0)	1 (0.0)
Tongue haemorrhage	0 (0.0)	1 (0.0)
Toothache	4 (0.2)	7 (0.3)
Umbilical hernia	4 (0.2)	0 (0.0)
Upper gastrointestinal haemorrhage	3 (0.1)	9 (0.4)
Vomiting	50 (2.3)	44 (2.0)
General disorders and administration site conditions	321 (14.9)	340 (15.8)
Adverse drug reaction	1 (0.0)	0 (0.0)
Asthenia	41 (1.9)	47 (2.2)
Cardiac complication associated with device	1 (0.0)	0 (0.0)
Catheter site haematoma	0 (0.0)	1 (0.0)
Catheter site haemorrhage	2 (0.1)	1 (0.0)
Catheter site pain	1 (0.0)	1 (0.0)
Catheter site phlebitis	0 (0.0)	1 (0.0)
Catheter site ulcer	0 (0.0)	1 (0.0)
Chest discomfort	15 (0.7)	17 (0.8)
Chest pain	50 (2.3)	66 (3.1)
Chills	2 (0.1)	3 (0.1)
Complication associated with device	1 (0.0)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Cyst	1 (0.0)	0 (0.0)
Device related thrombosis	0 (0.0)	1 (0.0)
Discomfort	2 (0.1)	2 (0.1)
Drug intolerance	4 (0.2)	4 (0.2)
Dysplasia	1 (0.0)	0 (0.0)
Effusion	0 (0.0)	1 (0.0)
Enanthema	0 (0.0)	1 (0.0)
Energy increased	0 (0.0)	1 (0.0)
Exercise tolerance decreased	0 (0.0)	2 (0.1)
Face oedema	1 (0.0)	1 (0.0)
Fat tissue increased	0 (0.0)	1 (0.0)
Fatigue	41 (1.9)	42 (2.0)
Gait disturbance	6 (0.3)	3 (0.1)
General physical health deterioration	8 (0.4)	4 (0.2)
Generalised oedema	3 (0.1)	1 (0.0)
Haemorrhagic cyst	0 (0.0)	1 (0.0)
Hernia	3 (0.1)	0 (0.0)
Hunger	0 (0.0)	1 (0.0)
Ill-defined disorder	1 (0.0)	1 (0.0)
Impaired healing	1 (0.0)	1 (0.0)
Implant site erythema	0 (0.0)	1 (0.0)
Implant site haematoma	2 (0.1)	0 (0.0)
Implant site haemorrhage	0 (0.0)	1 (0.0)
Inflammation	3 (0.1)	0 (0.0)
Influenza like illness	1 (0.0)	4 (0.2)
Infusion site inflammation	1 (0.0)	1 (0.0)
Infusion site pain	0 (0.0)	1 (0.0)
Infusion site phlebitis	0 (0.0)	1 (0.0)
Injection site reaction	1 (0.0)	0 (0.0)
Localised oedema	1 (0.0)	1 (0.0)
Malaise	7 (0.3)	8 (0.4)
Medical device pain	1 (0.0)	0 (0.0)
Medical device site haematoma	1 (0.0)	0 (0.0)
Medical device site haemorrhage	0 (0.0)	1 (0.0)
Medical device site pain	1 (0.0)	1 (0.0)
Medical device site pruritus	0 (0.0)	1 (0.0)
Medical device site swelling	0 (0.0)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Medical device site thrombosis	0 (0.0)	1 (0.0)
Mucosal inflammation	1 (0.0)	0 (0.0)
Multiple organ dysfunction syndrome	2 (0.1)	4 (0.2)
Non-cardiac chest pain	11 (0.5)	14 (0.7)
Oedema	15 (0.7)	21 (1.0)
Oedema due to renal disease	1 (0.0)	0 (0.0)
Oedema peripheral	82 (3.8)	80 (3.7)
Pain	3 (0.1)	8 (0.4)
Pelvic mass	0 (0.0)	1 (0.0)
Peripheral swelling	25 (1.2)	18 (0.8)
Physical deconditioning	0 (0.0)	1 (0.0)
Polyp	1 (0.0)	3 (0.1)
Pyrexia	29 (1.3)	30 (1.4)
Sensation of foreign body	1 (0.0)	0 (0.0)
Strangulated hernia	0 (0.0)	1 (0.0)
Sudden cardiac death	0 (0.0)	1 (0.0)
Swelling	1 (0.0)	3 (0.1)
Systemic inflammatory response syndrome	0 (0.0)	1 (0.0)
Temperature intolerance	0 (0.0)	1 (0.0)
Therapeutic response unexpected	0 (0.0)	1 (0.0)
Thirst	0 (0.0)	1 (0.0)
Treatment noncompliance	0 (0.0)	1 (0.0)
UGT1A1 gene polymorphism	0 (0.0)	1 (0.0)
Unevaluable event	0 (0.0)	1 (0.0)
Vascular stent occlusion	1 (0.0)	0 (0.0)
Vascular stent stenosis	1 (0.0)	1 (0.0)
Vascular stent thrombosis	0 (0.0)	1 (0.0)
Vessel puncture site haematoma	0 (0.0)	1 (0.0)
Hepatobiliary disorders	110 (5.1)	103 (4.8)
Acute hepatic failure	1 (0.0)	3 (0.1)
Bile duct obstruction	1 (0.0)	0 (0.0)
Bile duct stone	3 (0.1)	1 (0.0)
Biliary colic	2 (0.1)	0 (0.0)
Biliary dyskinesia	1 (0.0)	1 (0.0)
Biloma	0 (0.0)	1 (0.0)
Cardiac cirrhosis	1 (0.0)	3 (0.1)
Cholangitis	0 (0.0)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Cholangitis acute	0 (0.0)	1 (0.0)
Cholecystitis	6 (0.3)	7 (0.3)
Cholecystitis acute	6 (0.3)	5 (0.2)
Cholecystitis chronic	6 (0.3)	5 (0.2)
Cholelithiasis	20 (0.9)	18 (0.8)
Cholestasis	1 (0.0)	1 (0.0)
Chronic hepatic failure	0 (0.0)	1 (0.0)
Drug-induced liver injury	0 (0.0)	1 (0.0)
Gallbladder oedema	1 (0.0)	0 (0.0)
Gallbladder polyp	1 (0.0)	0 (0.0)
Hepatic calcification	0 (0.0)	1 (0.0)
Hepatic cirrhosis	5 (0.2)	5 (0.2)
Hepatic congestion	10 (0.5)	9 (0.4)
Hepatic cyst	2 (0.1)	1 (0.0)
Hepatic failure	3 (0.1)	2 (0.1)
Hepatic fibrosis	1 (0.0)	0 (0.0)
Hepatic function abnormal	10 (0.5)	19 (0.9)
Hepatic lesion	1 (0.0)	0 (0.0)
Hepatic mass	2 (0.1)	0 (0.0)
Hepatic steatosis	11 (0.5)	5 (0.2)
Hepatitis acute	1 (0.0)	1 (0.0)
Hepatitis toxic	0 (0.0)	1 (0.0)
Hepatocellular injury	2 (0.1)	0 (0.0)
Hepatomegaly	5 (0.2)	3 (0.1)
Hepatorenal syndrome	0 (0.0)	1 (0.0)
Hydrocholecystis	1 (0.0)	0 (0.0)
Hyperbilirubinaemia	7 (0.3)	9 (0.4)
Hyperplastic cholecystopathy	1 (0.0)	0 (0.0)
Ischaemic hepatitis	8 (0.4)	6 (0.3)
Jaundice	0 (0.0)	3 (0.1)
Jaundice cholestatic	1 (0.0)	0 (0.0)
Liver disorder	5 (0.2)	2 (0.1)
Liver injury	6 (0.3)	2 (0.1)
Non-alcoholic steatohepatitis	0 (0.0)	1 (0.0)
Portosplenomesenteric venous thrombosis	0 (0.0)	1 (0.0)
Immune system disorders	8 (0.4)	12 (0.6)
Amyloidosis	2 (0.1)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Contrast media allergy	2 (0.1)	0 (0.0)
Drug hypersensitivity	0 (0.0)	2 (0.1)
Hypersensitivity	2 (0.1)	6 (0.3)
Immunisation reaction	0 (0.0)	1 (0.0)
Multiple allergies	0 (0.0)	1 (0.0)
Seasonal allergy	2 (0.1)	3 (0.1)
Infections and infestations	745 (34.6)	743 (34.5)
Abdominal abscess	1 (0.0)	0 (0.0)
Abscess	0 (0.0)	1 (0.0)
Abscess limb	8 (0.4)	5 (0.2)
Abscess neck	1 (0.0)	1 (0.0)
Acarodermatitis	2 (0.1)	0 (0.0)
Acinetobacter bacteraemia	1 (0.0)	0 (0.0)
Acute sinusitis	0 (0.0)	1 (0.0)
Amoebic dysentery	1 (0.0)	0 (0.0)
Anal abscess	0 (0.0)	2 (0.1)
Appendicitis	0 (0.0)	1 (0.0)
Asymptomatic bacteriuria	1 (0.0)	0 (0.0)
Atypical pneumonia	1 (0.0)	1 (0.0)
Bacillus bacteraemia	1 (0.0)	0 (0.0)
Bacteraemia	1 (0.0)	2 (0.1)
Bacterial disease carrier	0 (0.0)	1 (0.0)
Bacterial sepsis	1 (0.0)	0 (0.0)
Bacteriuria	1 (0.0)	0 (0.0)
Body tinea	1 (0.0)	1 (0.0)
Borrelia infection	1 (0.0)	0 (0.0)
Bronchiolitis	0 (0.0)	1 (0.0)
Bronchitis	71 (3.3)	89 (4.1)
Bronchitis bacterial	1 (0.0)	1 (0.0)
Bronchitis viral	4 (0.2)	3 (0.1)
Campylobacter gastroenteritis	1 (0.0)	0 (0.0)
Candida infection	1 (0.0)	1 (0.0)
Carbuncle	1 (0.0)	0 (0.0)
Cellulitis	45 (2.1)	39 (1.8)
Cellulitis gangrenous	1 (0.0)	0 (0.0)
Chest wall abscess	1 (0.0)	0 (0.0)
Cholecystitis infective	0 (0.0)	2 (0.1)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Chronic sinusitis	3 (0.1)	2 (0.1)
Clostridium difficile colitis	4 (0.2)	0 (0.0)
Clostridium difficile infection	1 (0.0)	2 (0.1)
Complicated appendicitis	2 (0.1)	0 (0.0)
Conjunctivitis	12 (0.6)	5 (0.2)
Cystitis	10 (0.5)	7 (0.3)
Cystitis bacterial	0 (0.0)	1 (0.0)
Cytomegalovirus infection	1 (0.0)	0 (0.0)
Dermatophytosis of nail	3 (0.1)	0 (0.0)
Device related infection	6 (0.3)	2 (0.1)
Diabetic foot infection	1 (0.0)	2 (0.1)
Diarrhoea infectious	1 (0.0)	1 (0.0)
Diverticulitis	1 (0.0)	2 (0.1)
Ear infection	1 (0.0)	2 (0.1)
Ear infection fungal	1 (0.0)	0 (0.0)
Eczema infected	0 (0.0)	1 (0.0)
Encephalitis	1 (0.0)	0 (0.0)
Endocarditis	6 (0.3)	1 (0.0)
Enterobacter bacteraemia	1 (0.0)	0 (0.0)
Enterobiasis	1 (0.0)	0 (0.0)
Enterococcal bacteraemia	1 (0.0)	0 (0.0)
Enterococcal infection	0 (0.0)	1 (0.0)
Enterocolitis infectious	0 (0.0)	1 (0.0)
Enterocolitis viral	1 (0.0)	0 (0.0)
Epididymitis	4 (0.2)	1 (0.0)
Erysipelas	6 (0.3)	12 (0.6)
Escherichia urinary tract infection	2 (0.1)	0 (0.0)
Extradural abscess	1 (0.0)	0 (0.0)
Eye infection bacterial	0 (0.0)	1 (0.0)
Folliculitis	2 (0.1)	1 (0.0)
Fungaemia	1 (0.0)	0 (0.0)
Fungal infection	0 (0.0)	1 (0.0)
Fungal sepsis	0 (0.0)	1 (0.0)
Fungal skin infection	3 (0.1)	2 (0.1)
Furuncle	1 (0.0)	1 (0.0)
Gangrene	5 (0.2)	2 (0.1)
Gas gangrene	0 (0.0)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Gastroenteritis	36 (1.7)	31 (1.4)
Gastroenteritis bacterial	0 (0.0)	1 (0.0)
Gastroenteritis salmonella	1 (0.0)	0 (0.0)
Gastroenteritis viral	5 (0.2)	5 (0.2)
Gastrointestinal infection	1 (0.0)	1 (0.0)
Gastrointestinal viral infection	1 (0.0)	0 (0.0)
Genital abscess	1 (0.0)	0 (0.0)
Gingivitis	2 (0.1)	5 (0.2)
Groin abscess	0 (0.0)	1 (0.0)
H1N1 influenza	1 (0.0)	0 (0.0)
Haematoma infection	1 (0.0)	0 (0.0)
Helicobacter gastritis	0 (0.0)	2 (0.1)
Helicobacter infection	3 (0.1)	2 (0.1)
Hepatitis B	0 (0.0)	2 (0.1)
Hepatitis C	0 (0.0)	1 (0.0)
Herpes zoster	21 (1.0)	13 (0.6)
Hordeolum	0 (0.0)	1 (0.0)
Impetigo	1 (0.0)	1 (0.0)
Implant site cellulitis	1 (0.0)	0 (0.0)
Implant site infection	3 (0.1)	3 (0.1)
Infected bite	0 (0.0)	1 (0.0)
Infected dermal cyst	1 (0.0)	0 (0.0)
Infected skin ulcer	1 (0.0)	1 (0.0)
Infection	3 (0.1)	10 (0.5)
Infectious pleural effusion	0 (0.0)	1 (0.0)
Infective exacerbation of chronic obstructive airways disease	2 (0.1)	3 (0.1)
Infective keratitis	0 (0.0)	1 (0.0)
Influenza	65 (3.0)	49 (2.3)
Infusion site infection	0 (0.0)	1 (0.0)
Intervertebral discitis	1 (0.0)	1 (0.0)
Klebsiella sepsis	0 (0.0)	1 (0.0)
Large intestine infection	0 (0.0)	1 (0.0)
Laryngitis	3 (0.1)	1 (0.0)
Liver abscess	0 (0.0)	2 (0.1)
Localised infection	10 (0.5)	0 (0.0)
Lower respiratory tract infection	29 (1.3)	32 (1.5)
Lower respiratory tract infection viral	0 (0.0)	2 (0.1)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Lung infection	15 (0.7)	14 (0.7)
Lyme disease	0 (0.0)	1 (0.0)
Lymphangitis	0 (0.0)	1 (0.0)
Measles	1 (0.0)	0 (0.0)
Medical device site abscess	0 (0.0)	1 (0.0)
Myocarditis infectious	2 (0.1)	0 (0.0)
Nasal herpes	1 (0.0)	0 (0.0)
Nasopharyngitis	102 (4.7)	103 (4.8)
Necrotising fasciitis	2 (0.1)	0 (0.0)
Nosocomial infection	1 (0.0)	0 (0.0)
Oesophageal candidiasis	1 (0.0)	3 (0.1)
Onychomycosis	2 (0.1)	1 (0.0)
Ophthalmic herpes zoster	0 (0.0)	1 (0.0)
Oral candidiasis	3 (0.1)	3 (0.1)
Oral herpes	0 (0.0)	2 (0.1)
Orchitis	0 (0.0)	2 (0.1)
Osteomyelitis	9 (0.4)	8 (0.4)
Osteomyelitis acute	1 (0.0)	0 (0.0)
Osteomyelitis chronic	1 (0.0)	0 (0.0)
Otitis externa	6 (0.3)	0 (0.0)
Otitis media	3 (0.1)	4 (0.2)
Otitis media acute	0 (0.0)	1 (0.0)
Otitis media chronic	1 (0.0)	1 (0.0)
Parainfluenzae virus infection	1 (0.0)	1 (0.0)
Parasitic gastroenteritis	1 (0.0)	0 (0.0)
Paronychia	2 (0.1)	1 (0.0)
Parotid abscess	0 (0.0)	1 (0.0)
Periodontitis	3 (0.1)	8 (0.4)
Perirectal abscess	1 (0.0)	0 (0.0)
Peritonitis	0 (0.0)	1 (0.0)
Peritonitis bacterial	3 (0.1)	0 (0.0)
Pertussis	0 (0.0)	1 (0.0)
Pharyngitis	14 (0.7)	9 (0.4)
Pharyngitis bacterial	1 (0.0)	0 (0.0)
Pharyngitis streptococcal	1 (0.0)	0 (0.0)
Phlebitis infective	0 (0.0)	1 (0.0)
Pneumonia	135 (6.3)	157 (7.3)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Pneumonia bacterial	5 (0.2)	3 (0.1)
Pneumonia chlamydial	1 (0.0)	0 (0.0)
Pneumonia pneumococcal	0 (0.0)	1 (0.0)
Pneumonia respiratory syncytial viral	0 (0.0)	1 (0.0)
Pneumonia staphylococcal	0 (0.0)	1 (0.0)
Pneumonia streptococcal	1 (0.0)	0 (0.0)
Pneumonia viral	1 (0.0)	2 (0.1)
Postoperative wound infection	1 (0.0)	3 (0.1)
Pseudomembranous colitis	1 (0.0)	1 (0.0)
Psoas abscess	1 (0.0)	0 (0.0)
Pulmonary sepsis	2 (0.1)	3 (0.1)
Pulpitis dental	0 (0.0)	1 (0.0)
Pyelonephritis	3 (0.1)	0 (0.0)
Pyelonephritis acute	0 (0.0)	1 (0.0)
Pyelonephritis chronic	5 (0.2)	3 (0.1)
Pyuria	0 (0.0)	1 (0.0)
Rash pustular	1 (0.0)	1 (0.0)
Respiratory syncytial virus infection	1 (0.0)	1 (0.0)
Respiratory tract infection	27 (1.3)	32 (1.5)
Respiratory tract infection viral	2 (0.1)	8 (0.4)
Rhinitis	6 (0.3)	11 (0.5)
Rhinovirus infection	1 (0.0)	0 (0.0)
Salmonella bacteraemia	0 (0.0)	1 (0.0)
Scrotal abscess	1 (0.0)	0 (0.0)
Sepsis	19 (0.9)	26 (1.2)
Septic shock	12 (0.6)	12 (0.6)
Serratia bacteraemia	1 (0.0)	0 (0.0)
Sinusitis	6 (0.3)	8 (0.4)
Skin bacterial infection	1 (0.0)	1 (0.0)
Skin infection	3 (0.1)	3 (0.1)
Soft tissue infection	0 (0.0)	1 (0.0)
Staphylococcal bacteraemia	2 (0.1)	2 (0.1)
Staphylococcal infection	1 (0.0)	1 (0.0)
Staphylococcal sepsis	1 (0.0)	0 (0.0)
Staphylococcal skin infection	1 (0.0)	1 (0.0)
Streptococcal bacteraemia	1 (0.0)	0 (0.0)
Subcutaneous abscess	3 (0.1)	2 (0.1)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Systemic candida	1 (0.0)	0 (0.0)
Tinea cruris	1 (0.0)	1 (0.0)
Tinea infection	1 (0.0)	0 (0.0)
Tinea pedis	4 (0.2)	1 (0.0)
Tonsillitis	3 (0.1)	2 (0.1)
Tonsillitis bacterial	0 (0.0)	1 (0.0)
Tooth abscess	3 (0.1)	4 (0.2)
Tooth infection	4 (0.2)	3 (0.1)
Tracheitis	1 (0.0)	0 (0.0)
Tracheobronchitis	3 (0.1)	2 (0.1)
Typhoid fever	0 (0.0)	1 (0.0)
Upper respiratory tract infection	108 (5.0)	100 (4.6)
Urethritis	1 (0.0)	0 (0.0)
Urinary tract infection	79 (3.7)	81 (3.8)
Urinary tract infection bacterial	0 (0.0)	2 (0.1)
Urosepsis	3 (0.1)	1 (0.0)
Vascular device infection	0 (0.0)	1 (0.0)
Vestibular neuronitis	0 (0.0)	1 (0.0)
Viral diarrhoea	0 (0.0)	1 (0.0)
Viral infection	10 (0.5)	6 (0.3)
Viral pharyngitis	1 (0.0)	5 (0.2)
Viral upper respiratory tract infection	6 (0.3)	9 (0.4)
Vulvovaginal candidiasis	2 (0.1)	0 (0.0)
Wound infection	4 (0.2)	3 (0.1)
Wound infection bacterial	1 (0.0)	0 (0.0)
Wound sepsis	1 (0.0)	2 (0.1)
Injury, poisoning and procedural complications	266 (12.4)	270 (12.6)
Accidental overdose	58 (2.7)	40 (1.9)
Acetabulum fracture	0 (0.0)	1 (0.0)
Alcohol poisoning	2 (0.1)	0 (0.0)
Animal bite	2 (0.1)	1 (0.0)
Ankle fracture	5 (0.2)	3 (0.1)
Arteriovenous fistula site complication	1 (0.0)	0 (0.0)
Arteriovenous fistula thrombosis	0 (0.0)	1 (0.0)
Arthropod bite	3 (0.1)	2 (0.1)
Arthropod sting	1 (0.0)	0 (0.0)
Back injury	2 (0.1)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Bone fissure	1 (0.0)	0 (0.0)
Burns second degree	2 (0.1)	1 (0.0)
Burns third degree	0 (0.0)	1 (0.0)
Cardiac valve replacement complication	0 (0.0)	1 (0.0)
Cervical vertebral fracture	1 (0.0)	0 (0.0)
Chest injury	1 (0.0)	1 (0.0)
Chillblains	0 (0.0)	1 (0.0)
Clavicle fracture	0 (0.0)	2 (0.1)
Concussion	2 (0.1)	2 (0.1)
Contusion	18 (0.8)	27 (1.3)
Coronary vascular graft stenosis	0 (0.0)	1 (0.0)
Craniocerebral injury	2 (0.1)	1 (0.0)
Dermatitis artefacta	0 (0.0)	2 (0.1)
Device use issue	0 (0.0)	1 (0.0)
Ear canal abrasion	1 (0.0)	0 (0.0)
Eye contusion	2 (0.1)	1 (0.0)
Face injury	1 (0.0)	3 (0.1)
Facial bones fracture	3 (0.1)	4 (0.2)
Fall	51 (2.4)	51 (2.4)
Femoral neck fracture	0 (0.0)	5 (0.2)
Femur fracture	3 (0.1)	10 (0.5)
Fibula fracture	1 (0.0)	1 (0.0)
Foot fracture	5 (0.2)	2 (0.1)
Forearm fracture	1 (0.0)	0 (0.0)
Foreign body	0 (0.0)	1 (0.0)
Foreign body in ear	1 (0.0)	0 (0.0)
Foreign body in gastrointestinal tract	1 (0.0)	0 (0.0)
Fractured coccyx	1 (0.0)	0 (0.0)
Haematuria traumatic	0 (0.0)	1 (0.0)
Hand fracture	2 (0.1)	2 (0.1)
Head injury	12 (0.6)	14 (0.7)
Heart injury	1 (0.0)	0 (0.0)
Heat illness	0 (0.0)	1 (0.0)
Hip fracture	5 (0.2)	2 (0.1)
Human bite	0 (0.0)	1 (0.0)
Humerus fracture	1 (0.0)	5 (0.2)
Hyphaema	1 (0.0)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
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(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Hypotensive transfusion reaction	0 (0.0)	1 (0.0)
Incision site discharge	0 (0.0)	1 (0.0)
Incision site haematoma	0 (0.0)	1 (0.0)
Incision site haemorrhage	1 (0.0)	0 (0.0)
Incision site pain	0 (0.0)	2 (0.1)
Injury	0 (0.0)	1 (0.0)
Intentional overdose	2 (0.1)	0 (0.0)
Jaw fracture	0 (0.0)	1 (0.0)
Joint dislocation	1 (0.0)	2 (0.1)
Joint injury	4 (0.2)	5 (0.2)
Ligament rupture	1 (0.0)	0 (0.0)
Ligament sprain	9 (0.4)	6 (0.3)
Limb crushing injury	0 (0.0)	1 (0.0)
Limb injury	15 (0.7)	21 (1.0)
Lip injury	1 (0.0)	0 (0.0)
Lower limb fracture	1 (0.0)	3 (0.1)
Meniscus injury	0 (0.0)	1 (0.0)
Mouth injury	1 (0.0)	0 (0.0)
Multiple injuries	0 (0.0)	2 (0.1)
Muscle contusion	0 (0.0)	1 (0.0)
Muscle injury	1 (0.0)	0 (0.0)
Muscle strain	4 (0.2)	0 (0.0)
Nail avulsion	1 (0.0)	0 (0.0)
Nail injury	1 (0.0)	1 (0.0)
Nasal injury	0 (0.0)	1 (0.0)
Overdose	3 (0.1)	3 (0.1)
Penis injury	2 (0.1)	0 (0.0)
Periorbital haematoma	1 (0.0)	0 (0.0)
Post procedural contusion	1 (0.0)	0 (0.0)
Post procedural fever	0 (0.0)	1 (0.0)
Post procedural haematoma	0 (0.0)	3 (0.1)
Post procedural haematuria	1 (0.0)	1 (0.0)
Post procedural haemorrhage	1 (0.0)	8 (0.4)
Post procedural hypothyroidism	0 (0.0)	1 (0.0)
Post-traumatic neck syndrome	0 (0.0)	1 (0.0)
Post-traumatic pain	1 (0.0)	3 (0.1)
Procedural pain	6 (0.3)	2 (0.1)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Product administration error	0 (0.0)	1 (0.0)
Pubis fracture	1 (0.0)	1 (0.0)
Radius fracture	2 (0.1)	1 (0.0)
Reactive gastropathy	0 (0.0)	1 (0.0)
Rib fracture	4 (0.2)	9 (0.4)
Road traffic accident	2 (0.1)	0 (0.0)
Scratch	0 (0.0)	1 (0.0)
Sedation complication	1 (0.0)	0 (0.0)
Skin abrasion	11 (0.5)	5 (0.2)
Skin injury	2 (0.1)	0 (0.0)
Skin laceration	9 (0.4)	11 (0.5)
Skin wound	0 (0.0)	1 (0.0)
Snake bite	0 (0.0)	1 (0.0)
Soft tissue injury	2 (0.1)	2 (0.1)
Spinal compression fracture	5 (0.2)	3 (0.1)
Spinal fracture	2 (0.1)	1 (0.0)
Stoma site haemorrhage	1 (0.0)	0 (0.0)
Subcutaneous haematoma	5 (0.2)	0 (0.0)
Subdural haematoma	4 (0.2)	2 (0.1)
Subdural haemorrhage	0 (0.0)	1 (0.0)
Tendon rupture	1 (0.0)	0 (0.0)
Thermal burn	3 (0.1)	3 (0.1)
Thoracic vertebral fracture	0 (0.0)	1 (0.0)
Tibia fracture	2 (0.1)	2 (0.1)
Tooth fracture	1 (0.0)	2 (0.1)
Toxicity to various agents	4 (0.2)	12 (0.6)
Traumatic fracture	1 (0.0)	0 (0.0)
Traumatic haematoma	2 (0.1)	0 (0.0)
Traumatic ulcer	0 (0.0)	1 (0.0)
Ulna fracture	1 (0.0)	0 (0.0)
Upper limb fracture	2 (0.1)	3 (0.1)
Urethral injury	2 (0.1)	0 (0.0)
Urinary retention postoperative	0 (0.0)	1 (0.0)
Vascular pseudoaneurysm	0 (0.0)	2 (0.1)
Wound	7 (0.3)	0 (0.0)
Wound dehiscence	0 (0.0)	1 (0.0)
Wound haemorrhage	1 (0.0)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Wound secretion	0 (0.0)	3 (0.1)
Wrist fracture	2 (0.1)	1 (0.0)
Investigations	317 (14.7)	348 (16.2)
Aeromonas test positive	1 (0.0)	0 (0.0)
Alanine aminotransferase increased	9 (0.4)	5 (0.2)
Alpha 1 foetoprotein increased	0 (0.0)	1 (0.0)
Angiocardiogram	1 (0.0)	1 (0.0)
Anticoagulation drug level above therapeutic	7 (0.3)	4 (0.2)
Anticoagulation drug level below therapeutic	3 (0.1)	1 (0.0)
Aspartate aminotransferase increased	6 (0.3)	5 (0.2)
Bacterial test positive	1 (0.0)	0 (0.0)
Bilirubin conjugated increased	1 (0.0)	3 (0.1)
Blood albumin decreased	0 (0.0)	1 (0.0)
Blood alkaline phosphatase increased	13 (0.6)	15 (0.7)
Blood bicarbonate decreased	1 (0.0)	1 (0.0)
Blood bilirubin increased	14 (0.7)	23 (1.1)
Blood bilirubin unconjugated increased	1 (0.0)	1 (0.0)
Blood calcium decreased	2 (0.1)	1 (0.0)
Blood cholesterol increased	2 (0.1)	1 (0.0)
Blood creatine increased	2 (0.1)	0 (0.0)
Blood creatine phosphokinase increased	1 (0.0)	2 (0.1)
Blood creatinine decreased	0 (0.0)	1 (0.0)
Blood creatinine increased	45 (2.1)	46 (2.1)
Blood folate decreased	1 (0.0)	0 (0.0)
Blood glucose abnormal	0 (0.0)	1 (0.0)
Blood glucose fluctuation	1 (0.0)	1 (0.0)
Blood glucose increased	10 (0.5)	9 (0.4)
Blood lactate dehydrogenase increased	2 (0.1)	1 (0.0)
Blood magnesium decreased	1 (0.0)	0 (0.0)
Blood potassium abnormal	1 (0.0)	1 (0.0)
Blood potassium decreased	4 (0.2)	4 (0.2)
Blood potassium increased	20 (0.9)	22 (1.0)
Blood pressure decreased	2 (0.1)	5 (0.2)
Blood pressure diastolic decreased	0 (0.0)	1 (0.0)
Blood pressure diastolic increased	0 (0.0)	1 (0.0)
Blood pressure increased	5 (0.2)	15 (0.7)
Blood pressure systolic decreased	1 (0.0)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Blood sodium abnormal	0 (0.0)	1 (0.0)
Blood sodium decreased	2 (0.1)	3 (0.1)
Blood sodium increased	1 (0.0)	0 (0.0)
Blood thyroid stimulating hormone decreased	0 (0.0)	1 (0.0)
Blood thyroid stimulating hormone increased	0 (0.0)	3 (0.1)
Blood triglycerides increased	1 (0.0)	1 (0.0)
Blood urea increased	15 (0.7)	20 (0.9)
Blood uric acid increased	26 (1.2)	32 (1.5)
Blood urine	1 (0.0)	0 (0.0)
Blood urine present	0 (0.0)	1 (0.0)
Bone density abnormal	1 (0.0)	0 (0.0)
Brachial pulse decreased	0 (0.0)	1 (0.0)
Brain natriuretic peptide increased	4 (0.2)	4 (0.2)
C-reactive protein increased	8 (0.4)	5 (0.2)
Carcinoembryonic antigen increased	0 (0.0)	1 (0.0)
Cardiac index abnormal	1 (0.0)	0 (0.0)
Cardiac murmur	1 (0.0)	1 (0.0)
Cardiac stress test abnormal	0 (0.0)	1 (0.0)
Cardioactive drug level increased	0 (0.0)	1 (0.0)
Catheterisation cardiac	2 (0.1)	1 (0.0)
Cell marker increased	1 (0.0)	0 (0.0)
Central venous pressure increased	1 (0.0)	0 (0.0)
Clostridium test positive	1 (0.0)	0 (0.0)
Coagulation time prolonged	1 (0.0)	1 (0.0)
Cortisol decreased	0 (0.0)	1 (0.0)
Echocardiogram abnormal	1 (0.0)	0 (0.0)
Ejection fraction decreased	1 (0.0)	3 (0.1)
Electrocardiogram QT prolonged	0 (0.0)	5 (0.2)
Electrocardiogram R on T phenomenon	1 (0.0)	0 (0.0)
Electrocardiogram T wave abnormal	1 (0.0)	0 (0.0)
Eosinophil count increased	1 (0.0)	0 (0.0)
Fibrin D dimer increased	0 (0.0)	2 (0.1)
Gamma-glutamyltransferase abnormal	1 (0.0)	0 (0.0)
Gamma-glutamyltransferase increased	42 (2.0)	58 (2.7)
Glomerular filtration rate decreased	4 (0.2)	0 (0.0)
Glycosylated haemoglobin increased	20 (0.9)	26 (1.2)
Haematocrit decreased	2 (0.1)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Haemoglobin decreased	7 (0.3)	8 (0.4)
Haemoglobin increased	0 (0.0)	1 (0.0)
Heart rate decreased	1 (0.0)	2 (0.1)
Heart rate increased	0 (0.0)	4 (0.2)
Heart rate irregular	0 (0.0)	1 (0.0)
Hepatic enzyme abnormal	1 (0.0)	0 (0.0)
Hepatic enzyme increased	18 (0.8)	10 (0.5)
Hepatitis B core antibody positive	1 (0.0)	0 (0.0)
Human chorionic gonadotropin positive	1 (0.0)	0 (0.0)
Inflammatory marker increased	1 (0.0)	0 (0.0)
Influenza A virus test positive	0 (0.0)	1 (0.0)
Influenza B virus test positive	0 (0.0)	1 (0.0)
International normalised ratio fluctuation	3 (0.1)	2 (0.1)
International normalised ratio increased	15 (0.7)	7 (0.3)
Intraocular pressure increased	1 (0.0)	0 (0.0)
Lipase increased	1 (0.0)	0 (0.0)
Lipids increased	0 (0.0)	1 (0.0)
Liver function test abnormal	5 (0.2)	3 (0.1)
Liver function test increased	4 (0.2)	8 (0.4)
Low density lipoprotein increased	1 (0.0)	2 (0.1)
Lymphocyte percentage decreased	0 (0.0)	1 (0.0)
Mean cell haemoglobin concentration increased	1 (0.0)	0 (0.0)
Mean cell volume increased	2 (0.1)	0 (0.0)
N-terminal prohormone brain natriuretic peptide increased	1 (0.0)	2 (0.1)
Neutrophil percentage increased	0 (0.0)	1 (0.0)
Occult blood positive	3 (0.1)	4 (0.2)
Oesophagogastroduodenoscopy	0 (0.0)	1 (0.0)
Pancreatic enzymes increased	1 (0.0)	0 (0.0)
Paracentesis	0 (0.0)	1 (0.0)
Platelet count decreased	5 (0.2)	4 (0.2)
Prostatic specific antigen increased	1 (0.0)	4 (0.2)
Protein urine present	0 (0.0)	1 (0.0)
Prothrombin level increased	0 (0.0)	1 (0.0)
Prothrombin time prolonged	1 (0.0)	1 (0.0)
Pulse pressure increased	1 (0.0)	0 (0.0)
Red blood cell count decreased	4 (0.2)	3 (0.1)
Red blood cell sedimentation rate increased	1 (0.0)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Red cell distribution width increased	2 (0.1)	1 (0.0)
Reticulocyte count increased	3 (0.1)	0 (0.0)
Serum ferritin decreased	1 (0.0)	0 (0.0)
Serum ferritin increased	0 (0.0)	1 (0.0)
Thyroid hormones increased	0 (0.0)	1 (0.0)
Transaminases increased	5 (0.2)	3 (0.1)
Transvalvular pressure gradient	1 (0.0)	0 (0.0)
Tri-iodothyronine decreased	0 (0.0)	1 (0.0)
Troponin I increased	1 (0.0)	2 (0.1)
Troponin increased	4 (0.2)	3 (0.1)
Ultrasound kidney abnormal	1 (0.0)	0 (0.0)
Urine output decreased	4 (0.2)	2 (0.1)
Venous pressure jugular increased	1 (0.0)	0 (0.0)
Vitamin B12 decreased	0 (0.0)	1 (0.0)
Weight decreased	27 (1.3)	22 (1.0)
Weight increased	38 (1.8)	45 (2.1)
White blood cell count decreased	2 (0.1)	1 (0.0)
White blood cell count increased	1 (0.0)	2 (0.1)
White blood cells urine positive	0 (0.0)	1 (0.0)
Metabolism and nutrition disorders	470 (21.8)	523 (24.3)
Abnormal loss of weight	1 (0.0)	1 (0.0)
Acidosis	2 (0.1)	1 (0.0)
Alkalosis	1 (0.0)	0 (0.0)
Cachexia	2 (0.1)	2 (0.1)
Carbohydrate intolerance	0 (0.0)	1 (0.0)
Cardiometabolic syndrome	1 (0.0)	0 (0.0)
Decreased appetite	34 (1.6)	29 (1.3)
Dehydration	29 (1.3)	43 (2.0)
Diabetes mellitus	37 (1.7)	47 (2.2)
Diabetes mellitus inadequate control	19 (0.9)	18 (0.8)
Diabetes with hyperosmolarity	0 (0.0)	1 (0.0)
Diabetic ketoacidosis	5 (0.2)	2 (0.1)
Diabetic metabolic decompensation	6 (0.3)	7 (0.3)
Dyslipidaemia	6 (0.3)	4 (0.2)
Electrolyte imbalance	2 (0.1)	2 (0.1)
Failure to thrive	0 (0.0)	1 (0.0)
Fluid overload	8 (0.4)	7 (0.3)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Fluid retention	3 (0.1)	3 (0.1)
Folate deficiency	2 (0.1)	1 (0.0)
Glucose tolerance impaired	2 (0.1)	7 (0.3)
Gout	75 (3.5)	87 (4.0)
Hyperammonaemia	1 (0.0)	0 (0.0)
Hypercalcaemia	4 (0.2)	1 (0.0)
Hypercholesterolaemia	3 (0.1)	3 (0.1)
Hypercreatininaemia	1 (0.0)	0 (0.0)
Hyperglycaemia	24 (1.1)	20 (0.9)
Hyperglycaemic hyperosmolar nonketotic syndrome	4 (0.2)	2 (0.1)
Hyperhomocysteinaemia	1 (0.0)	2 (0.1)
Hyperkalaemia	95 (4.4)	118 (5.5)
Hyperlactacidaemia	2 (0.1)	0 (0.0)
Hyperlipidaemia	11 (0.5)	3 (0.1)
Hypermagnesaemia	1 (0.0)	3 (0.1)
Hypernatraemia	4 (0.2)	3 (0.1)
Hyperosmolar state	1 (0.0)	0 (0.0)
Hyperphosphataemia	0 (0.0)	3 (0.1)
Hypertriglyceridaemia	1 (0.0)	2 (0.1)
Hyperuricaemia	66 (3.1)	56 (2.6)
Hypervitaminosis D	0 (0.0)	1 (0.0)
Hypervolaemia	3 (0.1)	3 (0.1)
Hypoalbuminaemia	1 (0.0)	11 (0.5)
Hypocalcaemia	5 (0.2)	11 (0.5)
Hypochloraemia	4 (0.2)	1 (0.0)
Hypoglycaemia	34 (1.6)	32 (1.5)
Hypokalaemia	76 (3.5)	77 (3.6)
Hypomagnesaemia	10 (0.5)	7 (0.3)
Hyponatraemia	23 (1.1)	42 (2.0)
Hypophagia	2 (0.1)	2 (0.1)
Hypophosphataemia	2 (0.1)	2 (0.1)
Hypoproteinaemia	2 (0.1)	1 (0.0)
Hypovitaminosis	0 (0.0)	1 (0.0)
Hypovolaemia	5 (0.2)	1 (0.0)
Increased appetite	0 (0.0)	1 (0.0)
Insulin resistance	0 (0.0)	1 (0.0)
Iron deficiency	6 (0.3)	12 (0.6)

Summary of Adverse Events by System Organ Class and Preferred Term
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Ketoacidosis	0 (0.0)	1 (0.0)
Lactic acidosis	1 (0.0)	1 (0.0)
Malnutrition	1 (0.0)	1 (0.0)
Marasmus	1 (0.0)	0 (0.0)
Metabolic acidosis	8 (0.4)	9 (0.4)
Metabolic alkalosis	1 (0.0)	1 (0.0)
Mineral metabolism disorder	1 (0.0)	1 (0.0)
Obesity	2 (0.1)	1 (0.0)
Type 2 diabetes mellitus	19 (0.9)	21 (1.0)
Vitamin B complex deficiency	1 (0.0)	0 (0.0)
Vitamin B12 deficiency	2 (0.1)	0 (0.0)
Vitamin D deficiency	6 (0.3)	3 (0.1)
Weight fluctuation	1 (0.0)	1 (0.0)
Zinc deficiency	0 (0.0)	1 (0.0)
Musculoskeletal and connective tissue disorders	271 (12.6)	295 (13.7)
Amyotrophy	0 (0.0)	1 (0.0)
Arthralgia	43 (2.0)	46 (2.1)
Arthritis	11 (0.5)	10 (0.5)
Arthropathy	1 (0.0)	1 (0.0)
Back disorder	0 (0.0)	1 (0.0)
Back pain	52 (2.4)	50 (2.3)
Bone disorder	1 (0.0)	0 (0.0)
Bone formation increased	1 (0.0)	0 (0.0)
Bone pain	1 (0.0)	1 (0.0)
Bone swelling	1 (0.0)	0 (0.0)
Cervical spinal stenosis	0 (0.0)	2 (0.1)
Chondritis	1 (0.0)	0 (0.0)
Chondrocalcinosis pyrophosphate	0 (0.0)	1 (0.0)
Chondrodynia	1 (0.0)	0 (0.0)
Costochondritis	2 (0.1)	0 (0.0)
Dupuytren's contracture	1 (0.0)	0 (0.0)
Enthesopathy	1 (0.0)	0 (0.0)
Exostosis	1 (0.0)	3 (0.1)
Flank pain	3 (0.1)	5 (0.2)
Foot deformity	1 (0.0)	0 (0.0)
Gouty arthritis	14 (0.7)	15 (0.7)
Gouty tophus	0 (0.0)	4 (0.2)

Summary of Adverse Events by System Organ Class and Preferred Term
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(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Groin pain	1 (0.0)	1 (0.0)
Haemarthrosis	1 (0.0)	1 (0.0)
Haematoma muscle	0 (0.0)	3 (0.1)
Intervertebral disc degeneration	1 (0.0)	2 (0.1)
Intervertebral disc disorder	0 (0.0)	1 (0.0)
Intervertebral disc protrusion	1 (0.0)	4 (0.2)
Joint contracture	0 (0.0)	1 (0.0)
Joint effusion	1 (0.0)	3 (0.1)
Joint instability	2 (0.1)	0 (0.0)
Joint stiffness	0 (0.0)	1 (0.0)
Joint swelling	3 (0.1)	4 (0.2)
Limb discomfort	0 (0.0)	1 (0.0)
Lumbar spinal stenosis	3 (0.1)	2 (0.1)
Muscle contracture	0 (0.0)	1 (0.0)
Muscle fatigue	0 (0.0)	2 (0.1)
Muscle spasms	27 (1.3)	25 (1.2)
Muscle twitching	1 (0.0)	0 (0.0)
Muscular weakness	5 (0.2)	9 (0.4)
Musculoskeletal chest pain	9 (0.4)	10 (0.5)
Musculoskeletal discomfort	1 (0.0)	2 (0.1)
Musculoskeletal pain	22 (1.0)	29 (1.3)
Musculoskeletal stiffness	3 (0.1)	5 (0.2)
Myalgia	16 (0.7)	12 (0.6)
Myofascial pain syndrome	0 (0.0)	1 (0.0)
Myopathy	1 (0.0)	1 (0.0)
Myositis	1 (0.0)	0 (0.0)
Neck pain	11 (0.5)	14 (0.7)
Osteitis	0 (0.0)	1 (0.0)
Osteoarthritis	15 (0.7)	15 (0.7)
Osteochondrosis	1 (0.0)	6 (0.3)
Osteonecrosis	0 (0.0)	1 (0.0)
Osteonecrosis of jaw	0 (0.0)	1 (0.0)
Osteoporosis	3 (0.1)	5 (0.2)
Pain in extremity	41 (1.9)	44 (2.0)
Pain in jaw	1 (0.0)	3 (0.1)
Pathological fracture	0 (0.0)	1 (0.0)
Periarthritis	6 (0.3)	4 (0.2)

Summary of Adverse Events by System Organ Class and Preferred Term
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Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Plantar fasciitis	1 (0.0)	0 (0.0)
Polyarthritis	1 (0.0)	2 (0.1)
Polymyalgia rheumatica	0 (0.0)	1 (0.0)
Rhabdomyolysis	0 (0.0)	1 (0.0)
Rheumatic disorder	2 (0.1)	1 (0.0)
Rheumatoid arthritis	4 (0.2)	2 (0.1)
Rotator cuff syndrome	2 (0.1)	3 (0.1)
Sacroiliitis	2 (0.1)	0 (0.0)
Sarcopenia	0 (0.0)	1 (0.0)
Scleroderma	1 (0.0)	0 (0.0)
Sjogren's syndrome	2 (0.1)	0 (0.0)
Soft tissue necrosis	1 (0.0)	0 (0.0)
Soft tissue swelling	0 (0.0)	1 (0.0)
Spinal osteoarthritis	9 (0.4)	5 (0.2)
Spinal pain	6 (0.3)	5 (0.2)
Spinal stenosis	2 (0.1)	1 (0.0)
Spondylitis	2 (0.1)	0 (0.0)
Synovial cyst	0 (0.0)	1 (0.0)
Synovitis	1 (0.0)	0 (0.0)
Tendon disorder	0 (0.0)	2 (0.1)
Tendonitis	4 (0.2)	1 (0.0)
Tenosynovitis	2 (0.1)	3 (0.1)
Torticollis	1 (0.0)	1 (0.0)
Trigger finger	2 (0.1)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	64 (3.0)	65 (3.0)
Adenocarcinoma gastric	3 (0.1)	1 (0.0)
Adenocarcinoma of colon	1 (0.0)	0 (0.0)
Adenocarcinoma pancreas	0 (0.0)	1 (0.0)
Adrenal adenoma	0 (0.0)	1 (0.0)
Adrenal neoplasm	0 (0.0)	1 (0.0)
Angiocentric lymphoma	1 (0.0)	0 (0.0)
Basal cell carcinoma	2 (0.1)	2 (0.1)
Benign anorectal neoplasm	0 (0.0)	1 (0.0)
Benign gastric neoplasm	1 (0.0)	0 (0.0)
Benign neoplasm of bladder	1 (0.0)	0 (0.0)
Benign neoplasm of eyelid	0 (0.0)	1 (0.0)
Bladder cancer	1 (0.0)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Bladder cancer recurrent	1 (0.0)	0 (0.0)
Bladder neoplasm	3 (0.1)	0 (0.0)
Bladder transitional cell carcinoma	0 (0.0)	2 (0.1)
Bone cancer metastatic	0 (0.0)	1 (0.0)
Bowen's disease	0 (0.0)	1 (0.0)
Breast cancer	0 (0.0)	1 (0.0)
Bronchial carcinoma	1 (0.0)	0 (0.0)
Chronic lymphocytic leukaemia	0 (0.0)	1 (0.0)
Colon adenoma	1 (0.0)	4 (0.2)
Colon neoplasm	0 (0.0)	1 (0.0)
Cutaneous T-cell lymphoma	2 (0.1)	0 (0.0)
Diffuse large B-cell lymphoma	0 (0.0)	1 (0.0)
Enchondromatosis	1 (0.0)	0 (0.0)
Essential thrombocythaemia	0 (0.0)	1 (0.0)
Gallbladder cancer	0 (0.0)	1 (0.0)
Gastric cancer	2 (0.1)	1 (0.0)
Gastrointestinal tract adenoma	1 (0.0)	0 (0.0)
Glioblastoma multiforme	1 (0.0)	0 (0.0)
Glottis carcinoma	0 (0.0)	1 (0.0)
Haemangioma	1 (0.0)	1 (0.0)
Haemangioma of bone	0 (0.0)	1 (0.0)
Haemangioma of liver	0 (0.0)	2 (0.1)
Hepatic cancer	1 (0.0)	1 (0.0)
Hepatic cancer metastatic	0 (0.0)	1 (0.0)
Hepatic neoplasm	0 (0.0)	1 (0.0)
Hepatocellular carcinoma	0 (0.0)	2 (0.1)
Inflammatory pseudotumour	0 (0.0)	1 (0.0)
Intraductal papillary mucinous neoplasm	0 (0.0)	1 (0.0)
Kidney angiomyolipoma	1 (0.0)	0 (0.0)
Large intestine benign neoplasm	2 (0.1)	0 (0.0)
Lipoma	0 (0.0)	2 (0.1)
Lung adenocarcinoma	1 (0.0)	1 (0.0)
Lung cancer metastatic	1 (0.0)	0 (0.0)
Lung neoplasm malignant	0 (0.0)	3 (0.1)
Lymphoma	1 (0.0)	0 (0.0)
Lymphoproliferative disorder	0 (0.0)	1 (0.0)
Malignant melanoma	2 (0.1)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
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Participants with Screening Ejection Fraction < 40%

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Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Mediastinum neoplasm	0 (0.0)	1 (0.0)
Melanocytic naevus	1 (0.0)	1 (0.0)
Meningioma	0 (0.0)	1 (0.0)
Metastases to abdominal cavity	1 (0.0)	0 (0.0)
Metastases to bone	1 (0.0)	1 (0.0)
Metastases to lung	2 (0.1)	1 (0.0)
Metastases to lymph nodes	0 (0.0)	1 (0.0)
Metastatic neoplasm	0 (0.0)	1 (0.0)
Metastatic squamous cell carcinoma	1 (0.0)	0 (0.0)
Monoclonal gammopathy	1 (0.0)	0 (0.0)
Myelofibrosis	1 (0.0)	0 (0.0)
Neoplasm	1 (0.0)	0 (0.0)
Neoplasm skin	1 (0.0)	0 (0.0)
Oesophageal carcinoma	1 (0.0)	0 (0.0)
Oropharyngeal cancer	1 (0.0)	0 (0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	0 (0.0)
Ovarian cancer	0 (0.0)	1 (0.0)
Pancreatic carcinoma	1 (0.0)	1 (0.0)
Pancreatic carcinoma metastatic	1 (0.0)	0 (0.0)
Parathyroid tumour benign	1 (0.0)	0 (0.0)
Plasma cell myeloma	1 (0.0)	2 (0.1)
Plasmacytoma	0 (0.0)	1 (0.0)
Polycythaemia vera	0 (0.0)	2 (0.1)
Prostate cancer	3 (0.1)	6 (0.3)
Prostate cancer metastatic	1 (0.0)	0 (0.0)
Prostatic adenoma	0 (0.0)	1 (0.0)
Pyogenic granuloma	1 (0.0)	0 (0.0)
Queyrat erythroplasia	1 (0.0)	0 (0.0)
Rectal cancer	0 (0.0)	2 (0.1)
Rectosigmoid cancer	1 (0.0)	0 (0.0)
Renal cancer	2 (0.1)	1 (0.0)
Renal neoplasm	2 (0.1)	0 (0.0)
Retroperitoneal cancer	1 (0.0)	0 (0.0)
Seborrhoeic keratosis	0 (0.0)	1 (0.0)
Skin papilloma	0 (0.0)	1 (0.0)
Squamous cell carcinoma	1 (0.0)	2 (0.1)
Squamous cell carcinoma of head and neck	2 (0.1)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
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Participants with Screening Ejection Fraction < 40%

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Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Squamous cell carcinoma of lung	1 (0.0)	0 (0.0)
Squamous cell carcinoma of skin	2 (0.1)	0 (0.0)
Squamous cell carcinoma of the oral cavity	0 (0.0)	1 (0.0)
Sweat gland tumour	1 (0.0)	1 (0.0)
T-cell lymphoma	1 (0.0)	0 (0.0)
Tongue neoplasm malignant stage unspecified	1 (0.0)	0 (0.0)
Tumour ulceration	0 (0.0)	1 (0.0)
Uterine cancer	0 (0.0)	1 (0.0)
Uterine leiomyoma	3 (0.1)	0 (0.0)
Waldenstrom's macroglobulinaemia	1 (0.0)	0 (0.0)
Nervous system disorders	400 (18.6)	378 (17.6)
Altered state of consciousness	2 (0.1)	0 (0.0)
Amnesia	3 (0.1)	3 (0.1)
Aphasia	1 (0.0)	2 (0.1)
Ataxia	2 (0.1)	0 (0.0)
Autonomic nervous system imbalance	0 (0.0)	1 (0.0)
Autonomic neuropathy	2 (0.1)	0 (0.0)
Axonal neuropathy	1 (0.0)	0 (0.0)
Balance disorder	5 (0.2)	1 (0.0)
Brain hypoxia	1 (0.0)	0 (0.0)
Brain injury	2 (0.1)	2 (0.1)
Brain oedema	1 (0.0)	1 (0.0)
Burning sensation	0 (0.0)	2 (0.1)
Carotid arteriosclerosis	4 (0.2)	4 (0.2)
Carotid artery dolichoectasia	0 (0.0)	1 (0.0)
Carotid artery occlusion	0 (0.0)	1 (0.0)
Carotid artery stenosis	2 (0.1)	1 (0.0)
Carpal tunnel syndrome	2 (0.1)	5 (0.2)
Cauda equina syndrome	1 (0.0)	0 (0.0)
Cerebellar calcification	1 (0.0)	0 (0.0)
Cerebral arteriosclerosis	0 (0.0)	1 (0.0)
Cerebral artery stenosis	0 (0.0)	1 (0.0)
Cerebral atrophy	3 (0.1)	0 (0.0)
Cerebral disorder	1 (0.0)	1 (0.0)
Cerebral haemorrhage	1 (0.0)	1 (0.0)
Cerebral infarction	1 (0.0)	2 (0.1)
Cerebral ischaemia	3 (0.1)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Cerebral small vessel ischaemic disease	1 (0.0)	0 (0.0)
Cerebrovascular accident	5 (0.2)	8 (0.4)
Cerebrovascular disorder	2 (0.1)	0 (0.0)
Cerebrovascular insufficiency	0 (0.0)	1 (0.0)
Cervicobrachial syndrome	0 (0.0)	2 (0.1)
Cognitive disorder	8 (0.4)	9 (0.4)
Coma	1 (0.0)	0 (0.0)
Cubital tunnel syndrome	1 (0.0)	0 (0.0)
Dementia	7 (0.3)	3 (0.1)
Dementia Alzheimer's type	0 (0.0)	1 (0.0)
Diabetic mononeuropathy	0 (0.0)	1 (0.0)
Diabetic neuropathy	4 (0.2)	5 (0.2)
Dizziness	141 (6.6)	130 (6.0)
Dizziness postural	5 (0.2)	9 (0.4)
Dysaesthesia	1 (0.0)	0 (0.0)
Dysarthria	0 (0.0)	5 (0.2)
Dysgeusia	2 (0.1)	0 (0.0)
Dyskinesia	1 (0.0)	2 (0.1)
Encephalopathy	2 (0.1)	4 (0.2)
Epilepsy	2 (0.1)	1 (0.0)
Facial paralysis	1 (0.0)	1 (0.0)
Generalised tonic-clonic seizure	0 (0.0)	2 (0.1)
Head discomfort	1 (0.0)	0 (0.0)
Headache	74 (3.4)	55 (2.6)
Hemiparesis	2 (0.1)	2 (0.1)
Hemiplegia	0 (0.0)	1 (0.0)
Hepatic encephalopathy	0 (0.0)	1 (0.0)
Hydrocephalus	1 (0.0)	1 (0.0)
Hypersomnia	0 (0.0)	2 (0.1)
Hypertensive encephalopathy	1 (0.0)	0 (0.0)
Hypoaesthesia	15 (0.7)	10 (0.5)
Hyporesponsive to stimuli	1 (0.0)	0 (0.0)
Hypotonia	1 (0.0)	0 (0.0)
Hypoxic-ischaemic encephalopathy	1 (0.0)	2 (0.1)
Intention tremor	0 (0.0)	1 (0.0)
Ischaemic cerebral infarction	1 (0.0)	0 (0.0)
Ischaemic stroke	1 (0.0)	2 (0.1)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Lacunar infarction	1 (0.0)	2 (0.1)
Lethargy	1 (0.0)	5 (0.2)
Loss of consciousness	2 (0.1)	1 (0.0)
Lumbar radiculopathy	2 (0.1)	0 (0.0)
Memory impairment	4 (0.2)	3 (0.1)
Metabolic encephalopathy	0 (0.0)	2 (0.1)
Migraine	1 (0.0)	1 (0.0)
Mononeuropathy	0 (0.0)	1 (0.0)
Motor dysfunction	1 (0.0)	0 (0.0)
Muscle spasticity	1 (0.0)	0 (0.0)
Myelopathy	1 (0.0)	1 (0.0)
Myoclonus	0 (0.0)	5 (0.2)
Nervous system disorder	1 (0.0)	0 (0.0)
Neuralgia	4 (0.2)	3 (0.1)
Neurological symptom	1 (0.0)	0 (0.0)
Neuropathy peripheral	6 (0.3)	4 (0.2)
Paraesthesia	8 (0.4)	7 (0.3)
Paralysis	0 (0.0)	1 (0.0)
Parkinson's disease	0 (0.0)	1 (0.0)
Parkinsonism	1 (0.0)	0 (0.0)
Peripheral motor neuropathy	0 (0.0)	1 (0.0)
Peripheral nerve lesion	0 (0.0)	1 (0.0)
Peripheral sensory neuropathy	1 (0.0)	1 (0.0)
Peroneal nerve palsy	1 (0.0)	0 (0.0)
Phantom limb syndrome	1 (0.0)	0 (0.0)
Polyneuropathy	2 (0.1)	2 (0.1)
Poor quality sleep	2 (0.1)	2 (0.1)
Post cardiac arrest syndrome	1 (0.0)	0 (0.0)
Post herpetic neuralgia	1 (0.0)	2 (0.1)
Post stroke epilepsy	1 (0.0)	0 (0.0)
Presyncope	10 (0.5)	8 (0.4)
Psychomotor hyperactivity	0 (0.0)	1 (0.0)
Radiculopathy	2 (0.1)	0 (0.0)
Restless legs syndrome	1 (0.0)	2 (0.1)
Sciatica	6 (0.3)	6 (0.3)
Seizure	4 (0.2)	3 (0.1)
Sensory disturbance	1 (0.0)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Slow speech	0 (0.0)	1 (0.0)
Somnolence	7 (0.3)	6 (0.3)
Speech disorder	1 (0.0)	0 (0.0)
Spinal cord compression	0 (0.0)	1 (0.0)
Spinal cord disorder	0 (0.0)	1 (0.0)
Status epilepticus	1 (0.0)	0 (0.0)
Subarachnoid haemorrhage	1 (0.0)	0 (0.0)
Syncope	89 (4.1)	80 (3.7)
Tension headache	3 (0.1)	0 (0.0)
Thalamus haemorrhage	0 (0.0)	1 (0.0)
Tongue biting	1 (0.0)	1 (0.0)
Tonic convulsion	1 (0.0)	0 (0.0)
Transient ischaemic attack	4 (0.2)	2 (0.1)
Tremor	8 (0.4)	8 (0.4)
Tunnel vision	0 (0.0)	1 (0.0)
Vascular dementia	0 (0.0)	2 (0.1)
Vascular encephalopathy	0 (0.0)	1 (0.0)
Vascular parkinsonism	0 (0.0)	1 (0.0)
Vertebrobasilar dolichoectasia	0 (0.0)	1 (0.0)
Vertebrobasilar insufficiency	1 (0.0)	0 (0.0)
Vocal cord paralysis	0 (0.0)	1 (0.0)
White matter lesion	1 (0.0)	1 (0.0)
Product issues	10 (0.5)	16 (0.7)
Device battery issue	1 (0.0)	3 (0.1)
Device breakage	1 (0.0)	0 (0.0)
Device dislocation	0 (0.0)	2 (0.1)
Device failure	0 (0.0)	1 (0.0)
Device inappropriate shock delivery	3 (0.1)	0 (0.0)
Device ineffective	0 (0.0)	1 (0.0)
Device malfunction	3 (0.1)	5 (0.2)
Device stimulation issue	1 (0.0)	3 (0.1)
Lead dislodgement	1 (0.0)	1 (0.0)
Psychiatric disorders	91 (4.2)	121 (5.6)
Abnormal dreams	1 (0.0)	0 (0.0)
Adjustment disorder with anxiety	0 (0.0)	1 (0.0)
Aggression	0 (0.0)	1 (0.0)
Alcohol abuse	0 (0.0)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Alcohol use disorder	1 (0.0)	0 (0.0)
Anxiety	14 (0.7)	11 (0.5)
Anxiety disorder	0 (0.0)	3 (0.1)
Anxiety disorder due to a general medical condition	0 (0.0)	1 (0.0)
Bipolar disorder	0 (0.0)	1 (0.0)
Confusional state	5 (0.2)	5 (0.2)
Delirium	5 (0.2)	15 (0.7)
Depressed mood	4 (0.2)	4 (0.2)
Depression	16 (0.7)	21 (1.0)
Disorientation	2 (0.1)	1 (0.0)
Disruptive mood dysregulation disorder	1 (0.0)	0 (0.0)
Drug abuse	0 (0.0)	1 (0.0)
Drug use disorder	1 (0.0)	0 (0.0)
Hallucination	2 (0.1)	2 (0.1)
Head banging	1 (0.0)	0 (0.0)
Illusion	0 (0.0)	1 (0.0)
Initial insomnia	1 (0.0)	0 (0.0)
Insomnia	30 (1.4)	46 (2.1)
Major depression	1 (0.0)	0 (0.0)
Mania	1 (0.0)	0 (0.0)
Mental disorder	1 (0.0)	0 (0.0)
Mental disorder due to a general medical condition	1 (0.0)	0 (0.0)
Mental status changes	1 (0.0)	2 (0.1)
Middle insomnia	0 (0.0)	1 (0.0)
Nervousness	1 (0.0)	0 (0.0)
Neurologic somatic symptom disorder	1 (0.0)	0 (0.0)
Nightmare	0 (0.0)	1 (0.0)
Organic brain syndrome	1 (0.0)	0 (0.0)
Panic attack	1 (0.0)	1 (0.0)
Personality change	1 (0.0)	0 (0.0)
Psychotic disorder	1 (0.0)	0 (0.0)
Restlessness	1 (0.0)	3 (0.1)
Sleep disorder	3 (0.1)	10 (0.5)
Sleep terror	1 (0.0)	0 (0.0)
Somatic symptom disorder	0 (0.0)	2 (0.1)
Suicide attempt	2 (0.1)	0 (0.0)
Tension	0 (0.0)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Renal and urinary disorders	374 (17.4)	379 (17.6)
Acute kidney injury	118 (5.5)	112 (5.2)
Anuria	1 (0.0)	1 (0.0)
Azotaemia	2 (0.1)	3 (0.1)
Bladder cyst	1 (0.0)	0 (0.0)
Bladder dilatation	1 (0.0)	0 (0.0)
Bladder mass	0 (0.0)	1 (0.0)
Bladder outlet obstruction	0 (0.0)	1 (0.0)
Calculus bladder	2 (0.1)	0 (0.0)
Calculus urethral	0 (0.0)	1 (0.0)
Calculus urinary	2 (0.1)	1 (0.0)
Chronic kidney disease	77 (3.6)	77 (3.6)
Costovertebral angle tenderness	0 (0.0)	2 (0.1)
Diabetic nephropathy	2 (0.1)	5 (0.2)
Dysuria	4 (0.2)	7 (0.3)
End stage renal disease	1 (0.0)	1 (0.0)
Haematuria	18 (0.8)	21 (1.0)
Hydronephrosis	1 (0.0)	2 (0.1)
Hypertensive nephropathy	1 (0.0)	0 (0.0)
Hypertonic bladder	1 (0.0)	0 (0.0)
Incontinence	1 (0.0)	0 (0.0)
Kidney congestion	1 (0.0)	0 (0.0)
Lower urinary tract symptoms	0 (0.0)	1 (0.0)
Nephrolithiasis	6 (0.3)	9 (0.4)
Nephropathy	11 (0.5)	4 (0.2)
Nephropathy toxic	0 (0.0)	3 (0.1)
Nephroptosis	1 (0.0)	1 (0.0)
Neurogenic bladder	0 (0.0)	2 (0.1)
Nocturia	0 (0.0)	2 (0.1)
Oliguria	0 (0.0)	1 (0.0)
Pollakiuria	3 (0.1)	2 (0.1)
Polyuria	0 (0.0)	2 (0.1)
Prerenal failure	0 (0.0)	1 (0.0)
Proteinuria	2 (0.1)	2 (0.1)
Pyelocaliectasis	1 (0.0)	1 (0.0)
Renal artery stenosis	2 (0.1)	3 (0.1)
Renal atrophy	1 (0.0)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Renal colic	3 (0.1)	1 (0.0)
Renal cyst	19 (0.9)	11 (0.5)
Renal disorder	0 (0.0)	1 (0.0)
Renal failure	77 (3.6)	72 (3.3)
Renal impairment	56 (2.6)	59 (2.7)
Renal infarct	0 (0.0)	1 (0.0)
Renal injury	0 (0.0)	1 (0.0)
Renal ischaemia	1 (0.0)	0 (0.0)
Renal mass	2 (0.1)	1 (0.0)
Renal pain	2 (0.1)	1 (0.0)
Stress urinary incontinence	3 (0.1)	0 (0.0)
Urate nephropathy	2 (0.1)	0 (0.0)
Ureteric dilatation	1 (0.0)	0 (0.0)
Ureterolithiasis	2 (0.1)	0 (0.0)
Urethral stenosis	1 (0.0)	1 (0.0)
Urge incontinence	0 (0.0)	1 (0.0)
Urinary incontinence	2 (0.1)	4 (0.2)
Urinary retention	14 (0.7)	7 (0.3)
Urinary tract obstruction	0 (0.0)	2 (0.1)
Vesicoureteric reflux	1 (0.0)	0 (0.0)
Reproductive system and breast disorders	72 (3.3)	73 (3.4)
Adenomyosis	1 (0.0)	0 (0.0)
Adnexa uteri cyst	1 (0.0)	0 (0.0)
Atrophic vulvovaginitis	1 (0.0)	0 (0.0)
Benign prostatic hyperplasia	18 (0.8)	22 (1.0)
Breast calcifications	0 (0.0)	1 (0.0)
Breast discharge	0 (0.0)	1 (0.0)
Breast disorder	0 (0.0)	2 (0.1)
Breast fibrosis	0 (0.0)	1 (0.0)
Breast haematoma	0 (0.0)	1 (0.0)
Breast pain	4 (0.2)	2 (0.1)
Breast tenderness	0 (0.0)	1 (0.0)
Cystocele	1 (0.0)	0 (0.0)
Endometrial hyperplasia	1 (0.0)	0 (0.0)
Endometrial hypertrophy	0 (0.0)	1 (0.0)
Endometriosis	1 (0.0)	0 (0.0)
Erectile dysfunction	1 (0.0)	4 (0.2)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Erection increased	1 (0.0)	1 (0.0)
Genital erythema	1 (0.0)	0 (0.0)
Genital pain	0 (0.0)	1 (0.0)
Gynaecomastia	27 (1.3)	24 (1.1)
Haematospermia	1 (0.0)	0 (0.0)
Menorrhagia	0 (0.0)	1 (0.0)
Metrorrhagia	1 (0.0)	0 (0.0)
Nipple pain	2 (0.1)	0 (0.0)
Ovarian cyst	0 (0.0)	1 (0.0)
Ovarian mass	1 (0.0)	0 (0.0)
Pelvic pain	2 (0.1)	1 (0.0)
Penile discharge	1 (0.0)	0 (0.0)
Penile oedema	0 (0.0)	1 (0.0)
Penile pain	1 (0.0)	1 (0.0)
Postmenopausal haemorrhage	1 (0.0)	0 (0.0)
Priapism	1 (0.0)	0 (0.0)
Prostatic calcification	0 (0.0)	1 (0.0)
Prostatic disorder	1 (0.0)	0 (0.0)
Prostatitis	1 (0.0)	2 (0.1)
Prostatomegaly	0 (0.0)	1 (0.0)
Scrotal mass	0 (0.0)	1 (0.0)
Scrotal varicose veins	1 (0.0)	0 (0.0)
Sexual dysfunction	0 (0.0)	2 (0.1)
Spermatocele	1 (0.0)	0 (0.0)
Uterine enlargement	1 (0.0)	0 (0.0)
Vaginal haemorrhage	2 (0.1)	0 (0.0)
Varicocele	0 (0.0)	2 (0.1)
Vulvovaginal pain	1 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	426 (19.8)	434 (20.2)
Acute pulmonary oedema	3 (0.1)	2 (0.1)
Acute respiratory distress syndrome	1 (0.0)	0 (0.0)
Acute respiratory failure	8 (0.4)	9 (0.4)
Allergic bronchitis	0 (0.0)	1 (0.0)
Asthma	17 (0.8)	11 (0.5)
Asthma-chronic obstructive pulmonary disease overlap syndrome	0 (0.0)	1 (0.0)
Asthmatic crisis	0 (0.0)	1 (0.0)
Atelectasis	2 (0.1)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Bendopnoea	1 (0.0)	0 (0.0)
Bronchial haemorrhage	0 (0.0)	1 (0.0)
Bronchial hyperreactivity	1 (0.0)	0 (0.0)
Bronchitis chronic	6 (0.3)	6 (0.3)
Bronchospasm	9 (0.4)	6 (0.3)
Catarrh	0 (0.0)	1 (0.0)
Cheyne-Stokes respiration	0 (0.0)	1 (0.0)
Choking	1 (0.0)	0 (0.0)
Chronic obstructive pulmonary disease	63 (2.9)	46 (2.1)
Chronic respiratory failure	0 (0.0)	1 (0.0)
Cough	103 (4.8)	91 (4.2)
Diaphragmalgia	0 (0.0)	1 (0.0)
Dry throat	1 (0.0)	1 (0.0)
Dysphonia	3 (0.1)	4 (0.2)
Dyspnoea	121 (5.6)	113 (5.3)
Dyspnoea exertional	21 (1.0)	12 (0.6)
Dyspnoea paroxysmal nocturnal	1 (0.0)	3 (0.1)
Emphysema	2 (0.1)	5 (0.2)
Epistaxis	31 (1.4)	50 (2.3)
Haemoptysis	8 (0.4)	7 (0.3)
Haemothorax	0 (0.0)	2 (0.1)
Hiccups	3 (0.1)	5 (0.2)
Hydrothorax	1 (0.0)	7 (0.3)
Hyperventilation	1 (0.0)	1 (0.0)
Hypoxia	2 (0.1)	4 (0.2)
Increased bronchial secretion	1 (0.0)	0 (0.0)
Interstitial lung disease	0 (0.0)	3 (0.1)
Larynx irritation	1 (0.0)	0 (0.0)
Lower respiratory tract congestion	1 (0.0)	2 (0.1)
Lung consolidation	0 (0.0)	1 (0.0)
Lung disorder	2 (0.1)	2 (0.1)
Mediastinal mass	1 (0.0)	0 (0.0)
Nasal congestion	0 (0.0)	3 (0.1)
Nasal mucosal ulcer	1 (0.0)	0 (0.0)
Nasal obstruction	1 (0.0)	0 (0.0)
Nasal polyps	0 (0.0)	1 (0.0)
Nasal septum deviation	1 (0.0)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Nocturnal dyspnoea	1 (0.0)	1 (0.0)
Obstructive airways disorder	0 (0.0)	1 (0.0)
Oropharyngeal discomfort	2 (0.1)	0 (0.0)
Oropharyngeal pain	11 (0.5)	8 (0.4)
Orthopnoea	3 (0.1)	8 (0.4)
Paranasal sinus haemorrhage	0 (0.0)	1 (0.0)
Pickwickian syndrome	0 (0.0)	2 (0.1)
Pleural effusion	27 (1.3)	32 (1.5)
Pleural thickening	1 (0.0)	0 (0.0)
Pleurisy	0 (0.0)	4 (0.2)
Pleuritic pain	0 (0.0)	1 (0.0)
Pneumonia aspiration	9 (0.4)	5 (0.2)
Pneumonitis	0 (0.0)	1 (0.0)
Pneumothorax	4 (0.2)	6 (0.3)
Productive cough	12 (0.6)	19 (0.9)
Pulmonary arterial hypertension	2 (0.1)	1 (0.0)
Pulmonary congestion	3 (0.1)	3 (0.1)
Pulmonary embolism	5 (0.2)	7 (0.3)
Pulmonary fibrosis	1 (0.0)	2 (0.1)
Pulmonary hypertension	12 (0.6)	7 (0.3)
Pulmonary infarction	0 (0.0)	1 (0.0)
Pulmonary mass	2 (0.1)	5 (0.2)
Pulmonary oedema	8 (0.4)	6 (0.3)
Pulmonary pain	0 (0.0)	1 (0.0)
Rales	1 (0.0)	0 (0.0)
Rebound nasal congestion	1 (0.0)	0 (0.0)
Respiratory acidosis	1 (0.0)	1 (0.0)
Respiratory alkalosis	2 (0.1)	1 (0.0)
Respiratory disorder	4 (0.2)	3 (0.1)
Respiratory distress	0 (0.0)	1 (0.0)
Respiratory failure	5 (0.2)	9 (0.4)
Respiratory symptom	0 (0.0)	1 (0.0)
Rhinitis allergic	3 (0.1)	2 (0.1)
Rhinitis hypertrophic	1 (0.0)	0 (0.0)
Rhinorrhoea	6 (0.3)	5 (0.2)
Rhonchi	0 (0.0)	1 (0.0)
Sinus congestion	1 (0.0)	0 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Sinus disorder	1 (0.0)	0 (0.0)
Sinus polyp	0 (0.0)	1 (0.0)
Sleep apnoea syndrome	9 (0.4)	7 (0.3)
Snoring	0 (0.0)	1 (0.0)
Sputum increased	0 (0.0)	2 (0.1)
Throat irritation	3 (0.1)	0 (0.0)
Tonsillar haemorrhage	1 (0.0)	0 (0.0)
Upper respiratory tract congestion	0 (0.0)	2 (0.1)
Upper respiratory tract inflammation	4 (0.2)	3 (0.1)
Upper-airway cough syndrome	0 (0.0)	2 (0.1)
Vasomotor rhinitis	0 (0.0)	1 (0.0)
Wheezing	1 (0.0)	1 (0.0)
Skin and subcutaneous tissue disorders	187 (8.7)	193 (9.0)
Acne	2 (0.1)	2 (0.1)
Actinic keratosis	2 (0.1)	0 (0.0)
Alopecia	2 (0.1)	7 (0.3)
Angioedema	4 (0.2)	0 (0.0)
Asteatosis	2 (0.1)	2 (0.1)
Blister	4 (0.2)	5 (0.2)
Blood blister	0 (0.0)	1 (0.0)
Cold sweat	0 (0.0)	1 (0.0)
Decubitus ulcer	11 (0.5)	4 (0.2)
Dermal cyst	2 (0.1)	0 (0.0)
Dermatitis	2 (0.1)	11 (0.5)
Dermatitis allergic	3 (0.1)	3 (0.1)
Dermatitis atopic	1 (0.0)	0 (0.0)
Dermatitis contact	1 (0.0)	5 (0.2)
Diabetic foot	3 (0.1)	9 (0.4)
Diabetic ulcer	1 (0.0)	1 (0.0)
Drug eruption	3 (0.1)	1 (0.0)
Dry skin	5 (0.2)	5 (0.2)
Ecchymosis	6 (0.3)	6 (0.3)
Eczema	14 (0.7)	10 (0.5)
Eczema asteatotic	2 (0.1)	2 (0.1)
Eczema nummular	1 (0.0)	1 (0.0)
Eczema vesicular	1 (0.0)	0 (0.0)
Erythema	5 (0.2)	2 (0.1)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Haemorrhage subcutaneous	3 (0.1)	1 (0.0)
Henoch-Schonlein purpura	0 (0.0)	1 (0.0)
Hyperhidrosis	3 (0.1)	5 (0.2)
Hyperkeratosis	2 (0.1)	3 (0.1)
Hypersensitivity vasculitis	1 (0.0)	0 (0.0)
Intertrigo	1 (0.0)	0 (0.0)
Ischaemic skin ulcer	0 (0.0)	1 (0.0)
Lichen sclerosus	0 (0.0)	1 (0.0)
Mechanical urticaria	1 (0.0)	0 (0.0)
Neurodermatitis	2 (0.1)	1 (0.0)
Night sweats	0 (0.0)	1 (0.0)
Oedema blister	0 (0.0)	1 (0.0)
Onychoclasis	1 (0.0)	0 (0.0)
Onychogryphosis	1 (0.0)	0 (0.0)
Onycholysis	0 (0.0)	1 (0.0)
Palmar erythema	1 (0.0)	0 (0.0)
Papule	1 (0.0)	1 (0.0)
Peau d'orange	1 (0.0)	0 (0.0)
Pemphigoid	1 (0.0)	1 (0.0)
Petechiae	1 (0.0)	0 (0.0)
Photosensitivity reaction	1 (0.0)	1 (0.0)
Pruritus	32 (1.5)	42 (2.0)
Pruritus allergic	1 (0.0)	0 (0.0)
Pruritus generalised	3 (0.1)	4 (0.2)
Psoriasis	0 (0.0)	3 (0.1)
Purpura	2 (0.1)	0 (0.0)
Rash	23 (1.1)	24 (1.1)
Rash generalised	0 (0.0)	2 (0.1)
Rash macular	1 (0.0)	0 (0.0)
Rash maculo-papular	1 (0.0)	0 (0.0)
Rash papular	1 (0.0)	0 (0.0)
Rash pruritic	5 (0.2)	3 (0.1)
Seborrhoea	1 (0.0)	0 (0.0)
Skin discolouration	1 (0.0)	1 (0.0)
Skin disorder	1 (0.0)	0 (0.0)
Skin erosion	0 (0.0)	2 (0.1)
Skin exfoliation	2 (0.1)	2 (0.1)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Skin fibrosis	0 (0.0)	1 (0.0)
Skin fissures	1 (0.0)	0 (0.0)
Skin lesion	3 (0.1)	0 (0.0)
Skin maceration	0 (0.0)	1 (0.0)
Skin necrosis	2 (0.1)	1 (0.0)
Skin plaque	1 (0.0)	0 (0.0)
Skin ulcer	29 (1.3)	28 (1.3)
Stasis dermatitis	1 (0.0)	6 (0.3)
Swelling face	1 (0.0)	0 (0.0)
Telangiectasia	1 (0.0)	0 (0.0)
Toxic skin eruption	2 (0.1)	0 (0.0)
Urticaria	4 (0.2)	7 (0.3)
Urticaria papular	0 (0.0)	1 (0.0)
Vascular purpura	0 (0.0)	1 (0.0)
Social circumstances	1 (0.0)	0 (0.0)
Alcohol use	1 (0.0)	0 (0.0)
Surgical and medical procedures	38 (1.8)	41 (1.9)
Arrhythmia prophylaxis	0 (0.0)	1 (0.0)
Bladder catheterisation	1 (0.0)	0 (0.0)
Cardiac ablation	0 (0.0)	1 (0.0)
Cardiac contractility modulation therapy	1 (0.0)	0 (0.0)
Cardiac pacemaker replacement	1 (0.0)	1 (0.0)
Cardiac rehabilitation therapy	1 (0.0)	0 (0.0)
Cardiac resynchronisation therapy	6 (0.3)	9 (0.4)
Cardiovascular event prophylaxis	1 (0.0)	4 (0.2)
Cardioversion	8 (0.4)	4 (0.2)
Carpal tunnel decompression	1 (0.0)	1 (0.0)
Cataract operation	0 (0.0)	7 (0.3)
Central venous catheter removal	0 (0.0)	1 (0.0)
Dental care	1 (0.0)	0 (0.0)
Foot amputation	1 (0.0)	0 (0.0)
Implantable defibrillator insertion	8 (0.4)	3 (0.1)
Implantable defibrillator removal	1 (0.0)	0 (0.0)
Implantable defibrillator replacement	2 (0.1)	3 (0.1)
Inguinal hernia repair	1 (0.0)	0 (0.0)
Intraocular lens implant	0 (0.0)	2 (0.1)
Medical device battery replacement	0 (0.0)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Nephroprotective therapy	0 (0.0)	1 (0.0)
Pacemaker generated rhythm	0 (0.0)	1 (0.0)
Percutaneous coronary intervention	1 (0.0)	0 (0.0)
Rotator cuff repair	1 (0.0)	0 (0.0)
Skin lesion removal	1 (0.0)	0 (0.0)
Skin neoplasm excision	0 (0.0)	1 (0.0)
Therapeutic procedure	1 (0.0)	0 (0.0)
Toe operation	1 (0.0)	0 (0.0)
Tooth extraction	0 (0.0)	2 (0.1)
Vascular disorders	479 (22.3)	444 (20.6)
Accelerated hypertension	0 (0.0)	1 (0.0)
Aortic aneurysm	3 (0.1)	3 (0.1)
Aortic arteriosclerosis	0 (0.0)	2 (0.1)
Aortic dissection	1 (0.0)	0 (0.0)
Aortic stenosis	2 (0.1)	1 (0.0)
Arterial occlusive disease	1 (0.0)	1 (0.0)
Arteriosclerosis	5 (0.2)	1 (0.0)
Atheroembolism	1 (0.0)	1 (0.0)
Bleeding varicose vein	2 (0.1)	3 (0.1)
Blood pressure inadequately controlled	2 (0.1)	0 (0.0)
Brachiocephalic arteriosclerosis	0 (0.0)	1 (0.0)
Circulatory collapse	2 (0.1)	1 (0.0)
Deep vein thrombosis	5 (0.2)	5 (0.2)
Diabetic vascular disorder	1 (0.0)	2 (0.1)
Diastolic hypertension	1 (0.0)	0 (0.0)
Dry gangrene	0 (0.0)	1 (0.0)
Embolism arterial	1 (0.0)	0 (0.0)
Extremity necrosis	1 (0.0)	0 (0.0)
Flushing	0 (0.0)	1 (0.0)
Haematoma	15 (0.7)	18 (0.8)
Haemorrhage	2 (0.1)	0 (0.0)
Haemorrhagic vasculitis	0 (0.0)	1 (0.0)
Hot flush	1 (0.0)	1 (0.0)
Hypertension	42 (2.0)	54 (2.5)
Hypertensive crisis	7 (0.3)	5 (0.2)
Hypertensive emergency	2 (0.1)	1 (0.0)
Hypertensive urgency	1 (0.0)	1 (0.0)

Summary of Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Hypotension	339 (15.8)	311 (14.5)
Hypovolaemic shock	4 (0.2)	0 (0.0)
Iliac artery occlusion	1 (0.0)	0 (0.0)
Intermittent claudication	2 (0.1)	5 (0.2)
Internal haemorrhage	1 (0.0)	0 (0.0)
Lymphoedema	1 (0.0)	1 (0.0)
Lymphorrhoea	1 (0.0)	0 (0.0)
Lymphostasis	1 (0.0)	1 (0.0)
Orthostatic hypotension	23 (1.1)	24 (1.1)
Peripheral arterial occlusive disease	12 (0.6)	19 (0.9)
Peripheral artery aneurysm	0 (0.0)	1 (0.0)
Peripheral artery occlusion	3 (0.1)	0 (0.0)
Peripheral artery stenosis	2 (0.1)	1 (0.0)
Peripheral artery thrombosis	0 (0.0)	1 (0.0)
Peripheral coldness	1 (0.0)	1 (0.0)
Peripheral embolism	1 (0.0)	3 (0.1)
Peripheral ischaemia	2 (0.1)	5 (0.2)
Peripheral vascular disorder	7 (0.3)	5 (0.2)
Peripheral venous disease	5 (0.2)	3 (0.1)
Phlebitis	4 (0.2)	4 (0.2)
Phlebitis superficial	1 (0.0)	0 (0.0)
Post thrombotic syndrome	2 (0.1)	1 (0.0)
Shock	1 (0.0)	1 (0.0)
Shock haemorrhagic	0 (0.0)	2 (0.1)
Subclavian vein stenosis	0 (0.0)	1 (0.0)
Systolic hypertension	0 (0.0)	1 (0.0)
Thrombophlebitis	3 (0.1)	6 (0.3)
Thrombophlebitis superficial	0 (0.0)	1 (0.0)
Thrombosis	1 (0.0)	0 (0.0)
Varicose ulceration	1 (0.0)	1 (0.0)
Varicose vein	5 (0.2)	7 (0.3)
Varicose vein ruptured	2 (0.1)	1 (0.0)
Vascular occlusion	1 (0.0)	0 (0.0)
Vasculitis	0 (0.0)	1 (0.0)
Venous thrombosis limb	1 (0.0)	1 (0.0)

a: Database Cutoff Date: 18JUN2019
b: A SOC or specific adverse event appears on this report only if its incidence is > 0% in one or more treatment groups
c: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
PT: Preferred Term; SOC: System Organ Class

1.3.2 Serious Adverse Events by SOC and PT

Table 11
Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Participants with one or more adverse events	702 (32.6)	743 (34.5)
Blood and lymphatic system disorders	39 (1.8)	20 (0.9)
Anaemia	28 (1.3)	16 (0.7)
Autoimmune haemolytic anaemia	1 (0.0)	0 (0.0)
Blood loss anaemia	0 (0.0)	1 (0.0)
Coagulopathy	1 (0.0)	0 (0.0)
Disseminated intravascular coagulation	1 (0.0)	0 (0.0)
Hypocoagulable state	1 (0.0)	0 (0.0)
Iron deficiency anaemia	3 (0.1)	2 (0.1)
Normochromic normocytic anaemia	1 (0.0)	0 (0.0)
Normocytic anaemia	1 (0.0)	0 (0.0)
Pancytopenia	1 (0.0)	0 (0.0)
Splenic infarction	1 (0.0)	0 (0.0)
Thrombocytopenia	2 (0.1)	1 (0.0)
Cardiac disorders	169 (7.9)	240 (11.2)
Acute coronary syndrome	1 (0.0)	3 (0.1)
Acute myocardial infarction	5 (0.2)	3 (0.1)
Angina pectoris	7 (0.3)	6 (0.3)
Angina unstable	1 (0.0)	7 (0.3)
Aortic valve calcification	1 (0.0)	0 (0.0)
Aortic valve incompetence	0 (0.0)	1 (0.0)
Aortic valve stenosis	2 (0.1)	3 (0.1)
Arteriosclerosis coronary artery	2 (0.1)	0 (0.0)
Atrial fibrillation	9 (0.4)	26 (1.2)
Atrial flutter	5 (0.2)	7 (0.3)
Atrial tachycardia	0 (0.0)	1 (0.0)
Atrial thrombosis	0 (0.0)	1 (0.0)
Atrioventricular block	1 (0.0)	0 (0.0)
Atrioventricular block complete	0 (0.0)	1 (0.0)
Bradyarrhythmia	0 (0.0)	1 (0.0)
Bradycardia	0 (0.0)	2 (0.1)
Bundle branch block left	0 (0.0)	2 (0.1)
Cardiac arrest	3 (0.1)	1 (0.0)
Cardiac failure	67 (3.1)	99 (4.6)
Cardiac failure acute	2 (0.1)	4 (0.2)
Cardiac failure chronic	4 (0.2)	9 (0.4)
Cardiac failure congestive	11 (0.5)	22 (1.0)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Cardiac perforation	0 (0.0)	1 (0.0)
Cardiac ventricular thrombosis	2 (0.1)	0 (0.0)
Cardio-respiratory arrest	4 (0.2)	1 (0.0)
Cardiogenic shock	5 (0.2)	4 (0.2)
Cardiopulmonary failure	1 (0.0)	0 (0.0)
Cardiorenal syndrome	2 (0.1)	2 (0.1)
Cardiovascular disorder	1 (0.0)	0 (0.0)
Congestive cardiomyopathy	3 (0.1)	3 (0.1)
Coronary artery disease	5 (0.2)	2 (0.1)
Coronary artery occlusion	0 (0.0)	1 (0.0)
Coronary artery stenosis	2 (0.1)	1 (0.0)
Extrasystoles	1 (0.0)	0 (0.0)
Intracardiac thrombus	0 (0.0)	2 (0.1)
Ischaemic cardiomyopathy	1 (0.0)	2 (0.1)
Left ventricular dysfunction	1 (0.0)	1 (0.0)
Left ventricular failure	0 (0.0)	2 (0.1)
Mitral valve incompetence	5 (0.2)	5 (0.2)
Myocardial infarction	6 (0.3)	3 (0.1)
Myocardial ischaemia	3 (0.1)	1 (0.0)
Palpitations	1 (0.0)	1 (0.0)
Pericardial effusion	0 (0.0)	1 (0.0)
Sinus bradycardia	1 (0.0)	0 (0.0)
Sinus node dysfunction	1 (0.0)	2 (0.1)
Supraventricular tachycardia	1 (0.0)	0 (0.0)
Tachycardia	0 (0.0)	1 (0.0)
Ventricular arrhythmia	2 (0.1)	1 (0.0)
Ventricular dysfunction	0 (0.0)	1 (0.0)
Ventricular extrasystoles	2 (0.1)	2 (0.1)
Ventricular fibrillation	8 (0.4)	6 (0.3)
Ventricular tachycardia	12 (0.6)	23 (1.1)
Congenital, familial and genetic disorders	4 (0.2)	0 (0.0)
Corneal dystrophy	1 (0.0)	0 (0.0)
Gastrointestinal arteriovenous malformation	1 (0.0)	0 (0.0)
Hydrocele	1 (0.0)	0 (0.0)
Phimosis	1 (0.0)	0 (0.0)
Ear and labyrinth disorders	4 (0.2)	7 (0.3)
Vertigo	3 (0.1)	5 (0.2)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Vertigo positional	1 (0.0)	2 (0.1)
Endocrine disorders	7 (0.3)	2 (0.1)
Basedow's disease	1 (0.0)	0 (0.0)
Carcinoid syndrome	1 (0.0)	0 (0.0)
Glucocorticoid deficiency	1 (0.0)	0 (0.0)
Hyperthyroidism	4 (0.2)	1 (0.0)
Hypoparathyroidism secondary	0 (0.0)	1 (0.0)
Hypothyroidism	0 (0.0)	1 (0.0)
Eye disorders	13 (0.6)	7 (0.3)
Cataract	8 (0.4)	4 (0.2)
Diabetic retinopathy	2 (0.1)	1 (0.0)
Diplopia	1 (0.0)	0 (0.0)
Glaucoma	1 (0.0)	0 (0.0)
Macular cyst	0 (0.0)	1 (0.0)
Retinal artery thrombosis	1 (0.0)	0 (0.0)
Retinal haemorrhage	0 (0.0)	1 (0.0)
Vitreous haemorrhage	2 (0.1)	1 (0.0)
Gastrointestinal disorders	85 (3.9)	78 (3.6)
Abdominal pain	4 (0.2)	4 (0.2)
Abdominal pain lower	0 (0.0)	1 (0.0)
Abdominal pain upper	4 (0.2)	2 (0.1)
Abdominal rigidity	1 (0.0)	0 (0.0)
Alcoholic pancreatitis	1 (0.0)	0 (0.0)
Anorectal ulcer	1 (0.0)	0 (0.0)
Ascites	8 (0.4)	3 (0.1)
Barrett's oesophagus	0 (0.0)	1 (0.0)
Colitis	1 (0.0)	2 (0.1)
Colitis ischaemic	1 (0.0)	1 (0.0)
Constipation	2 (0.1)	1 (0.0)
Diarrhoea	7 (0.3)	5 (0.2)
Diverticulum	1 (0.0)	0 (0.0)
Diverticulum intestinal	0 (0.0)	1 (0.0)
Duodenal ulcer	0 (0.0)	3 (0.1)
Erosive oesophagitis	1 (0.0)	0 (0.0)
Faecaloma	0 (0.0)	1 (0.0)
Gastric haemorrhage	2 (0.1)	0 (0.0)
Gastric perforation	1 (0.0)	0 (0.0)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Gastric ulcer	1 (0.0)	2 (0.1)
Gastric ulcer haemorrhage	0 (0.0)	1 (0.0)
Gastritis	3 (0.1)	6 (0.3)
Gastritis erosive	1 (0.0)	2 (0.1)
Gastrointestinal angiodysplasia	1 (0.0)	2 (0.1)
Gastrointestinal haemorrhage	11 (0.5)	6 (0.3)
Gastrointestinal toxicity	1 (0.0)	0 (0.0)
Gastrooesophageal reflux disease	0 (0.0)	3 (0.1)
Haematemesis	1 (0.0)	0 (0.0)
Haematochezia	0 (0.0)	1 (0.0)
Haemorrhoids	3 (0.1)	2 (0.1)
Ileus	2 (0.1)	0 (0.0)
Impaired gastric emptying	2 (0.1)	0 (0.0)
Incarcerated inguinal hernia	0 (0.0)	3 (0.1)
Incarcerated umbilical hernia	1 (0.0)	0 (0.0)
Inguinal hernia	9 (0.4)	6 (0.3)
Inguinal hernia strangulated	1 (0.0)	0 (0.0)
Inguinal hernia, obstructive	1 (0.0)	0 (0.0)
Intestinal infarction	0 (0.0)	1 (0.0)
Intestinal ischaemia	1 (0.0)	1 (0.0)
Intra-abdominal haematoma	0 (0.0)	1 (0.0)
Ischaemic enteritis	0 (0.0)	1 (0.0)
Large intestinal haemorrhage	1 (0.0)	0 (0.0)
Large intestinal stenosis	0 (0.0)	1 (0.0)
Large intestinal ulcer	0 (0.0)	1 (0.0)
Large intestinal ulcer haemorrhage	0 (0.0)	1 (0.0)
Large intestinal ulcer perforation	1 (0.0)	0 (0.0)
Large intestine polyp	1 (0.0)	4 (0.2)
Lower gastrointestinal haemorrhage	1 (0.0)	1 (0.0)
Melaena	1 (0.0)	1 (0.0)
Oesophageal achalasia	0 (0.0)	1 (0.0)
Oesophageal varices haemorrhage	0 (0.0)	1 (0.0)
Pancreatitis	1 (0.0)	0 (0.0)
Pancreatitis acute	2 (0.1)	1 (0.0)
Pancreatitis chronic	1 (0.0)	0 (0.0)
Pancreatolithiasis	1 (0.0)	0 (0.0)
Peptic ulcer	0 (0.0)	1 (0.0)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Pneumatosis intestinalis	0 (0.0)	1 (0.0)
Rectal haemorrhage	3 (0.1)	1 (0.0)
Small intestinal obstruction	1 (0.0)	0 (0.0)
Subileus	0 (0.0)	1 (0.0)
Umbilical hernia	2 (0.1)	0 (0.0)
Upper gastrointestinal haemorrhage	2 (0.1)	5 (0.2)
Vomiting	3 (0.1)	2 (0.1)
General disorders and administration site conditions	37 (1.7)	37 (1.7)
Asthenia	4 (0.2)	2 (0.1)
Cardiac complication associated with device	1 (0.0)	0 (0.0)
Chest discomfort	1 (0.0)	1 (0.0)
Chest pain	9 (0.4)	7 (0.3)
Device related thrombosis	0 (0.0)	1 (0.0)
Discomfort	1 (0.0)	0 (0.0)
General physical health deterioration	6 (0.3)	1 (0.0)
Generalised oedema	1 (0.0)	0 (0.0)
Hernia	1 (0.0)	0 (0.0)
Impaired healing	0 (0.0)	1 (0.0)
Implant site erythema	0 (0.0)	1 (0.0)
Implant site haematoma	2 (0.1)	0 (0.0)
Implant site haemorrhage	0 (0.0)	1 (0.0)
Influenza like illness	0 (0.0)	1 (0.0)
Medical device pain	1 (0.0)	0 (0.0)
Medical device site haematoma	1 (0.0)	0 (0.0)
Medical device site swelling	0 (0.0)	1 (0.0)
Medical device site thrombosis	0 (0.0)	1 (0.0)
Multiple organ dysfunction syndrome	2 (0.1)	4 (0.2)
Non-cardiac chest pain	4 (0.2)	6 (0.3)
Oedema	0 (0.0)	1 (0.0)
Oedema peripheral	0 (0.0)	3 (0.1)
Physical deconditioning	0 (0.0)	1 (0.0)
Pyrexia	3 (0.1)	1 (0.0)
Sensation of foreign body	1 (0.0)	0 (0.0)
Strangulated hernia	0 (0.0)	1 (0.0)
Sudden cardiac death	0 (0.0)	1 (0.0)
UGT1A1 gene polymorphism	0 (0.0)	1 (0.0)
Vascular stent occlusion	1 (0.0)	0 (0.0)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Vascular stent thrombosis	0 (0.0)	1 (0.0)
Hepatobiliary disorders	34 (1.6)	20 (0.9)
Acute hepatic failure	1 (0.0)	3 (0.1)
Bile duct stone	1 (0.0)	1 (0.0)
Biloma	0 (0.0)	1 (0.0)
Cholangitis	0 (0.0)	1 (0.0)
Cholangitis acute	0 (0.0)	1 (0.0)
Cholecystitis	4 (0.2)	3 (0.1)
Cholecystitis acute	4 (0.2)	5 (0.2)
Cholecystitis chronic	1 (0.0)	0 (0.0)
Cholelithiasis	3 (0.1)	1 (0.0)
Cholestasis	1 (0.0)	0 (0.0)
Chronic hepatic failure	0 (0.0)	1 (0.0)
Hepatic cirrhosis	2 (0.1)	1 (0.0)
Hepatic congestion	4 (0.2)	0 (0.0)
Hepatic failure	1 (0.0)	0 (0.0)
Hepatitis acute	1 (0.0)	1 (0.0)
Hepatitis toxic	0 (0.0)	1 (0.0)
Hepatocellular injury	2 (0.1)	0 (0.0)
Ischaemic hepatitis	4 (0.2)	2 (0.1)
Jaundice cholestatic	1 (0.0)	0 (0.0)
Liver disorder	2 (0.1)	0 (0.0)
Liver injury	5 (0.2)	2 (0.1)
Portosplenomesenteric venous thrombosis	0 (0.0)	1 (0.0)
Immune system disorders	1 (0.0)	0 (0.0)
Amyloidosis	1 (0.0)	0 (0.0)
Infections and infestations	231 (10.7)	230 (10.7)
Abscess limb	3 (0.1)	2 (0.1)
Acinetobacter bacteraemia	1 (0.0)	0 (0.0)
Amoebic dysentery	1 (0.0)	0 (0.0)
Anal abscess	0 (0.0)	1 (0.0)
Appendicitis	0 (0.0)	1 (0.0)
Atypical pneumonia	0 (0.0)	1 (0.0)
Bacteraemia	0 (0.0)	1 (0.0)
Bacterial sepsis	1 (0.0)	0 (0.0)
Bronchitis	9 (0.4)	7 (0.3)
Bronchitis viral	2 (0.1)	1 (0.0)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Campylobacter gastroenteritis	1 (0.0)	0 (0.0)
Cellulitis	23 (1.1)	17 (0.8)
Cellulitis gangrenous	1 (0.0)	0 (0.0)
Chest wall abscess	1 (0.0)	0 (0.0)
Cholecystitis infective	0 (0.0)	2 (0.1)
Chronic sinusitis	1 (0.0)	1 (0.0)
Clostridium difficile colitis	2 (0.1)	0 (0.0)
Complicated appendicitis	2 (0.1)	0 (0.0)
Cystitis	1 (0.0)	0 (0.0)
Cystitis bacterial	0 (0.0)	1 (0.0)
Device related infection	4 (0.2)	2 (0.1)
Diabetic foot infection	1 (0.0)	2 (0.1)
Diarrhoea infectious	1 (0.0)	1 (0.0)
Diverticulitis	1 (0.0)	2 (0.1)
Endocarditis	4 (0.2)	1 (0.0)
Enterobacter bacteraemia	1 (0.0)	0 (0.0)
Enterococcal bacteraemia	1 (0.0)	0 (0.0)
Enterococcal infection	0 (0.0)	1 (0.0)
Epididymitis	2 (0.1)	0 (0.0)
Erysipelas	2 (0.1)	6 (0.3)
Escherichia urinary tract infection	1 (0.0)	0 (0.0)
Extradural abscess	1 (0.0)	0 (0.0)
Eye infection bacterial	0 (0.0)	1 (0.0)
Fungaemia	1 (0.0)	0 (0.0)
Gangrene	4 (0.2)	2 (0.1)
Gas gangrene	0 (0.0)	1 (0.0)
Gastroenteritis	16 (0.7)	6 (0.3)
Gastroenteritis bacterial	0 (0.0)	1 (0.0)
Gastroenteritis salmonella	1 (0.0)	0 (0.0)
Groin abscess	0 (0.0)	1 (0.0)
H1N1 influenza	1 (0.0)	0 (0.0)
Haematoma infection	1 (0.0)	0 (0.0)
Herpes zoster	0 (0.0)	1 (0.0)
Implant site cellulitis	1 (0.0)	0 (0.0)
Implant site infection	3 (0.1)	3 (0.1)
Infected bite	0 (0.0)	1 (0.0)
Infected skin ulcer	1 (0.0)	0 (0.0)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Infection	0 (0.0)	2 (0.1)
Infectious pleural effusion	0 (0.0)	1 (0.0)
Infective exacerbation of chronic obstructive airways disease	1 (0.0)	3 (0.1)
Influenza	9 (0.4)	5 (0.2)
Intervertebral discitis	1 (0.0)	1 (0.0)
Klebsiella sepsis	0 (0.0)	1 (0.0)
Liver abscess	0 (0.0)	1 (0.0)
Localised infection	1 (0.0)	0 (0.0)
Lower respiratory tract infection	7 (0.3)	4 (0.2)
Lower respiratory tract infection viral	0 (0.0)	1 (0.0)
Lung infection	8 (0.4)	3 (0.1)
Measles	1 (0.0)	0 (0.0)
Medical device site abscess	0 (0.0)	1 (0.0)
Myocarditis infectious	1 (0.0)	0 (0.0)
Necrotising fasciitis	2 (0.1)	0 (0.0)
Nosocomial infection	1 (0.0)	0 (0.0)
Ophthalmic herpes zoster	0 (0.0)	1 (0.0)
Osteomyelitis	6 (0.3)	4 (0.2)
Osteomyelitis acute	1 (0.0)	0 (0.0)
Osteomyelitis chronic	1 (0.0)	0 (0.0)
Otitis externa	1 (0.0)	0 (0.0)
Parainfluenzae virus infection	1 (0.0)	1 (0.0)
Parotid abscess	0 (0.0)	1 (0.0)
Periodontitis	1 (0.0)	0 (0.0)
Perirectal abscess	1 (0.0)	0 (0.0)
Peritonitis	0 (0.0)	1 (0.0)
Peritonitis bacterial	2 (0.1)	0 (0.0)
Pertussis	0 (0.0)	1 (0.0)
Pneumonia	81 (3.8)	100 (4.6)
Pneumonia bacterial	3 (0.1)	3 (0.1)
Pneumonia chlamydial	1 (0.0)	0 (0.0)
Pneumonia pneumococcal	0 (0.0)	1 (0.0)
Pneumonia respiratory syncytial viral	0 (0.0)	1 (0.0)
Pneumonia staphylococcal	0 (0.0)	1 (0.0)
Pneumonia streptococcal	1 (0.0)	0 (0.0)
Pneumonia viral	1 (0.0)	1 (0.0)
Postoperative wound infection	1 (0.0)	1 (0.0)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Pseudomembranous colitis	0 (0.0)	1 (0.0)
Psoas abscess	1 (0.0)	0 (0.0)
Pulmonary sepsis	2 (0.1)	3 (0.1)
Pyelonephritis	1 (0.0)	0 (0.0)
Pyelonephritis acute	0 (0.0)	1 (0.0)
Pyelonephritis chronic	0 (0.0)	1 (0.0)
Respiratory tract infection	4 (0.2)	3 (0.1)
Respiratory tract infection viral	0 (0.0)	1 (0.0)
Salmonella bacteraemia	0 (0.0)	1 (0.0)
Sepsis	13 (0.6)	22 (1.0)
Septic shock	10 (0.5)	12 (0.6)
Serratia bacteraemia	1 (0.0)	0 (0.0)
Sinusitis	0 (0.0)	1 (0.0)
Skin bacterial infection	1 (0.0)	0 (0.0)
Skin infection	2 (0.1)	0 (0.0)
Staphylococcal bacteraemia	2 (0.1)	1 (0.0)
Staphylococcal infection	1 (0.0)	0 (0.0)
Staphylococcal sepsis	1 (0.0)	0 (0.0)
Staphylococcal skin infection	1 (0.0)	0 (0.0)
Streptococcal bacteraemia	1 (0.0)	0 (0.0)
Subcutaneous abscess	1 (0.0)	0 (0.0)
Systemic candida	1 (0.0)	0 (0.0)
Tooth abscess	0 (0.0)	1 (0.0)
Tracheobronchitis	1 (0.0)	0 (0.0)
Typhoid fever	0 (0.0)	1 (0.0)
Upper respiratory tract infection	9 (0.4)	10 (0.5)
Urinary tract infection	15 (0.7)	12 (0.6)
Urosepsis	3 (0.1)	0 (0.0)
Vestibular neuronitis	0 (0.0)	1 (0.0)
Viral diarrhoea	0 (0.0)	1 (0.0)
Viral infection	2 (0.1)	0 (0.0)
Viral upper respiratory tract infection	2 (0.1)	0 (0.0)
Wound infection	0 (0.0)	2 (0.1)
Wound sepsis	0 (0.0)	2 (0.1)
Injury, poisoning and procedural complications	52 (2.4)	60 (2.8)
Accidental overdose	1 (0.0)	0 (0.0)
Acetabulum fracture	0 (0.0)	1 (0.0)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Alcohol poisoning	1 (0.0)	0 (0.0)
Ankle fracture	2 (0.1)	0 (0.0)
Arteriovenous fistula site complication	1 (0.0)	0 (0.0)
Bone fissure	1 (0.0)	0 (0.0)
Burns second degree	1 (0.0)	1 (0.0)
Burns third degree	0 (0.0)	1 (0.0)
Cardiac valve replacement complication	0 (0.0)	1 (0.0)
Cervical vertebral fracture	1 (0.0)	0 (0.0)
Concussion	2 (0.1)	0 (0.0)
Contusion	1 (0.0)	0 (0.0)
Coronary vascular graft stenosis	0 (0.0)	1 (0.0)
Craniocerebral injury	1 (0.0)	0 (0.0)
Fall	5 (0.2)	4 (0.2)
Femoral neck fracture	0 (0.0)	5 (0.2)
Femur fracture	3 (0.1)	10 (0.5)
Fibula fracture	1 (0.0)	1 (0.0)
Foot fracture	2 (0.1)	1 (0.0)
Head injury	3 (0.1)	1 (0.0)
Heat illness	0 (0.0)	1 (0.0)
Hip fracture	5 (0.2)	2 (0.1)
Humerus fracture	0 (0.0)	3 (0.1)
Incision site haemorrhage	1 (0.0)	0 (0.0)
Limb crushing injury	0 (0.0)	1 (0.0)
Limb injury	1 (0.0)	4 (0.2)
Lower limb fracture	1 (0.0)	2 (0.1)
Multiple injuries	0 (0.0)	2 (0.1)
Overdose	1 (0.0)	0 (0.0)
Penis injury	1 (0.0)	0 (0.0)
Post procedural haematuria	0 (0.0)	1 (0.0)
Post procedural haemorrhage	0 (0.0)	1 (0.0)
Post procedural hypothyroidism	0 (0.0)	1 (0.0)
Pubis fracture	1 (0.0)	1 (0.0)
Radius fracture	1 (0.0)	0 (0.0)
Rib fracture	1 (0.0)	1 (0.0)
Road traffic accident	1 (0.0)	0 (0.0)
Sedation complication	1 (0.0)	0 (0.0)
Skin laceration	3 (0.1)	0 (0.0)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Snake bite	0 (0.0)	1 (0.0)
Spinal compression fracture	1 (0.0)	1 (0.0)
Spinal fracture	0 (0.0)	1 (0.0)
Subdural haematoma	4 (0.2)	1 (0.0)
Subdural haemorrhage	0 (0.0)	1 (0.0)
Tendon rupture	1 (0.0)	0 (0.0)
Thermal burn	0 (0.0)	1 (0.0)
Thoracic vertebral fracture	0 (0.0)	1 (0.0)
Tibia fracture	1 (0.0)	1 (0.0)
Toxicity to various agents	1 (0.0)	6 (0.3)
Traumatic fracture	1 (0.0)	0 (0.0)
Traumatic ulcer	0 (0.0)	1 (0.0)
Upper limb fracture	1 (0.0)	0 (0.0)
Urinary retention postoperative	0 (0.0)	1 (0.0)
Vascular pseudoaneurysm	0 (0.0)	2 (0.1)
Wrist fracture	1 (0.0)	0 (0.0)
Investigations	15 (0.7)	20 (0.9)
Alanine aminotransferase increased	0 (0.0)	1 (0.0)
Angiocardiogram	1 (0.0)	1 (0.0)
Anticoagulation drug level above therapeutic	2 (0.1)	0 (0.0)
Aspartate aminotransferase increased	0 (0.0)	1 (0.0)
Blood bilirubin increased	0 (0.0)	2 (0.1)
Blood creatinine increased	1 (0.0)	1 (0.0)
Blood potassium increased	1 (0.0)	0 (0.0)
Blood urea increased	0 (0.0)	1 (0.0)
Bone density abnormal	1 (0.0)	0 (0.0)
Cardiac index abnormal	1 (0.0)	0 (0.0)
Cardiac stress test abnormal	0 (0.0)	1 (0.0)
Catheterisation cardiac	1 (0.0)	1 (0.0)
Cortisol decreased	0 (0.0)	1 (0.0)
Ejection fraction decreased	0 (0.0)	3 (0.1)
Gamma-glutamyltransferase increased	0 (0.0)	1 (0.0)
Haemoglobin decreased	1 (0.0)	1 (0.0)
Hepatic enzyme abnormal	1 (0.0)	0 (0.0)
Hepatic enzyme increased	1 (0.0)	1 (0.0)
Influenza A virus test positive	0 (0.0)	1 (0.0)
International normalised ratio increased	1 (0.0)	2 (0.1)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Liver function test abnormal	1 (0.0)	0 (0.0)
Liver function test increased	1 (0.0)	1 (0.0)
Transaminases increased	0 (0.0)	1 (0.0)
Troponin increased	1 (0.0)	0 (0.0)
Weight decreased	1 (0.0)	1 (0.0)
Weight increased	0 (0.0)	1 (0.0)
Metabolism and nutrition disorders	67 (3.1)	80 (3.7)
Cachexia	1 (0.0)	0 (0.0)
Dehydration	6 (0.3)	11 (0.5)
Diabetes mellitus	5 (0.2)	9 (0.4)
Diabetes mellitus inadequate control	0 (0.0)	2 (0.1)
Diabetes with hyperosmolarity	0 (0.0)	1 (0.0)
Diabetic ketoacidosis	4 (0.2)	2 (0.1)
Fluid overload	1 (0.0)	1 (0.0)
Gout	10 (0.5)	12 (0.6)
Hyperammonaemia	1 (0.0)	0 (0.0)
Hypercalcaemia	1 (0.0)	1 (0.0)
Hyperglycaemia	4 (0.2)	3 (0.1)
Hyperglycaemic hyperosmolar nonketotic syndrome	3 (0.1)	2 (0.1)
Hyperkalaemia	9 (0.4)	11 (0.5)
Hypernatraemia	1 (0.0)	0 (0.0)
Hyperosmolar state	1 (0.0)	0 (0.0)
Hypoalbuminaemia	0 (0.0)	2 (0.1)
Hypocalcaemia	1 (0.0)	0 (0.0)
Hypochloraemia	1 (0.0)	0 (0.0)
Hypoglycaemia	10 (0.5)	7 (0.3)
Hypokalaemia	5 (0.2)	6 (0.3)
Hypomagnesaemia	1 (0.0)	0 (0.0)
Hyponatraemia	4 (0.2)	5 (0.2)
Hypophosphataemia	1 (0.0)	0 (0.0)
Hypovolaemia	0 (0.0)	1 (0.0)
Ketoacidosis	0 (0.0)	1 (0.0)
Marasmus	1 (0.0)	0 (0.0)
Metabolic acidosis	2 (0.1)	3 (0.1)
Metabolic alkalosis	0 (0.0)	1 (0.0)
Mineral metabolism disorder	1 (0.0)	0 (0.0)
Type 2 diabetes mellitus	5 (0.2)	5 (0.2)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Musculoskeletal and connective tissue disorders	26 (1.2)	30 (1.4)
Arthralgia	3 (0.1)	0 (0.0)
Arthritis	0 (0.0)	2 (0.1)
Back pain	5 (0.2)	3 (0.1)
Chondritis	1 (0.0)	0 (0.0)
Enthesopathy	1 (0.0)	0 (0.0)
Gouty arthritis	7 (0.3)	5 (0.2)
Gouty tophus	0 (0.0)	2 (0.1)
Haematoma muscle	0 (0.0)	1 (0.0)
Intervertebral disc disorder	0 (0.0)	1 (0.0)
Intervertebral disc protrusion	0 (0.0)	1 (0.0)
Lumbar spinal stenosis	1 (0.0)	2 (0.1)
Muscular weakness	1 (0.0)	1 (0.0)
Musculoskeletal chest pain	1 (0.0)	3 (0.1)
Musculoskeletal pain	3 (0.1)	0 (0.0)
Osteoarthritis	2 (0.1)	1 (0.0)
Osteonecrosis	0 (0.0)	1 (0.0)
Pain in extremity	0 (0.0)	2 (0.1)
Pathological fracture	0 (0.0)	1 (0.0)
Polyarthritis	1 (0.0)	1 (0.0)
Rhabdomyolysis	0 (0.0)	1 (0.0)
Rheumatoid arthritis	0 (0.0)	1 (0.0)
Sjogren's syndrome	1 (0.0)	0 (0.0)
Spinal pain	1 (0.0)	3 (0.1)
Spinal stenosis	0 (0.0)	1 (0.0)
Spondylitis	1 (0.0)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	40 (1.9)	38 (1.8)
Adenocarcinoma gastric	3 (0.1)	1 (0.0)
Adenocarcinoma of colon	1 (0.0)	0 (0.0)
Adenocarcinoma pancreas	0 (0.0)	1 (0.0)
Angiocentric lymphoma	1 (0.0)	0 (0.0)
Basal cell carcinoma	0 (0.0)	1 (0.0)
Benign gastric neoplasm	1 (0.0)	0 (0.0)
Benign neoplasm of bladder	1 (0.0)	0 (0.0)
Bladder cancer	1 (0.0)	0 (0.0)
Bladder cancer recurrent	1 (0.0)	0 (0.0)
Bladder neoplasm	1 (0.0)	0 (0.0)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Bladder transitional cell carcinoma	0 (0.0)	2 (0.1)
Bowen's disease	0 (0.0)	1 (0.0)
Breast cancer	0 (0.0)	1 (0.0)
Bronchial carcinoma	1 (0.0)	0 (0.0)
Chronic lymphocytic leukaemia	0 (0.0)	1 (0.0)
Colon adenoma	0 (0.0)	1 (0.0)
Colon neoplasm	0 (0.0)	1 (0.0)
Cutaneous T-cell lymphoma	1 (0.0)	0 (0.0)
Diffuse large B-cell lymphoma	0 (0.0)	1 (0.0)
Gastric cancer	2 (0.1)	1 (0.0)
Glioblastoma multiforme	1 (0.0)	0 (0.0)
Hepatic cancer	1 (0.0)	0 (0.0)
Hepatic cancer metastatic	0 (0.0)	1 (0.0)
Hepatic neoplasm	0 (0.0)	1 (0.0)
Hepatocellular carcinoma	0 (0.0)	2 (0.1)
Inflammatory pseudotumour	0 (0.0)	1 (0.0)
Lung adenocarcinoma	1 (0.0)	0 (0.0)
Lung cancer metastatic	1 (0.0)	0 (0.0)
Lung neoplasm malignant	0 (0.0)	3 (0.1)
Lymphoma	1 (0.0)	0 (0.0)
Lymphoproliferative disorder	0 (0.0)	1 (0.0)
Malignant melanoma	1 (0.0)	0 (0.0)
Meningioma	0 (0.0)	1 (0.0)
Metastases to abdominal cavity	1 (0.0)	0 (0.0)
Metastases to bone	1 (0.0)	0 (0.0)
Metastases to lung	1 (0.0)	0 (0.0)
Metastases to lymph nodes	0 (0.0)	1 (0.0)
Metastatic neoplasm	0 (0.0)	1 (0.0)
Oesophageal carcinoma	1 (0.0)	0 (0.0)
Oropharyngeal cancer	1 (0.0)	0 (0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	0 (0.0)
Ovarian cancer	0 (0.0)	1 (0.0)
Pancreatic carcinoma	1 (0.0)	1 (0.0)
Pancreatic carcinoma metastatic	1 (0.0)	0 (0.0)
Plasma cell myeloma	1 (0.0)	2 (0.1)
Plasmacytoma	0 (0.0)	1 (0.0)
Polycythaemia vera	0 (0.0)	1 (0.0)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Prostate cancer	1 (0.0)	5 (0.2)
Prostate cancer metastatic	1 (0.0)	0 (0.0)
Rectal cancer	0 (0.0)	2 (0.1)
Rectosigmoid cancer	1 (0.0)	0 (0.0)
Renal cancer	1 (0.0)	1 (0.0)
Renal neoplasm	2 (0.1)	0 (0.0)
Retroperitoneal cancer	1 (0.0)	0 (0.0)
Squamous cell carcinoma	1 (0.0)	0 (0.0)
Squamous cell carcinoma of head and neck	2 (0.1)	0 (0.0)
Squamous cell carcinoma of lung	1 (0.0)	0 (0.0)
Squamous cell carcinoma of the oral cavity	0 (0.0)	1 (0.0)
Sweat gland tumour	1 (0.0)	0 (0.0)
T-cell lymphoma	1 (0.0)	0 (0.0)
Tongue neoplasm malignant stage unspecified	1 (0.0)	0 (0.0)
Tumour ulceration	0 (0.0)	1 (0.0)
Uterine cancer	0 (0.0)	1 (0.0)
Uterine leiomyoma	1 (0.0)	0 (0.0)
Waldenstrom's macroglobulinaemia	1 (0.0)	0 (0.0)
Nervous system disorders	71 (3.3)	71 (3.3)
Altered state of consciousness	1 (0.0)	0 (0.0)
Autonomic neuropathy	1 (0.0)	0 (0.0)
Axonal neuropathy	1 (0.0)	0 (0.0)
Brain hypoxia	1 (0.0)	0 (0.0)
Brain injury	2 (0.1)	1 (0.0)
Carotid artery stenosis	0 (0.0)	1 (0.0)
Cauda equina syndrome	1 (0.0)	0 (0.0)
Cerebral artery stenosis	0 (0.0)	1 (0.0)
Cerebral haemorrhage	1 (0.0)	1 (0.0)
Cerebral infarction	0 (0.0)	2 (0.1)
Cerebral ischaemia	1 (0.0)	1 (0.0)
Cerebrovascular accident	2 (0.1)	6 (0.3)
Cerebrovascular disorder	1 (0.0)	0 (0.0)
Cognitive disorder	0 (0.0)	1 (0.0)
Coma	1 (0.0)	0 (0.0)
Dementia	1 (0.0)	0 (0.0)
Dementia Alzheimer's type	0 (0.0)	1 (0.0)
Diabetic neuropathy	0 (0.0)	2 (0.1)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Dizziness	4 (0.2)	1 (0.0)
Dizziness postural	0 (0.0)	1 (0.0)
Dysarthria	0 (0.0)	2 (0.1)
Encephalopathy	0 (0.0)	2 (0.1)
Facial paralysis	0 (0.0)	1 (0.0)
Generalised tonic-clonic seizure	0 (0.0)	1 (0.0)
Headache	0 (0.0)	1 (0.0)
Hemiparesis	1 (0.0)	0 (0.0)
Hepatic encephalopathy	0 (0.0)	1 (0.0)
Hydrocephalus	0 (0.0)	1 (0.0)
Hypoxic-ischaemic encephalopathy	0 (0.0)	1 (0.0)
Ischaemic stroke	1 (0.0)	2 (0.1)
Lethargy	0 (0.0)	1 (0.0)
Loss of consciousness	0 (0.0)	1 (0.0)
Lumbar radiculopathy	2 (0.1)	0 (0.0)
Metabolic encephalopathy	0 (0.0)	2 (0.1)
Myoclonus	0 (0.0)	2 (0.1)
Neuropathy peripheral	1 (0.0)	0 (0.0)
Paraesthesia	0 (0.0)	1 (0.0)
Post stroke epilepsy	1 (0.0)	0 (0.0)
Presyncope	3 (0.1)	0 (0.0)
Seizure	2 (0.1)	1 (0.0)
Spinal cord compression	0 (0.0)	1 (0.0)
Status epilepticus	1 (0.0)	0 (0.0)
Subarachnoid haemorrhage	1 (0.0)	0 (0.0)
Syncope	39 (1.8)	30 (1.4)
Tension headache	1 (0.0)	0 (0.0)
Transient ischaemic attack	2 (0.1)	2 (0.1)
Vascular dementia	0 (0.0)	1 (0.0)
Vertebrobasilar insufficiency	1 (0.0)	0 (0.0)
Product issues	3 (0.1)	11 (0.5)
Device battery issue	1 (0.0)	3 (0.1)
Device dislocation	0 (0.0)	2 (0.1)
Device failure	0 (0.0)	1 (0.0)
Device ineffective	0 (0.0)	1 (0.0)
Device malfunction	1 (0.0)	4 (0.2)
Lead dislodgement	1 (0.0)	0 (0.0)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Psychiatric disorders	4 (0.2)	7 (0.3)
Anxiety	1 (0.0)	0 (0.0)
Anxiety disorder	0 (0.0)	1 (0.0)
Confusional state	0 (0.0)	1 (0.0)
Delirium	0 (0.0)	3 (0.1)
Drug use disorder	1 (0.0)	0 (0.0)
Mental status changes	0 (0.0)	2 (0.1)
Panic attack	1 (0.0)	0 (0.0)
Suicide attempt	1 (0.0)	0 (0.0)
Renal and urinary disorders	121 (5.6)	116 (5.4)
Acute kidney injury	58 (2.7)	47 (2.2)
Azotaemia	0 (0.0)	1 (0.0)
Bladder cyst	1 (0.0)	0 (0.0)
Bladder mass	0 (0.0)	1 (0.0)
Calculus bladder	2 (0.1)	0 (0.0)
Chronic kidney disease	35 (1.6)	25 (1.2)
Costovertebral angle tenderness	0 (0.0)	1 (0.0)
End stage renal disease	1 (0.0)	0 (0.0)
Haematuria	1 (0.0)	7 (0.3)
Nephrolithiasis	1 (0.0)	0 (0.0)
Nephropathy	2 (0.1)	1 (0.0)
Renal artery stenosis	1 (0.0)	1 (0.0)
Renal colic	1 (0.0)	0 (0.0)
Renal failure	18 (0.8)	25 (1.2)
Renal impairment	4 (0.2)	6 (0.3)
Renal infarct	0 (0.0)	1 (0.0)
Renal mass	1 (0.0)	0 (0.0)
Urate nephropathy	1 (0.0)	0 (0.0)
Ureterolithiasis	1 (0.0)	0 (0.0)
Urethral stenosis	0 (0.0)	1 (0.0)
Urinary retention	2 (0.1)	2 (0.1)
Reproductive system and breast disorders	2 (0.1)	6 (0.3)
Benign prostatic hyperplasia	1 (0.0)	6 (0.3)
Endometrial hyperplasia	1 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	78 (3.6)	79 (3.7)
Acute pulmonary oedema	3 (0.1)	1 (0.0)
Acute respiratory failure	8 (0.4)	6 (0.3)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Asthma	6 (0.3)	3 (0.1)
Bronchial haemorrhage	0 (0.0)	1 (0.0)
Bronchitis chronic	1 (0.0)	0 (0.0)
Bronchospasm	0 (0.0)	1 (0.0)
Chronic obstructive pulmonary disease	30 (1.4)	27 (1.3)
Cough	0 (0.0)	2 (0.1)
Dyspnoea	11 (0.5)	5 (0.2)
Dyspnoea exertional	0 (0.0)	3 (0.1)
Epistaxis	1 (0.0)	1 (0.0)
Haemoptysis	0 (0.0)	2 (0.1)
Haemothorax	0 (0.0)	2 (0.1)
Hyperventilation	1 (0.0)	0 (0.0)
Hypoxia	0 (0.0)	1 (0.0)
Obstructive airways disorder	0 (0.0)	1 (0.0)
Pleural effusion	5 (0.2)	12 (0.6)
Pleurisy	0 (0.0)	1 (0.0)
Pleuritic pain	0 (0.0)	1 (0.0)
Pneumonia aspiration	6 (0.3)	2 (0.1)
Pneumothorax	2 (0.1)	4 (0.2)
Pulmonary congestion	1 (0.0)	0 (0.0)
Pulmonary embolism	4 (0.2)	6 (0.3)
Pulmonary hypertension	1 (0.0)	0 (0.0)
Pulmonary infarction	0 (0.0)	1 (0.0)
Pulmonary mass	0 (0.0)	1 (0.0)
Pulmonary oedema	4 (0.2)	2 (0.1)
Respiratory disorder	1 (0.0)	0 (0.0)
Respiratory failure	3 (0.1)	4 (0.2)
Rhinitis hypertrophic	1 (0.0)	0 (0.0)
Sleep apnoea syndrome	1 (0.0)	1 (0.0)
Tonsillar haemorrhage	1 (0.0)	0 (0.0)
Skin and subcutaneous tissue disorders	11 (0.5)	15 (0.7)
Angioedema	1 (0.0)	0 (0.0)
Diabetic foot	1 (0.0)	4 (0.2)
Drug eruption	1 (0.0)	0 (0.0)
Ecchymosis	0 (0.0)	1 (0.0)
Haemorrhage subcutaneous	1 (0.0)	0 (0.0)
Henoch-Schonlein purpura	0 (0.0)	1 (0.0)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Neurodermatitis	0 (0.0)	1 (0.0)
Skin necrosis	1 (0.0)	0 (0.0)
Skin ulcer	5 (0.2)	7 (0.3)
Stasis dermatitis	0 (0.0)	1 (0.0)
Urticaria	1 (0.0)	0 (0.0)
Surgical and medical procedures	13 (0.6)	18 (0.8)
Arrhythmia prophylaxis	0 (0.0)	1 (0.0)
Cardiac pacemaker replacement	0 (0.0)	1 (0.0)
Cardiac rehabilitation therapy	1 (0.0)	0 (0.0)
Cardiac resynchronisation therapy	2 (0.1)	7 (0.3)
Cardiovascular event prophylaxis	1 (0.0)	4 (0.2)
Cardioversion	1 (0.0)	0 (0.0)
Central venous catheter removal	0 (0.0)	1 (0.0)
Implantable defibrillator insertion	4 (0.2)	2 (0.1)
Implantable defibrillator removal	1 (0.0)	0 (0.0)
Implantable defibrillator replacement	1 (0.0)	0 (0.0)
Inguinal hernia repair	1 (0.0)	0 (0.0)
Intraocular lens implant	0 (0.0)	1 (0.0)
Nephroprotective therapy	0 (0.0)	1 (0.0)
Therapeutic procedure	1 (0.0)	0 (0.0)
Toe operation	1 (0.0)	0 (0.0)
Vascular disorders	72 (3.3)	74 (3.4)
Aortic aneurysm	0 (0.0)	1 (0.0)
Aortic dissection	1 (0.0)	0 (0.0)
Aortic stenosis	1 (0.0)	0 (0.0)
Arterial occlusive disease	0 (0.0)	1 (0.0)
Bleeding varicose vein	1 (0.0)	2 (0.1)
Circulatory collapse	0 (0.0)	1 (0.0)
Deep vein thrombosis	1 (0.0)	1 (0.0)
Dry gangrene	0 (0.0)	1 (0.0)
Extremity necrosis	1 (0.0)	0 (0.0)
Haematoma	4 (0.2)	2 (0.1)
Haemorrhagic vasculitis	0 (0.0)	1 (0.0)
Hypertension	5 (0.2)	4 (0.2)
Hypertensive crisis	1 (0.0)	3 (0.1)
Hypotension	31 (1.4)	38 (1.8)
Hypovolaemic shock	2 (0.1)	0 (0.0)

Summary of Serious Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Iliac artery occlusion	1 (0.0)	0 (0.0)
Intermittent claudication	1 (0.0)	1 (0.0)
Lymphorrhoea	1 (0.0)	0 (0.0)
Orthostatic hypotension	4 (0.2)	1 (0.0)
Peripheral arterial occlusive disease	5 (0.2)	9 (0.4)
Peripheral artery occlusion	1 (0.0)	0 (0.0)
Peripheral artery stenosis	1 (0.0)	0 (0.0)
Peripheral artery thrombosis	0 (0.0)	1 (0.0)
Peripheral embolism	1 (0.0)	2 (0.1)
Peripheral ischaemia	2 (0.1)	2 (0.1)
Peripheral vascular disorder	4 (0.2)	3 (0.1)
Peripheral venous disease	1 (0.0)	0 (0.0)
Shock	1 (0.0)	1 (0.0)
Shock haemorrhagic	0 (0.0)	2 (0.1)
Thrombophlebitis	1 (0.0)	2 (0.1)
Varicose vein	1 (0.0)	0 (0.0)
Vascular occlusion	1 (0.0)	0 (0.0)

a: Database Cutoff Date: 18JUN2019
b: A SOC or specific adverse event appears on this report only if its incidence is > 0% in one or more treatment groups
c: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
PT: Preferred Term; SOC: System Organ Class

1.3.3 Adverse Events by severity by SOC and PT

Table 12
Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Participants with one or more adverse events	1441 (67.0)	1459 (67.8)
Blood and lymphatic system disorders	128 (5.9)	104 (4.8)
Anaemia	88 (4.1)	64 (3.0)
Anaemia macrocytic	1 (0.0)	2 (0.1)
Blood loss anaemia	2 (0.1)	0 (0.0)
Bone marrow oedema	1 (0.0)	0 (0.0)
Coagulopathy	1 (0.0)	0 (0.0)
Cytopenia	0 (0.0)	1 (0.0)
Haemolytic anaemia	0 (0.0)	1 (0.0)
Haemorrhagic diathesis	0 (0.0)	1 (0.0)
Hypergammaglobulinaemia	1 (0.0)	0 (0.0)
Hypochromic anaemia	1 (0.0)	1 (0.0)
Immune thrombocytopenic purpura	1 (0.0)	0 (0.0)
Increased tendency to bruise	1 (0.0)	0 (0.0)
Iron deficiency anaemia	10 (0.5)	10 (0.5)
Leukocytosis	2 (0.1)	2 (0.1)
Leukopenia	2 (0.1)	1 (0.0)
Lymphadenitis	0 (0.0)	1 (0.0)
Lymphadenopathy	1 (0.0)	0 (0.0)
Lymphadenopathy mediastinal	0 (0.0)	1 (0.0)
Macrocytosis	1 (0.0)	1 (0.0)
Microcytic anaemia	3 (0.1)	0 (0.0)
Nephrogenic anaemia	1 (0.0)	2 (0.1)
Neutropenia	0 (0.0)	2 (0.1)
Normochromic normocytic anaemia	2 (0.1)	0 (0.0)
Pancytopenia	1 (0.0)	0 (0.0)
Polycythaemia	4 (0.2)	0 (0.0)
Splenomegaly	2 (0.1)	1 (0.0)
Spontaneous haematoma	1 (0.0)	1 (0.0)
Thrombocytopenia	11 (0.5)	20 (0.9)
Cardiac disorders	229 (10.6)	233 (10.8)
Acute left ventricular failure	1 (0.0)	0 (0.0)
Acute myocardial infarction	0 (0.0)	1 (0.0)
Angina pectoris	10 (0.5)	11 (0.5)
Angina unstable	0 (0.0)	1 (0.0)
Aortic valve incompetence	1 (0.0)	3 (0.1)
Arrhythmia	2 (0.1)	4 (0.2)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Arteriosclerosis coronary artery	0 (0.0)	1 (0.0)
Atrial fibrillation	33 (1.5)	24 (1.1)
Atrial flutter	6 (0.3)	7 (0.3)
Atrial tachycardia	0 (0.0)	3 (0.1)
Atrial thrombosis	1 (0.0)	1 (0.0)
Atrioventricular block first degree	9 (0.4)	7 (0.3)
Atrioventricular block second degree	0 (0.0)	4 (0.2)
Bradyarrhythmia	1 (0.0)	0 (0.0)
Bradycardia	13 (0.6)	16 (0.7)
Bundle branch block	0 (0.0)	1 (0.0)
Bundle branch block left	4 (0.2)	1 (0.0)
Bundle branch block right	3 (0.1)	1 (0.0)
Cardiac disorder	1 (0.0)	0 (0.0)
Cardiac failure	63 (2.9)	69 (3.2)
Cardiac failure acute	1 (0.0)	2 (0.1)
Cardiac failure chronic	4 (0.2)	12 (0.6)
Cardiac failure congestive	9 (0.4)	14 (0.7)
Cardiac ventricular thrombosis	1 (0.0)	0 (0.0)
Cardiomegaly	1 (0.0)	1 (0.0)
Cardiomyopathy	0 (0.0)	1 (0.0)
Cardiorenal syndrome	0 (0.0)	1 (0.0)
Congestive cardiomyopathy	1 (0.0)	0 (0.0)
Coronary artery disease	2 (0.1)	0 (0.0)
Coronary artery occlusion	2 (0.1)	0 (0.0)
Coronary ostial stenosis	1 (0.0)	0 (0.0)
Cyanosis	0 (0.0)	1 (0.0)
Defect conduction intraventricular	1 (0.0)	0 (0.0)
Extrasystoles	2 (0.1)	0 (0.0)
Hypertensive heart disease	1 (0.0)	0 (0.0)
Intracardiac thrombus	1 (0.0)	1 (0.0)
Ischaemic cardiomyopathy	0 (0.0)	1 (0.0)
Left ventricular dysfunction	1 (0.0)	1 (0.0)
Left ventricular failure	1 (0.0)	0 (0.0)
Mitral valve disease	1 (0.0)	0 (0.0)
Mitral valve incompetence	1 (0.0)	2 (0.1)
Myocardial ischaemia	2 (0.1)	1 (0.0)
Myocarditis	0 (0.0)	1 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Palpitations	24 (1.1)	16 (0.7)
Pericardial effusion	1 (0.0)	1 (0.0)
Pulmonary valve incompetence	0 (0.0)	1 (0.0)
Right ventricular failure	1 (0.0)	0 (0.0)
Sinus arrhythmia	0 (0.0)	1 (0.0)
Sinus bradycardia	5 (0.2)	4 (0.2)
Sinus tachycardia	6 (0.3)	2 (0.1)
Supraventricular extrasystoles	4 (0.2)	4 (0.2)
Supraventricular tachycardia	1 (0.0)	3 (0.1)
Tachyarrhythmia	2 (0.1)	0 (0.0)
Tachycardia	12 (0.6)	11 (0.5)
Tricuspid valve incompetence	0 (0.0)	1 (0.0)
Ventricular arrhythmia	0 (0.0)	2 (0.1)
Ventricular dyssynchrony	0 (0.0)	1 (0.0)
Ventricular extrasystoles	14 (0.7)	12 (0.6)
Ventricular fibrillation	1 (0.0)	2 (0.1)
Ventricular tachycardia	11 (0.5)	15 (0.7)
Wolff-Parkinson-White syndrome	0 (0.0)	1 (0.0)
Congenital, familial and genetic disorders	4 (0.2)	7 (0.3)
Adenomatous polyposis coli	0 (0.0)	1 (0.0)
Congenital inguinal hernia	0 (0.0)	1 (0.0)
Dolichocolon	0 (0.0)	1 (0.0)
Epidermolysis	1 (0.0)	0 (0.0)
Gastrointestinal arteriovenous malformation	0 (0.0)	1 (0.0)
Hydrocele	2 (0.1)	2 (0.1)
Renal dysplasia	0 (0.0)	1 (0.0)
Spine malformation	1 (0.0)	0 (0.0)
Ear and labyrinth disorders	44 (2.0)	29 (1.3)
Auditory disorder	1 (0.0)	0 (0.0)
Ear congestion	1 (0.0)	0 (0.0)
Ear haemorrhage	1 (0.0)	0 (0.0)
Ear pain	2 (0.1)	0 (0.0)
Eustachian tube dysfunction	1 (0.0)	0 (0.0)
Excessive cerumen production	4 (0.2)	0 (0.0)
Hypoacusis	1 (0.0)	1 (0.0)
Meniere's disease	1 (0.0)	0 (0.0)
Middle ear effusion	1 (0.0)	0 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Presbyacusis	1 (0.0)	0 (0.0)
Sudden hearing loss	1 (0.0)	0 (0.0)
Tinnitus	7 (0.3)	2 (0.1)
Vertigo	24 (1.1)	24 (1.1)
Vertigo positional	0 (0.0)	1 (0.0)
Vestibular disorder	1 (0.0)	1 (0.0)
Endocrine disorders	36 (1.7)	37 (1.7)
Empty sella syndrome	1 (0.0)	0 (0.0)
Euthyroid sick syndrome	0 (0.0)	1 (0.0)
Goitre	2 (0.1)	5 (0.2)
Hyperparathyroidism	0 (0.0)	1 (0.0)
Hyperparathyroidism secondary	1 (0.0)	0 (0.0)
Hyperplasia adrenal	1 (0.0)	0 (0.0)
Hyperthyroidism	8 (0.4)	5 (0.2)
Hypothyroidism	22 (1.0)	22 (1.0)
Thyroid disorder	1 (0.0)	0 (0.0)
Thyroid mass	2 (0.1)	2 (0.1)
Toxic goitre	0 (0.0)	1 (0.0)
Eye disorders	48 (2.2)	57 (2.6)
Age-related macular degeneration	0 (0.0)	2 (0.1)
Asthenopia	0 (0.0)	1 (0.0)
Astigmatism	0 (0.0)	1 (0.0)
Blepharitis	1 (0.0)	1 (0.0)
Blepharospasm	0 (0.0)	1 (0.0)
Cataract	11 (0.5)	11 (0.5)
Chalazion	0 (0.0)	1 (0.0)
Conjunctival haemorrhage	4 (0.2)	4 (0.2)
Conjunctival irritation	0 (0.0)	1 (0.0)
Conjunctivitis allergic	1 (0.0)	1 (0.0)
Corneal erosion	1 (0.0)	0 (0.0)
Corneal lesion	0 (0.0)	1 (0.0)
Diabetic retinopathy	1 (0.0)	2 (0.1)
Dry eye	4 (0.2)	3 (0.1)
Eye colour change	0 (0.0)	1 (0.0)
Eye haematoma	0 (0.0)	2 (0.1)
Eye haemorrhage	1 (0.0)	0 (0.0)
Eye inflammation	0 (0.0)	1 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Eye oedema	0 (0.0)	1 (0.0)
Eye ulcer	1 (0.0)	0 (0.0)
Eyelid oedema	1 (0.0)	1 (0.0)
Eyelid ptosis	1 (0.0)	0 (0.0)
Foreign body sensation in eyes	0 (0.0)	1 (0.0)
Glaucoma	4 (0.2)	1 (0.0)
Hypermetropia	0 (0.0)	1 (0.0)
Iritis	0 (0.0)	1 (0.0)
Keratitis	1 (0.0)	0 (0.0)
Lacrimation increased	1 (0.0)	0 (0.0)
Macular degeneration	1 (0.0)	0 (0.0)
Maculopathy	1 (0.0)	0 (0.0)
Meibomian gland dysfunction	0 (0.0)	1 (0.0)
Neovascular age-related macular degeneration	1 (0.0)	0 (0.0)
Ocular hyperaemia	0 (0.0)	5 (0.2)
Periorbital swelling	1 (0.0)	0 (0.0)
Presbyopia	1 (0.0)	0 (0.0)
Retinal degeneration	1 (0.0)	0 (0.0)
Retinal vascular disorder	1 (0.0)	1 (0.0)
Retinopathy	1 (0.0)	0 (0.0)
Retinopathy hypertensive	2 (0.1)	0 (0.0)
Swelling of eyelid	0 (0.0)	1 (0.0)
Trichiasis	0 (0.0)	1 (0.0)
Vision blurred	8 (0.4)	9 (0.4)
Visual acuity reduced	1 (0.0)	2 (0.1)
Visual impairment	3 (0.1)	0 (0.0)
Vitreous degeneration	1 (0.0)	0 (0.0)
Vitreous floaters	0 (0.0)	1 (0.0)
Vitreous haemorrhage	1 (0.0)	0 (0.0)
Xanthopsia	0 (0.0)	1 (0.0)
Gastrointestinal disorders	386 (17.9)	334 (15.5)
Abdominal discomfort	13 (0.6)	7 (0.3)
Abdominal distension	12 (0.6)	14 (0.7)
Abdominal hernia	0 (0.0)	1 (0.0)
Abdominal mass	1 (0.0)	0 (0.0)
Abdominal pain	14 (0.7)	13 (0.6)
Abdominal pain lower	1 (0.0)	1 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Abdominal pain upper	22 (1.0)	18 (0.8)
Abdominal tenderness	0 (0.0)	1 (0.0)
Abnormal faeces	0 (0.0)	1 (0.0)
Acid peptic disease	1 (0.0)	1 (0.0)
Anal fistula	1 (0.0)	0 (0.0)
Anal haemorrhage	0 (0.0)	1 (0.0)
Anal incontinence	1 (0.0)	1 (0.0)
Anal pruritus	0 (0.0)	1 (0.0)
Anorectal disorder	1 (0.0)	0 (0.0)
Ascites	2 (0.1)	6 (0.3)
Barrett's oesophagus	1 (0.0)	0 (0.0)
Chronic gastritis	14 (0.7)	10 (0.5)
Coating in mouth	0 (0.0)	1 (0.0)
Colitis	1 (0.0)	1 (0.0)
Constipation	49 (2.3)	46 (2.1)
Dental caries	5 (0.2)	6 (0.3)
Diaphragmatic hernia	1 (0.0)	0 (0.0)
Diarrhoea	73 (3.4)	82 (3.8)
Diverticulum	5 (0.2)	2 (0.1)
Diverticulum intestinal	6 (0.3)	6 (0.3)
Dry mouth	4 (0.2)	9 (0.4)
Duodenal ulcer	2 (0.1)	0 (0.0)
Duodenitis	5 (0.2)	3 (0.1)
Duodenogastric reflux	1 (0.0)	1 (0.0)
Dyspepsia	40 (1.9)	23 (1.1)
Dysphagia	5 (0.2)	5 (0.2)
Enteritis	1 (0.0)	1 (0.0)
Enterocolitis	0 (0.0)	1 (0.0)
Epigastric discomfort	2 (0.1)	5 (0.2)
Erosive oesophagitis	2 (0.1)	0 (0.0)
Eructation	2 (0.1)	0 (0.0)
Faecaloma	1 (0.0)	0 (0.0)
Faeces discoloured	4 (0.2)	0 (0.0)
Faeces soft	2 (0.1)	0 (0.0)
Flatulence	2 (0.1)	3 (0.1)
Food poisoning	0 (0.0)	2 (0.1)
Frequent bowel movements	1 (0.0)	0 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Functional gastrointestinal disorder	0 (0.0)	1 (0.0)
Gastric dilatation	1 (0.0)	0 (0.0)
Gastric disorder	0 (0.0)	3 (0.1)
Gastric mucosa erythema	3 (0.1)	1 (0.0)
Gastric polyps	5 (0.2)	2 (0.1)
Gastric ulcer	5 (0.2)	2 (0.1)
Gastritis	14 (0.7)	15 (0.7)
Gastritis erosive	9 (0.4)	3 (0.1)
Gastroduodenal ulcer	0 (0.0)	1 (0.0)
Gastrointestinal angiodysplasia	0 (0.0)	1 (0.0)
Gastrointestinal disorder	3 (0.1)	1 (0.0)
Gastrointestinal erosion	1 (0.0)	0 (0.0)
Gastrointestinal haemorrhage	1 (0.0)	2 (0.1)
Gastrointestinal melanosis	1 (0.0)	0 (0.0)
Gastrooesophageal reflux disease	29 (1.3)	5 (0.2)
Gingival bleeding	2 (0.1)	2 (0.1)
Gingival pain	2 (0.1)	1 (0.0)
Gingival swelling	1 (0.0)	0 (0.0)
Haematemesis	0 (0.0)	2 (0.1)
Haematochezia	2 (0.1)	5 (0.2)
Haemorrhoidal haemorrhage	2 (0.1)	1 (0.0)
Haemorrhoids	12 (0.6)	10 (0.5)
Haemorrhoids thrombosed	0 (0.0)	1 (0.0)
Hiatus hernia	7 (0.3)	6 (0.3)
Impaired gastric emptying	2 (0.1)	0 (0.0)
Inguinal hernia	8 (0.4)	3 (0.1)
Intestinal haemorrhage	0 (0.0)	1 (0.0)
Intestinal obstruction	1 (0.0)	0 (0.0)
Intestinal polyp	0 (0.0)	1 (0.0)
Intra-abdominal fluid collection	0 (0.0)	1 (0.0)
Intra-abdominal haematoma	1 (0.0)	0 (0.0)
Irritable bowel syndrome	2 (0.1)	1 (0.0)
Large intestine polyp	10 (0.5)	8 (0.4)
Lip dry	1 (0.0)	0 (0.0)
Lip ulceration	1 (0.0)	0 (0.0)
Loose tooth	0 (0.0)	1 (0.0)
Lower gastrointestinal haemorrhage	1 (0.0)	1 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Melaena	1 (0.0)	2 (0.1)
Mouth haemorrhage	2 (0.1)	1 (0.0)
Mouth ulceration	4 (0.2)	2 (0.1)
Nausea	54 (2.5)	46 (2.1)
Oesophagitis	5 (0.2)	1 (0.0)
Oral contusion	1 (0.0)	0 (0.0)
Oral pain	0 (0.0)	1 (0.0)
Pancreatic cyst	1 (0.0)	0 (0.0)
Pancreatic disorder	1 (0.0)	1 (0.0)
Pancreatic enlargement	1 (0.0)	0 (0.0)
Pancreatic steatosis	1 (0.0)	1 (0.0)
Pancreatitis	0 (0.0)	1 (0.0)
Pancreatitis chronic	2 (0.1)	2 (0.1)
Peptic ulcer	2 (0.1)	1 (0.0)
Periodontal disease	0 (0.0)	1 (0.0)
Peritoneal haemorrhage	0 (0.0)	1 (0.0)
Pharyngo-oesophageal diverticulum	0 (0.0)	1 (0.0)
Portal hypertensive gastropathy	1 (0.0)	0 (0.0)
Rectal haemorrhage	9 (0.4)	3 (0.1)
Rectal polyp	0 (0.0)	3 (0.1)
Small intestine polyp	1 (0.0)	0 (0.0)
Tongue dry	0 (0.0)	1 (0.0)
Tongue haemorrhage	0 (0.0)	1 (0.0)
Toothache	3 (0.1)	5 (0.2)
Umbilical hernia	2 (0.1)	0 (0.0)
Upper gastrointestinal haemorrhage	1 (0.0)	0 (0.0)
Vomiting	25 (1.2)	32 (1.5)
General disorders and administration site conditions	217 (10.1)	217 (10.1)
Adverse drug reaction	1 (0.0)	0 (0.0)
Asthenia	27 (1.3)	29 (1.3)
Catheter site haematoma	0 (0.0)	1 (0.0)
Catheter site haemorrhage	1 (0.0)	0 (0.0)
Catheter site pain	1 (0.0)	1 (0.0)
Catheter site phlebitis	0 (0.0)	1 (0.0)
Catheter site ulcer	0 (0.0)	1 (0.0)
Chest discomfort	10 (0.5)	11 (0.5)
Chest pain	25 (1.2)	38 (1.8)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Chills	2 (0.1)	2 (0.1)
Discomfort	2 (0.1)	1 (0.0)
Drug intolerance	3 (0.1)	1 (0.0)
Dysplasia	1 (0.0)	0 (0.0)
Effusion	0 (0.0)	1 (0.0)
Enanthema	0 (0.0)	1 (0.0)
Energy increased	0 (0.0)	1 (0.0)
Exercise tolerance decreased	0 (0.0)	2 (0.1)
Face oedema	1 (0.0)	1 (0.0)
Fat tissue increased	0 (0.0)	1 (0.0)
Fatigue	26 (1.2)	30 (1.4)
Gait disturbance	4 (0.2)	1 (0.0)
General physical health deterioration	3 (0.1)	1 (0.0)
Generalised oedema	2 (0.1)	0 (0.0)
Haemorrhagic cyst	0 (0.0)	1 (0.0)
Hernia	2 (0.1)	0 (0.0)
Hunger	0 (0.0)	1 (0.0)
Ill-defined disorder	1 (0.0)	0 (0.0)
Impaired healing	1 (0.0)	1 (0.0)
Implant site haematoma	1 (0.0)	0 (0.0)
Inflammation	2 (0.1)	0 (0.0)
Influenza like illness	1 (0.0)	3 (0.1)
Infusion site inflammation	1 (0.0)	1 (0.0)
Infusion site pain	0 (0.0)	1 (0.0)
Injection site reaction	1 (0.0)	0 (0.0)
Localised oedema	1 (0.0)	1 (0.0)
Malaise	6 (0.3)	6 (0.3)
Medical device site pain	1 (0.0)	0 (0.0)
Mucosal inflammation	1 (0.0)	0 (0.0)
Non-cardiac chest pain	5 (0.2)	4 (0.2)
Oedema	13 (0.6)	12 (0.6)
Oedema due to renal disease	1 (0.0)	0 (0.0)
Oedema peripheral	62 (2.9)	55 (2.6)
Pain	2 (0.1)	6 (0.3)
Peripheral swelling	15 (0.7)	11 (0.5)
Polyp	0 (0.0)	2 (0.1)
Pyrexia	20 (0.9)	18 (0.8)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Swelling	0 (0.0)	2 (0.1)
Temperature intolerance	0 (0.0)	1 (0.0)
Thirst	0 (0.0)	1 (0.0)
UGT1A1 gene polymorphism	0 (0.0)	1 (0.0)
Unevaluable event	0 (0.0)	1 (0.0)
Vascular stent stenosis	1 (0.0)	0 (0.0)
Vessel puncture site haematoma	0 (0.0)	1 (0.0)
Hepatobiliary disorders	53 (2.5)	54 (2.5)
Bile duct obstruction	1 (0.0)	0 (0.0)
Bile duct stone	1 (0.0)	0 (0.0)
Biliary dyskinesia	1 (0.0)	1 (0.0)
Cardiac cirrhosis	0 (0.0)	1 (0.0)
Cholecystitis	1 (0.0)	2 (0.1)
Cholecystitis chronic	5 (0.2)	5 (0.2)
Cholelithiasis	14 (0.7)	15 (0.7)
Drug-induced liver injury	0 (0.0)	1 (0.0)
Gallbladder oedema	1 (0.0)	0 (0.0)
Gallbladder polyp	1 (0.0)	0 (0.0)
Hepatic calcification	0 (0.0)	1 (0.0)
Hepatic cirrhosis	1 (0.0)	2 (0.1)
Hepatic congestion	3 (0.1)	1 (0.0)
Hepatic cyst	2 (0.1)	1 (0.0)
Hepatic failure	1 (0.0)	0 (0.0)
Hepatic function abnormal	6 (0.3)	15 (0.7)
Hepatic lesion	1 (0.0)	0 (0.0)
Hepatic mass	1 (0.0)	0 (0.0)
Hepatic steatosis	10 (0.5)	4 (0.2)
Hepatomegaly	5 (0.2)	2 (0.1)
Hyperbilirubinaemia	4 (0.2)	5 (0.2)
Hyperplastic cholecystopathy	1 (0.0)	0 (0.0)
Ischaemic hepatitis	1 (0.0)	0 (0.0)
Jaundice	0 (0.0)	2 (0.1)
Liver injury	1 (0.0)	0 (0.0)
Non-alcoholic steatohepatitis	0 (0.0)	1 (0.0)
Immune system disorders	5 (0.2)	9 (0.4)
Contrast media allergy	2 (0.1)	0 (0.0)
Drug hypersensitivity	0 (0.0)	1 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Hypersensitivity	1 (0.0)	4 (0.2)
Immunisation reaction	0 (0.0)	1 (0.0)
Multiple allergies	0 (0.0)	1 (0.0)
Seasonal allergy	2 (0.1)	3 (0.1)
Infections and infestations	437 (20.3)	428 (19.9)
Abdominal abscess	1 (0.0)	0 (0.0)
Abscess	0 (0.0)	1 (0.0)
Abscess limb	3 (0.1)	3 (0.1)
Abscess neck	1 (0.0)	1 (0.0)
Acarodermatitis	1 (0.0)	0 (0.0)
Acute sinusitis	0 (0.0)	1 (0.0)
Asymptomatic bacteriuria	1 (0.0)	0 (0.0)
Atypical pneumonia	1 (0.0)	0 (0.0)
Bacterial disease carrier	0 (0.0)	1 (0.0)
Bronchitis	40 (1.9)	41 (1.9)
Bronchitis viral	2 (0.1)	1 (0.0)
Candida infection	1 (0.0)	1 (0.0)
Carbuncle	1 (0.0)	0 (0.0)
Cellulitis	17 (0.8)	13 (0.6)
Chronic sinusitis	0 (0.0)	1 (0.0)
Clostridium difficile colitis	2 (0.1)	0 (0.0)
Conjunctivitis	9 (0.4)	4 (0.2)
Cystitis	6 (0.3)	6 (0.3)
Dermatophytosis of nail	3 (0.1)	0 (0.0)
Device related infection	3 (0.1)	0 (0.0)
Ear infection	0 (0.0)	1 (0.0)
Ear infection fungal	1 (0.0)	0 (0.0)
Enterobiasis	1 (0.0)	0 (0.0)
Enterocolitis infectious	0 (0.0)	1 (0.0)
Enterocolitis viral	1 (0.0)	0 (0.0)
Epididymitis	0 (0.0)	1 (0.0)
Erysipelas	1 (0.0)	3 (0.1)
Folliculitis	2 (0.1)	1 (0.0)
Fungal infection	0 (0.0)	1 (0.0)
Fungal skin infection	2 (0.1)	2 (0.1)
Furuncle	0 (0.0)	1 (0.0)
Gangrene	1 (0.0)	0 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Gastroenteritis	11 (0.5)	13 (0.6)
Gastroenteritis viral	4 (0.2)	4 (0.2)
Gastrointestinal infection	1 (0.0)	1 (0.0)
Gastrointestinal viral infection	1 (0.0)	0 (0.0)
Genital abscess	1 (0.0)	0 (0.0)
Gingivitis	1 (0.0)	3 (0.1)
H1N1 influenza	1 (0.0)	0 (0.0)
Helicobacter gastritis	0 (0.0)	1 (0.0)
Helicobacter infection	3 (0.1)	2 (0.1)
Hepatitis B	0 (0.0)	1 (0.0)
Herpes zoster	14 (0.7)	9 (0.4)
Hordeolum	0 (0.0)	1 (0.0)
Impetigo	1 (0.0)	1 (0.0)
Implant site infection	1 (0.0)	1 (0.0)
Infected dermal cyst	1 (0.0)	0 (0.0)
Infected skin ulcer	0 (0.0)	1 (0.0)
Infection	1 (0.0)	6 (0.3)
Infective keratitis	0 (0.0)	1 (0.0)
Influenza	50 (2.3)	32 (1.5)
Infusion site infection	0 (0.0)	1 (0.0)
Laryngitis	2 (0.1)	1 (0.0)
Localised infection	3 (0.1)	0 (0.0)
Lower respiratory tract infection	11 (0.5)	9 (0.4)
Lung infection	2 (0.1)	6 (0.3)
Lyme disease	0 (0.0)	1 (0.0)
Lymphangitis	0 (0.0)	1 (0.0)
Measles	1 (0.0)	0 (0.0)
Nasal herpes	1 (0.0)	0 (0.0)
Nasopharyngitis	88 (4.1)	88 (4.1)
Oesophageal candidiasis	1 (0.0)	2 (0.1)
Onychomycosis	1 (0.0)	1 (0.0)
Oral candidiasis	2 (0.1)	2 (0.1)
Oral herpes	0 (0.0)	2 (0.1)
Osteomyelitis	2 (0.1)	3 (0.1)
Otitis externa	5 (0.2)	0 (0.0)
Otitis media	2 (0.1)	1 (0.0)
Otitis media chronic	1 (0.0)	0 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Paronychia	2 (0.1)	1 (0.0)
Periodontitis	2 (0.1)	6 (0.3)
Pharyngitis	11 (0.5)	6 (0.3)
Pharyngitis bacterial	1 (0.0)	0 (0.0)
Pneumonia	22 (1.0)	26 (1.2)
Pneumonia bacterial	2 (0.1)	0 (0.0)
Pneumonia viral	0 (0.0)	1 (0.0)
Postoperative wound infection	0 (0.0)	2 (0.1)
Pyelonephritis chronic	4 (0.2)	3 (0.1)
Pyuria	0 (0.0)	1 (0.0)
Rash pustular	0 (0.0)	1 (0.0)
Respiratory syncytial virus infection	0 (0.0)	1 (0.0)
Respiratory tract infection	13 (0.6)	19 (0.9)
Respiratory tract infection viral	0 (0.0)	4 (0.2)
Rhinitis	6 (0.3)	10 (0.5)
Rhinovirus infection	1 (0.0)	0 (0.0)
Scrotal abscess	1 (0.0)	0 (0.0)
Sepsis	0 (0.0)	1 (0.0)
Sinusitis	4 (0.2)	5 (0.2)
Skin bacterial infection	0 (0.0)	1 (0.0)
Skin infection	2 (0.1)	1 (0.0)
Subcutaneous abscess	0 (0.0)	1 (0.0)
Tinea cruris	1 (0.0)	1 (0.0)
Tinea infection	1 (0.0)	0 (0.0)
Tinea pedis	4 (0.2)	1 (0.0)
Tonsillitis	3 (0.1)	0 (0.0)
Tooth abscess	2 (0.1)	3 (0.1)
Tooth infection	3 (0.1)	1 (0.0)
Tracheitis	1 (0.0)	0 (0.0)
Tracheobronchitis	1 (0.0)	0 (0.0)
Upper respiratory tract infection	78 (3.6)	72 (3.3)
Urethritis	1 (0.0)	0 (0.0)
Urinary tract infection	38 (1.8)	51 (2.4)
Viral infection	3 (0.1)	3 (0.1)
Viral pharyngitis	1 (0.0)	4 (0.2)
Viral upper respiratory tract infection	2 (0.1)	2 (0.1)
Vulvovaginal candidiasis	1 (0.0)	0 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Wound infection	3 (0.1)	0 (0.0)
Injury, poisoning and procedural complications	159 (7.4)	132 (6.1)
Accidental overdose	31 (1.4)	21 (1.0)
Alcohol poisoning	1 (0.0)	0 (0.0)
Animal bite	2 (0.1)	1 (0.0)
Ankle fracture	2 (0.1)	0 (0.0)
Arthropod bite	2 (0.1)	2 (0.1)
Back injury	2 (0.1)	0 (0.0)
Chillblains	0 (0.0)	1 (0.0)
Clavicle fracture	0 (0.0)	1 (0.0)
Contusion	12 (0.6)	14 (0.7)
Coronary vascular graft stenosis	0 (0.0)	1 (0.0)
Dermatitis artefacta	0 (0.0)	1 (0.0)
Device use issue	0 (0.0)	1 (0.0)
Ear canal abrasion	1 (0.0)	0 (0.0)
Eye contusion	2 (0.1)	1 (0.0)
Face injury	0 (0.0)	2 (0.1)
Facial bones fracture	0 (0.0)	2 (0.1)
Fall	35 (1.6)	30 (1.4)
Foot fracture	2 (0.1)	0 (0.0)
Foreign body	0 (0.0)	1 (0.0)
Foreign body in ear	1 (0.0)	0 (0.0)
Hand fracture	2 (0.1)	0 (0.0)
Head injury	7 (0.3)	7 (0.3)
Heart injury	1 (0.0)	0 (0.0)
Humerus fracture	0 (0.0)	1 (0.0)
Hyphaema	1 (0.0)	0 (0.0)
Hypotensive transfusion reaction	0 (0.0)	1 (0.0)
Incision site discharge	0 (0.0)	1 (0.0)
Injury	0 (0.0)	1 (0.0)
Joint dislocation	1 (0.0)	1 (0.0)
Joint injury	3 (0.1)	1 (0.0)
Ligament sprain	7 (0.3)	4 (0.2)
Limb injury	11 (0.5)	11 (0.5)
Lip injury	1 (0.0)	0 (0.0)
Mouth injury	1 (0.0)	0 (0.0)
Muscle contusion	0 (0.0)	1 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Muscle strain	3 (0.1)	0 (0.0)
Nail injury	1 (0.0)	1 (0.0)
Nasal injury	0 (0.0)	1 (0.0)
Overdose	1 (0.0)	1 (0.0)
Penis injury	1 (0.0)	0 (0.0)
Periorbital haematoma	1 (0.0)	0 (0.0)
Post procedural contusion	1 (0.0)	0 (0.0)
Post procedural fever	0 (0.0)	1 (0.0)
Post procedural haematoma	0 (0.0)	2 (0.1)
Post procedural haematuria	1 (0.0)	0 (0.0)
Post procedural haemorrhage	1 (0.0)	2 (0.1)
Post-traumatic neck syndrome	0 (0.0)	1 (0.0)
Post-traumatic pain	0 (0.0)	2 (0.1)
Procedural pain	5 (0.2)	1 (0.0)
Radius fracture	0 (0.0)	1 (0.0)
Reactive gastropathy	0 (0.0)	1 (0.0)
Rib fracture	1 (0.0)	3 (0.1)
Road traffic accident	1 (0.0)	0 (0.0)
Scratch	0 (0.0)	1 (0.0)
Skin abrasion	11 (0.5)	5 (0.2)
Skin injury	2 (0.1)	0 (0.0)
Skin laceration	3 (0.1)	9 (0.4)
Skin wound	0 (0.0)	1 (0.0)
Soft tissue injury	1 (0.0)	2 (0.1)
Spinal compression fracture	2 (0.1)	1 (0.0)
Spinal fracture	1 (0.0)	0 (0.0)
Stoma site haemorrhage	1 (0.0)	0 (0.0)
Subcutaneous haematoma	4 (0.2)	0 (0.0)
Tendon rupture	1 (0.0)	0 (0.0)
Thermal burn	0 (0.0)	2 (0.1)
Tooth fracture	1 (0.0)	2 (0.1)
Toxicity to various agents	0 (0.0)	3 (0.1)
Traumatic haematoma	2 (0.1)	0 (0.0)
Upper limb fracture	0 (0.0)	2 (0.1)
Urethral injury	2 (0.1)	0 (0.0)
Wound	6 (0.3)	0 (0.0)
Wound dehiscence	0 (0.0)	1 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Wound haemorrhage	1 (0.0)	0 (0.0)
Wound secretion	0 (0.0)	1 (0.0)
Wrist fracture	1 (0.0)	0 (0.0)
Investigations	218 (10.1)	238 (11.1)
Aeromonas test positive	1 (0.0)	0 (0.0)
Alanine aminotransferase increased	5 (0.2)	2 (0.1)
Anticoagulation drug level above therapeutic	3 (0.1)	1 (0.0)
Anticoagulation drug level below therapeutic	3 (0.1)	1 (0.0)
Aspartate aminotransferase increased	2 (0.1)	2 (0.1)
Bilirubin conjugated increased	0 (0.0)	2 (0.1)
Blood albumin decreased	0 (0.0)	1 (0.0)
Blood alkaline phosphatase increased	10 (0.5)	11 (0.5)
Blood bicarbonate decreased	1 (0.0)	1 (0.0)
Blood bilirubin increased	11 (0.5)	16 (0.7)
Blood bilirubin unconjugated increased	0 (0.0)	1 (0.0)
Blood calcium decreased	2 (0.1)	1 (0.0)
Blood cholesterol increased	2 (0.1)	1 (0.0)
Blood creatine increased	1 (0.0)	0 (0.0)
Blood creatine phosphokinase increased	1 (0.0)	1 (0.0)
Blood creatinine increased	28 (1.3)	30 (1.4)
Blood folate decreased	1 (0.0)	0 (0.0)
Blood glucose fluctuation	1 (0.0)	0 (0.0)
Blood glucose increased	7 (0.3)	4 (0.2)
Blood lactate dehydrogenase increased	2 (0.1)	1 (0.0)
Blood magnesium decreased	1 (0.0)	0 (0.0)
Blood potassium abnormal	1 (0.0)	1 (0.0)
Blood potassium decreased	4 (0.2)	3 (0.1)
Blood potassium increased	15 (0.7)	19 (0.9)
Blood pressure decreased	1 (0.0)	5 (0.2)
Blood pressure diastolic decreased	0 (0.0)	1 (0.0)
Blood pressure diastolic increased	0 (0.0)	1 (0.0)
Blood pressure increased	3 (0.1)	7 (0.3)
Blood pressure systolic decreased	1 (0.0)	0 (0.0)
Blood sodium abnormal	0 (0.0)	1 (0.0)
Blood sodium decreased	2 (0.1)	3 (0.1)
Blood sodium increased	1 (0.0)	0 (0.0)
Blood thyroid stimulating hormone decreased	0 (0.0)	1 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Blood thyroid stimulating hormone increased	0 (0.0)	3 (0.1)
Blood triglycerides increased	0 (0.0)	1 (0.0)
Blood urea increased	12 (0.6)	14 (0.7)
Blood uric acid increased	23 (1.1)	23 (1.1)
Blood urine	1 (0.0)	0 (0.0)
Brachial pulse decreased	0 (0.0)	1 (0.0)
Brain natriuretic peptide increased	0 (0.0)	1 (0.0)
C-reactive protein increased	6 (0.3)	3 (0.1)
Carcinoembryonic antigen increased	0 (0.0)	1 (0.0)
Cardiac murmur	1 (0.0)	1 (0.0)
Cardioactive drug level increased	0 (0.0)	1 (0.0)
Catheterisation cardiac	1 (0.0)	0 (0.0)
Central venous pressure increased	1 (0.0)	0 (0.0)
Echocardiogram abnormal	1 (0.0)	0 (0.0)
Electrocardiogram QT prolonged	0 (0.0)	3 (0.1)
Electrocardiogram T wave abnormal	1 (0.0)	0 (0.0)
Eosinophil count increased	1 (0.0)	0 (0.0)
Fibrin D dimer increased	0 (0.0)	2 (0.1)
Gamma-glutamyltransferase abnormal	1 (0.0)	0 (0.0)
Gamma-glutamyltransferase increased	29 (1.3)	41 (1.9)
Glomerular filtration rate decreased	1 (0.0)	0 (0.0)
Glycosylated haemoglobin increased	13 (0.6)	20 (0.9)
Haematocrit decreased	1 (0.0)	1 (0.0)
Haemoglobin decreased	3 (0.1)	5 (0.2)
Heart rate decreased	1 (0.0)	1 (0.0)
Heart rate increased	0 (0.0)	3 (0.1)
Heart rate irregular	0 (0.0)	1 (0.0)
Hepatic enzyme increased	4 (0.2)	4 (0.2)
Hepatitis B core antibody positive	1 (0.0)	0 (0.0)
Human chorionic gonadotropin positive	1 (0.0)	0 (0.0)
International normalised ratio fluctuation	3 (0.1)	1 (0.0)
International normalised ratio increased	3 (0.1)	4 (0.2)
Intraocular pressure increased	1 (0.0)	0 (0.0)
Lipase increased	1 (0.0)	0 (0.0)
Lipids increased	0 (0.0)	1 (0.0)
Liver function test abnormal	2 (0.1)	2 (0.1)
Liver function test increased	2 (0.1)	7 (0.3)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
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(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Low density lipoprotein increased	1 (0.0)	2 (0.1)
Lymphocyte percentage decreased	0 (0.0)	1 (0.0)
Mean cell haemoglobin concentration increased	1 (0.0)	0 (0.0)
Mean cell volume increased	2 (0.1)	0 (0.0)
N-terminal prohormone brain natriuretic peptide increased	0 (0.0)	1 (0.0)
Neutrophil percentage increased	0 (0.0)	1 (0.0)
Occult blood positive	3 (0.1)	4 (0.2)
Pancreatic enzymes increased	1 (0.0)	0 (0.0)
Platelet count decreased	3 (0.1)	2 (0.1)
Prostatic specific antigen increased	1 (0.0)	4 (0.2)
Protein urine present	0 (0.0)	1 (0.0)
Prothrombin level increased	0 (0.0)	1 (0.0)
Red blood cell count decreased	2 (0.1)	3 (0.1)
Red blood cell sedimentation rate increased	1 (0.0)	0 (0.0)
Red cell distribution width increased	2 (0.1)	1 (0.0)
Reticulocyte count increased	3 (0.1)	0 (0.0)
Serum ferritin decreased	1 (0.0)	0 (0.0)
Serum ferritin increased	0 (0.0)	1 (0.0)
Thyroid hormones increased	0 (0.0)	1 (0.0)
Transaminases increased	1 (0.0)	1 (0.0)
Tri-iodothyronine decreased	0 (0.0)	1 (0.0)
Troponin I increased	0 (0.0)	2 (0.1)
Troponin increased	2 (0.1)	0 (0.0)
Ultrasound kidney abnormal	1 (0.0)	0 (0.0)
Urine output decreased	4 (0.2)	1 (0.0)
Venous pressure jugular increased	1 (0.0)	0 (0.0)
Vitamin B12 decreased	0 (0.0)	1 (0.0)
Weight decreased	18 (0.8)	15 (0.7)
Weight increased	29 (1.3)	28 (1.3)
White blood cell count increased	1 (0.0)	1 (0.0)
White blood cells urine positive	0 (0.0)	1 (0.0)
Metabolism and nutrition disorders	321 (14.9)	347 (16.1)
Abnormal loss of weight	1 (0.0)	1 (0.0)
Acidosis	0 (0.0)	1 (0.0)
Cachexia	1 (0.0)	0 (0.0)
Carbohydrate intolerance	0 (0.0)	1 (0.0)
Cardiometabolic syndrome	1 (0.0)	0 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Decreased appetite	27 (1.3)	24 (1.1)
Dehydration	12 (0.6)	21 (1.0)
Diabetes mellitus	22 (1.0)	21 (1.0)
Diabetes mellitus inadequate control	8 (0.4)	12 (0.6)
Diabetic metabolic decompensation	2 (0.1)	4 (0.2)
Dyslipidaemia	6 (0.3)	1 (0.0)
Electrolyte imbalance	1 (0.0)	2 (0.1)
Failure to thrive	0 (0.0)	1 (0.0)
Fluid overload	4 (0.2)	1 (0.0)
Fluid retention	2 (0.1)	1 (0.0)
Folate deficiency	2 (0.1)	0 (0.0)
Glucose tolerance impaired	2 (0.1)	7 (0.3)
Gout	42 (2.0)	42 (2.0)
Hypercalcaemia	3 (0.1)	0 (0.0)
Hypercholesterolaemia	2 (0.1)	3 (0.1)
Hyperglycaemia	11 (0.5)	8 (0.4)
Hyperhomocysteinaemia	1 (0.0)	2 (0.1)
Hyperkalaemia	70 (3.3)	82 (3.8)
Hyperlipidaemia	11 (0.5)	1 (0.0)
Hypermagnesaemia	1 (0.0)	2 (0.1)
Hypernatraemia	1 (0.0)	2 (0.1)
Hypertriglyceridaemia	1 (0.0)	1 (0.0)
Hyperuricaemia	56 (2.6)	48 (2.2)
Hypervitaminosis D	0 (0.0)	1 (0.0)
Hypervolaemia	2 (0.1)	2 (0.1)
Hypoalbuminaemia	1 (0.0)	7 (0.3)
Hypocalcaemia	2 (0.1)	6 (0.3)
Hypochloraemia	2 (0.1)	1 (0.0)
Hypoglycaemia	13 (0.6)	15 (0.7)
Hypokalaemia	53 (2.5)	58 (2.7)
Hypomagnesaemia	4 (0.2)	4 (0.2)
Hyponatraemia	17 (0.8)	22 (1.0)
Hypophagia	2 (0.1)	1 (0.0)
Hypophosphataemia	0 (0.0)	1 (0.0)
Hypoproteinaemia	2 (0.1)	1 (0.0)
Hypovolaemia	2 (0.1)	0 (0.0)
Insulin resistance	0 (0.0)	1 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
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(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Iron deficiency	4 (0.2)	7 (0.3)
Malnutrition	1 (0.0)	0 (0.0)
Metabolic acidosis	3 (0.1)	1 (0.0)
Metabolic alkalosis	1 (0.0)	0 (0.0)
Obesity	2 (0.1)	0 (0.0)
Type 2 diabetes mellitus	10 (0.5)	10 (0.5)
Vitamin B complex deficiency	1 (0.0)	0 (0.0)
Vitamin B12 deficiency	2 (0.1)	0 (0.0)
Vitamin D deficiency	2 (0.1)	2 (0.1)
Weight fluctuation	0 (0.0)	1 (0.0)
Zinc deficiency	0 (0.0)	1 (0.0)
Musculoskeletal and connective tissue disorders	183 (8.5)	181 (8.4)
Amyotrophy	0 (0.0)	1 (0.0)
Arthralgia	24 (1.1)	30 (1.4)
Arthritis	7 (0.3)	2 (0.1)
Arthropathy	1 (0.0)	1 (0.0)
Back disorder	0 (0.0)	1 (0.0)
Back pain	26 (1.2)	26 (1.2)
Bone formation increased	1 (0.0)	0 (0.0)
Bone swelling	1 (0.0)	0 (0.0)
Cervical spinal stenosis	0 (0.0)	1 (0.0)
Chondrocalcinosis pyrophosphate	0 (0.0)	1 (0.0)
Costochondritis	2 (0.1)	0 (0.0)
Dupuytren's contracture	1 (0.0)	0 (0.0)
Exostosis	1 (0.0)	3 (0.1)
Flank pain	1 (0.0)	1 (0.0)
Gouty arthritis	5 (0.2)	3 (0.1)
Gouty tophus	0 (0.0)	1 (0.0)
Groin pain	1 (0.0)	0 (0.0)
Haemarthrosis	1 (0.0)	1 (0.0)
Haematoma muscle	0 (0.0)	1 (0.0)
Intervertebral disc protrusion	1 (0.0)	0 (0.0)
Joint contracture	0 (0.0)	1 (0.0)
Joint instability	2 (0.1)	0 (0.0)
Joint stiffness	0 (0.0)	1 (0.0)
Joint swelling	3 (0.1)	3 (0.1)
Limb discomfort	0 (0.0)	1 (0.0)

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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Lumbar spinal stenosis	1 (0.0)	0 (0.0)
Muscle contracture	0 (0.0)	1 (0.0)
Muscle fatigue	0 (0.0)	2 (0.1)
Muscle spasms	22 (1.0)	21 (1.0)
Muscle twitching	1 (0.0)	0 (0.0)
Muscular weakness	2 (0.1)	7 (0.3)
Musculoskeletal chest pain	3 (0.1)	5 (0.2)
Musculoskeletal discomfort	1 (0.0)	1 (0.0)
Musculoskeletal pain	13 (0.6)	21 (1.0)
Musculoskeletal stiffness	2 (0.1)	5 (0.2)
Myalgia	12 (0.6)	8 (0.4)
Myofascial pain syndrome	0 (0.0)	1 (0.0)
Myopathy	1 (0.0)	0 (0.0)
Neck pain	8 (0.4)	10 (0.5)
Osteoarthritis	9 (0.4)	8 (0.4)
Osteochondrosis	1 (0.0)	3 (0.1)
Osteoporosis	3 (0.1)	2 (0.1)
Pain in extremity	32 (1.5)	28 (1.3)
Pain in jaw	1 (0.0)	2 (0.1)
Periarthritis	5 (0.2)	3 (0.1)
Plantar fasciitis	1 (0.0)	0 (0.0)
Polymyalgia rheumatica	0 (0.0)	1 (0.0)
Rheumatic disorder	1 (0.0)	1 (0.0)
Rheumatoid arthritis	2 (0.1)	0 (0.0)
Rotator cuff syndrome	2 (0.1)	2 (0.1)
Sacroiliitis	1 (0.0)	0 (0.0)
Scleroderma	1 (0.0)	0 (0.0)
Sjogren's syndrome	1 (0.0)	0 (0.0)
Soft tissue swelling	0 (0.0)	1 (0.0)
Spinal osteoarthritis	6 (0.3)	3 (0.1)
Spinal pain	4 (0.2)	0 (0.0)
Spondylitis	1 (0.0)	0 (0.0)
Synovial cyst	0 (0.0)	1 (0.0)
Synovitis	1 (0.0)	0 (0.0)
Tendonitis	4 (0.2)	1 (0.0)
Tenosynovitis	1 (0.0)	1 (0.0)
Torticollis	1 (0.0)	1 (0.0)

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Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Trigger finger	2 (0.1)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	20 (0.9)	25 (1.2)
Adrenal adenoma	0 (0.0)	1 (0.0)
Basal cell carcinoma	1 (0.0)	2 (0.1)
Benign anorectal neoplasm	0 (0.0)	1 (0.0)
Bladder cancer	1 (0.0)	0 (0.0)
Bladder cancer recurrent	1 (0.0)	0 (0.0)
Bladder neoplasm	2 (0.1)	0 (0.0)
Bladder transitional cell carcinoma	0 (0.0)	1 (0.0)
Bowen's disease	0 (0.0)	1 (0.0)
Colon adenoma	1 (0.0)	2 (0.1)
Cutaneous T-cell lymphoma	1 (0.0)	0 (0.0)
Enchondromatosis	1 (0.0)	0 (0.0)
Essential thrombocythaemia	0 (0.0)	1 (0.0)
Gallbladder cancer	0 (0.0)	1 (0.0)
Gastrointestinal tract adenoma	1 (0.0)	0 (0.0)
Haemangioma	0 (0.0)	1 (0.0)
Haemangioma of bone	0 (0.0)	1 (0.0)
Haemangioma of liver	0 (0.0)	2 (0.1)
Inflammatory pseudotumour	0 (0.0)	1 (0.0)
Intraductal papillary mucinous neoplasm	0 (0.0)	1 (0.0)
Large intestine benign neoplasm	2 (0.1)	0 (0.0)
Lipoma	0 (0.0)	1 (0.0)
Malignant melanoma	1 (0.0)	1 (0.0)
Melanocytic naevus	1 (0.0)	1 (0.0)
Metastases to lung	1 (0.0)	1 (0.0)
Monoclonal gammopathy	1 (0.0)	0 (0.0)
Myelofibrosis	1 (0.0)	0 (0.0)
Ovarian cancer	0 (0.0)	1 (0.0)
Plasma cell myeloma	1 (0.0)	0 (0.0)
Prostate cancer	2 (0.1)	1 (0.0)
Prostatic adenoma	0 (0.0)	1 (0.0)
Pyogenic granuloma	1 (0.0)	0 (0.0)
Queyrat erythroplasia	1 (0.0)	0 (0.0)
Seborrhoeic keratosis	0 (0.0)	1 (0.0)
Skin papilloma	0 (0.0)	1 (0.0)
Squamous cell carcinoma	0 (0.0)	2 (0.1)

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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Squamous cell carcinoma of skin	1 (0.0)	0 (0.0)
Sweat gland tumour	0 (0.0)	1 (0.0)
Uterine cancer	0 (0.0)	1 (0.0)
Uterine leiomyoma	2 (0.1)	0 (0.0)
Nervous system disorders	258 (12.0)	236 (11.0)
Amnesia	3 (0.1)	3 (0.1)
Aphasia	0 (0.0)	2 (0.1)
Autonomic nervous system imbalance	0 (0.0)	1 (0.0)
Balance disorder	5 (0.2)	1 (0.0)
Brain oedema	0 (0.0)	1 (0.0)
Burning sensation	0 (0.0)	2 (0.1)
Carotid arteriosclerosis	2 (0.1)	3 (0.1)
Carotid artery dolichoectasia	0 (0.0)	1 (0.0)
Carotid artery occlusion	0 (0.0)	1 (0.0)
Carotid artery stenosis	1 (0.0)	0 (0.0)
Carpal tunnel syndrome	2 (0.1)	2 (0.1)
Cerebellar calcification	1 (0.0)	0 (0.0)
Cerebral arteriosclerosis	0 (0.0)	1 (0.0)
Cerebral atrophy	2 (0.1)	0 (0.0)
Cerebral disorder	1 (0.0)	1 (0.0)
Cerebral infarction	1 (0.0)	0 (0.0)
Cerebral ischaemia	2 (0.1)	0 (0.0)
Cerebral small vessel ischaemic disease	1 (0.0)	0 (0.0)
Cerebrovascular accident	1 (0.0)	1 (0.0)
Cerebrovascular disorder	1 (0.0)	0 (0.0)
Cerebrovascular insufficiency	0 (0.0)	1 (0.0)
Cervicobrachial syndrome	0 (0.0)	1 (0.0)
Cognitive disorder	4 (0.2)	3 (0.1)
Dementia	5 (0.2)	2 (0.1)
Dementia Alzheimer's type	0 (0.0)	1 (0.0)
Diabetic mononeuropathy	0 (0.0)	1 (0.0)
Diabetic neuropathy	3 (0.1)	0 (0.0)
Dizziness	114 (5.3)	106 (4.9)
Dizziness postural	4 (0.2)	7 (0.3)
Dysaesthesia	1 (0.0)	0 (0.0)
Dysarthria	0 (0.0)	2 (0.1)
Dysgeusia	2 (0.1)	0 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Dyskinesia	1 (0.0)	2 (0.1)
Epilepsy	1 (0.0)	1 (0.0)
Facial paralysis	1 (0.0)	0 (0.0)
Head discomfort	1 (0.0)	0 (0.0)
Headache	55 (2.6)	41 (1.9)
Hemiparesis	0 (0.0)	2 (0.1)
Hemiplegia	0 (0.0)	1 (0.0)
Hydrocephalus	1 (0.0)	0 (0.0)
Hypersomnia	0 (0.0)	1 (0.0)
Hypertensive encephalopathy	1 (0.0)	0 (0.0)
Hypoaesthesia	12 (0.6)	8 (0.4)
Hyporesponsive to stimuli	1 (0.0)	0 (0.0)
Hypotonia	1 (0.0)	0 (0.0)
Intention tremor	0 (0.0)	1 (0.0)
Ischaemic stroke	0 (0.0)	1 (0.0)
Lacunar infarction	1 (0.0)	1 (0.0)
Lethargy	0 (0.0)	3 (0.1)
Loss of consciousness	1 (0.0)	0 (0.0)
Memory impairment	2 (0.1)	1 (0.0)
Migraine	1 (0.0)	0 (0.0)
Mononeuropathy	0 (0.0)	1 (0.0)
Motor dysfunction	1 (0.0)	0 (0.0)
Myelopathy	1 (0.0)	1 (0.0)
Myoclonus	0 (0.0)	1 (0.0)
Nervous system disorder	1 (0.0)	0 (0.0)
Neuralgia	2 (0.1)	2 (0.1)
Neuropathy peripheral	2 (0.1)	4 (0.2)
Paraesthesia	6 (0.3)	5 (0.2)
Parkinson's disease	0 (0.0)	1 (0.0)
Parkinsonism	1 (0.0)	0 (0.0)
Peripheral motor neuropathy	0 (0.0)	1 (0.0)
Peripheral sensory neuropathy	0 (0.0)	1 (0.0)
Peroneal nerve palsy	1 (0.0)	0 (0.0)
Poor quality sleep	1 (0.0)	2 (0.1)
Post herpetic neuralgia	1 (0.0)	1 (0.0)
Presyncope	5 (0.2)	5 (0.2)
Radiculopathy	1 (0.0)	0 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Restless legs syndrome	0 (0.0)	2 (0.1)
Sciatica	2 (0.1)	5 (0.2)
Seizure	1 (0.0)	1 (0.0)
Sensory disturbance	1 (0.0)	0 (0.0)
Slow speech	0 (0.0)	1 (0.0)
Somnolence	6 (0.3)	3 (0.1)
Spinal cord disorder	0 (0.0)	1 (0.0)
Syncope	22 (1.0)	18 (0.8)
Tongue biting	1 (0.0)	1 (0.0)
Tonic convulsion	1 (0.0)	0 (0.0)
Tremor	7 (0.3)	6 (0.3)
Tunnel vision	0 (0.0)	1 (0.0)
Vascular dementia	0 (0.0)	1 (0.0)
Vascular parkinsonism	0 (0.0)	1 (0.0)
Vertebrobasilar dolichoectasia	0 (0.0)	1 (0.0)
White matter lesion	1 (0.0)	1 (0.0)
Product issues	5 (0.2)	3 (0.1)
Device battery issue	0 (0.0)	1 (0.0)
Device breakage	1 (0.0)	0 (0.0)
Device failure	0 (0.0)	1 (0.0)
Device inappropriate shock delivery	2 (0.1)	0 (0.0)
Device malfunction	2 (0.1)	1 (0.0)
Psychiatric disorders	55 (2.6)	74 (3.4)
Abnormal dreams	1 (0.0)	0 (0.0)
Aggression	0 (0.0)	1 (0.0)
Anxiety	10 (0.5)	8 (0.4)
Anxiety disorder	0 (0.0)	1 (0.0)
Anxiety disorder due to a general medical condition	0 (0.0)	1 (0.0)
Bipolar disorder	0 (0.0)	1 (0.0)
Confusional state	4 (0.2)	3 (0.1)
Delirium	3 (0.1)	6 (0.3)
Depressed mood	1 (0.0)	2 (0.1)
Depression	8 (0.4)	11 (0.5)
Disorientation	1 (0.0)	1 (0.0)
Hallucination	1 (0.0)	1 (0.0)
Head banging	1 (0.0)	0 (0.0)
Illusion	0 (0.0)	1 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Initial insomnia	1 (0.0)	0 (0.0)
Insomnia	23 (1.1)	30 (1.4)
Mental disorder due to a general medical condition	1 (0.0)	0 (0.0)
Middle insomnia	0 (0.0)	1 (0.0)
Nightmare	0 (0.0)	1 (0.0)
Psychotic disorder	1 (0.0)	0 (0.0)
Restlessness	1 (0.0)	3 (0.1)
Sleep disorder	2 (0.1)	9 (0.4)
Somatic symptom disorder	0 (0.0)	1 (0.0)
Tension	0 (0.0)	1 (0.0)
Renal and urinary disorders	151 (7.0)	162 (7.5)
Acute kidney injury	26 (1.2)	37 (1.7)
Azotaemia	1 (0.0)	1 (0.0)
Bladder outlet obstruction	0 (0.0)	1 (0.0)
Calculus bladder	1 (0.0)	0 (0.0)
Calculus urinary	1 (0.0)	1 (0.0)
Chronic kidney disease	25 (1.2)	24 (1.1)
Diabetic nephropathy	0 (0.0)	2 (0.1)
Dysuria	4 (0.2)	6 (0.3)
Haematuria	8 (0.4)	9 (0.4)
Hydronephrosis	0 (0.0)	1 (0.0)
Hypertensive nephropathy	1 (0.0)	0 (0.0)
Hypertonic bladder	1 (0.0)	0 (0.0)
Incontinence	1 (0.0)	0 (0.0)
Kidney congestion	1 (0.0)	0 (0.0)
Lower urinary tract symptoms	0 (0.0)	1 (0.0)
Nephrolithiasis	5 (0.2)	8 (0.4)
Nephropathy	6 (0.3)	1 (0.0)
Nephroptosis	1 (0.0)	1 (0.0)
Neurogenic bladder	0 (0.0)	2 (0.1)
Nocturia	0 (0.0)	1 (0.0)
Oliguria	0 (0.0)	1 (0.0)
Pollakiuria	1 (0.0)	2 (0.1)
Polyuria	0 (0.0)	2 (0.1)
Prerenal failure	0 (0.0)	1 (0.0)
Proteinuria	1 (0.0)	1 (0.0)
Pyelocaliectasis	1 (0.0)	1 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
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(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Renal atrophy	1 (0.0)	0 (0.0)
Renal colic	0 (0.0)	1 (0.0)
Renal cyst	18 (0.8)	11 (0.5)
Renal disorder	0 (0.0)	1 (0.0)
Renal failure	23 (1.1)	15 (0.7)
Renal impairment	25 (1.2)	30 (1.4)
Renal injury	0 (0.0)	1 (0.0)
Renal ischaemia	1 (0.0)	0 (0.0)
Renal mass	1 (0.0)	1 (0.0)
Renal pain	2 (0.1)	1 (0.0)
Stress urinary incontinence	3 (0.1)	0 (0.0)
Urate nephropathy	1 (0.0)	0 (0.0)
Ureteric dilatation	1 (0.0)	0 (0.0)
Ureterolithiasis	1 (0.0)	0 (0.0)
Urethral stenosis	1 (0.0)	0 (0.0)
Urge incontinence	0 (0.0)	1 (0.0)
Urinary incontinence	2 (0.1)	1 (0.0)
Urinary retention	3 (0.1)	4 (0.2)
Urinary tract obstruction	0 (0.0)	1 (0.0)
Vesicoureteric reflux	1 (0.0)	0 (0.0)
Reproductive system and breast disorders	55 (2.6)	51 (2.4)
Adenomyosis	1 (0.0)	0 (0.0)
Adnexa uteri cyst	1 (0.0)	0 (0.0)
Benign prostatic hyperplasia	12 (0.6)	13 (0.6)
Breast calcifications	0 (0.0)	1 (0.0)
Breast discharge	0 (0.0)	1 (0.0)
Breast disorder	0 (0.0)	1 (0.0)
Breast fibrosis	0 (0.0)	1 (0.0)
Breast haematoma	0 (0.0)	1 (0.0)
Breast pain	2 (0.1)	2 (0.1)
Breast tenderness	0 (0.0)	1 (0.0)
Cystocele	1 (0.0)	0 (0.0)
Endometrial hypertrophy	0 (0.0)	1 (0.0)
Endometriosis	1 (0.0)	0 (0.0)
Erectile dysfunction	0 (0.0)	1 (0.0)
Erection increased	1 (0.0)	1 (0.0)
Genital erythema	1 (0.0)	0 (0.0)

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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Genital pain	0 (0.0)	1 (0.0)
Gynaecomastia	23 (1.1)	19 (0.9)
Menorrhagia	0 (0.0)	1 (0.0)
Metrorrhagia	1 (0.0)	0 (0.0)
Nipple pain	2 (0.1)	0 (0.0)
Ovarian cyst	0 (0.0)	1 (0.0)
Pelvic pain	2 (0.1)	0 (0.0)
Penile discharge	1 (0.0)	0 (0.0)
Penile pain	1 (0.0)	1 (0.0)
Priapism	1 (0.0)	0 (0.0)
Prostatic calcification	0 (0.0)	1 (0.0)
Prostatic disorder	1 (0.0)	0 (0.0)
Prostatitis	1 (0.0)	1 (0.0)
Prostatomegaly	0 (0.0)	1 (0.0)
Scrotal varicose veins	1 (0.0)	0 (0.0)
Sexual dysfunction	0 (0.0)	2 (0.1)
Spermatocele	1 (0.0)	0 (0.0)
Vaginal haemorrhage	2 (0.1)	0 (0.0)
Varicocele	0 (0.0)	1 (0.0)
Vulvovaginal pain	1 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	263 (12.2)	270 (12.6)
Allergic bronchitis	0 (0.0)	1 (0.0)
Asthma	8 (0.4)	9 (0.4)
Asthma-chronic obstructive pulmonary disease overlap syndrome	0 (0.0)	1 (0.0)
Asthmatic crisis	0 (0.0)	1 (0.0)
Atelectasis	1 (0.0)	0 (0.0)
Bronchial hyperreactivity	1 (0.0)	0 (0.0)
Bronchitis chronic	3 (0.1)	3 (0.1)
Bronchospasm	7 (0.3)	4 (0.2)
Catarrh	0 (0.0)	1 (0.0)
Cheyne-Stokes respiration	0 (0.0)	1 (0.0)
Chronic obstructive pulmonary disease	18 (0.8)	12 (0.6)
Cough	88 (4.1)	76 (3.5)
Diaphragmalgia	0 (0.0)	1 (0.0)
Dry throat	1 (0.0)	1 (0.0)
Dysphonia	2 (0.1)	2 (0.1)
Dyspnoea	62 (2.9)	54 (2.5)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Dyspnoea exertional	15 (0.7)	6 (0.3)
Dyspnoea paroxysmal nocturnal	0 (0.0)	2 (0.1)
Emphysema	2 (0.1)	4 (0.2)
Epistaxis	20 (0.9)	39 (1.8)
Haemoptysis	6 (0.3)	3 (0.1)
Hiccups	2 (0.1)	2 (0.1)
Hydrothorax	1 (0.0)	3 (0.1)
Hypoxia	2 (0.1)	0 (0.0)
Increased bronchial secretion	1 (0.0)	0 (0.0)
Interstitial lung disease	0 (0.0)	2 (0.1)
Larynx irritation	1 (0.0)	0 (0.0)
Lower respiratory tract congestion	1 (0.0)	2 (0.1)
Lung consolidation	0 (0.0)	1 (0.0)
Lung disorder	2 (0.1)	1 (0.0)
Nasal congestion	0 (0.0)	3 (0.1)
Nasal mucosal ulcer	1 (0.0)	0 (0.0)
Nasal obstruction	1 (0.0)	0 (0.0)
Nasal polyps	0 (0.0)	1 (0.0)
Nocturnal dyspnoea	1 (0.0)	1 (0.0)
Oropharyngeal discomfort	2 (0.1)	0 (0.0)
Oropharyngeal pain	9 (0.4)	6 (0.3)
Orthopnoea	2 (0.1)	4 (0.2)
Pleural effusion	9 (0.4)	11 (0.5)
Pleurisy	0 (0.0)	2 (0.1)
Pneumonia aspiration	2 (0.1)	0 (0.0)
Pneumonitis	0 (0.0)	1 (0.0)
Pneumothorax	2 (0.1)	1 (0.0)
Productive cough	9 (0.4)	14 (0.7)
Pulmonary arterial hypertension	1 (0.0)	0 (0.0)
Pulmonary congestion	0 (0.0)	1 (0.0)
Pulmonary fibrosis	1 (0.0)	2 (0.1)
Pulmonary hypertension	2 (0.1)	1 (0.0)
Pulmonary mass	2 (0.1)	4 (0.2)
Pulmonary oedema	1 (0.0)	2 (0.1)
Rebound nasal congestion	1 (0.0)	0 (0.0)
Respiratory alkalosis	1 (0.0)	1 (0.0)
Respiratory disorder	1 (0.0)	3 (0.1)

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Mild Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Respiratory failure	0 (0.0)	2 (0.1)
Respiratory symptom	0 (0.0)	1 (0.0)
Rhinitis allergic	3 (0.1)	2 (0.1)
Rhinorrhoea	6 (0.3)	5 (0.2)
Rhonchi	0 (0.0)	1 (0.0)
Sinus congestion	1 (0.0)	0 (0.0)
Sinus disorder	1 (0.0)	0 (0.0)
Sinus polyp	0 (0.0)	1 (0.0)
Sleep apnoea syndrome	6 (0.3)	1 (0.0)
Sputum increased	0 (0.0)	2 (0.1)
Throat irritation	3 (0.1)	0 (0.0)
Upper respiratory tract congestion	0 (0.0)	1 (0.0)
Upper respiratory tract inflammation	3 (0.1)	3 (0.1)
Upper-airway cough syndrome	0 (0.0)	2 (0.1)
Vasomotor rhinitis	0 (0.0)	1 (0.0)
Wheezing	0 (0.0)	1 (0.0)
Skin and subcutaneous tissue disorders	138 (6.4)	136 (6.3)
Acne	2 (0.1)	2 (0.1)
Actinic keratosis	2 (0.1)	0 (0.0)
Alopecia	0 (0.0)	4 (0.2)
Angioedema	2 (0.1)	0 (0.0)
Asteatosis	2 (0.1)	2 (0.1)
Blister	4 (0.2)	4 (0.2)
Blood blister	0 (0.0)	1 (0.0)
Cold sweat	0 (0.0)	1 (0.0)
Decubitus ulcer	7 (0.3)	3 (0.1)
Dermal cyst	2 (0.1)	0 (0.0)
Dermatitis	1 (0.0)	10 (0.5)
Dermatitis allergic	2 (0.1)	1 (0.0)
Dermatitis atopic	1 (0.0)	0 (0.0)
Dermatitis contact	1 (0.0)	4 (0.2)
Diabetic foot	2 (0.1)	4 (0.2)
Drug eruption	2 (0.1)	1 (0.0)
Dry skin	5 (0.2)	5 (0.2)
Ecchymosis	5 (0.2)	5 (0.2)
Eczema	10 (0.5)	9 (0.4)
Eczema asteatotic	2 (0.1)	2 (0.1)

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Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Eczema nummular	0 (0.0)	1 (0.0)
Eczema vesicular	1 (0.0)	0 (0.0)
Erythema	5 (0.2)	1 (0.0)
Haemorrhage subcutaneous	1 (0.0)	1 (0.0)
Henoch-Schonlein purpura	0 (0.0)	1 (0.0)
Hyperhidrosis	3 (0.1)	4 (0.2)
Hyperkeratosis	2 (0.1)	3 (0.1)
Intertrigo	1 (0.0)	0 (0.0)
Mechanical urticaria	1 (0.0)	0 (0.0)
Neurodermatitis	2 (0.1)	0 (0.0)
Night sweats	0 (0.0)	1 (0.0)
Oedema blister	0 (0.0)	1 (0.0)
Onychoclasis	1 (0.0)	0 (0.0)
Onychogryphosis	1 (0.0)	0 (0.0)
Palmar erythema	1 (0.0)	0 (0.0)
Papule	1 (0.0)	1 (0.0)
Petechiae	1 (0.0)	0 (0.0)
Photosensitivity reaction	1 (0.0)	0 (0.0)
Pruritus	27 (1.3)	34 (1.6)
Pruritus generalised	3 (0.1)	4 (0.2)
Psoriasis	0 (0.0)	2 (0.1)
Purpura	1 (0.0)	0 (0.0)
Rash	18 (0.8)	19 (0.9)
Rash macular	1 (0.0)	0 (0.0)
Rash maculo-papular	1 (0.0)	0 (0.0)
Rash papular	1 (0.0)	0 (0.0)
Rash pruritic	4 (0.2)	3 (0.1)
Seborrhoea	1 (0.0)	0 (0.0)
Skin discolouration	1 (0.0)	1 (0.0)
Skin erosion	0 (0.0)	2 (0.1)
Skin exfoliation	2 (0.1)	2 (0.1)
Skin fibrosis	0 (0.0)	1 (0.0)
Skin fissures	1 (0.0)	0 (0.0)
Skin lesion	2 (0.1)	0 (0.0)
Skin maceration	0 (0.0)	1 (0.0)
Skin plaque	1 (0.0)	0 (0.0)
Skin ulcer	13 (0.6)	10 (0.5)

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Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Stasis dermatitis	1 (0.0)	2 (0.1)
Swelling face	1 (0.0)	0 (0.0)
Toxic skin eruption	1 (0.0)	0 (0.0)
Urticaria	4 (0.2)	4 (0.2)
Vascular purpura	0 (0.0)	1 (0.0)
Social circumstances	1 (0.0)	0 (0.0)
Alcohol use	1 (0.0)	0 (0.0)
Surgical and medical procedures	17 (0.8)	15 (0.7)
Cardiac ablation	0 (0.0)	1 (0.0)
Cardiac pacemaker replacement	1 (0.0)	0 (0.0)
Cardiac resynchronisation therapy	3 (0.1)	2 (0.1)
Cardioversion	6 (0.3)	1 (0.0)
Carpal tunnel decompression	1 (0.0)	1 (0.0)
Cataract operation	0 (0.0)	4 (0.2)
Central venous catheter removal	0 (0.0)	1 (0.0)
Dental care	1 (0.0)	0 (0.0)
Implantable defibrillator insertion	3 (0.1)	1 (0.0)
Implantable defibrillator replacement	1 (0.0)	1 (0.0)
Intraocular lens implant	0 (0.0)	1 (0.0)
Medical device battery replacement	0 (0.0)	1 (0.0)
Skin lesion removal	1 (0.0)	0 (0.0)
Tooth extraction	0 (0.0)	1 (0.0)
Vascular disorders	287 (13.3)	252 (11.7)
Accelerated hypertension	0 (0.0)	1 (0.0)
Aortic aneurysm	3 (0.1)	0 (0.0)
Aortic arteriosclerosis	0 (0.0)	2 (0.1)
Arteriosclerosis	4 (0.2)	1 (0.0)
Bleeding varicose vein	0 (0.0)	1 (0.0)
Blood pressure inadequately controlled	1 (0.0)	0 (0.0)
Brachiocephalic arteriosclerosis	0 (0.0)	1 (0.0)
Deep vein thrombosis	1 (0.0)	1 (0.0)
Diabetic vascular disorder	0 (0.0)	1 (0.0)
Diastolic hypertension	1 (0.0)	0 (0.0)
Flushing	0 (0.0)	1 (0.0)
Haematoma	8 (0.4)	14 (0.7)
Haemorrhage	2 (0.1)	0 (0.0)
Hot flush	1 (0.0)	1 (0.0)

Summary of Mild Adverse Events by System Organ Class and Preferred Term
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Hypertension	26 (1.2)	33 (1.5)
Hypertensive crisis	1 (0.0)	0 (0.0)
Hypertensive emergency	0 (0.0)	1 (0.0)
Hypertensive urgency	0 (0.0)	1 (0.0)
Hypotension	214 (9.9)	172 (8.0)
Intermittent claudication	1 (0.0)	2 (0.1)
Internal haemorrhage	1 (0.0)	0 (0.0)
Lymphoedema	1 (0.0)	1 (0.0)
Lymphostasis	0 (0.0)	1 (0.0)
Orthostatic hypotension	14 (0.7)	13 (0.6)
Peripheral arterial occlusive disease	6 (0.3)	5 (0.2)
Peripheral coldness	1 (0.0)	1 (0.0)
Peripheral ischaemia	0 (0.0)	1 (0.0)
Peripheral vascular disorder	3 (0.1)	1 (0.0)
Peripheral venous disease	1 (0.0)	1 (0.0)
Phlebitis	3 (0.1)	3 (0.1)
Phlebitis superficial	1 (0.0)	0 (0.0)
Post thrombotic syndrome	1 (0.0)	1 (0.0)
Subclavian vein stenosis	0 (0.0)	1 (0.0)
Systolic hypertension	0 (0.0)	1 (0.0)
Thrombophlebitis	2 (0.1)	1 (0.0)
Varicose ulceration	0 (0.0)	1 (0.0)
Varicose vein	3 (0.1)	4 (0.2)
Varicose vein ruptured	2 (0.1)	0 (0.0)
Venous thrombosis limb	1 (0.0)	1 (0.0)

a: Database Cutoff Date: 18JUN2019
b: A SOC or specific adverse event appears on this report only if its incidence is > 0% in one or more treatment groups
c: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
PT: Preferred Term; SOC: System Organ Class

Table 13
Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Participants with one or more adverse events	941 (43.7)	954 (44.4)
Blood and lymphatic system disorders	76 (3.5)	55 (2.6)
Anaemia	50 (2.3)	39 (1.8)
Coagulopathy	1 (0.0)	0 (0.0)
Eosinophilia	1 (0.0)	0 (0.0)
Hypercoagulation	0 (0.0)	1 (0.0)
Hypochromasia	1 (0.0)	0 (0.0)
Hypochromic anaemia	0 (0.0)	1 (0.0)
Iron deficiency anaemia	9 (0.4)	4 (0.2)
Leukocytosis	2 (0.1)	4 (0.2)
Leukopenia	0 (0.0)	2 (0.1)
Lymphatic insufficiency	0 (0.0)	1 (0.0)
Microcytic anaemia	2 (0.1)	0 (0.0)
Normochromic normocytic anaemia	5 (0.2)	2 (0.1)
Normocytic anaemia	1 (0.0)	0 (0.0)
Pancytopenia	2 (0.1)	0 (0.0)
Pernicious anaemia	0 (0.0)	1 (0.0)
Polycythaemia	1 (0.0)	0 (0.0)
Spontaneous haematoma	0 (0.0)	1 (0.0)
Thrombocytopenia	8 (0.4)	4 (0.2)
Cardiac disorders	218 (10.1)	241 (11.2)
Acute coronary syndrome	0 (0.0)	1 (0.0)
Acute left ventricular failure	0 (0.0)	1 (0.0)
Acute myocardial infarction	1 (0.0)	1 (0.0)
Angina pectoris	9 (0.4)	8 (0.4)
Angina unstable	1 (0.0)	1 (0.0)
Aortic valve incompetence	0 (0.0)	1 (0.0)
Aortic valve stenosis	1 (0.0)	0 (0.0)
Arrhythmia	4 (0.2)	2 (0.1)
Atrial fibrillation	32 (1.5)	39 (1.8)
Atrial flutter	8 (0.4)	12 (0.6)
Atrial tachycardia	1 (0.0)	3 (0.1)
Atrial thrombosis	2 (0.1)	2 (0.1)
Atrioventricular block first degree	2 (0.1)	1 (0.0)
Atrioventricular block second degree	0 (0.0)	1 (0.0)
Bifascicular block	1 (0.0)	0 (0.0)
Bradycardia	4 (0.2)	6 (0.3)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Bundle branch block left	1 (0.0)	2 (0.1)
Cardiac aneurysm	1 (0.0)	0 (0.0)
Cardiac failure	89 (4.1)	99 (4.6)
Cardiac failure acute	4 (0.2)	12 (0.6)
Cardiac failure chronic	9 (0.4)	15 (0.7)
Cardiac failure congestive	14 (0.7)	12 (0.6)
Cardiac ventricular thrombosis	1 (0.0)	0 (0.0)
Cardiogenic shock	0 (0.0)	1 (0.0)
Cardiomegaly	1 (0.0)	1 (0.0)
Cardiorenal syndrome	0 (0.0)	4 (0.2)
Coronary artery disease	4 (0.2)	3 (0.1)
Coronary artery stenosis	0 (0.0)	1 (0.0)
Extrasystoles	0 (0.0)	2 (0.1)
Intracardiac thrombus	0 (0.0)	1 (0.0)
Ischaemic cardiomyopathy	1 (0.0)	0 (0.0)
Left atrial dilatation	1 (0.0)	1 (0.0)
Left ventricular dysfunction	2 (0.1)	1 (0.0)
Left ventricular failure	1 (0.0)	0 (0.0)
Mitral valve incompetence	5 (0.2)	2 (0.1)
Myocardial infarction	1 (0.0)	1 (0.0)
Myocardial ischaemia	1 (0.0)	0 (0.0)
Myocarditis	0 (0.0)	1 (0.0)
Palpitations	4 (0.2)	6 (0.3)
Pericardial effusion	2 (0.1)	1 (0.0)
Pericarditis	0 (0.0)	1 (0.0)
Pulmonary valve incompetence	1 (0.0)	0 (0.0)
Restrictive cardiomyopathy	1 (0.0)	0 (0.0)
Sinus arrest	0 (0.0)	1 (0.0)
Sinus bradycardia	2 (0.1)	2 (0.1)
Sinus node dysfunction	1 (0.0)	1 (0.0)
Sinus tachycardia	2 (0.1)	2 (0.1)
Supraventricular extrasystoles	2 (0.1)	0 (0.0)
Supraventricular tachycardia	2 (0.1)	2 (0.1)
Tachyarrhythmia	2 (0.1)	0 (0.0)
Tachycardia	7 (0.3)	9 (0.4)
Tricuspid valve incompetence	5 (0.2)	3 (0.1)
Ventricular arrhythmia	2 (0.1)	2 (0.1)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Ventricular extrasystoles	8 (0.4)	7 (0.3)
Ventricular fibrillation	2 (0.1)	2 (0.1)
Ventricular flutter	0 (0.0)	1 (0.0)
Ventricular tachycardia	14 (0.7)	18 (0.8)
Congenital, familial and genetic disorders	4 (0.2)	1 (0.0)
Bronchogenic cyst	1 (0.0)	0 (0.0)
Dermoid cyst	1 (0.0)	0 (0.0)
Epidermolysis	1 (0.0)	0 (0.0)
Hydrocele	1 (0.0)	0 (0.0)
Hypospadias	0 (0.0)	1 (0.0)
Ear and labyrinth disorders	16 (0.7)	13 (0.6)
Deafness bilateral	2 (0.1)	1 (0.0)
Deafness neurosensory	2 (0.1)	0 (0.0)
Ear pain	0 (0.0)	1 (0.0)
Hypoacusis	1 (0.0)	0 (0.0)
Vertigo	8 (0.4)	8 (0.4)
Vertigo positional	3 (0.1)	3 (0.1)
Endocrine disorders	13 (0.6)	10 (0.5)
Autoimmune thyroiditis	0 (0.0)	1 (0.0)
Cushingoid	1 (0.0)	0 (0.0)
Goitre	0 (0.0)	1 (0.0)
Hyperaldosteronism	1 (0.0)	0 (0.0)
Hyperparathyroidism secondary	0 (0.0)	1 (0.0)
Hyperthyroidism	4 (0.2)	2 (0.1)
Hypothyroidism	8 (0.4)	6 (0.3)
Eye disorders	22 (1.0)	28 (1.3)
Cataract	7 (0.3)	10 (0.5)
Conjunctival haemorrhage	1 (0.0)	1 (0.0)
Diabetic retinopathy	6 (0.3)	3 (0.1)
Dry eye	1 (0.0)	1 (0.0)
Eye haematoma	0 (0.0)	1 (0.0)
Eye haemorrhage	0 (0.0)	1 (0.0)
Flat anterior chamber of eye	0 (0.0)	1 (0.0)
Lacrimation increased	0 (0.0)	1 (0.0)
Macular cyst	0 (0.0)	1 (0.0)
Macular degeneration	1 (0.0)	0 (0.0)
Myopia	0 (0.0)	1 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Ocular hyperaemia	1 (0.0)	0 (0.0)
Oculorespiratory syndrome	0 (0.0)	1 (0.0)
Optic neuropathy	1 (0.0)	0 (0.0)
Posterior capsule opacification	0 (0.0)	1 (0.0)
Retinal detachment	1 (0.0)	0 (0.0)
Retinal haemorrhage	1 (0.0)	0 (0.0)
Tractional retinal detachment	1 (0.0)	1 (0.0)
Ulcerative keratitis	1 (0.0)	0 (0.0)
Vision blurred	0 (0.0)	1 (0.0)
Visual acuity reduced	0 (0.0)	2 (0.1)
Visual impairment	1 (0.0)	4 (0.2)
Vitreous detachment	1 (0.0)	0 (0.0)
Vitreous haemorrhage	2 (0.1)	3 (0.1)
Gastrointestinal disorders	175 (8.1)	153 (7.1)
Abdominal discomfort	1 (0.0)	0 (0.0)
Abdominal distension	4 (0.2)	6 (0.3)
Abdominal hernia	0 (0.0)	1 (0.0)
Abdominal pain	14 (0.7)	10 (0.5)
Abdominal pain lower	0 (0.0)	1 (0.0)
Abdominal pain upper	10 (0.5)	5 (0.2)
Abdominal wall haematoma	0 (0.0)	1 (0.0)
Anal fissure	0 (0.0)	1 (0.0)
Anal incontinence	1 (0.0)	1 (0.0)
Angular cheilitis	1 (0.0)	0 (0.0)
Ascites	11 (0.5)	10 (0.5)
Barrett's oesophagus	0 (0.0)	1 (0.0)
Chronic gastritis	1 (0.0)	3 (0.1)
Colitis	0 (0.0)	3 (0.1)
Colitis ischaemic	1 (0.0)	1 (0.0)
Constipation	18 (0.8)	17 (0.8)
Dental caries	1 (0.0)	0 (0.0)
Diarrhoea	33 (1.5)	34 (1.6)
Diverticulum	0 (0.0)	1 (0.0)
Diverticulum intestinal	1 (0.0)	0 (0.0)
Duodenitis	0 (0.0)	2 (0.1)
Dyspepsia	15 (0.7)	2 (0.1)
Dysphagia	4 (0.2)	2 (0.1)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Enteritis	0 (0.0)	1 (0.0)
Enterocolitis	0 (0.0)	1 (0.0)
Epigastric discomfort	1 (0.0)	1 (0.0)
Erosive duodenitis	1 (0.0)	1 (0.0)
Eructation	1 (0.0)	0 (0.0)
Faecaloma	0 (0.0)	1 (0.0)
Flatulence	1 (0.0)	0 (0.0)
Food poisoning	1 (0.0)	0 (0.0)
Gastric antral vascular ectasia	0 (0.0)	1 (0.0)
Gastric disorder	2 (0.1)	3 (0.1)
Gastric ulcer	0 (0.0)	2 (0.1)
Gastric ulcer haemorrhage	0 (0.0)	1 (0.0)
Gastritis	4 (0.2)	6 (0.3)
Gastritis erosive	3 (0.1)	3 (0.1)
Gastritis haemorrhagic	0 (0.0)	1 (0.0)
Gastritis hypertrophic	0 (0.0)	1 (0.0)
Gastrointestinal angiodysplasia	1 (0.0)	3 (0.1)
Gastrointestinal haemorrhage	5 (0.2)	5 (0.2)
Gastrointestinal motility disorder	0 (0.0)	1 (0.0)
Gastrointestinal polyp	0 (0.0)	1 (0.0)
Gastrointestinal toxicity	1 (0.0)	0 (0.0)
Gastrointestinal ulcer	1 (0.0)	0 (0.0)
Gastrooesophageal reflux disease	10 (0.5)	7 (0.3)
Gingival bleeding	0 (0.0)	1 (0.0)
Gingival pain	1 (0.0)	0 (0.0)
Haematemesis	2 (0.1)	1 (0.0)
Haematochezia	0 (0.0)	1 (0.0)
Haemorrhoidal haemorrhage	0 (0.0)	2 (0.1)
Haemorrhoids	2 (0.1)	3 (0.1)
Hiatus hernia	3 (0.1)	0 (0.0)
Ileus	0 (0.0)	2 (0.1)
Ileus paralytic	1 (0.0)	0 (0.0)
Impaired gastric emptying	1 (0.0)	0 (0.0)
Incarcerated inguinal hernia	0 (0.0)	1 (0.0)
Inguinal hernia	6 (0.3)	2 (0.1)
Intestinal congestion	1 (0.0)	0 (0.0)
Intestinal polyp	0 (0.0)	1 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Intra-abdominal fluid collection	0 (0.0)	1 (0.0)
Intra-abdominal haematoma	1 (0.0)	0 (0.0)
Large intestine polyp	1 (0.0)	3 (0.1)
Melaena	1 (0.0)	0 (0.0)
Nausea	29 (1.3)	17 (0.8)
Oesophageal achalasia	0 (0.0)	2 (0.1)
Oesophageal disorder	1 (0.0)	0 (0.0)
Oesophageal irritation	1 (0.0)	0 (0.0)
Oesophageal stenosis	1 (0.0)	0 (0.0)
Oesophagitis	2 (0.1)	0 (0.0)
Oesophagitis ulcerative	0 (0.0)	1 (0.0)
Pancreatitis	1 (0.0)	2 (0.1)
Pancreatitis acute	1 (0.0)	0 (0.0)
Pancreatitis chronic	1 (0.0)	1 (0.0)
Pancreatolithiasis	1 (0.0)	0 (0.0)
Peptic ulcer	0 (0.0)	2 (0.1)
Periodontal disease	2 (0.1)	0 (0.0)
Rectal haemorrhage	2 (0.1)	2 (0.1)
Rectal polyp	0 (0.0)	2 (0.1)
Regurgitation	0 (0.0)	1 (0.0)
Swollen tongue	1 (0.0)	1 (0.0)
Toothache	1 (0.0)	2 (0.1)
Umbilical hernia	1 (0.0)	0 (0.0)
Upper gastrointestinal haemorrhage	1 (0.0)	3 (0.1)
Vomiting	24 (1.1)	10 (0.5)
General disorders and administration site conditions	102 (4.7)	128 (6.0)
Asthenia	12 (0.6)	16 (0.7)
Catheter site haemorrhage	1 (0.0)	1 (0.0)
Chest discomfort	6 (0.3)	6 (0.3)
Chest pain	20 (0.9)	25 (1.2)
Chills	0 (0.0)	1 (0.0)
Complication associated with device	1 (0.0)	0 (0.0)
Cyst	1 (0.0)	0 (0.0)
Device related thrombosis	0 (0.0)	1 (0.0)
Discomfort	1 (0.0)	1 (0.0)
Drug intolerance	1 (0.0)	3 (0.1)
Fatigue	14 (0.7)	14 (0.7)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Gait disturbance	2 (0.1)	2 (0.1)
General physical health deterioration	1 (0.0)	2 (0.1)
Generalised oedema	0 (0.0)	1 (0.0)
Ill-defined disorder	0 (0.0)	1 (0.0)
Impaired healing	0 (0.0)	1 (0.0)
Inflammation	1 (0.0)	0 (0.0)
Infusion site phlebitis	0 (0.0)	1 (0.0)
Malaise	1 (0.0)	2 (0.1)
Medical device site haematoma	1 (0.0)	0 (0.0)
Medical device site haemorrhage	0 (0.0)	1 (0.0)
Medical device site pain	0 (0.0)	1 (0.0)
Medical device site pruritus	0 (0.0)	1 (0.0)
Medical device site swelling	0 (0.0)	1 (0.0)
Medical device site thrombosis	0 (0.0)	1 (0.0)
Non-cardiac chest pain	3 (0.1)	4 (0.2)
Oedema	3 (0.1)	10 (0.5)
Oedema peripheral	23 (1.1)	21 (1.0)
Pain	1 (0.0)	2 (0.1)
Pelvic mass	0 (0.0)	1 (0.0)
Peripheral swelling	9 (0.4)	7 (0.3)
Physical deconditioning	0 (0.0)	1 (0.0)
Polyp	1 (0.0)	1 (0.0)
Pyrexia	6 (0.3)	12 (0.6)
Sensation of foreign body	1 (0.0)	0 (0.0)
Swelling	1 (0.0)	1 (0.0)
Systemic inflammatory response syndrome	0 (0.0)	1 (0.0)
Therapeutic response unexpected	0 (0.0)	1 (0.0)
Treatment noncompliance	0 (0.0)	1 (0.0)
UGT1A1 gene polymorphism	0 (0.0)	1 (0.0)
Vascular stent occlusion	1 (0.0)	0 (0.0)
Vascular stent thrombosis	0 (0.0)	1 (0.0)
Hepatobiliary disorders	32 (1.5)	33 (1.5)
Biliary colic	2 (0.1)	0 (0.0)
Cardiac cirrhosis	1 (0.0)	2 (0.1)
Cholecystitis	3 (0.1)	3 (0.1)
Cholecystitis acute	1 (0.0)	1 (0.0)
Cholelithiasis	3 (0.1)	2 (0.1)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Cholestasis	0 (0.0)	1 (0.0)
Chronic hepatic failure	0 (0.0)	1 (0.0)
Hepatic cirrhosis	3 (0.1)	2 (0.1)
Hepatic congestion	5 (0.2)	7 (0.3)
Hepatic failure	1 (0.0)	2 (0.1)
Hepatic fibrosis	1 (0.0)	0 (0.0)
Hepatic function abnormal	4 (0.2)	5 (0.2)
Hepatic mass	1 (0.0)	0 (0.0)
Hepatic steatosis	1 (0.0)	1 (0.0)
Hepatomegaly	0 (0.0)	1 (0.0)
Hydrocholecystis	1 (0.0)	0 (0.0)
Hyperbilirubinaemia	3 (0.1)	3 (0.1)
Ischaemic hepatitis	2 (0.1)	4 (0.2)
Jaundice	0 (0.0)	1 (0.0)
Liver disorder	3 (0.1)	1 (0.0)
Immune system disorders	2 (0.1)	3 (0.1)
Amyloidosis	1 (0.0)	0 (0.0)
Drug hypersensitivity	0 (0.0)	1 (0.0)
Hypersensitivity	1 (0.0)	2 (0.1)
Infections and infestations	259 (12.0)	274 (12.7)
Abscess limb	2 (0.1)	0 (0.0)
Acarodermatitis	1 (0.0)	0 (0.0)
Acute sinusitis	0 (0.0)	1 (0.0)
Anal abscess	0 (0.0)	1 (0.0)
Appendicitis	0 (0.0)	1 (0.0)
Bacillus bacteraemia	1 (0.0)	0 (0.0)
Bacteraemia	1 (0.0)	1 (0.0)
Bacteriuria	1 (0.0)	0 (0.0)
Body tinea	1 (0.0)	1 (0.0)
Borrelia infection	1 (0.0)	0 (0.0)
Bronchiolitis	0 (0.0)	1 (0.0)
Bronchitis	26 (1.2)	43 (2.0)
Bronchitis bacterial	1 (0.0)	1 (0.0)
Bronchitis viral	0 (0.0)	2 (0.1)
Cellulitis	11 (0.5)	15 (0.7)
Chest wall abscess	1 (0.0)	0 (0.0)
Chronic sinusitis	2 (0.1)	1 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Clostridium difficile colitis	1 (0.0)	0 (0.0)
Clostridium difficile infection	1 (0.0)	2 (0.1)
Conjunctivitis	3 (0.1)	1 (0.0)
Cystitis	3 (0.1)	0 (0.0)
Cytomegalovirus infection	1 (0.0)	0 (0.0)
Device related infection	1 (0.0)	1 (0.0)
Diarrhoea infectious	0 (0.0)	1 (0.0)
Diverticulitis	0 (0.0)	1 (0.0)
Ear infection	1 (0.0)	1 (0.0)
Eczema infected	0 (0.0)	1 (0.0)
Endocarditis	1 (0.0)	0 (0.0)
Enterobacter bacteraemia	1 (0.0)	0 (0.0)
Epididymitis	2 (0.1)	1 (0.0)
Erysipelas	4 (0.2)	4 (0.2)
Escherichia urinary tract infection	1 (0.0)	0 (0.0)
Fungal sepsis	0 (0.0)	1 (0.0)
Fungal skin infection	1 (0.0)	0 (0.0)
Furuncle	1 (0.0)	0 (0.0)
Gangrene	1 (0.0)	0 (0.0)
Gastroenteritis	13 (0.6)	13 (0.6)
Gastroenteritis viral	1 (0.0)	1 (0.0)
Gingivitis	1 (0.0)	2 (0.1)
Helicobacter gastritis	0 (0.0)	1 (0.0)
Hepatitis B	0 (0.0)	1 (0.0)
Hepatitis C	0 (0.0)	1 (0.0)
Herpes zoster	7 (0.3)	3 (0.1)
Implant site infection	1 (0.0)	0 (0.0)
Infection	2 (0.1)	3 (0.1)
Infective exacerbation of chronic obstructive airways disease	2 (0.1)	1 (0.0)
Influenza	10 (0.5)	12 (0.6)
Large intestine infection	0 (0.0)	1 (0.0)
Laryngitis	1 (0.0)	0 (0.0)
Localised infection	7 (0.3)	0 (0.0)
Lower respiratory tract infection	11 (0.5)	19 (0.9)
Lower respiratory tract infection viral	0 (0.0)	1 (0.0)
Lung infection	7 (0.3)	6 (0.3)
Nasopharyngitis	16 (0.7)	19 (0.9)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Oesophageal candidiasis	0 (0.0)	1 (0.0)
Onychomycosis	1 (0.0)	0 (0.0)
Oral candidiasis	1 (0.0)	1 (0.0)
Orchitis	0 (0.0)	2 (0.1)
Osteomyelitis	3 (0.1)	1 (0.0)
Osteomyelitis chronic	1 (0.0)	0 (0.0)
Otitis media	1 (0.0)	3 (0.1)
Otitis media acute	0 (0.0)	1 (0.0)
Otitis media chronic	1 (0.0)	1 (0.0)
Parasitic gastroenteritis	1 (0.0)	0 (0.0)
Periodontitis	1 (0.0)	2 (0.1)
Pertussis	0 (0.0)	1 (0.0)
Pharyngitis	3 (0.1)	4 (0.2)
Pharyngitis streptococcal	1 (0.0)	0 (0.0)
Phlebitis infective	0 (0.0)	1 (0.0)
Pneumonia	46 (2.1)	55 (2.6)
Pneumonia bacterial	1 (0.0)	1 (0.0)
Pneumonia streptococcal	1 (0.0)	0 (0.0)
Postoperative wound infection	0 (0.0)	1 (0.0)
Pseudomembranous colitis	1 (0.0)	1 (0.0)
Pulmonary sepsis	0 (0.0)	1 (0.0)
Pulpitis dental	0 (0.0)	1 (0.0)
Pyelonephritis	2 (0.1)	0 (0.0)
Pyelonephritis chronic	1 (0.0)	0 (0.0)
Rash pustular	1 (0.0)	0 (0.0)
Respiratory syncytial virus infection	1 (0.0)	0 (0.0)
Respiratory tract infection	12 (0.6)	9 (0.4)
Respiratory tract infection viral	2 (0.1)	3 (0.1)
Rhinitis	0 (0.0)	2 (0.1)
Sepsis	8 (0.4)	3 (0.1)
Septic shock	2 (0.1)	0 (0.0)
Serratia bacteraemia	1 (0.0)	0 (0.0)
Sinusitis	1 (0.0)	3 (0.1)
Skin bacterial infection	1 (0.0)	0 (0.0)
Skin infection	1 (0.0)	2 (0.1)
Soft tissue infection	0 (0.0)	1 (0.0)
Staphylococcal bacteraemia	1 (0.0)	1 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Staphylococcal infection	0 (0.0)	1 (0.0)
Staphylococcal skin infection	0 (0.0)	1 (0.0)
Subcutaneous abscess	2 (0.1)	1 (0.0)
Tonsillitis	0 (0.0)	2 (0.1)
Tonsillitis bacterial	0 (0.0)	1 (0.0)
Tooth abscess	1 (0.0)	1 (0.0)
Tooth infection	1 (0.0)	2 (0.1)
Tracheobronchitis	0 (0.0)	2 (0.1)
Upper respiratory tract infection	28 (1.3)	23 (1.1)
Urinary tract infection	33 (1.5)	25 (1.2)
Urinary tract infection bacterial	0 (0.0)	2 (0.1)
Vascular device infection	0 (0.0)	1 (0.0)
Vestibular neuronitis	0 (0.0)	1 (0.0)
Viral infection	5 (0.2)	3 (0.1)
Viral pharyngitis	0 (0.0)	1 (0.0)
Viral upper respiratory tract infection	2 (0.1)	7 (0.3)
Vulvovaginal candidiasis	1 (0.0)	0 (0.0)
Wound infection	1 (0.0)	1 (0.0)
Wound infection bacterial	1 (0.0)	0 (0.0)
Wound sepsis	1 (0.0)	0 (0.0)
Injury, poisoning and procedural complications	65 (3.0)	92 (4.3)
Accidental overdose	3 (0.1)	1 (0.0)
Ankle fracture	1 (0.0)	1 (0.0)
Arteriovenous fistula site complication	1 (0.0)	0 (0.0)
Arteriovenous fistula thrombosis	0 (0.0)	1 (0.0)
Arthropod bite	1 (0.0)	0 (0.0)
Arthropod sting	1 (0.0)	0 (0.0)
Back injury	0 (0.0)	1 (0.0)
Burns second degree	1 (0.0)	0 (0.0)
Chest injury	0 (0.0)	1 (0.0)
Clavicle fracture	0 (0.0)	1 (0.0)
Concussion	1 (0.0)	2 (0.1)
Contusion	6 (0.3)	12 (0.6)
Craniocerebral injury	0 (0.0)	1 (0.0)
Dermatitis artefacta	0 (0.0)	1 (0.0)
Face injury	0 (0.0)	1 (0.0)
Facial bones fracture	3 (0.1)	1 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Fall	15 (0.7)	17 (0.8)
Femur fracture	0 (0.0)	2 (0.1)
Foot fracture	1 (0.0)	1 (0.0)
Forearm fracture	1 (0.0)	0 (0.0)
Foreign body in gastrointestinal tract	1 (0.0)	0 (0.0)
Fractured coccyx	1 (0.0)	0 (0.0)
Haematuria traumatic	0 (0.0)	1 (0.0)
Hand fracture	0 (0.0)	1 (0.0)
Head injury	3 (0.1)	6 (0.3)
Human bite	0 (0.0)	1 (0.0)
Humerus fracture	0 (0.0)	2 (0.1)
Hyphaema	1 (0.0)	0 (0.0)
Incision site haematoma	0 (0.0)	1 (0.0)
Incision site pain	0 (0.0)	2 (0.1)
Intentional overdose	1 (0.0)	0 (0.0)
Jaw fracture	0 (0.0)	1 (0.0)
Joint dislocation	0 (0.0)	1 (0.0)
Joint injury	0 (0.0)	4 (0.2)
Ligament rupture	1 (0.0)	0 (0.0)
Ligament sprain	2 (0.1)	2 (0.1)
Limb injury	3 (0.1)	6 (0.3)
Lower limb fracture	0 (0.0)	1 (0.0)
Meniscus injury	0 (0.0)	1 (0.0)
Muscle injury	1 (0.0)	0 (0.0)
Muscle strain	1 (0.0)	0 (0.0)
Nail avulsion	1 (0.0)	0 (0.0)
Overdose	1 (0.0)	2 (0.1)
Post procedural haematoma	0 (0.0)	1 (0.0)
Post procedural haemorrhage	0 (0.0)	6 (0.3)
Post-traumatic pain	1 (0.0)	1 (0.0)
Procedural pain	0 (0.0)	1 (0.0)
Product administration error	0 (0.0)	1 (0.0)
Radius fracture	1 (0.0)	0 (0.0)
Rib fracture	2 (0.1)	6 (0.3)
Skin abrasion	0 (0.0)	1 (0.0)
Skin laceration	4 (0.2)	2 (0.1)
Soft tissue injury	1 (0.0)	0 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Spinal compression fracture	2 (0.1)	3 (0.1)
Spinal fracture	1 (0.0)	0 (0.0)
Subcutaneous haematoma	1 (0.0)	0 (0.0)
Subdural haematoma	0 (0.0)	1 (0.0)
Tendon rupture	1 (0.0)	0 (0.0)
Thermal burn	3 (0.1)	0 (0.0)
Tibia fracture	2 (0.1)	1 (0.0)
Toxicity to various agents	3 (0.1)	4 (0.2)
Traumatic ulcer	0 (0.0)	1 (0.0)
Ulna fracture	1 (0.0)	0 (0.0)
Upper limb fracture	1 (0.0)	1 (0.0)
Wound	1 (0.0)	0 (0.0)
Wound haemorrhage	0 (0.0)	1 (0.0)
Wound secretion	0 (0.0)	2 (0.1)
Wrist fracture	0 (0.0)	1 (0.0)
Investigations	115 (5.3)	124 (5.8)
Alanine aminotransferase increased	4 (0.2)	2 (0.1)
Alpha 1 foetoprotein increased	0 (0.0)	1 (0.0)
Angiocardiogram	1 (0.0)	0 (0.0)
Anticoagulation drug level above therapeutic	2 (0.1)	1 (0.0)
Aspartate aminotransferase increased	4 (0.2)	2 (0.1)
Bacterial test positive	1 (0.0)	0 (0.0)
Bilirubin conjugated increased	1 (0.0)	1 (0.0)
Blood alkaline phosphatase increased	3 (0.1)	4 (0.2)
Blood bilirubin increased	3 (0.1)	6 (0.3)
Blood bilirubin unconjugated increased	1 (0.0)	0 (0.0)
Blood creatine increased	1 (0.0)	0 (0.0)
Blood creatine phosphokinase increased	0 (0.0)	1 (0.0)
Blood creatinine decreased	0 (0.0)	1 (0.0)
Blood creatinine increased	15 (0.7)	17 (0.8)
Blood glucose abnormal	0 (0.0)	1 (0.0)
Blood glucose fluctuation	0 (0.0)	1 (0.0)
Blood glucose increased	3 (0.1)	5 (0.2)
Blood potassium decreased	0 (0.0)	1 (0.0)
Blood potassium increased	5 (0.2)	3 (0.1)
Blood pressure decreased	1 (0.0)	0 (0.0)
Blood pressure increased	3 (0.1)	9 (0.4)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Blood triglycerides increased	1 (0.0)	0 (0.0)
Blood urea increased	3 (0.1)	5 (0.2)
Blood uric acid increased	3 (0.1)	9 (0.4)
Blood urine present	0 (0.0)	1 (0.0)
Bone density abnormal	1 (0.0)	0 (0.0)
Brain natriuretic peptide increased	4 (0.2)	3 (0.1)
C-reactive protein increased	2 (0.1)	2 (0.1)
Cell marker increased	1 (0.0)	0 (0.0)
Clostridium test positive	1 (0.0)	0 (0.0)
Coagulation time prolonged	1 (0.0)	1 (0.0)
Ejection fraction decreased	1 (0.0)	0 (0.0)
Electrocardiogram QT prolonged	0 (0.0)	2 (0.1)
Electrocardiogram R on T phenomenon	1 (0.0)	0 (0.0)
Gamma-glutamyltransferase increased	14 (0.7)	17 (0.8)
Glomerular filtration rate decreased	3 (0.1)	0 (0.0)
Glycosylated haemoglobin increased	7 (0.3)	6 (0.3)
Haematocrit decreased	1 (0.0)	0 (0.0)
Haemoglobin decreased	3 (0.1)	1 (0.0)
Haemoglobin increased	0 (0.0)	1 (0.0)
Heart rate decreased	0 (0.0)	1 (0.0)
Heart rate increased	0 (0.0)	1 (0.0)
Hepatic enzyme increased	12 (0.6)	5 (0.2)
Inflammatory marker increased	1 (0.0)	0 (0.0)
Influenza B virus test positive	0 (0.0)	1 (0.0)
International normalised ratio fluctuation	0 (0.0)	1 (0.0)
International normalised ratio increased	11 (0.5)	2 (0.1)
Liver function test abnormal	2 (0.1)	1 (0.0)
Liver function test increased	1 (0.0)	1 (0.0)
Paracentesis	0 (0.0)	1 (0.0)
Platelet count decreased	2 (0.1)	2 (0.1)
Prothrombin time prolonged	1 (0.0)	1 (0.0)
Pulse pressure increased	1 (0.0)	0 (0.0)
Red blood cell count decreased	2 (0.1)	0 (0.0)
Transaminases increased	3 (0.1)	2 (0.1)
Transvalvular pressure gradient	1 (0.0)	0 (0.0)
Troponin I increased	1 (0.0)	0 (0.0)
Troponin increased	1 (0.0)	2 (0.1)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Weight decreased	9 (0.4)	6 (0.3)
Weight increased	10 (0.5)	17 (0.8)
White blood cell count decreased	2 (0.1)	1 (0.0)
White blood cell count increased	0 (0.0)	1 (0.0)
Metabolism and nutrition disorders	167 (7.8)	193 (9.0)
Acidosis	1 (0.0)	0 (0.0)
Alkalosis	1 (0.0)	0 (0.0)
Cachexia	0 (0.0)	1 (0.0)
Decreased appetite	8 (0.4)	6 (0.3)
Dehydration	13 (0.6)	13 (0.6)
Diabetes mellitus	11 (0.5)	20 (0.9)
Diabetes mellitus inadequate control	10 (0.5)	6 (0.3)
Diabetic ketoacidosis	2 (0.1)	0 (0.0)
Diabetic metabolic decompensation	4 (0.2)	3 (0.1)
Dyslipidaemia	0 (0.0)	3 (0.1)
Electrolyte imbalance	1 (0.0)	0 (0.0)
Fluid overload	5 (0.2)	4 (0.2)
Fluid retention	1 (0.0)	2 (0.1)
Folate deficiency	0 (0.0)	1 (0.0)
Gout	30 (1.4)	36 (1.7)
Hypercalcaemia	0 (0.0)	1 (0.0)
Hypercholesterolaemia	1 (0.0)	0 (0.0)
Hypercreatininaemia	1 (0.0)	0 (0.0)
Hyperglycaemia	10 (0.5)	10 (0.5)
Hyperglycaemic hyperosmolar nonketotic syndrome	1 (0.0)	0 (0.0)
Hyperkalaemia	23 (1.1)	38 (1.8)
Hyperlactacidaemia	2 (0.1)	0 (0.0)
Hyperlipidaemia	0 (0.0)	2 (0.1)
Hypermagnesaemia	0 (0.0)	1 (0.0)
Hypernatraemia	1 (0.0)	1 (0.0)
Hyperphosphataemia	0 (0.0)	3 (0.1)
Hypertriglyceridaemia	0 (0.0)	1 (0.0)
Hyperuricaemia	11 (0.5)	9 (0.4)
Hypervolaemia	1 (0.0)	1 (0.0)
Hypoalbuminaemia	0 (0.0)	2 (0.1)
Hypocalcaemia	3 (0.1)	5 (0.2)
Hypochloraemia	1 (0.0)	0 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Hypoglycaemia	17 (0.8)	7 (0.3)
Hypokalaemia	23 (1.1)	20 (0.9)
Hypomagnesaemia	5 (0.2)	3 (0.1)
Hyponatraemia	4 (0.2)	15 (0.7)
Hypophagia	0 (0.0)	2 (0.1)
Hypophosphataemia	1 (0.0)	1 (0.0)
Hypovolaemia	2 (0.1)	1 (0.0)
Increased appetite	0 (0.0)	1 (0.0)
Iron deficiency	2 (0.1)	5 (0.2)
Lactic acidosis	1 (0.0)	1 (0.0)
Malnutrition	0 (0.0)	1 (0.0)
Metabolic acidosis	2 (0.1)	4 (0.2)
Mineral metabolism disorder	0 (0.0)	1 (0.0)
Obesity	0 (0.0)	1 (0.0)
Type 2 diabetes mellitus	5 (0.2)	6 (0.3)
Vitamin D deficiency	4 (0.2)	1 (0.0)
Weight fluctuation	1 (0.0)	0 (0.0)
Musculoskeletal and connective tissue disorders	91 (4.2)	117 (5.4)
Arthralgia	17 (0.8)	16 (0.7)
Arthritis	4 (0.2)	5 (0.2)
Back pain	24 (1.1)	23 (1.1)
Bone disorder	1 (0.0)	0 (0.0)
Bone pain	1 (0.0)	1 (0.0)
Cervical spinal stenosis	0 (0.0)	1 (0.0)
Chondritis	1 (0.0)	0 (0.0)
Chondrodynia	1 (0.0)	0 (0.0)
Enthesopathy	1 (0.0)	0 (0.0)
Flank pain	2 (0.1)	4 (0.2)
Foot deformity	1 (0.0)	0 (0.0)
Gouty arthritis	4 (0.2)	10 (0.5)
Gouty tophus	0 (0.0)	1 (0.0)
Groin pain	0 (0.0)	1 (0.0)
Haematoma muscle	0 (0.0)	1 (0.0)
Intervertebral disc degeneration	1 (0.0)	2 (0.1)
Intervertebral disc disorder	0 (0.0)	1 (0.0)
Intervertebral disc protrusion	0 (0.0)	4 (0.2)
Joint effusion	1 (0.0)	3 (0.1)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Joint swelling	0 (0.0)	1 (0.0)
Lumbar spinal stenosis	1 (0.0)	1 (0.0)
Muscle spasms	6 (0.3)	5 (0.2)
Muscular weakness	2 (0.1)	2 (0.1)
Musculoskeletal chest pain	5 (0.2)	3 (0.1)
Musculoskeletal discomfort	0 (0.0)	1 (0.0)
Musculoskeletal pain	8 (0.4)	7 (0.3)
Musculoskeletal stiffness	1 (0.0)	0 (0.0)
Myalgia	3 (0.1)	5 (0.2)
Myopathy	0 (0.0)	1 (0.0)
Myositis	1 (0.0)	0 (0.0)
Neck pain	3 (0.1)	4 (0.2)
Osteoarthritis	4 (0.2)	5 (0.2)
Osteochondrosis	0 (0.0)	2 (0.1)
Osteonecrosis of jaw	0 (0.0)	1 (0.0)
Osteoporosis	0 (0.0)	3 (0.1)
Pain in extremity	9 (0.4)	13 (0.6)
Pain in jaw	0 (0.0)	1 (0.0)
Periarthritis	1 (0.0)	1 (0.0)
Polyarthritis	0 (0.0)	1 (0.0)
Rheumatic disorder	1 (0.0)	0 (0.0)
Rheumatoid arthritis	2 (0.1)	1 (0.0)
Rotator cuff syndrome	0 (0.0)	1 (0.0)
Sacroiliitis	1 (0.0)	0 (0.0)
Sarcopenia	0 (0.0)	1 (0.0)
Soft tissue necrosis	1 (0.0)	0 (0.0)
Spinal osteoarthritis	3 (0.1)	2 (0.1)
Spinal pain	1 (0.0)	1 (0.0)
Spinal stenosis	2 (0.1)	0 (0.0)
Tendon disorder	0 (0.0)	2 (0.1)
Tenosynovitis	1 (0.0)	2 (0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	15 (0.7)	14 (0.7)
Adrenal neoplasm	0 (0.0)	1 (0.0)
Basal cell carcinoma	1 (0.0)	0 (0.0)
Benign neoplasm of eyelid	0 (0.0)	1 (0.0)
Bladder neoplasm	1 (0.0)	0 (0.0)
Bronchial carcinoma	1 (0.0)	0 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Chronic lymphocytic leukaemia	0 (0.0)	1 (0.0)
Colon adenoma	0 (0.0)	2 (0.1)
Gastric cancer	0 (0.0)	1 (0.0)
Haemangioma	1 (0.0)	0 (0.0)
Kidney angiomyolipoma	1 (0.0)	0 (0.0)
Lipoma	0 (0.0)	1 (0.0)
Lung adenocarcinoma	1 (0.0)	1 (0.0)
Lung neoplasm malignant	0 (0.0)	1 (0.0)
Lymphoproliferative disorder	0 (0.0)	1 (0.0)
Mediastinum neoplasm	0 (0.0)	1 (0.0)
Metastatic squamous cell carcinoma	1 (0.0)	0 (0.0)
Neoplasm	1 (0.0)	0 (0.0)
Neoplasm skin	1 (0.0)	0 (0.0)
Pancreatic carcinoma	1 (0.0)	1 (0.0)
Parathyroid tumour benign	1 (0.0)	0 (0.0)
Plasmacytoma	0 (0.0)	1 (0.0)
Polycythaemia vera	0 (0.0)	1 (0.0)
Renal cancer	1 (0.0)	0 (0.0)
Renal neoplasm	2 (0.1)	0 (0.0)
Squamous cell carcinoma of lung	1 (0.0)	0 (0.0)
Squamous cell carcinoma of skin	1 (0.0)	0 (0.0)
Uterine cancer	0 (0.0)	1 (0.0)
Nervous system disorders	120 (5.6)	121 (5.6)
Altered state of consciousness	1 (0.0)	0 (0.0)
Aphasia	1 (0.0)	0 (0.0)
Ataxia	2 (0.1)	0 (0.0)
Autonomic neuropathy	1 (0.0)	0 (0.0)
Brain injury	0 (0.0)	1 (0.0)
Carotid arteriosclerosis	2 (0.1)	1 (0.0)
Carotid artery stenosis	1 (0.0)	0 (0.0)
Carpal tunnel syndrome	0 (0.0)	2 (0.1)
Cerebral atrophy	1 (0.0)	0 (0.0)
Cerebral disorder	1 (0.0)	0 (0.0)
Cerebrovascular accident	2 (0.1)	2 (0.1)
Cervicobrachial syndrome	0 (0.0)	1 (0.0)
Cognitive disorder	4 (0.2)	5 (0.2)
Cubital tunnel syndrome	1 (0.0)	0 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Dementia	1 (0.0)	0 (0.0)
Diabetic neuropathy	1 (0.0)	3 (0.1)
Dizziness	30 (1.4)	25 (1.2)
Dizziness postural	1 (0.0)	2 (0.1)
Dysarthria	0 (0.0)	1 (0.0)
Encephalopathy	2 (0.1)	3 (0.1)
Epilepsy	1 (0.0)	0 (0.0)
Generalised tonic-clonic seizure	0 (0.0)	1 (0.0)
Headache	18 (0.8)	14 (0.7)
Hemiparesis	2 (0.1)	0 (0.0)
Hydrocephalus	0 (0.0)	1 (0.0)
Hypersomnia	0 (0.0)	1 (0.0)
Hypoaesthesia	3 (0.1)	2 (0.1)
Ischaemic stroke	0 (0.0)	1 (0.0)
Lacunar infarction	0 (0.0)	1 (0.0)
Lethargy	1 (0.0)	1 (0.0)
Loss of consciousness	1 (0.0)	0 (0.0)
Memory impairment	2 (0.1)	2 (0.1)
Metabolic encephalopathy	0 (0.0)	1 (0.0)
Migraine	0 (0.0)	1 (0.0)
Muscle spasticity	1 (0.0)	0 (0.0)
Myoclonus	0 (0.0)	2 (0.1)
Neuralgia	2 (0.1)	1 (0.0)
Neurological symptom	1 (0.0)	0 (0.0)
Neuropathy peripheral	2 (0.1)	0 (0.0)
Paraesthesia	2 (0.1)	0 (0.0)
Paralysis	0 (0.0)	1 (0.0)
Peripheral nerve lesion	0 (0.0)	1 (0.0)
Peripheral sensory neuropathy	1 (0.0)	0 (0.0)
Phantom limb syndrome	1 (0.0)	0 (0.0)
Polyneuropathy	2 (0.1)	2 (0.1)
Poor quality sleep	1 (0.0)	0 (0.0)
Post herpetic neuralgia	0 (0.0)	1 (0.0)
Presyncope	2 (0.1)	3 (0.1)
Psychomotor hyperactivity	0 (0.0)	1 (0.0)
Radiculopathy	1 (0.0)	0 (0.0)
Restless legs syndrome	1 (0.0)	0 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Sciatica	4 (0.2)	1 (0.0)
Seizure	2 (0.1)	2 (0.1)
Somnolence	1 (0.0)	3 (0.1)
Speech disorder	1 (0.0)	0 (0.0)
Subarachnoid haemorrhage	1 (0.0)	0 (0.0)
Syncope	30 (1.4)	34 (1.6)
Tension headache	2 (0.1)	0 (0.0)
Thalamus haemorrhage	0 (0.0)	1 (0.0)
Transient ischaemic attack	2 (0.1)	0 (0.0)
Tremor	1 (0.0)	2 (0.1)
Vascular dementia	0 (0.0)	1 (0.0)
Vascular encephalopathy	0 (0.0)	1 (0.0)
Vocal cord paralysis	0 (0.0)	1 (0.0)
Product issues	4 (0.2)	7 (0.3)
Device battery issue	1 (0.0)	0 (0.0)
Device dislocation	0 (0.0)	2 (0.1)
Device inappropriate shock delivery	1 (0.0)	0 (0.0)
Device ineffective	0 (0.0)	1 (0.0)
Device malfunction	1 (0.0)	0 (0.0)
Device stimulation issue	1 (0.0)	3 (0.1)
Lead dislodgement	0 (0.0)	1 (0.0)
Psychiatric disorders	35 (1.6)	44 (2.0)
Adjustment disorder with anxiety	0 (0.0)	1 (0.0)
Alcohol abuse	0 (0.0)	1 (0.0)
Alcohol use disorder	1 (0.0)	0 (0.0)
Anxiety	3 (0.1)	2 (0.1)
Anxiety disorder	0 (0.0)	1 (0.0)
Confusional state	1 (0.0)	1 (0.0)
Delirium	1 (0.0)	7 (0.3)
Depressed mood	3 (0.1)	2 (0.1)
Depression	7 (0.3)	9 (0.4)
Disruptive mood dysregulation disorder	1 (0.0)	0 (0.0)
Drug abuse	0 (0.0)	1 (0.0)
Hallucination	1 (0.0)	1 (0.0)
Insomnia	7 (0.3)	17 (0.8)
Major depression	1 (0.0)	0 (0.0)
Mania	1 (0.0)	0 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Mental disorder	1 (0.0)	0 (0.0)
Mental status changes	1 (0.0)	1 (0.0)
Nervousness	1 (0.0)	0 (0.0)
Neurologic somatic symptom disorder	1 (0.0)	0 (0.0)
Organic brain syndrome	1 (0.0)	0 (0.0)
Panic attack	0 (0.0)	1 (0.0)
Personality change	1 (0.0)	0 (0.0)
Sleep disorder	1 (0.0)	1 (0.0)
Sleep terror	1 (0.0)	0 (0.0)
Somatic symptom disorder	0 (0.0)	1 (0.0)
Suicide attempt	1 (0.0)	0 (0.0)
Renal and urinary disorders	155 (7.2)	154 (7.2)
Acute kidney injury	44 (2.0)	38 (1.8)
Azotaemia	1 (0.0)	1 (0.0)
Bladder dilatation	1 (0.0)	0 (0.0)
Calculus urethral	0 (0.0)	1 (0.0)
Calculus urinary	1 (0.0)	0 (0.0)
Chronic kidney disease	30 (1.4)	33 (1.5)
Diabetic nephropathy	1 (0.0)	3 (0.1)
Dysuria	0 (0.0)	1 (0.0)
Haematuria	9 (0.4)	8 (0.4)
Hydronephrosis	1 (0.0)	0 (0.0)
Nephrolithiasis	0 (0.0)	1 (0.0)
Nephropathy	3 (0.1)	2 (0.1)
Nephropathy toxic	0 (0.0)	3 (0.1)
Nocturia	0 (0.0)	1 (0.0)
Pollakiuria	2 (0.1)	0 (0.0)
Proteinuria	1 (0.0)	1 (0.0)
Renal artery stenosis	1 (0.0)	2 (0.1)
Renal atrophy	0 (0.0)	1 (0.0)
Renal colic	2 (0.1)	0 (0.0)
Renal cyst	1 (0.0)	0 (0.0)
Renal failure	40 (1.9)	40 (1.9)
Renal impairment	25 (1.2)	26 (1.2)
Urinary incontinence	0 (0.0)	3 (0.1)
Urinary retention	10 (0.5)	2 (0.1)
Urinary tract obstruction	0 (0.0)	1 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Reproductive system and breast disorders	18 (0.8)	18 (0.8)
Atrophic vulvovaginitis	1 (0.0)	0 (0.0)
Benign prostatic hyperplasia	6 (0.3)	5 (0.2)
Breast disorder	0 (0.0)	1 (0.0)
Breast pain	2 (0.1)	0 (0.0)
Endometrial hyperplasia	1 (0.0)	0 (0.0)
Erectile dysfunction	1 (0.0)	3 (0.1)
Gynaecomastia	4 (0.2)	5 (0.2)
Haematospermia	1 (0.0)	0 (0.0)
Ovarian mass	1 (0.0)	0 (0.0)
Pelvic pain	0 (0.0)	1 (0.0)
Postmenopausal haemorrhage	1 (0.0)	0 (0.0)
Prostatitis	0 (0.0)	1 (0.0)
Scrotal mass	0 (0.0)	1 (0.0)
Uterine enlargement	1 (0.0)	0 (0.0)
Varicocele	0 (0.0)	1 (0.0)
Respiratory, thoracic and mediastinal disorders	153 (7.1)	153 (7.1)
Acute pulmonary oedema	1 (0.0)	1 (0.0)
Acute respiratory failure	0 (0.0)	4 (0.2)
Asthma	5 (0.2)	2 (0.1)
Atelectasis	1 (0.0)	1 (0.0)
Bendopnoea	1 (0.0)	0 (0.0)
Bronchitis chronic	2 (0.1)	3 (0.1)
Bronchospasm	2 (0.1)	1 (0.0)
Chronic obstructive pulmonary disease	25 (1.2)	12 (0.6)
Chronic respiratory failure	0 (0.0)	1 (0.0)
Cough	15 (0.7)	15 (0.7)
Dysphonia	1 (0.0)	2 (0.1)
Dyspnoea	60 (2.8)	55 (2.6)
Dyspnoea exertional	5 (0.2)	4 (0.2)
Dyspnoea paroxysmal nocturnal	1 (0.0)	1 (0.0)
Emphysema	0 (0.0)	1 (0.0)
Epistaxis	12 (0.6)	12 (0.6)
Haemoptysis	2 (0.1)	4 (0.2)
Hiccups	0 (0.0)	3 (0.1)
Hydrothorax	0 (0.0)	4 (0.2)
Hyperventilation	0 (0.0)	1 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Hypoxia	0 (0.0)	3 (0.1)
Interstitial lung disease	0 (0.0)	1 (0.0)
Lung disorder	0 (0.0)	1 (0.0)
Mediastinal mass	1 (0.0)	0 (0.0)
Nasal septum deviation	1 (0.0)	0 (0.0)
Oropharyngeal pain	2 (0.1)	3 (0.1)
Orthopnoea	1 (0.0)	3 (0.1)
Paranasal sinus haemorrhage	0 (0.0)	1 (0.0)
Pickwickian syndrome	0 (0.0)	2 (0.1)
Pleural effusion	14 (0.7)	12 (0.6)
Pleural thickening	1 (0.0)	0 (0.0)
Pleurisy	0 (0.0)	1 (0.0)
Pneumonia aspiration	3 (0.1)	3 (0.1)
Pneumothorax	0 (0.0)	1 (0.0)
Productive cough	3 (0.1)	5 (0.2)
Pulmonary arterial hypertension	0 (0.0)	1 (0.0)
Pulmonary congestion	2 (0.1)	1 (0.0)
Pulmonary embolism	2 (0.1)	2 (0.1)
Pulmonary hypertension	9 (0.4)	5 (0.2)
Pulmonary mass	0 (0.0)	2 (0.1)
Pulmonary oedema	3 (0.1)	1 (0.0)
Pulmonary pain	0 (0.0)	1 (0.0)
Rales	1 (0.0)	0 (0.0)
Respiratory acidosis	0 (0.0)	1 (0.0)
Respiratory alkalosis	1 (0.0)	0 (0.0)
Respiratory disorder	3 (0.1)	0 (0.0)
Respiratory distress	0 (0.0)	1 (0.0)
Respiratory failure	0 (0.0)	2 (0.1)
Sleep apnoea syndrome	1 (0.0)	6 (0.3)
Snoring	0 (0.0)	1 (0.0)
Sputum increased	0 (0.0)	1 (0.0)
Upper respiratory tract congestion	0 (0.0)	1 (0.0)
Upper respiratory tract inflammation	1 (0.0)	0 (0.0)
Wheezing	1 (0.0)	0 (0.0)
Skin and subcutaneous tissue disorders	47 (2.2)	51 (2.4)
Alopecia	2 (0.1)	3 (0.1)
Angioedema	1 (0.0)	0 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Blister	0 (0.0)	1 (0.0)
Decubitus ulcer	4 (0.2)	1 (0.0)
Dermatitis	1 (0.0)	1 (0.0)
Dermatitis allergic	1 (0.0)	1 (0.0)
Dermatitis contact	0 (0.0)	1 (0.0)
Diabetic foot	1 (0.0)	3 (0.1)
Diabetic ulcer	1 (0.0)	1 (0.0)
Ecchymosis	2 (0.1)	0 (0.0)
Eczema	3 (0.1)	1 (0.0)
Eczema nummular	1 (0.0)	0 (0.0)
Erythema	0 (0.0)	1 (0.0)
Haemorrhage subcutaneous	1 (0.0)	0 (0.0)
Hyperhidrosis	0 (0.0)	1 (0.0)
Hypersensitivity vasculitis	1 (0.0)	0 (0.0)
Ischaemic skin ulcer	0 (0.0)	1 (0.0)
Lichen sclerosus	0 (0.0)	1 (0.0)
Neurodermatitis	0 (0.0)	1 (0.0)
Onycholysis	0 (0.0)	1 (0.0)
Peau d'orange	1 (0.0)	0 (0.0)
Pemphigoid	1 (0.0)	1 (0.0)
Photosensitivity reaction	0 (0.0)	1 (0.0)
Pruritus	4 (0.2)	9 (0.4)
Pruritus allergic	1 (0.0)	0 (0.0)
Psoriasis	0 (0.0)	1 (0.0)
Purpura	1 (0.0)	0 (0.0)
Rash	6 (0.3)	5 (0.2)
Rash generalised	0 (0.0)	2 (0.1)
Rash pruritic	1 (0.0)	0 (0.0)
Skin disorder	1 (0.0)	0 (0.0)
Skin lesion	1 (0.0)	0 (0.0)
Skin necrosis	1 (0.0)	1 (0.0)
Skin ulcer	13 (0.6)	12 (0.6)
Stasis dermatitis	0 (0.0)	2 (0.1)
Toxic skin eruption	1 (0.0)	0 (0.0)
Urticaria	0 (0.0)	2 (0.1)
Urticaria papular	0 (0.0)	1 (0.0)
Surgical and medical procedures	10 (0.5)	13 (0.6)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Bladder catheterisation	1 (0.0)	0 (0.0)
Cardiac resynchronisation therapy	1 (0.0)	3 (0.1)
Cardiovascular event prophylaxis	0 (0.0)	1 (0.0)
Cardioversion	1 (0.0)	2 (0.1)
Cataract operation	0 (0.0)	3 (0.1)
Foot amputation	1 (0.0)	0 (0.0)
Implantable defibrillator insertion	4 (0.2)	0 (0.0)
Implantable defibrillator replacement	0 (0.0)	2 (0.1)
Pacemaker generated rhythm	0 (0.0)	1 (0.0)
Percutaneous coronary intervention	1 (0.0)	0 (0.0)
Rotator cuff repair	1 (0.0)	0 (0.0)
Skin neoplasm excision	0 (0.0)	1 (0.0)
Tooth extraction	0 (0.0)	1 (0.0)
Vascular disorders	171 (7.9)	183 (8.5)
Aortic aneurysm	0 (0.0)	2 (0.1)
Arterial occlusive disease	1 (0.0)	0 (0.0)
Arteriosclerosis	1 (0.0)	0 (0.0)
Atheroembolism	1 (0.0)	1 (0.0)
Bleeding varicose vein	1 (0.0)	0 (0.0)
Blood pressure inadequately controlled	1 (0.0)	0 (0.0)
Circulatory collapse	2 (0.1)	0 (0.0)
Deep vein thrombosis	3 (0.1)	2 (0.1)
Diabetic vascular disorder	1 (0.0)	1 (0.0)
Haematoma	3 (0.1)	3 (0.1)
Haemorrhagic vasculitis	0 (0.0)	1 (0.0)
Hypertension	13 (0.6)	21 (1.0)
Hypertensive crisis	5 (0.2)	4 (0.2)
Hypertensive emergency	2 (0.1)	0 (0.0)
Hypertensive urgency	1 (0.0)	0 (0.0)
Hypotension	117 (5.4)	129 (6.0)
Hypovolaemic shock	1 (0.0)	0 (0.0)
Iliac artery occlusion	1 (0.0)	0 (0.0)
Intermittent claudication	0 (0.0)	3 (0.1)
Lymphostasis	1 (0.0)	0 (0.0)
Orthostatic hypotension	9 (0.4)	12 (0.6)
Peripheral arterial occlusive disease	4 (0.2)	6 (0.3)
Peripheral artery aneurysm	0 (0.0)	1 (0.0)

Summary of Moderate Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Peripheral artery occlusion	2 (0.1)	0 (0.0)
Peripheral artery stenosis	1 (0.0)	1 (0.0)
Peripheral embolism	0 (0.0)	1 (0.0)
Peripheral ischaemia	0 (0.0)	2 (0.1)
Peripheral vascular disorder	2 (0.1)	3 (0.1)
Peripheral venous disease	2 (0.1)	2 (0.1)
Phlebitis	2 (0.1)	1 (0.0)
Thrombophlebitis	0 (0.0)	2 (0.1)
Thrombophlebitis superficial	0 (0.0)	1 (0.0)
Thrombosis	1 (0.0)	0 (0.0)
Varicose ulceration	1 (0.0)	0 (0.0)
Varicose vein	1 (0.0)	3 (0.1)
Varicose vein ruptured	0 (0.0)	1 (0.0)
Vasculitis	0 (0.0)	1 (0.0)

a: Database Cutoff Date: 18JUN2019
b: A SOC or specific adverse event appears on this report only if its incidence is > 0% in one or more treatment groups
c: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
PT: Preferred Term; SOC: System Organ Class

Table 14
Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Participants with one or more adverse events	701 (32.6)	728 (33.8)
Blood and lymphatic system disorders	38 (1.8)	21 (1.0)
Anaemia	28 (1.3)	15 (0.7)
Autoimmune haemolytic anaemia	1 (0.0)	0 (0.0)
Blood loss anaemia	0 (0.0)	2 (0.1)
Coagulopathy	2 (0.1)	1 (0.0)
Disseminated intravascular coagulation	1 (0.0)	0 (0.0)
Hypochromic anaemia	1 (0.0)	0 (0.0)
Hypocoagulable state	1 (0.0)	0 (0.0)
Iron deficiency anaemia	2 (0.1)	1 (0.0)
Normocytic anaemia	1 (0.0)	0 (0.0)
Pancytopenia	1 (0.0)	0 (0.0)
Splenic infarction	1 (0.0)	0 (0.0)
Thrombocytopenia	1 (0.0)	2 (0.1)
Cardiac disorders	173 (8.0)	228 (10.6)
Acute coronary syndrome	1 (0.0)	4 (0.2)
Acute myocardial infarction	5 (0.2)	5 (0.2)
Angina pectoris	6 (0.3)	5 (0.2)
Angina unstable	2 (0.1)	7 (0.3)
Aortic valve calcification	1 (0.0)	0 (0.0)
Aortic valve incompetence	0 (0.0)	1 (0.0)
Aortic valve stenosis	2 (0.1)	3 (0.1)
Arteriosclerosis coronary artery	2 (0.1)	0 (0.0)
Atrial fibrillation	11 (0.5)	27 (1.3)
Atrial flutter	6 (0.3)	6 (0.3)
Atrial tachycardia	0 (0.0)	1 (0.0)
Atrial thrombosis	1 (0.0)	1 (0.0)
Atrioventricular block	1 (0.0)	0 (0.0)
Atrioventricular block complete	0 (0.0)	1 (0.0)
Bradyarrhythmia	0 (0.0)	1 (0.0)
Bradycardia	0 (0.0)	2 (0.1)
Bundle branch block left	1 (0.0)	2 (0.1)
Cardiac arrest	3 (0.1)	1 (0.0)
Cardiac failure	65 (3.0)	88 (4.1)
Cardiac failure acute	1 (0.0)	6 (0.3)
Cardiac failure chronic	6 (0.3)	8 (0.4)
Cardiac failure congestive	10 (0.5)	19 (0.9)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Cardiac perforation	0 (0.0)	1 (0.0)
Cardiac ventricular thrombosis	2 (0.1)	0 (0.0)
Cardio-respiratory arrest	4 (0.2)	1 (0.0)
Cardiogenic shock	5 (0.2)	4 (0.2)
Cardiopulmonary failure	1 (0.0)	0 (0.0)
Cardiorenal syndrome	2 (0.1)	1 (0.0)
Cardiovascular disorder	1 (0.0)	0 (0.0)
Congestive cardiomyopathy	3 (0.1)	3 (0.1)
Coronary artery disease	3 (0.1)	2 (0.1)
Coronary artery occlusion	0 (0.0)	1 (0.0)
Coronary artery stenosis	2 (0.1)	1 (0.0)
Extrasystoles	1 (0.0)	0 (0.0)
Intracardiac thrombus	0 (0.0)	2 (0.1)
Ischaemic cardiomyopathy	1 (0.0)	2 (0.1)
Left ventricular dysfunction	1 (0.0)	1 (0.0)
Left ventricular failure	0 (0.0)	2 (0.1)
Mitral valve incompetence	5 (0.2)	5 (0.2)
Myocardial infarction	5 (0.2)	3 (0.1)
Myocardial ischaemia	2 (0.1)	2 (0.1)
Palpitations	1 (0.0)	1 (0.0)
Pericardial effusion	0 (0.0)	1 (0.0)
Pulseless electrical activity	0 (0.0)	1 (0.0)
Sinus bradycardia	2 (0.1)	0 (0.0)
Sinus node dysfunction	1 (0.0)	2 (0.1)
Tachycardia	1 (0.0)	1 (0.0)
Ventricular arrhythmia	2 (0.1)	1 (0.0)
Ventricular dysfunction	0 (0.0)	1 (0.0)
Ventricular extrasystoles	3 (0.1)	2 (0.1)
Ventricular fibrillation	9 (0.4)	7 (0.3)
Ventricular tachycardia	14 (0.7)	23 (1.1)
Congenital, familial and genetic disorders	4 (0.2)	0 (0.0)
Corneal dystrophy	1 (0.0)	0 (0.0)
Gastrointestinal arteriovenous malformation	1 (0.0)	0 (0.0)
Hydrocele	1 (0.0)	0 (0.0)
Phimosis	1 (0.0)	0 (0.0)
Ear and labyrinth disorders	3 (0.1)	5 (0.2)
Vertigo	3 (0.1)	4 (0.2)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Vertigo positional	0 (0.0)	1 (0.0)
Endocrine disorders	7 (0.3)	2 (0.1)
Adrenal insufficiency	1 (0.0)	0 (0.0)
Basedow's disease	1 (0.0)	0 (0.0)
Carcinoid syndrome	1 (0.0)	0 (0.0)
Glucocorticoid deficiency	1 (0.0)	0 (0.0)
Hyperthyroidism	3 (0.1)	1 (0.0)
Hypoparathyroidism secondary	0 (0.0)	1 (0.0)
Hypothyroidism	0 (0.0)	1 (0.0)
Eye disorders	12 (0.6)	8 (0.4)
Amaurosis fugax	1 (0.0)	0 (0.0)
Cataract	5 (0.2)	5 (0.2)
Diabetic retinopathy	2 (0.1)	1 (0.0)
Diplopia	1 (0.0)	0 (0.0)
Glaucoma	1 (0.0)	0 (0.0)
Macular cyst	0 (0.0)	1 (0.0)
Ocular hyperaemia	1 (0.0)	0 (0.0)
Retinal artery thrombosis	1 (0.0)	0 (0.0)
Retinal detachment	0 (0.0)	1 (0.0)
Retinal haemorrhage	0 (0.0)	1 (0.0)
Vitreous haemorrhage	2 (0.1)	0 (0.0)
Gastrointestinal disorders	73 (3.4)	78 (3.6)
Abdominal pain	3 (0.1)	5 (0.2)
Abdominal pain upper	3 (0.1)	3 (0.1)
Abdominal rigidity	1 (0.0)	0 (0.0)
Alcoholic pancreatitis	1 (0.0)	0 (0.0)
Anorectal ulcer	1 (0.0)	0 (0.0)
Ascites	5 (0.2)	4 (0.2)
Barrett's oesophagus	0 (0.0)	1 (0.0)
Colitis	1 (0.0)	1 (0.0)
Colitis ischaemic	1 (0.0)	1 (0.0)
Constipation	2 (0.1)	0 (0.0)
Diarrhoea	5 (0.2)	6 (0.3)
Diverticulum	1 (0.0)	0 (0.0)
Diverticulum intestinal	0 (0.0)	1 (0.0)
Duodenal ulcer	0 (0.0)	3 (0.1)
Dyspepsia	1 (0.0)	0 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Dysphagia	1 (0.0)	1 (0.0)
Erosive oesophagitis	1 (0.0)	0 (0.0)
Faecaloma	0 (0.0)	2 (0.1)
Flatulence	1 (0.0)	0 (0.0)
Gastric haemorrhage	2 (0.1)	0 (0.0)
Gastric perforation	1 (0.0)	0 (0.0)
Gastric ulcer	1 (0.0)	2 (0.1)
Gastritis	3 (0.1)	5 (0.2)
Gastritis erosive	1 (0.0)	2 (0.1)
Gastrointestinal angiodysplasia	0 (0.0)	2 (0.1)
Gastrointestinal haemorrhage	9 (0.4)	6 (0.3)
Gastrooesophageal reflux disease	0 (0.0)	3 (0.1)
Haematemesis	1 (0.0)	0 (0.0)
Haematochezia	0 (0.0)	1 (0.0)
Haemorrhoids	3 (0.1)	2 (0.1)
Ileus	2 (0.1)	0 (0.0)
Impaired gastric emptying	1 (0.0)	0 (0.0)
Incarcerated inguinal hernia	0 (0.0)	3 (0.1)
Incarcerated umbilical hernia	1 (0.0)	0 (0.0)
Inguinal hernia	6 (0.3)	6 (0.3)
Inguinal hernia strangulated	1 (0.0)	0 (0.0)
Inguinal hernia, obstructive	1 (0.0)	0 (0.0)
Intestinal infarction	0 (0.0)	1 (0.0)
Intestinal ischaemia	1 (0.0)	1 (0.0)
Intra-abdominal haematoma	0 (0.0)	1 (0.0)
Ischaemic enteritis	0 (0.0)	1 (0.0)
Large intestinal haemorrhage	1 (0.0)	0 (0.0)
Large intestinal stenosis	0 (0.0)	1 (0.0)
Large intestinal ulcer	0 (0.0)	1 (0.0)
Large intestinal ulcer haemorrhage	0 (0.0)	1 (0.0)
Large intestinal ulcer perforation	1 (0.0)	0 (0.0)
Large intestine polyp	1 (0.0)	3 (0.1)
Lower gastrointestinal haemorrhage	1 (0.0)	1 (0.0)
Melaena	1 (0.0)	2 (0.1)
Nausea	2 (0.1)	0 (0.0)
Oesophageal achalasia	0 (0.0)	1 (0.0)
Oesophageal varices haemorrhage	0 (0.0)	1 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Oesophagitis	1 (0.0)	0 (0.0)
Pancreatitis acute	2 (0.1)	1 (0.0)
Pancreatitis chronic	1 (0.0)	0 (0.0)
Peptic ulcer	0 (0.0)	2 (0.1)
Pneumatosis intestinalis	0 (0.0)	1 (0.0)
Rectal haemorrhage	2 (0.1)	0 (0.0)
Small intestinal obstruction	1 (0.0)	0 (0.0)
Subileus	0 (0.0)	1 (0.0)
Umbilical hernia	1 (0.0)	0 (0.0)
Upper gastrointestinal haemorrhage	1 (0.0)	6 (0.3)
Vomiting	3 (0.1)	2 (0.1)
General disorders and administration site conditions	34 (1.6)	32 (1.5)
Asthenia	4 (0.2)	2 (0.1)
Cardiac complication associated with device	1 (0.0)	0 (0.0)
Chest discomfort	1 (0.0)	0 (0.0)
Chest pain	9 (0.4)	7 (0.3)
Discomfort	1 (0.0)	0 (0.0)
Fatigue	1 (0.0)	1 (0.0)
General physical health deterioration	4 (0.2)	1 (0.0)
Generalised oedema	1 (0.0)	0 (0.0)
Hernia	1 (0.0)	0 (0.0)
Implant site erythema	0 (0.0)	1 (0.0)
Implant site haematoma	1 (0.0)	0 (0.0)
Implant site haemorrhage	0 (0.0)	1 (0.0)
Influenza like illness	0 (0.0)	1 (0.0)
Medical device pain	1 (0.0)	0 (0.0)
Multiple organ dysfunction syndrome	2 (0.1)	4 (0.2)
Non-cardiac chest pain	3 (0.1)	6 (0.3)
Oedema peripheral	0 (0.0)	4 (0.2)
Peripheral swelling	1 (0.0)	1 (0.0)
Pyrexia	3 (0.1)	1 (0.0)
Strangulated hernia	0 (0.0)	1 (0.0)
Sudden cardiac death	0 (0.0)	1 (0.0)
Vascular stent occlusion	1 (0.0)	0 (0.0)
Vascular stent stenosis	0 (0.0)	1 (0.0)
Hepatobiliary disorders	33 (1.5)	23 (1.1)
Acute hepatic failure	1 (0.0)	3 (0.1)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Bile duct stone	2 (0.1)	1 (0.0)
Biloma	0 (0.0)	1 (0.0)
Cholangitis	0 (0.0)	1 (0.0)
Cholangitis acute	0 (0.0)	1 (0.0)
Cholecystitis	3 (0.1)	2 (0.1)
Cholecystitis acute	5 (0.2)	5 (0.2)
Cholecystitis chronic	1 (0.0)	0 (0.0)
Cholelithiasis	3 (0.1)	1 (0.0)
Cholestasis	1 (0.0)	0 (0.0)
Hepatic cirrhosis	1 (0.0)	1 (0.0)
Hepatic congestion	3 (0.1)	1 (0.0)
Hepatic failure	1 (0.0)	0 (0.0)
Hepatitis acute	1 (0.0)	1 (0.0)
Hepatitis toxic	0 (0.0)	1 (0.0)
Hepatocellular injury	2 (0.1)	0 (0.0)
Hepatorenal syndrome	0 (0.0)	1 (0.0)
Hyperbilirubinaemia	0 (0.0)	1 (0.0)
Ischaemic hepatitis	5 (0.2)	2 (0.1)
Jaundice cholestatic	1 (0.0)	0 (0.0)
Liver disorder	2 (0.1)	1 (0.0)
Liver injury	5 (0.2)	2 (0.1)
Portosplenomesenteric venous thrombosis	0 (0.0)	1 (0.0)
Immune system disorders	1 (0.0)	0 (0.0)
Amyloidosis	1 (0.0)	0 (0.0)
Infections and infestations	214 (9.9)	218 (10.1)
Abscess limb	3 (0.1)	2 (0.1)
Acinetobacter bacteraemia	1 (0.0)	0 (0.0)
Amoebic dysentery	1 (0.0)	0 (0.0)
Anal abscess	0 (0.0)	1 (0.0)
Atypical pneumonia	0 (0.0)	1 (0.0)
Bacteraemia	0 (0.0)	1 (0.0)
Bacterial sepsis	1 (0.0)	0 (0.0)
Bronchitis	8 (0.4)	7 (0.3)
Bronchitis viral	2 (0.1)	1 (0.0)
Campylobacter gastroenteritis	1 (0.0)	0 (0.0)
Cellulitis	18 (0.8)	16 (0.7)
Cellulitis gangrenous	1 (0.0)	0 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Cholecystitis infective	0 (0.0)	2 (0.1)
Chronic sinusitis	1 (0.0)	0 (0.0)
Clostridium difficile colitis	2 (0.1)	0 (0.0)
Complicated appendicitis	2 (0.1)	0 (0.0)
Cystitis	1 (0.0)	1 (0.0)
Cystitis bacterial	0 (0.0)	1 (0.0)
Device related infection	2 (0.1)	1 (0.0)
Diabetic foot infection	1 (0.0)	2 (0.1)
Diarrhoea infectious	1 (0.0)	0 (0.0)
Diverticulitis	1 (0.0)	1 (0.0)
Encephalitis	1 (0.0)	0 (0.0)
Endocarditis	5 (0.2)	1 (0.0)
Enterococcal bacteraemia	1 (0.0)	0 (0.0)
Enterococcal infection	0 (0.0)	1 (0.0)
Epididymitis	2 (0.1)	0 (0.0)
Erysipelas	1 (0.0)	5 (0.2)
Escherichia urinary tract infection	1 (0.0)	0 (0.0)
Extradural abscess	1 (0.0)	0 (0.0)
Eye infection bacterial	0 (0.0)	1 (0.0)
Fungaemia	1 (0.0)	0 (0.0)
Gangrene	3 (0.1)	2 (0.1)
Gas gangrene	0 (0.0)	1 (0.0)
Gastroenteritis	14 (0.7)	5 (0.2)
Gastroenteritis bacterial	0 (0.0)	1 (0.0)
Gastroenteritis salmonella	1 (0.0)	0 (0.0)
Groin abscess	0 (0.0)	1 (0.0)
Haematoma infection	1 (0.0)	0 (0.0)
Herpes zoster	0 (0.0)	1 (0.0)
Implant site cellulitis	1 (0.0)	0 (0.0)
Implant site infection	2 (0.1)	2 (0.1)
Infected bite	0 (0.0)	1 (0.0)
Infected skin ulcer	1 (0.0)	0 (0.0)
Infection	0 (0.0)	1 (0.0)
Infectious pleural effusion	0 (0.0)	1 (0.0)
Infective exacerbation of chronic obstructive airways disease	0 (0.0)	2 (0.1)
Influenza	7 (0.3)	5 (0.2)
Intervertebral discitis	1 (0.0)	1 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Klebsiella sepsis	0 (0.0)	1 (0.0)
Liver abscess	0 (0.0)	2 (0.1)
Lower respiratory tract infection	7 (0.3)	5 (0.2)
Lower respiratory tract infection viral	0 (0.0)	1 (0.0)
Lung infection	7 (0.3)	3 (0.1)
Measles	1 (0.0)	0 (0.0)
Medical device site abscess	0 (0.0)	1 (0.0)
Myocarditis infectious	2 (0.1)	0 (0.0)
Necrotising fasciitis	2 (0.1)	0 (0.0)
Nosocomial infection	1 (0.0)	0 (0.0)
Ophthalmic herpes zoster	0 (0.0)	1 (0.0)
Osteomyelitis	6 (0.3)	4 (0.2)
Osteomyelitis acute	1 (0.0)	0 (0.0)
Otitis externa	1 (0.0)	0 (0.0)
Parainfluenzae virus infection	1 (0.0)	1 (0.0)
Parotid abscess	0 (0.0)	1 (0.0)
Periodontitis	1 (0.0)	0 (0.0)
Perirectal abscess	1 (0.0)	0 (0.0)
Peritonitis	0 (0.0)	1 (0.0)
Peritonitis bacterial	3 (0.1)	0 (0.0)
Pertussis	0 (0.0)	1 (0.0)
Pneumonia	77 (3.6)	92 (4.3)
Pneumonia bacterial	2 (0.1)	3 (0.1)
Pneumonia chlamydial	1 (0.0)	0 (0.0)
Pneumonia pneumococcal	0 (0.0)	1 (0.0)
Pneumonia respiratory syncytial viral	0 (0.0)	1 (0.0)
Pneumonia staphylococcal	0 (0.0)	1 (0.0)
Pneumonia streptococcal	1 (0.0)	0 (0.0)
Pneumonia viral	1 (0.0)	1 (0.0)
Postoperative wound infection	1 (0.0)	0 (0.0)
Psoas abscess	1 (0.0)	0 (0.0)
Pulmonary sepsis	2 (0.1)	2 (0.1)
Pyelonephritis	1 (0.0)	0 (0.0)
Pyelonephritis acute	0 (0.0)	1 (0.0)
Pyelonephritis chronic	0 (0.0)	1 (0.0)
Respiratory tract infection	4 (0.2)	4 (0.2)
Respiratory tract infection viral	0 (0.0)	1 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Salmonella bacteraemia	0 (0.0)	1 (0.0)
Sepsis	11 (0.5)	22 (1.0)
Septic shock	10 (0.5)	12 (0.6)
Sinusitis	1 (0.0)	1 (0.0)
Skin bacterial infection	1 (0.0)	0 (0.0)
Skin infection	1 (0.0)	0 (0.0)
Staphylococcal bacteraemia	1 (0.0)	1 (0.0)
Staphylococcal infection	1 (0.0)	0 (0.0)
Staphylococcal sepsis	1 (0.0)	0 (0.0)
Staphylococcal skin infection	1 (0.0)	0 (0.0)
Streptococcal bacteraemia	1 (0.0)	0 (0.0)
Subcutaneous abscess	1 (0.0)	0 (0.0)
Systemic candida	1 (0.0)	0 (0.0)
Tracheobronchitis	2 (0.1)	0 (0.0)
Typhoid fever	0 (0.0)	1 (0.0)
Upper respiratory tract infection	8 (0.4)	9 (0.4)
Urinary tract infection	11 (0.5)	10 (0.5)
Urosepsis	3 (0.1)	1 (0.0)
Viral diarrhoea	0 (0.0)	1 (0.0)
Viral infection	2 (0.1)	0 (0.0)
Viral upper respiratory tract infection	2 (0.1)	0 (0.0)
Wound infection	0 (0.0)	2 (0.1)
Wound sepsis	0 (0.0)	2 (0.1)
Injury, poisoning and procedural complications	52 (2.4)	61 (2.8)
Accidental overdose	1 (0.0)	1 (0.0)
Acetabulum fracture	0 (0.0)	1 (0.0)
Alcohol poisoning	1 (0.0)	0 (0.0)
Ankle fracture	2 (0.1)	2 (0.1)
Arteriovenous fistula site complication	1 (0.0)	0 (0.0)
Bone fissure	1 (0.0)	0 (0.0)
Burns second degree	1 (0.0)	1 (0.0)
Burns third degree	0 (0.0)	1 (0.0)
Cardiac valve replacement complication	0 (0.0)	1 (0.0)
Cervical vertebral fracture	1 (0.0)	0 (0.0)
Chest injury	1 (0.0)	0 (0.0)
Concussion	1 (0.0)	0 (0.0)
Contusion	1 (0.0)	1 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Craniocerebral injury	2 (0.1)	0 (0.0)
Face injury	1 (0.0)	0 (0.0)
Facial bones fracture	0 (0.0)	1 (0.0)
Fall	4 (0.2)	6 (0.3)
Femoral neck fracture	0 (0.0)	5 (0.2)
Femur fracture	3 (0.1)	8 (0.4)
Fibula fracture	1 (0.0)	1 (0.0)
Foot fracture	2 (0.1)	1 (0.0)
Hand fracture	0 (0.0)	1 (0.0)
Head injury	3 (0.1)	1 (0.0)
Heat illness	0 (0.0)	1 (0.0)
Hip fracture	5 (0.2)	2 (0.1)
Humerus fracture	1 (0.0)	2 (0.1)
Hyphaema	1 (0.0)	0 (0.0)
Incision site haemorrhage	1 (0.0)	0 (0.0)
Joint injury	1 (0.0)	0 (0.0)
Limb crushing injury	0 (0.0)	1 (0.0)
Limb injury	1 (0.0)	5 (0.2)
Lower limb fracture	1 (0.0)	2 (0.1)
Multiple injuries	0 (0.0)	2 (0.1)
Overdose	1 (0.0)	0 (0.0)
Penis injury	1 (0.0)	0 (0.0)
Post procedural haematuria	0 (0.0)	1 (0.0)
Post procedural hypothyroidism	0 (0.0)	1 (0.0)
Procedural pain	1 (0.0)	0 (0.0)
Pubis fracture	1 (0.0)	1 (0.0)
Radius fracture	1 (0.0)	0 (0.0)
Rib fracture	1 (0.0)	1 (0.0)
Road traffic accident	1 (0.0)	0 (0.0)
Sedation complication	1 (0.0)	0 (0.0)
Skin laceration	2 (0.1)	0 (0.0)
Snake bite	0 (0.0)	1 (0.0)
Spinal compression fracture	1 (0.0)	0 (0.0)
Spinal fracture	0 (0.0)	1 (0.0)
Subdural haematoma	4 (0.2)	1 (0.0)
Subdural haemorrhage	0 (0.0)	1 (0.0)
Tendon rupture	1 (0.0)	0 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Thermal burn	0 (0.0)	1 (0.0)
Thoracic vertebral fracture	0 (0.0)	1 (0.0)
Tibia fracture	0 (0.0)	1 (0.0)
Toxicity to various agents	1 (0.0)	6 (0.3)
Traumatic fracture	1 (0.0)	0 (0.0)
Upper limb fracture	1 (0.0)	0 (0.0)
Urinary retention postoperative	0 (0.0)	1 (0.0)
Vascular pseudoaneurysm	0 (0.0)	2 (0.1)
Wrist fracture	1 (0.0)	0 (0.0)
Investigations	20 (0.9)	25 (1.2)
Alanine aminotransferase increased	0 (0.0)	1 (0.0)
Angiocardiogram	0 (0.0)	1 (0.0)
Anticoagulation drug level above therapeutic	2 (0.1)	2 (0.1)
Aspartate aminotransferase increased	0 (0.0)	1 (0.0)
Blood bilirubin increased	0 (0.0)	1 (0.0)
Blood creatinine increased	4 (0.2)	2 (0.1)
Blood potassium increased	2 (0.1)	0 (0.0)
Blood urea increased	0 (0.0)	2 (0.1)
C-reactive protein increased	1 (0.0)	0 (0.0)
Cardiac index abnormal	1 (0.0)	0 (0.0)
Cardiac stress test abnormal	0 (0.0)	1 (0.0)
Catheterisation cardiac	1 (0.0)	1 (0.0)
Cortisol decreased	0 (0.0)	1 (0.0)
Ejection fraction decreased	0 (0.0)	3 (0.1)
Gamma-glutamyltransferase increased	0 (0.0)	2 (0.1)
Haemoglobin decreased	1 (0.0)	2 (0.1)
Hepatic enzyme abnormal	1 (0.0)	0 (0.0)
Hepatic enzyme increased	2 (0.1)	1 (0.0)
Influenza A virus test positive	0 (0.0)	1 (0.0)
International normalised ratio increased	1 (0.0)	1 (0.0)
Liver function test abnormal	1 (0.0)	0 (0.0)
Liver function test increased	1 (0.0)	0 (0.0)
N-terminal prohormone brain natriuretic peptide increased	1 (0.0)	1 (0.0)
Oesophagogastroduodenoscopy	0 (0.0)	1 (0.0)
Transaminases increased	1 (0.0)	0 (0.0)
Troponin increased	1 (0.0)	1 (0.0)
Urine output decreased	0 (0.0)	1 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Weight decreased	1 (0.0)	1 (0.0)
Weight increased	0 (0.0)	2 (0.1)
Metabolism and nutrition disorders	65 (3.0)	89 (4.1)
Acidosis	1 (0.0)	0 (0.0)
Cachexia	1 (0.0)	1 (0.0)
Dehydration	4 (0.2)	10 (0.5)
Diabetes mellitus	4 (0.2)	9 (0.4)
Diabetes mellitus inadequate control	1 (0.0)	1 (0.0)
Diabetes with hyperosmolarity	0 (0.0)	1 (0.0)
Diabetic ketoacidosis	3 (0.1)	2 (0.1)
Fluid overload	0 (0.0)	2 (0.1)
Gout	8 (0.4)	14 (0.7)
Hyperammonaemia	1 (0.0)	0 (0.0)
Hypercalcaemia	1 (0.0)	0 (0.0)
Hyperglycaemia	4 (0.2)	2 (0.1)
Hyperglycaemic hyperosmolar nonketotic syndrome	3 (0.1)	2 (0.1)
Hyperkalaemia	8 (0.4)	11 (0.5)
Hypernatraemia	2 (0.1)	0 (0.0)
Hyperosmolar state	1 (0.0)	0 (0.0)
Hypervolaemia	0 (0.0)	1 (0.0)
Hypoalbuminaemia	0 (0.0)	2 (0.1)
Hypochloraemia	1 (0.0)	0 (0.0)
Hypoglycaemia	6 (0.3)	10 (0.5)
Hypokalaemia	8 (0.4)	10 (0.5)
Hypomagnesaemia	1 (0.0)	0 (0.0)
Hyponatraemia	3 (0.1)	6 (0.3)
Hypophosphataemia	1 (0.0)	0 (0.0)
Hypovitaminosis	0 (0.0)	1 (0.0)
Hypovolaemia	1 (0.0)	1 (0.0)
Ketoacidosis	0 (0.0)	1 (0.0)
Marasmus	1 (0.0)	0 (0.0)
Metabolic acidosis	3 (0.1)	4 (0.2)
Metabolic alkalosis	0 (0.0)	1 (0.0)
Mineral metabolism disorder	1 (0.0)	0 (0.0)
Type 2 diabetes mellitus	5 (0.2)	5 (0.2)
Musculoskeletal and connective tissue disorders	22 (1.0)	38 (1.8)
Arthralgia	2 (0.1)	1 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Arthritis	0 (0.0)	3 (0.1)
Back pain	4 (0.2)	2 (0.1)
Chondritis	1 (0.0)	0 (0.0)
Gouty arthritis	7 (0.3)	5 (0.2)
Gouty tophus	0 (0.0)	2 (0.1)
Haematoma muscle	0 (0.0)	1 (0.0)
Intervertebral disc disorder	0 (0.0)	1 (0.0)
Intervertebral disc protrusion	0 (0.0)	1 (0.0)
Lumbar spinal stenosis	1 (0.0)	2 (0.1)
Muscle spasms	1 (0.0)	1 (0.0)
Muscular weakness	1 (0.0)	1 (0.0)
Musculoskeletal chest pain	1 (0.0)	3 (0.1)
Musculoskeletal pain	1 (0.0)	1 (0.0)
Myalgia	1 (0.0)	0 (0.0)
Osteitis	0 (0.0)	1 (0.0)
Osteoarthritis	2 (0.1)	3 (0.1)
Osteochondrosis	0 (0.0)	1 (0.0)
Osteonecrosis	0 (0.0)	1 (0.0)
Pain in extremity	0 (0.0)	4 (0.2)
Pathological fracture	0 (0.0)	1 (0.0)
Polyarthritis	1 (0.0)	1 (0.0)
Rhabdomyolysis	0 (0.0)	1 (0.0)
Rheumatoid arthritis	0 (0.0)	1 (0.0)
Sjogren's syndrome	1 (0.0)	0 (0.0)
Spinal pain	1 (0.0)	4 (0.2)
Spinal stenosis	0 (0.0)	1 (0.0)
Spondylitis	1 (0.0)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	37 (1.7)	34 (1.6)
Adenocarcinoma gastric	3 (0.1)	1 (0.0)
Adenocarcinoma of colon	1 (0.0)	0 (0.0)
Adenocarcinoma pancreas	0 (0.0)	1 (0.0)
Angiocentric lymphoma	1 (0.0)	0 (0.0)
Benign gastric neoplasm	1 (0.0)	0 (0.0)
Benign neoplasm of bladder	1 (0.0)	0 (0.0)
Bladder transitional cell carcinoma	0 (0.0)	1 (0.0)
Bone cancer metastatic	0 (0.0)	1 (0.0)
Breast cancer	0 (0.0)	1 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Bronchial carcinoma	1 (0.0)	0 (0.0)
Colon neoplasm	0 (0.0)	1 (0.0)
Cutaneous T-cell lymphoma	1 (0.0)	0 (0.0)
Diffuse large B-cell lymphoma	0 (0.0)	1 (0.0)
Gastric cancer	2 (0.1)	0 (0.0)
Glioblastoma multiforme	1 (0.0)	0 (0.0)
Glottis carcinoma	0 (0.0)	1 (0.0)
Hepatic cancer	1 (0.0)	1 (0.0)
Hepatic cancer metastatic	0 (0.0)	1 (0.0)
Hepatic neoplasm	0 (0.0)	1 (0.0)
Hepatocellular carcinoma	0 (0.0)	2 (0.1)
Lung adenocarcinoma	1 (0.0)	0 (0.0)
Lung cancer metastatic	1 (0.0)	0 (0.0)
Lung neoplasm malignant	0 (0.0)	3 (0.1)
Lymphoma	1 (0.0)	0 (0.0)
Malignant melanoma	1 (0.0)	0 (0.0)
Meningioma	0 (0.0)	1 (0.0)
Metastases to abdominal cavity	1 (0.0)	0 (0.0)
Metastases to bone	1 (0.0)	1 (0.0)
Metastases to lung	1 (0.0)	0 (0.0)
Metastases to lymph nodes	0 (0.0)	1 (0.0)
Metastatic neoplasm	0 (0.0)	1 (0.0)
Oesophageal carcinoma	1 (0.0)	0 (0.0)
Oropharyngeal cancer	1 (0.0)	0 (0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	0 (0.0)
Ovarian cancer	0 (0.0)	1 (0.0)
Pancreatic carcinoma metastatic	1 (0.0)	0 (0.0)
Plasma cell myeloma	1 (0.0)	2 (0.1)
Plasmacytoma	0 (0.0)	1 (0.0)
Polycythaemia vera	0 (0.0)	1 (0.0)
Prostate cancer	2 (0.1)	6 (0.3)
Prostate cancer metastatic	1 (0.0)	0 (0.0)
Rectal cancer	0 (0.0)	2 (0.1)
Rectosigmoid cancer	1 (0.0)	0 (0.0)
Renal cancer	1 (0.0)	1 (0.0)
Renal neoplasm	1 (0.0)	0 (0.0)
Retroperitoneal cancer	1 (0.0)	0 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Squamous cell carcinoma	1 (0.0)	0 (0.0)
Squamous cell carcinoma of head and neck	2 (0.1)	0 (0.0)
Squamous cell carcinoma of lung	1 (0.0)	0 (0.0)
Squamous cell carcinoma of the oral cavity	0 (0.0)	1 (0.0)
Sweat gland tumour	1 (0.0)	0 (0.0)
T-cell lymphoma	1 (0.0)	0 (0.0)
Tongue neoplasm malignant stage unspecified	1 (0.0)	0 (0.0)
Tumour ulceration	0 (0.0)	1 (0.0)
Uterine leiomyoma	1 (0.0)	0 (0.0)
Waldenstrom's macroglobulinaemia	1 (0.0)	0 (0.0)
Nervous system disorders	79 (3.7)	70 (3.3)
Altered state of consciousness	1 (0.0)	0 (0.0)
Autonomic neuropathy	1 (0.0)	0 (0.0)
Axonal neuropathy	1 (0.0)	0 (0.0)
Brain hypoxia	1 (0.0)	0 (0.0)
Brain injury	2 (0.1)	1 (0.0)
Brain oedema	1 (0.0)	0 (0.0)
Carotid artery stenosis	0 (0.0)	1 (0.0)
Carpal tunnel syndrome	0 (0.0)	1 (0.0)
Cauda equina syndrome	1 (0.0)	0 (0.0)
Cerebral artery stenosis	0 (0.0)	1 (0.0)
Cerebral haemorrhage	1 (0.0)	1 (0.0)
Cerebral infarction	0 (0.0)	2 (0.1)
Cerebral ischaemia	1 (0.0)	1 (0.0)
Cerebrovascular accident	2 (0.1)	5 (0.2)
Cerebrovascular disorder	1 (0.0)	0 (0.0)
Cognitive disorder	0 (0.0)	1 (0.0)
Coma	1 (0.0)	0 (0.0)
Cubital tunnel syndrome	1 (0.0)	0 (0.0)
Dementia	1 (0.0)	1 (0.0)
Diabetic neuropathy	0 (0.0)	2 (0.1)
Dizziness	4 (0.2)	4 (0.2)
Dysarthria	0 (0.0)	2 (0.1)
Encephalopathy	0 (0.0)	1 (0.0)
Facial paralysis	0 (0.0)	1 (0.0)
Generalised tonic-clonic seizure	0 (0.0)	1 (0.0)
Headache	2 (0.1)	1 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Hepatic encephalopathy	0 (0.0)	1 (0.0)
Hypoxic-ischaemic encephalopathy	1 (0.0)	2 (0.1)
Ischaemic cerebral infarction	1 (0.0)	0 (0.0)
Ischaemic stroke	1 (0.0)	0 (0.0)
Lethargy	0 (0.0)	1 (0.0)
Loss of consciousness	0 (0.0)	1 (0.0)
Lumbar radiculopathy	2 (0.1)	0 (0.0)
Metabolic encephalopathy	0 (0.0)	2 (0.1)
Myoclonus	0 (0.0)	2 (0.1)
Neuropathy peripheral	2 (0.1)	0 (0.0)
Paraesthesia	0 (0.0)	2 (0.1)
Post cardiac arrest syndrome	1 (0.0)	0 (0.0)
Post stroke epilepsy	1 (0.0)	0 (0.0)
Presyncope	3 (0.1)	0 (0.0)
Seizure	1 (0.0)	0 (0.0)
Spinal cord compression	0 (0.0)	1 (0.0)
Status epilepticus	1 (0.0)	0 (0.0)
Subarachnoid haemorrhage	1 (0.0)	0 (0.0)
Syncope	41 (1.9)	30 (1.4)
Tension headache	1 (0.0)	0 (0.0)
Transient ischaemic attack	2 (0.1)	2 (0.1)
Vertebrobasilar insufficiency	1 (0.0)	0 (0.0)
Product issues	1 (0.0)	7 (0.3)
Device battery issue	0 (0.0)	2 (0.1)
Device dislocation	0 (0.0)	1 (0.0)
Device malfunction	0 (0.0)	4 (0.2)
Lead dislodgement	1 (0.0)	0 (0.0)
Psychiatric disorders	7 (0.3)	7 (0.3)
Anxiety	1 (0.0)	1 (0.0)
Anxiety disorder	0 (0.0)	1 (0.0)
Confusional state	0 (0.0)	1 (0.0)
Delirium	1 (0.0)	2 (0.1)
Depression	1 (0.0)	1 (0.0)
Disorientation	1 (0.0)	0 (0.0)
Drug use disorder	1 (0.0)	0 (0.0)
Mental status changes	0 (0.0)	1 (0.0)
Panic attack	1 (0.0)	0 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Suicide attempt	1 (0.0)	0 (0.0)
Renal and urinary disorders	122 (5.7)	111 (5.2)
Acute kidney injury	55 (2.6)	43 (2.0)
Anuria	1 (0.0)	1 (0.0)
Azotaemia	0 (0.0)	1 (0.0)
Bladder cyst	1 (0.0)	0 (0.0)
Bladder mass	0 (0.0)	1 (0.0)
Calculus bladder	1 (0.0)	0 (0.0)
Chronic kidney disease	29 (1.3)	25 (1.2)
Costovertebral angle tenderness	0 (0.0)	2 (0.1)
Diabetic nephropathy	1 (0.0)	0 (0.0)
End stage renal disease	1 (0.0)	1 (0.0)
Haematuria	1 (0.0)	5 (0.2)
Hydronephrosis	0 (0.0)	1 (0.0)
Nephrolithiasis	1 (0.0)	0 (0.0)
Nephropathy	2 (0.1)	1 (0.0)
Renal artery stenosis	1 (0.0)	1 (0.0)
Renal colic	1 (0.0)	0 (0.0)
Renal failure	25 (1.2)	22 (1.0)
Renal impairment	6 (0.3)	7 (0.3)
Renal infarct	0 (0.0)	1 (0.0)
Renal mass	1 (0.0)	0 (0.0)
Urate nephropathy	1 (0.0)	0 (0.0)
Ureterolithiasis	1 (0.0)	0 (0.0)
Urethral stenosis	0 (0.0)	1 (0.0)
Urinary retention	2 (0.1)	2 (0.1)
Reproductive system and breast disorders	0 (0.0)	7 (0.3)
Benign prostatic hyperplasia	0 (0.0)	6 (0.3)
Penile oedema	0 (0.0)	1 (0.0)
Respiratory, thoracic and mediastinal disorders	84 (3.9)	84 (3.9)
Acute pulmonary oedema	2 (0.1)	1 (0.0)
Acute respiratory distress syndrome	1 (0.0)	0 (0.0)
Acute respiratory failure	8 (0.4)	5 (0.2)
Asthma	6 (0.3)	3 (0.1)
Bronchial haemorrhage	0 (0.0)	1 (0.0)
Bronchitis chronic	1 (0.0)	0 (0.0)
Bronchospasm	0 (0.0)	1 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Choking	1 (0.0)	0 (0.0)
Chronic obstructive pulmonary disease	26 (1.2)	26 (1.2)
Cough	0 (0.0)	2 (0.1)
Dyspnoea	12 (0.6)	11 (0.5)
Dyspnoea exertional	2 (0.1)	2 (0.1)
Epistaxis	1 (0.0)	1 (0.0)
Haemoptysis	0 (0.0)	1 (0.0)
Haemothorax	0 (0.0)	2 (0.1)
Hiccups	1 (0.0)	0 (0.0)
Hyperventilation	1 (0.0)	0 (0.0)
Hypoxia	0 (0.0)	1 (0.0)
Obstructive airways disorder	0 (0.0)	1 (0.0)
Orthopnoea	0 (0.0)	1 (0.0)
Pleural effusion	5 (0.2)	10 (0.5)
Pleurisy	0 (0.0)	1 (0.0)
Pleuritic pain	0 (0.0)	1 (0.0)
Pneumonia aspiration	5 (0.2)	2 (0.1)
Pneumothorax	2 (0.1)	4 (0.2)
Pulmonary arterial hypertension	1 (0.0)	0 (0.0)
Pulmonary congestion	1 (0.0)	1 (0.0)
Pulmonary embolism	3 (0.1)	5 (0.2)
Pulmonary hypertension	2 (0.1)	1 (0.0)
Pulmonary infarction	0 (0.0)	1 (0.0)
Pulmonary oedema	4 (0.2)	5 (0.2)
Respiratory acidosis	1 (0.0)	0 (0.0)
Respiratory disorder	1 (0.0)	0 (0.0)
Respiratory failure	5 (0.2)	6 (0.3)
Rhinitis hypertrophic	1 (0.0)	0 (0.0)
Sleep apnoea syndrome	3 (0.1)	0 (0.0)
Tonsillar haemorrhage	1 (0.0)	0 (0.0)
Skin and subcutaneous tissue disorders	14 (0.7)	18 (0.8)
Angioedema	1 (0.0)	0 (0.0)
Dermatitis allergic	0 (0.0)	1 (0.0)
Diabetic foot	1 (0.0)	3 (0.1)
Drug eruption	1 (0.0)	0 (0.0)
Ecchymosis	0 (0.0)	1 (0.0)
Eczema	1 (0.0)	0 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Haemorrhage subcutaneous	1 (0.0)	0 (0.0)
Henoch-Schonlein purpura	0 (0.0)	1 (0.0)
Neurodermatitis	0 (0.0)	1 (0.0)
Pruritus	1 (0.0)	0 (0.0)
Rash	1 (0.0)	1 (0.0)
Skin necrosis	1 (0.0)	0 (0.0)
Skin ulcer	4 (0.2)	7 (0.3)
Stasis dermatitis	0 (0.0)	2 (0.1)
Telangiectasia	1 (0.0)	0 (0.0)
Urticaria	1 (0.0)	1 (0.0)
Surgical and medical procedures	11 (0.5)	14 (0.7)
Arrhythmia prophylaxis	0 (0.0)	1 (0.0)
Cardiac contractility modulation therapy	1 (0.0)	0 (0.0)
Cardiac pacemaker replacement	0 (0.0)	1 (0.0)
Cardiac rehabilitation therapy	1 (0.0)	0 (0.0)
Cardiac resynchronisation therapy	2 (0.1)	4 (0.2)
Cardiovascular event prophylaxis	1 (0.0)	3 (0.1)
Cardioversion	1 (0.0)	1 (0.0)
Implantable defibrillator insertion	1 (0.0)	2 (0.1)
Implantable defibrillator removal	1 (0.0)	0 (0.0)
Implantable defibrillator replacement	1 (0.0)	0 (0.0)
Inguinal hernia repair	1 (0.0)	0 (0.0)
Intraocular lens implant	0 (0.0)	1 (0.0)
Nephroprotective therapy	0 (0.0)	1 (0.0)
Therapeutic procedure	1 (0.0)	0 (0.0)
Toe operation	1 (0.0)	0 (0.0)
Vascular disorders	72 (3.3)	81 (3.8)
Aortic aneurysm	0 (0.0)	1 (0.0)
Aortic dissection	1 (0.0)	0 (0.0)
Aortic stenosis	2 (0.1)	1 (0.0)
Arterial occlusive disease	0 (0.0)	1 (0.0)
Bleeding varicose vein	1 (0.0)	2 (0.1)
Circulatory collapse	0 (0.0)	1 (0.0)
Deep vein thrombosis	1 (0.0)	2 (0.1)
Dry gangrene	0 (0.0)	1 (0.0)
Embolism arterial	1 (0.0)	0 (0.0)
Extremity necrosis	1 (0.0)	0 (0.0)

Summary of Severe Adverse Events by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe Adverse Events by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Haematoma	4 (0.2)	2 (0.1)
Haemorrhagic vasculitis	0 (0.0)	1 (0.0)
Hypertension	5 (0.2)	5 (0.2)
Hypertensive crisis	1 (0.0)	1 (0.0)
Hypotension	34 (1.6)	42 (2.0)
Hypovolaemic shock	3 (0.1)	0 (0.0)
Iliac artery occlusion	1 (0.0)	0 (0.0)
Intermittent claudication	1 (0.0)	1 (0.0)
Lymphorrhoea	1 (0.0)	0 (0.0)
Orthostatic hypotension	1 (0.0)	1 (0.0)
Peripheral arterial occlusive disease	2 (0.1)	9 (0.4)
Peripheral artery occlusion	1 (0.0)	0 (0.0)
Peripheral artery stenosis	1 (0.0)	0 (0.0)
Peripheral artery thrombosis	0 (0.0)	1 (0.0)
Peripheral embolism	1 (0.0)	2 (0.1)
Peripheral ischaemia	2 (0.1)	2 (0.1)
Peripheral vascular disorder	2 (0.1)	1 (0.0)
Peripheral venous disease	2 (0.1)	0 (0.0)
Post thrombotic syndrome	1 (0.0)	0 (0.0)
Shock	1 (0.0)	1 (0.0)
Shock haemorrhagic	0 (0.0)	2 (0.1)
Thrombophlebitis	1 (0.0)	4 (0.2)
Varicose vein	1 (0.0)	0 (0.0)
Vascular occlusion	1 (0.0)	0 (0.0)

a: Database Cutoff Date: 18JUN2019
b: A SOC or specific adverse event appears on this report only if its incidence is > 0% in one or more treatment groups
c: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
PT: Preferred Term; SOC: System Organ Class

1.3.4 Adverse Events Leading to Treatment Discontinuation by SOC and PT

Table 15
Summary of Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events Leading to Discontinuation by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Participants with one or more adverse events	139 (6.5)	134 (6.2)
Blood and lymphatic system disorders	2 (0.1)	0 (0.0)
Anaemia	1 (0.0)	0 (0.0)
Pancytopenia	1 (0.0)	0 (0.0)
Cardiac disorders	7 (0.3)	13 (0.6)
Angina pectoris	1 (0.0)	1 (0.0)
Aortic valve calcification	1 (0.0)	0 (0.0)
Aortic valve stenosis	0 (0.0)	1 (0.0)
Cardiac arrest	1 (0.0)	0 (0.0)
Cardiac failure	3 (0.1)	5 (0.2)
Cardiac failure acute	0 (0.0)	1 (0.0)
Cardiac failure chronic	0 (0.0)	2 (0.1)
Cardiac failure congestive	0 (0.0)	1 (0.0)
Cardio-respiratory arrest	0 (0.0)	1 (0.0)
Cardiogenic shock	0 (0.0)	1 (0.0)
Ventricular tachycardia	1 (0.0)	1 (0.0)
Ear and labyrinth disorders	1 (0.0)	1 (0.0)
Vertigo	1 (0.0)	1 (0.0)
Endocrine disorders	1 (0.0)	0 (0.0)
Carcinoid syndrome	1 (0.0)	0 (0.0)
Gastrointestinal disorders	14 (0.7)	13 (0.6)
Abdominal distension	1 (0.0)	0 (0.0)
Abdominal pain	1 (0.0)	1 (0.0)
Ascites	1 (0.0)	0 (0.0)
Diarrhoea	1 (0.0)	3 (0.1)
Dyspepsia	3 (0.1)	1 (0.0)
Faecaloma	0 (0.0)	1 (0.0)
Faeces discoloured	1 (0.0)	0 (0.0)
Gastritis	0 (0.0)	2 (0.1)
Gastrointestinal angiodysplasia	0 (0.0)	1 (0.0)
Gastrointestinal haemorrhage	0 (0.0)	1 (0.0)
Gastrooesophageal reflux disease	1 (0.0)	0 (0.0)
Melaena	1 (0.0)	0 (0.0)
Nausea	6 (0.3)	0 (0.0)
Oesophageal achalasia	0 (0.0)	1 (0.0)
Oesophageal varices haemorrhage	0 (0.0)	1 (0.0)
Pancreatolithiasis	1 (0.0)	0 (0.0)

Summary of Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events Leading to Discontinuation by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Peptic ulcer	0 (0.0)	1 (0.0)
Vomiting	1 (0.0)	0 (0.0)
General disorders and administration site conditions	5 (0.2)	5 (0.2)
Asthenia	2 (0.1)	1 (0.0)
Chest discomfort	0 (0.0)	1 (0.0)
Chest pain	0 (0.0)	1 (0.0)
Fatigue	1 (0.0)	1 (0.0)
General physical health deterioration	2 (0.1)	1 (0.0)
Hepatobiliary disorders	4 (0.2)	2 (0.1)
Hepatic congestion	1 (0.0)	0 (0.0)
Hepatic function abnormal	0 (0.0)	1 (0.0)
Hyperbilirubinaemia	0 (0.0)	1 (0.0)
Ischaemic hepatitis	1 (0.0)	0 (0.0)
Liver disorder	1 (0.0)	0 (0.0)
Liver injury	1 (0.0)	0 (0.0)
Immune system disorders	3 (0.1)	0 (0.0)
Amyloidosis	1 (0.0)	0 (0.0)
Hypersensitivity	1 (0.0)	0 (0.0)
Seasonal allergy	1 (0.0)	0 (0.0)
Infections and infestations	6 (0.3)	13 (0.6)
Cellulitis	0 (0.0)	2 (0.1)
Device related infection	0 (0.0)	1 (0.0)
Intervertebral discitis	1 (0.0)	0 (0.0)
Necrotising fasciitis	1 (0.0)	0 (0.0)
Pneumonia	2 (0.1)	5 (0.2)
Pneumonia bacterial	0 (0.0)	1 (0.0)
Respiratory tract infection	1 (0.0)	0 (0.0)
Salmonella bacteraemia	0 (0.0)	1 (0.0)
Sepsis	1 (0.0)	0 (0.0)
Septic shock	0 (0.0)	1 (0.0)
Upper respiratory tract infection	0 (0.0)	1 (0.0)
Urinary tract infection	0 (0.0)	1 (0.0)
Injury, poisoning and procedural complications	4 (0.2)	3 (0.1)
Cervical vertebral fracture	1 (0.0)	0 (0.0)
Fall	0 (0.0)	1 (0.0)
Femoral neck fracture	0 (0.0)	1 (0.0)
Femur fracture	1 (0.0)	0 (0.0)

Summary of Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events Leading to Discontinuation by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Intentional overdose	1 (0.0)	0 (0.0)
Limb injury	1 (0.0)	0 (0.0)
Rib fracture	0 (0.0)	1 (0.0)
Subdural haematoma	0 (0.0)	1 (0.0)
Thermal burn	0 (0.0)	1 (0.0)
Wound secretion	0 (0.0)	1 (0.0)
Investigations	7 (0.3)	4 (0.2)
Blood creatinine increased	3 (0.1)	1 (0.0)
Cardiac index abnormal	1 (0.0)	0 (0.0)
Gamma-glutamyltransferase increased	0 (0.0)	1 (0.0)
Hepatic enzyme increased	2 (0.1)	0 (0.0)
Liver function test increased	0 (0.0)	1 (0.0)
Platelet count decreased	1 (0.0)	0 (0.0)
Weight increased	0 (0.0)	1 (0.0)
Metabolism and nutrition disorders	5 (0.2)	7 (0.3)
Decreased appetite	2 (0.1)	0 (0.0)
Dehydration	0 (0.0)	1 (0.0)
Fluid overload	0 (0.0)	1 (0.0)
Gout	1 (0.0)	1 (0.0)
Hypercalcaemia	0 (0.0)	1 (0.0)
Hyperkalaemia	0 (0.0)	2 (0.1)
Hyponatraemia	0 (0.0)	1 (0.0)
Ketoacidosis	0 (0.0)	1 (0.0)
Marasmus	1 (0.0)	0 (0.0)
Metabolic acidosis	1 (0.0)	1 (0.0)
Musculoskeletal and connective tissue disorders	2 (0.1)	1 (0.0)
Haematoma muscle	0 (0.0)	1 (0.0)
Myalgia	1 (0.0)	0 (0.0)
Sjogren's syndrome	1 (0.0)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (0.2)	8 (0.4)
Breast cancer	0 (0.0)	1 (0.0)
Bronchial carcinoma	1 (0.0)	0 (0.0)
Diffuse large B-cell lymphoma	0 (0.0)	1 (0.0)
Hepatic cancer metastatic	0 (0.0)	1 (0.0)
Hepatic neoplasm	0 (0.0)	1 (0.0)
Lung cancer metastatic	1 (0.0)	0 (0.0)
Lung neoplasm malignant	0 (0.0)	2 (0.1)

Summary of Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events Leading to Discontinuation by SOC and PT[b]	**Vericiguat (N^c=2152)**	**Placebo (N^c=2151)**
Metastases to lymph nodes	0 (0.0)	1 (0.0)
Oesophageal carcinoma	1 (0.0)	0 (0.0)
Pancreatic carcinoma	0 (0.0)	1 (0.0)
Pancreatic carcinoma metastatic	1 (0.0)	0 (0.0)
Plasmacytoma	0 (0.0)	1 (0.0)
Squamous cell carcinoma of head and neck	1 (0.0)	0 (0.0)
Nervous system disorders	14 (0.7)	16 (0.7)
Axonal neuropathy	1 (0.0)	0 (0.0)
Brain injury	2 (0.1)	0 (0.0)
Cerebrovascular accident	0 (0.0)	1 (0.0)
Cognitive disorder	0 (0.0)	1 (0.0)
Coma	1 (0.0)	0 (0.0)
Dementia	1 (0.0)	0 (0.0)
Dizziness	6 (0.3)	3 (0.1)
Dysarthria	0 (0.0)	1 (0.0)
Dysgeusia	1 (0.0)	0 (0.0)
Dyskinesia	0 (0.0)	1 (0.0)
Generalised tonic-clonic seizure	0 (0.0)	1 (0.0)
Headache	0 (0.0)	1 (0.0)
Hypoxic-ischaemic encephalopathy	1 (0.0)	1 (0.0)
Ischaemic stroke	1 (0.0)	0 (0.0)
Metabolic encephalopathy	0 (0.0)	1 (0.0)
Syncope	0 (0.0)	5 (0.2)
Psychiatric disorders	2 (0.1)	2 (0.1)
Drug use disorder	1 (0.0)	0 (0.0)
Mental status changes	0 (0.0)	1 (0.0)
Sleep disorder	0 (0.0)	1 (0.0)
Suicide attempt	1 (0.0)	0 (0.0)
Renal and urinary disorders	20 (0.9)	32 (1.5)
Acute kidney injury	8 (0.4)	9 (0.4)
Chronic kidney disease	6 (0.3)	12 (0.6)
Nephropathy	1 (0.0)	0 (0.0)
Renal cyst	0 (0.0)	1 (0.0)
Renal failure	4 (0.2)	8 (0.4)
Renal impairment	1 (0.0)	2 (0.1)
Reproductive system and breast disorders	1 (0.0)	1 (0.0)
Erectile dysfunction	0 (0.0)	1 (0.0)

Summary of Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events Leading to Discontinuation by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Erection increased	1 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	6 (0.3)	4 (0.2)
Acute pulmonary oedema	1 (0.0)	0 (0.0)
Acute respiratory failure	1 (0.0)	1 (0.0)
Chronic obstructive pulmonary disease	1 (0.0)	0 (0.0)
Dyspnoea	1 (0.0)	0 (0.0)
Haemoptysis	1 (0.0)	0 (0.0)
Nasal congestion	0 (0.0)	1 (0.0)
Pleural effusion	0 (0.0)	1 (0.0)
Productive cough	0 (0.0)	1 (0.0)
Pulmonary hypertension	1 (0.0)	1 (0.0)
Skin and subcutaneous tissue disorders	3 (0.1)	5 (0.2)
Henoch-Schonlein purpura	0 (0.0)	1 (0.0)
Pruritus	2 (0.1)	1 (0.0)
Rash	0 (0.0)	1 (0.0)
Rash generalised	0 (0.0)	1 (0.0)
Rash pruritic	1 (0.0)	0 (0.0)
Urticaria	0 (0.0)	1 (0.0)
Surgical and medical procedures	1 (0.0)	0 (0.0)
Cardioversion	1 (0.0)	0 (0.0)
Vascular disorders	45 (2.1)	31 (1.4)
Bleeding varicose vein	1 (0.0)	0 (0.0)
Circulatory collapse	0 (0.0)	1 (0.0)
Haematoma	1 (0.0)	0 (0.0)
Hypertension	0 (0.0)	1 (0.0)
Hypotension	43 (2.0)	27 (1.3)
Orthostatic hypotension	1 (0.0)	0 (0.0)
Shock haemorrhagic	0 (0.0)	1 (0.0)
Vasculitis	0 (0.0)	1 (0.0)

a: Database Cutoff Date: 18JUN2019
b: A SOC or specific adverse event appears on this report only if its incidence is > 0% in one or more treatment groups
c: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
PT: Preferred Term; SOC: System Organ Class

1.3.5 Adverse Events Resulting to Death by SOC and PT

Table 16
Summary of Adverse Events Resulting to Death by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events Leading to Discontinuation by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Participants with one or more adverse events	71 (3.3)	70 (3.3)
Blood and lymphatic system disorders	1 (0.0)	0 (0.0)
Coagulopathy	1 (0.0)	0 (0.0)
Cardiac disorders	15 (0.7)	27 (1.3)
Acute myocardial infarction	1 (0.0)	0 (0.0)
Atrial fibrillation	0 (0.0)	1 (0.0)
Atrial flutter	0 (0.0)	1 (0.0)
Cardiac arrest	1 (0.0)	0 (0.0)
Cardiac failure	7 (0.3)	14 (0.7)
Cardiac failure acute	0 (0.0)	2 (0.1)
Cardiac failure congestive	1 (0.0)	4 (0.2)
Cardiogenic shock	2 (0.1)	1 (0.0)
Cardiopulmonary failure	1 (0.0)	0 (0.0)
Left ventricular failure	0 (0.0)	1 (0.0)
Myocardial infarction	2 (0.1)	3 (0.1)
Endocrine disorders	1 (0.0)	0 (0.0)
Carcinoid syndrome	1 (0.0)	0 (0.0)
Gastrointestinal disorders	0 (0.0)	1 (0.0)
Upper gastrointestinal haemorrhage	0 (0.0)	1 (0.0)
General disorders and administration site conditions	0 (0.0)	3 (0.1)
Asthenia	0 (0.0)	1 (0.0)
Multiple organ dysfunction syndrome	0 (0.0)	1 (0.0)
Sudden cardiac death	0 (0.0)	1 (0.0)
Hepatobiliary disorders	1 (0.0)	1 (0.0)
Cholecystitis acute	1 (0.0)	0 (0.0)
Hepatic cirrhosis	0 (0.0)	1 (0.0)
Infections and infestations	23 (1.1)	20 (0.9)
Acinetobacter bacteraemia	1 (0.0)	0 (0.0)
Cellulitis gangrenous	1 (0.0)	0 (0.0)
Diverticulitis	0 (0.0)	1 (0.0)
Endocarditis	2 (0.1)	0 (0.0)
Influenza	0 (0.0)	1 (0.0)
Osteomyelitis	1 (0.0)	0 (0.0)
Peritonitis bacterial	1 (0.0)	0 (0.0)
Pneumonia	6 (0.3)	12 (0.6)
Pneumonia bacterial	1 (0.0)	0 (0.0)
Pulmonary sepsis	1 (0.0)	1 (0.0)

Summary of Adverse Events Resulting to Death by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events Leading to Discontinuation by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Respiratory tract infection	1 (0.0)	0 (0.0)
Sepsis	5 (0.2)	6 (0.3)
Septic shock	5 (0.2)	3 (0.1)
Systemic candida	1 (0.0)	0 (0.0)
Injury, poisoning and procedural complications	2 (0.1)	3 (0.1)
Burns third degree	0 (0.0)	1 (0.0)
Femur fracture	0 (0.0)	1 (0.0)
Road traffic accident	1 (0.0)	0 (0.0)
Subdural haematoma	1 (0.0)	0 (0.0)
Toxicity to various agents	0 (0.0)	1 (0.0)
Investigations	1 (0.0)	0 (0.0)
Weight decreased	1 (0.0)	0 (0.0)
Metabolism and nutrition disorders	2 (0.1)	2 (0.1)
Hyperglycaemic hyperosmolar nonketotic syndrome	1 (0.0)	0 (0.0)
Marasmus	1 (0.0)	0 (0.0)
Metabolic acidosis	0 (0.0)	2 (0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (0.4)	8 (0.4)
Bronchial carcinoma	1 (0.0)	0 (0.0)
Diffuse large B-cell lymphoma	0 (0.0)	1 (0.0)
Gastric cancer	1 (0.0)	0 (0.0)
Glioblastoma multiforme	1 (0.0)	0 (0.0)
Hepatic cancer metastatic	0 (0.0)	1 (0.0)
Hepatic neoplasm	0 (0.0)	1 (0.0)
Lung cancer metastatic	1 (0.0)	0 (0.0)
Lung neoplasm malignant	0 (0.0)	2 (0.1)
Metastases to lymph nodes	0 (0.0)	1 (0.0)
Metastatic neoplasm	0 (0.0)	1 (0.0)
Pancreatic carcinoma metastatic	1 (0.0)	0 (0.0)
Plasma cell myeloma	1 (0.0)	0 (0.0)
Plasmacytoma	0 (0.0)	1 (0.0)
Squamous cell carcinoma	1 (0.0)	0 (0.0)
T-cell lymphoma	1 (0.0)	0 (0.0)
Tumour ulceration	0 (0.0)	1 (0.0)
Nervous system disorders	5 (0.2)	2 (0.1)
Cerebral haemorrhage	1 (0.0)	0 (0.0)
Cerebrovascular accident	2 (0.1)	1 (0.0)
Hepatic encephalopathy	0 (0.0)	1 (0.0)

Summary of Adverse Events Resulting to Death by System Organ Class and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Adverse Events Leading to Discontinuation by SOC and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Ischaemic stroke	1 (0.0)	0 (0.0)
Seizure	1 (0.0)	0 (0.0)
Psychiatric disorders	0 (0.0)	1 (0.0)
Confusional state	0 (0.0)	1 (0.0)
Renal and urinary disorders	9 (0.4)	5 (0.2)
Acute kidney injury	5 (0.2)	4 (0.2)
Azotaemia	0 (0.0)	1 (0.0)
Chronic kidney disease	2 (0.1)	0 (0.0)
End stage renal disease	1 (0.0)	0 (0.0)
Renal failure	1 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	6 (0.3)	3 (0.1)
Acute respiratory failure	2 (0.1)	1 (0.0)
Chronic obstructive pulmonary disease	2 (0.1)	0 (0.0)
Pleural effusion	0 (0.0)	1 (0.0)
Pulmonary embolism	2 (0.1)	1 (0.0)
Vascular disorders	3 (0.1)	2 (0.1)
Aortic stenosis	1 (0.0)	0 (0.0)
Circulatory collapse	0 (0.0)	1 (0.0)
Hypotension	1 (0.0)	0 (0.0)
Peripheral ischaemia	0 (0.0)	1 (0.0)
Shock	1 (0.0)	0 (0.0)

a: Database Cutoff Date: 18JUN2019
b: A SOC or specific adverse event appears on this report only if its incidence is > 0% in one or more treatment groups
c: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
PT: Preferred Term; SOC: System Organ Class

1.4 Adverse Events of Clinical Interest Endpoints

1.4.1 ECI

Table 17
Adverse Event of Clinical Interest Related Endpoints
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**			
	Vericiguat (N[b]=2152)	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**
Any ECI	289 (13.4)	246 (11.4)	1.99 [0.02; 3.97]	1.20 [1.00; 1.44]	1.17 [1.00; 1.38]	0.048
Hepatic ECI	22 (1.0)	12 (0.6)	0.46 [-0.07; 1.04]	1.81 [0.92; 3.55]	1.81 [0.92; 3.55]	0.085
Symptomatic hypotension	197 (9.2)	174 (8.1)	1.07 [-0.61; 2.75]	1.14 [0.93; 1.42]	1.13 [0.93; 1.38]	0.214
Syncope	89 (4.1)	79 (3.7)	0.46 [-0.70; 1.64]	1.13 [0.83; 1.54]	1.13 [0.84; 1.52]	0.433

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

CI: Confidence Interval; ECI: Adverse Events of Clinical Interest.

Table 18
Participants With Liver Function Laboratory Findings That Met Predetermined Criteria
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

	Vericiguat		Placebo	
Criteria	**n/m**	**(%)**	**n/m**	**(%)**
Aminotransferase (ALT or AST) and Bilirubin				
AT >=3 x ULN and BILI >=1.5 x ULN	12/1933	(0.6)	7/1954	(0.4)
AT >=3 x ULN and BILI >=2 x ULN	8/1933	(0.4)	2/1954	(0.1)
Aminotransferase (ALT or AST) and Bilirubin and Alkaline Phosphatase				
AT >=3 x ULN and BILI >=2 x ULN and ALP <2 x ULN	6/1933	(0.3)	1/1954	(0.1)

n = Number of participants with postbaseline test results (or combination of test results from the same day) that met predetermined criteria.

m = Number of participants with at least one postbaseline test result or combination of test results from the same day.

ALP = Alkaline phosphatase; ALT = Alanine aminotransferase; AST = Aspartate aminotransferase; AT = Aminotransferase (ALT or AST); BILI = Bilirubin; ULN = Upper limit of normal range.

Note: Includes events/measurements from the day of first dose of study drug to 14 days after the last dose of study drug.

1.4.2 Serious ECI

Table 19
Serious Adverse Event of Clinical Interest Related Endpoints
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**			
	Vericiguat (N[b]=2152)	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**
Any Serious ECI	74 (3.4)	66 (3.1)	0.37 [-0.70; 1.45]	1.12 [0.80; 1.58]	1.12 [0.81; 1.55]	0.494
Hepatic ECI	14 (0.7)	6 (0.3)	0.37 [-0.04; 0.84]	2.23 [0.93; 5.37]	2.23 [0.93; 5.37]	0.073
Symptomatic hypotension	26 (1.2)	32 (1.5)	-0.28 [-1.00; 0.42]	0.81 [0.48; 1.36]	0.81 [0.49; 1.36]	0.427
Syncope	39 (1.8)	31 (1.4)	0.37 [-0.39; 1.15]	1.26 [0.78; 2.03]	1.26 [0.79; 2.01]	0.337

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

CI: Confidence Interval; ECI: Adverse Events of Clinical Interest.

1.4.3 ECI by severity

Table 20
Mild Adverse Event of Clinical Interest Related Endpoints
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**			
	Vericiguat (N[b]=2152)	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**
Any Mild ECI	122 (5.7)	83 (3.9)	1.81 [0.54; 3.10]	1.50 [1.13; 1.99]	1.47 [1.12; 1.93]	0.006
Hepatic ECI	2 (0.1)	3 (0.1)	-0.05 [-0.33; 0.21]	0.67 [0.12; 3.87]	0.67 [0.12; 3.87]	0.654
Symptomatic hypotension	101 (4.7)	65 (3.0)	1.67 [0.53; 2.85]	1.58 [1.15; 2.17]	1.55 [1.14; 2.11]	0.005
Syncope	22 (1.0)	18 (0.8)	0.19 [-0.41; 0.79]	1.22 [0.66; 2.28]	1.22 [0.66; 2.28]	0.526

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

CI: Confidence Interval; ECI: Adverse Events of Clinical Interest.

Table 21
Moderate Adverse Event of Clinical Interest Related Endpoints
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**			
	Vericiguat (N[b]=2152)	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**
Any Moderate ECI	115 (5.3)	118 (5.5)	-0.14 [-1.50; 1.22]	0.97 [0.75; 1.27]	0.97 [0.76; 1.25]	0.837
Hepatic ECI	6 (0.3)	3 (0.1)	0.14 [-0.16; 0.48]	1.95 [0.53; 7.21]	1.95 [0.53; 7.21]	0.317
Symptomatic hypotension	82 (3.8)	89 (4.1)	-0.33 [-1.51; 0.85]	0.92 [0.68; 1.25]	0.92 [0.69; 1.24]	0.583
Syncope	30 (1.4)	32 (1.5)	-0.09 [-0.83; 0.64]	0.94 [0.57; 1.55]	0.94 [0.57; 1.54]	0.797

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

CI: Confidence Interval; ECI: Adverse Events of Clinical Interest.

Table 22
Severe Adverse Event of Clinical Interest Related Endpoints
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**Participants with Event n (%)**		**Vericiguat vs. Placebo**			
	Vericiguat (N[b]=2152)	**Placebo (N[b]=2151)**	**Difference in % vs. Placebo [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**
Any Severe ECI	82 (3.8)	72 (3.3)	0.46 [-0.65; 1.59]	1.14 [0.83; 1.58]	1.14 [0.83; 1.55]	0.414
Hepatic ECI	15 (0.7)	6 (0.3)	0.42 [0.00; 0.90]	2.36 [1.00; 5.57]	2.36 [1.00; 5.57]	0.049
Symptomatic hypotension	29 (1.3)	37 (1.7)	-0.37 [-1.14; 0.37]	0.78 [0.48; 1.27]	0.78 [0.48; 1.27]	0.321
Syncope	41 (1.9)	31 (1.4)	0.46 [-0.31; 1.26]	1.33 [0.83; 2.13]	1.32 [0.83; 2.10]	0.237

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

CI: Confidence Interval; ECI: Adverse Events of Clinical Interest.

1.5 Incidences of Adverse Events of Clinical Interest by Category and PT

1.5.1 ECI by Category and PT

Table 23
Summary of Adverse Events of Clinical Interest by ECI Category and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
ECI by Category and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Participants with one or more adverse events	289 (13.4)	246 (11.4)
Hepatic ECI	22 (1.0)	12 (0.6)
Acute hepatic failure	0 (0.0)	3 (0.1)
Alanine aminotransferase increased	2 (0.1)	1 (0.0)
Aspartate aminotransferase increased	1 (0.0)	1 (0.0)
Blood alkaline phosphatase increased	1 (0.0)	0 (0.0)
Blood bilirubin increased	2 (0.1)	1 (0.0)
Hepatic congestion	2 (0.1)	0 (0.0)
Hepatic enzyme abnormal	1 (0.0)	0 (0.0)
Hepatic enzyme increased	5 (0.2)	2 (0.1)
Hepatic function abnormal	1 (0.0)	3 (0.1)
Hepatitis acute	1 (0.0)	0 (0.0)
Hepatitis toxic	0 (0.0)	1 (0.0)
Ischaemic hepatitis	3 (0.1)	1 (0.0)
Liver function test abnormal	2 (0.1)	0 (0.0)
Liver function test increased	1 (0.0)	1 (0.0)
Liver injury	3 (0.1)	0 (0.0)
Multiple organ dysfunction syndrome	1 (0.0)	0 (0.0)
Symptomatic Hypotension	197 (9.2)	174 (8.1)
Circulatory collapse	1 (0.0)	0 (0.0)
Dizziness	0 (0.0)	1 (0.0)
Dizziness postural	1 (0.0)	0 (0.0)
Hypotension	185 (8.6)	160 (7.4)
Orthostatic hypotension	15 (0.7)	19 (0.9)
Presyncope	3 (0.1)	1 (0.0)
Syncope	89 (4.1)	79 (3.7)
Loss of consciousness	0 (0.0)	1 (0.0)
Syncope	89 (4.1)	78 (3.6)

a: Database Cutoff Date: 18JUN2019
b: A category or specific adverse event appears on this report only if its incidence is > 0% in one or more treatment groups
c: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
ECI: Events of Clinical Interest; PT: Preferred Term

1.5.2 Serious ECI by Category and PT

Table 24
Summary of Serious Adverse Events of Clinical Interest by ECI Category and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Serious ECI by Category and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Participants with one or more adverse events	74 (3.4)	66 (3.1)
Hepatic ECI	14 (0.7)	6 (0.3)
Acute hepatic failure	0 (0.0)	3 (0.1)
Alanine aminotransferase increased	0 (0.0)	1 (0.0)
Aspartate aminotransferase increased	0 (0.0)	1 (0.0)
Blood bilirubin increased	0 (0.0)	1 (0.0)
Hepatic congestion	2 (0.1)	0 (0.0)
Hepatic enzyme abnormal	1 (0.0)	0 (0.0)
Hepatic enzyme increased	1 (0.0)	0 (0.0)
Hepatitis acute	1 (0.0)	0 (0.0)
Hepatitis toxic	0 (0.0)	1 (0.0)
Ischaemic hepatitis	3 (0.1)	1 (0.0)
Liver function test abnormal	1 (0.0)	0 (0.0)
Liver function test increased	1 (0.0)	0 (0.0)
Liver injury	3 (0.1)	0 (0.0)
Multiple organ dysfunction syndrome	1 (0.0)	0 (0.0)
Symptomatic Hypotension	26 (1.2)	32 (1.5)
Dizziness	0 (0.0)	1 (0.0)
Hypotension	24 (1.1)	31 (1.4)
Orthostatic hypotension	3 (0.1)	1 (0.0)
Presyncope	1 (0.0)	0 (0.0)
Syncope	39 (1.8)	31 (1.4)
Loss of consciousness	0 (0.0)	1 (0.0)
Syncope	39 (1.8)	30 (1.4)

a: Database Cutoff Date: 18JUN2019
b: A category or specific adverse event appears on this report only if its incidence is > 0% in one or more treatment groups
c: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
ECI: Events of Clinical Interest; PT: Preferred Term

1.5.3 ECI by severity by Category and PT

Table 25
Summary of Mild Adverse Events of Clinical Interest by ECI Category and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Mild ECI by Category and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Participants with one or more adverse events	122 (5.7)	83 (3.9)
Hepatic ECI	2 (0.1)	3 (0.1)
Alanine aminotransferase increased	1 (0.0)	0 (0.0)
Blood alkaline phosphatase increased	1 (0.0)	0 (0.0)
Blood bilirubin increased	1 (0.0)	0 (0.0)
Hepatic function abnormal	0 (0.0)	2 (0.1)

Liver function test abnormal	1 (0.0)	0 (0.0)
Liver function test increased	0 (0.0)	1 (0.0)
Symptomatic Hypotension	101 (4.7)	65 (3.0)
Hypotension	93 (4.3)	58 (2.7)
Orthostatic hypotension	9 (0.4)	8 (0.4)
Presyncope	1 (0.0)	0 (0.0)
Syncope	22 (1.0)	18 (0.8)
Syncope	22 (1.0)	18 (0.8)

a: Database Cutoff Date: 18JUN2019
b: A category or specific adverse event appears on this report only if its incidence is > 0% in one or more treatment groups
c: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
ECI: Events of Clinical Interest; PT: Preferred Term

Table 26
Summary of Moderate Adverse Events of Clinical Interest by ECI Category and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Moderate ECI by Category and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Participants with one or more adverse events	115 (5.3)	118 (5.5)
Hepatic ECI	6 (0.3)	3 (0.1)
Alanine aminotransferase increased	1 (0.0)	0 (0.0)
Aspartate aminotransferase increased	1 (0.0)	0 (0.0)
Blood bilirubin increased	1 (0.0)	0 (0.0)
Hepatic congestion	1 (0.0)	0 (0.0)
Hepatic enzyme increased	3 (0.1)	2 (0.1)
Hepatic function abnormal	1 (0.0)	1 (0.0)
Symptomatic Hypotension	82 (3.8)	89 (4.1)
Circulatory collapse	1 (0.0)	0 (0.0)
Dizziness postural	1 (0.0)	0 (0.0)
Hypotension	75 (3.5)	81 (3.8)
Orthostatic hypotension	7 (0.3)	12 (0.6)
Presyncope	1 (0.0)	1 (0.0)
Syncope	30 (1.4)	32 (1.5)
Syncope	30 (1.4)	32 (1.5)

a: Database Cutoff Date: 18JUN2019
b: A category or specific adverse event appears on this report only if its incidence is > 0% in one or more treatment groups
c: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
ECI: Events of Clinical Interest; PT: Preferred Term

Table 27
Summary of Severe Adverse Events of Clinical Interest by ECI Category and Preferred Term
(Incidence > 0% in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Participants with Event n(%)**	
Severe ECI by Category and PT[b]	**Vericiguat (N[c]=2152)**	**Placebo (N[c]=2151)**
Participants with one or more adverse events	82 (3.8)	72 (3.3)
Hepatic ECI	15 (0.7)	6 (0.3)
Acute hepatic failure	0 (0.0)	3 (0.1)
Alanine aminotransferase increased	0 (0.0)	1 (0.0)
Aspartate aminotransferase increased	0 (0.0)	1 (0.0)
Blood bilirubin increased	0 (0.0)	1 (0.0)
Hepatic congestion	2 (0.1)	0 (0.0)
Hepatic enzyme abnormal	1 (0.0)	0 (0.0)
Hepatic enzyme increased	2 (0.1)	0 (0.0)
Hepatitis acute	1 (0.0)	0 (0.0)
Hepatitis toxic	0 (0.0)	1 (0.0)
Ischaemic hepatitis	3 (0.1)	1 (0.0)
Liver function test abnormal	1 (0.0)	0 (0.0)
Liver function test increased	1 (0.0)	0 (0.0)
Liver injury	3 (0.1)	0 (0.0)
Multiple organ dysfunction syndrome	1 (0.0)	0 (0.0)
Symptomatic Hypotension	29 (1.3)	37 (1.7)
Dizziness	0 (0.0)	1 (0.0)
Hypotension	29 (1.3)	35 (1.6)
Orthostatic hypotension	0 (0.0)	1 (0.0)
Presyncope	1 (0.0)	0 (0.0)
Syncope	41 (1.9)	31 (1.4)
Loss of consciousness	0 (0.0)	1 (0.0)
Syncope	41 (1.9)	30 (1.4)

a: Database Cutoff Date: 18JUN2019
b: A category or specific adverse event appears on this report only if its incidence is > 0% in one or more treatment groups
c: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
ECI: Events of Clinical Interest; PT: Preferred Term

1.6 Adverse Event Endpoints by Subgroup

Table 28
Overview of Subgroup Analyses for Adverse Event Related Endpoints
Treatment by Subgroup Interaction
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**						
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 0 / >30 to ≤ 60 / >60)**	**NYHA Group at Baseline (Class I or II / Class III or IV)**	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**
Adverse Events - Event							
Adverse Events	0.291	0.138	0.943	0.171	0.842	0.436	0.142
Serious Adverse Events	0.331	0.341	0.634	0.721	0.424	0.199	0.790
Mild Adverse Events	0.558	0.345	0.303	0.636	0.923	0.906	0.611
Moderate Adverse Events	**0.012[c]**	0.179	0.397	0.103	0.400	0.858	0.096
Severe Adverse Events	0.530	0.329	0.275	0.871	0.157	0.493	0.650
Adverse Events leading to treatment discontinuation	0.143	0.507	0.660	0.875	0.543	0.138	0.977

Overview of Subgroup Analyses for Adverse Event Related Endpoints
Treatment by Subgroup Interaction
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**					
	NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**
Adverse Events - Event						
Adverse Events	0.209	0.624	0.470	0.525	0.347	0.431
Serious Adverse Events	0.136	0.987	0.494	0.348	0.457	0.508
Mild Adverse Events	0.810	0.525	0.373	0.491	0.276	0.635
Moderate Adverse Events	0.452	0.971	0.298	0.892	**0.045[c]**	0.428
Severe Adverse Events	0.259	0.689	0.874	0.554	0.339	0.444
Adverse Events leading to treatment discontinuation	0.700	0.350	0.746	0.985	0.963	**0.046[c]**

a: Database Cutoff Date: 18JUN2019

b: Based on a Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if Participant has 0 event in at least one cell of the stratum.

c: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

1.6.1 Results for Subgroups with Interaction Nominal P-value < 0.05

Table 29
Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test < 0.05
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
Age category 1									
<65	831	368 (44.3)	851	342 (40.2)	4.10 [-0.63; 8.80]	1.18 [0.97; 1.44]	1.10 [0.99; 1.23]	0.089	0.012
≥65	1321	573 (43.4)	1300	612 (47.1)	-3.70 [-7.50; 0.11]	0.86 [0.74; 1.00]	0.92 [0.85; 1.00]	0.057	
Medical History of Diabetes Mellitus									
Yes	1047	509 (48.6)	984	455 (46.2)	2.38 [-1.97; 6.71]	1.10 [0.92; 1.31]	1.05 [0.96; 1.15]	0.285	0.045
No	1105	432 (39.1)	1167	499 (42.8)	-3.66 [-7.70; 0.38]	0.86 [0.73; 1.02]	0.91 [0.83; 1.01]	0.076	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 30
Analyses of Adverse Event Leading to Treatment Discontinuation for Subgroups with P-value for Interaction Test < 0.05
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Adverse Events leading to treatment discontinuation	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
Index Event									
HF Hospitalization within 3 Months	1439	86 (6.0)	1474	96 (6.5)	-0.54 [-2.31; 1.23]	0.91 [0.68; 1.23]	0.92 [0.69; 1.22]	0.550	0.046
HF Hospitalization 3-6 Months	386	23 (6.0)	362	24 (6.6)	-0.67 [-4.31; 2.87]	0.89 [0.49; 1.61]	0.90 [0.52; 1.56]	0.705	
IV diuretic for HF (without hospitalization) within 3 Months	327	30 (9.2)	315	14 (4.4)	4.73 [0.85; 8.82]	2.17 [1.13; 4.18]	2.06 [1.12; 3.82]	0.021	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

1.6.2 Results for Subgroups with Interaction Nominal P-value ≥ 0.05 or Rule of Ten not Met

Table 31
Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Age category 1									
<65	831	665 (80.0)	851	674 (79.2)	0.82 [-3.04; 4.68]	1.05 [0.83; 1.33]	1.01 [0.96; 1.06]	0.675	0.291
≥65	1321	1061 (80.3)	1300	1067 (82.1)	-1.76 [-4.75; 1.24]	0.89 [0.73; 1.08]	0.98 [0.94; 1.02]	0.249	
Age category 2									
<75	1519	1203 (79.2)	1533	1210 (78.9)	0.27 [-2.62; 3.16]	1.02 [0.85; 1.21]	1.00 [0.97; 1.04]	0.856	0.138
≥75	633	523 (82.6)	618	531 (85.9)	-3.30 [-7.35; 0.74]	0.78 [0.57; 1.06]	0.96 [0.92; 1.01]	0.109	
Gender									
Male	1656	1334 (80.6)	1652	1342 (81.2)	-0.68 [-3.36; 2.00]	0.96 [0.80; 1.14]	0.99 [0.96; 1.03]	0.619	0.943
Female	496	392 (79.0)	499	399 (80.0)	-0.93 [-5.96; 4.10]	0.94 [0.69; 1.29]	0.99 [0.93; 1.05]	0.717	
Geographic Region									
Asia Pacific	510	444 (87.1)	502	434 (86.5)	0.60 [-3.60; 4.82]	1.05 [0.73; 1.52]	1.01 [0.96; 1.06]	0.777	0.171
Eastern Europe	721	546 (75.7)	718	529 (73.7)	2.05 [-2.44; 6.54]	1.11 [0.88; 1.41]	1.03 [0.97; 1.09]	0.371	
Latin and South America	316	223 (70.6)	324	250 (77.2)	-6.59 [-13.38; 0.22]	0.71 [0.50; 1.01]	0.91 [0.83; 1.00]	0.059	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	203 (84.6)	241	215 (89.2)	-4.63 [-10.78; 1.43]	0.66 [0.39; 1.14]	0.95 [0.88; 1.02]	0.134	
Western Europe	365	310 (84.9)	366	313 (85.5)	-0.59 [-5.78; 4.60]	0.95 [0.63; 1.44]	0.99 [0.93; 1.05]	0.823	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	183 (85.9)	202	171 (84.7)	1.26 [-5.61; 8.22]	1.11 [0.64; 1.90]	1.01 [0.94; 1.10]	0.717	0.842
>30 to ≤60	882	732 (83.0)	895	746 (83.4)	-0.36 [-3.85; 3.13]	0.97 [0.76; 1.25]	1.00 [0.95; 1.04]	0.840	
>60	1021	786 (77.0)	1022	799 (78.2)	-1.20 [-4.82; 2.42]	0.93 [0.76; 1.15]	0.98 [0.94; 1.03]	0.517	
NYHA Group at Baseline									
Class I or II	1236	984 (79.6)	1267	1009 (79.6)	-0.03 [-3.19; 3.13]	1.00 [0.82; 1.21]	1.00 [0.96; 1.04]	0.987	0.436
Class III or IV	914	740 (81.0)	884	732 (82.8)	-1.84 [-5.41; 1.73]	0.88 [0.69; 1.12]	0.98 [0.94; 1.02]	0.310	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	279 (84.8)	330	269 (81.5)	3.29 [-2.45; 9.04]	1.27 [0.84; 1.91]	1.04 [0.97; 1.11]	0.260	0.142
No	1823	1447 (79.4)	1820	1472 (80.9)	-1.50 [-4.10; 1.09]	0.91 [0.77; 1.07]	0.98 [0.95; 1.01]	0.255	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	397 (81.2)	507	397 (78.3)	2.88 [-2.13; 7.88]	1.20 [0.88; 1.63]	1.04 [0.97; 1.10]	0.258	0.209

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q2 (1556 - 2816)	520	418 (80.4)	493	400 (81.1)	-0.75 [-5.61; 4.13]	0.95 [0.70; 1.30]	0.99 [0.93; 1.05]	0.762	
Q3 (2816 - 5314)	511	405 (79.3)	518	434 (83.8)	-4.53 [-9.29; 0.22]	0.74 [0.54; 1.02]	0.95 [0.89; 1.00]	0.062	
Q4 (>5314)	548	438 (79.9)	523	423 (80.9)	-0.95 [-5.71; 3.82]	0.94 [0.70; 1.27]	0.99 [0.93; 1.05]	0.695	
Baseline Ejection Fraction Group 2									
<35	1719	1372 (79.8)	1734	1402 (80.9)	-1.04 [-3.69; 1.61]	0.94 [0.79; 1.11]	0.99 [0.96; 1.02]	0.442	0.624
≥35	433	354 (81.8)	417	339 (81.3)	0.46 [-4.77; 5.71]	1.03 [0.73; 1.46]	1.01 [0.94; 1.07]	0.863	
Race group									
White	1344	1058 (78.7)	1353	1068 (78.9)	-0.22 [-3.30; 2.87]	0.99 [0.82; 1.19]	1.00 [0.96; 1.04]	0.891	0.470
Asian	500	419 (83.8)	474	395 (83.3)	0.47 [-4.20; 5.16]	1.03 [0.74; 1.45]	1.01 [0.95; 1.06]	0.844	
Black	111	88 (79.3)	118	100 (84.7)	-5.47 [-15.65; 4.55]	0.69 [0.35; 1.36]	0.94 [0.83; 1.06]	0.284	
Other	196	160 (81.6)	206	178 (86.4)	-4.78 [-12.08; 2.41]	0.70 [0.41; 1.20]	0.94 [0.87; 1.03]	0.194	
CCSA class at Randomization									
No Angina	1843	1492 (81.0)	1850	1518 (82.1)	-1.10 [-3.61; 1.41]	0.93 [0.79; 1.10]	0.99 [0.96; 1.02]	0.390	0.525

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Angina Class 1 or 2	265	201 (75.8)	260	190 (73.1)	2.77 [-4.70; 10.24]	1.16 [0.78; 1.71]	1.04 [0.94; 1.15]	0.467	
Angina Class 3 or 4	44	33 (75.0)	41	33 (80.5)	-5.49 [-23.22; 12.70]	0.73 [0.26; 2.04]	0.93 [0.74; 1.17]	0.543	
Medical History of Diabetes Mellitus									
Yes	1047	861 (82.2)	984	805 (81.8)	0.43 [-2.91; 3.78]	1.03 [0.82; 1.29]	1.01 [0.97; 1.05]	0.803	0.347
No	1105	865 (78.3)	1167	936 (80.2)	-1.93 [-5.27; 1.41]	0.89 [0.73; 1.09]	0.98 [0.94; 1.02]	0.259	
Index Event									
HF Hospitalization within 3 Months	1439	1161 (80.7)	1474	1185 (80.4)	0.29 [-2.59; 3.16]	1.02 [0.85; 1.22]	1.00 [0.97; 1.04]	0.845	0.431
HF Hospitalization 3-6 Months	386	321 (83.2)	362	308 (85.1)	-1.92 [-7.18; 3.36]	0.87 [0.58; 1.28]	0.98 [0.92; 1.04]	0.472	
IV diuretic for HF (without hospitalization) within 3 Months	327	244 (74.6)	315	248 (78.7)	-4.11 [-10.64; 2.45]	0.79 [0.55; 1.15]	0.95 [0.87; 1.03]	0.218	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 32
Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
Age category 1									
<65	831	243 (29.2)	851	250 (29.4)	-0.14 [-4.48; 4.22]	0.99 [0.81; 1.23]	1.00 [0.86; 1.15]	0.951	0.331
≥65	1321	459 (34.7)	1300	493 (37.9)	-3.18 [-6.85; 0.51]	0.87 [0.74; 1.02]	0.92 [0.83; 1.01]	0.091	
Age category 2									
<75	1519	470 (30.9)	1533	490 (32.0)	-1.02 [-4.31; 2.27]	0.95 [0.82; 1.11]	0.97 [0.87; 1.07]	0.543	0.341
≥75	633	232 (36.7)	618	253 (40.9)	-4.29 [-9.67; 1.11]	0.83 [0.66; 1.05]	0.90 [0.78; 1.03]	0.120	
Gender									
Male	1656	550 (33.2)	1652	587 (35.5)	-2.32 [-5.55; 0.92]	0.90 [0.78; 1.04]	0.93 [0.85; 1.03]	0.160	0.634
Female	496	152 (30.6)	499	156 (31.3)	-0.62 [-6.36; 5.13]	0.97 [0.74; 1.27]	0.98 [0.81; 1.18]	0.833	
Geographic Region									
Asia Pacific	510	181 (35.5)	502	172 (34.3)	1.23 [-4.65; 7.09]	1.06 [0.82; 1.37]	1.04 [0.88; 1.23]	0.682	0.721
Eastern Europe	721	207 (28.7)	718	218 (30.4)	-1.65 [-6.36; 3.06]	0.92 [0.74; 1.16]	0.95 [0.81; 1.11]	0.492	
Latin and South America	316	70 (22.2)	324	83 (25.6)	-3.47 [-10.07; 3.16]	0.83 [0.57; 1.19]	0.86 [0.66; 1.14]	0.305	

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	90 (37.5)	241	103 (42.7)	-5.24 [-13.93; 3.53]	0.80 [0.56; 1.16]	0.88 [0.70; 1.09]	0.242	
Western Europe	365	154 (42.2)	366	167 (45.6)	-3.44 [-10.60; 3.76]	0.87 [0.65; 1.17]	0.92 [0.78; 1.09]	0.350	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	85 (39.9)	202	91 (45.0)	-5.14 [-14.58; 4.37]	0.81 [0.55; 1.20]	0.89 [0.71; 1.11]	0.290	0.424
>30 to ≤60	882	327 (37.1)	895	361 (40.3)	-3.26 [-7.78; 1.27]	0.87 [0.72; 1.06]	0.92 [0.82; 1.03]	0.159	
>60	1021	281 (27.5)	1022	278 (27.2)	0.32 [-3.55; 4.19]	1.02 [0.84; 1.23]	1.01 [0.88; 1.17]	0.871	
NYHA Group at Baseline									
Class I or II	1236	392 (31.7)	1267	406 (32.0)	-0.33 [-3.98; 3.32]	0.98 [0.83; 1.17]	0.99 [0.88; 1.11]	0.860	0.199
Class III or IV	914	310 (33.9)	884	337 (38.1)	-4.21 [-8.63; 0.23]	0.83 [0.69; 1.01]	0.89 [0.79; 1.01]	0.064	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	119 (36.2)	330	123 (37.3)	-1.10 [-8.45; 6.25]	0.95 [0.69; 1.31]	0.97 [0.79; 1.19]	0.769	0.790
No	1823	583 (32.0)	1820	620 (34.1)	-2.09 [-5.14; 0.97]	0.91 [0.79; 1.04]	0.94 [0.86; 1.03]	0.181	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	151 (30.9)	507	149 (29.4)	1.49 [-4.21; 7.19]	1.07 [0.82; 1.41]	1.05 [0.87; 1.27]	0.608	0.136

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q2 (1556 - 2816)	520	171 (32.9)	493	160 (32.5)	0.43 [-5.35; 6.20]	1.02 [0.78; 1.33]	1.01 [0.85; 1.21]	0.884	
Q3 (2816 - 5314)	511	169 (33.1)	518	175 (33.8)	-0.71 [-6.47; 5.05]	0.97 [0.75; 1.25]	0.98 [0.82; 1.16]	0.809	
Q4 (>5314)	548	186 (33.9)	523	217 (41.5)	-7.55 [-13.32; -1.74]	0.72 [0.57; 0.93]	0.82 [0.70; 0.96]	0.011	
Baseline Ejection Fraction Group 2									
<35	1719	561 (32.6)	1734	599 (34.5)	-1.91 [-5.06; 1.24]	0.92 [0.80; 1.06]	0.94 [0.86; 1.04]	0.235	0.987
≥35	433	141 (32.6)	417	144 (34.5)	-1.97 [-8.31; 4.38]	0.92 [0.69; 1.22]	0.94 [0.78; 1.14]	0.543	
Race group									
White	1344	457 (34.0)	1353	491 (36.3)	-2.29 [-5.89; 1.32]	0.90 [0.77; 1.06]	0.94 [0.85; 1.04]	0.214	0.494
Asian	500	161 (32.2)	474	147 (31.0)	1.19 [-4.66; 7.02]	1.06 [0.81; 1.38]	1.04 [0.86; 1.25]	0.691	
Black	111	31 (27.9)	118	43 (36.4)	-8.51 [-20.40; 3.65]	0.68 [0.39; 1.18]	0.77 [0.52; 1.12]	0.172	
Other	196	52 (26.5)	206	62 (30.1)	-3.57 [-12.33; 5.28]	0.84 [0.54; 1.30]	0.88 [0.64; 1.20]	0.429	
CCSA class at Randomization									
No Angina	1843	605 (32.8)	1850	636 (34.4)	-1.55 [-4.60; 1.50]	0.93 [0.81; 1.07]	0.95 [0.87; 1.05]	0.318	0.348

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Angina Class 1 or 2	265	86 (32.5)	260	90 (34.6)	-2.16 [-10.22; 5.91]	0.91 [0.63; 1.30]	0.94 [0.74; 1.19]	0.600	
Angina Class 3 or 4	44	11 (25.0)	41	17 (41.5)	-16.46 [-35.62; 3.66]	0.47 [0.19; 1.18]	0.60 [0.32; 1.13]	0.114	
Medical History of Diabetes Mellitus									
Yes	1047	392 (37.4)	984	380 (38.6)	-1.18 [-5.40; 3.04]	0.95 [0.80; 1.14]	0.97 [0.87; 1.08]	0.585	0.457
No	1105	310 (28.1)	1167	363 (31.1)	-3.05 [-6.80; 0.71]	0.86 [0.72; 1.03]	0.90 [0.79; 1.02]	0.112	
Index Event									
HF Hospitalization within 3 Months	1439	473 (32.9)	1474	516 (35.0)	-2.14 [-5.57; 1.30]	0.91 [0.78; 1.06]	0.94 [0.85; 1.04]	0.224	0.508
HF Hospitalization 3-6 Months	386	131 (33.9)	362	138 (38.1)	-4.18 [-11.05; 2.70]	0.83 [0.62; 1.12]	0.89 [0.74; 1.08]	0.234	
IV diuretic for HF (without hospitalization) within 3 Months	327	98 (30.0)	315	89 (28.3)	1.72 [-5.33; 8.73]	1.09 [0.77; 1.53]	1.06 [0.83; 1.35]	0.633	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 33
Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
Age category 1									
<65	831	560 (67.4)	851	572 (67.2)	0.17 [-4.31; 4.65]	1.01 [0.82; 1.24]	1.00 [0.94; 1.07]	0.939	0.558
≥65	1321	881 (66.7)	1300	887 (68.2)	-1.54 [-5.12; 2.05]	0.93 [0.79; 1.10]	0.98 [0.93; 1.03]	0.400	
Age category 2									
<75	1519	1011 (66.6)	1533	1021 (66.6)	-0.04 [-3.39; 3.30]	1.00 [0.86; 1.16]	1.00 [0.95; 1.05]	0.979	0.345
≥75	633	430 (67.9)	618	438 (70.9)	-2.94 [-8.04; 2.17]	0.87 [0.68; 1.11]	0.96 [0.89; 1.03]	0.259	
Gender									
Male	1656	1100 (66.4)	1652	1125 (68.1)	-1.67 [-4.87; 1.52]	0.93 [0.80; 1.07]	0.98 [0.93; 1.02]	0.305	0.303
Female	496	341 (68.8)	499	334 (66.9)	1.82 [-3.99; 7.61]	1.09 [0.83; 1.42]	1.03 [0.94; 1.12]	0.540	
Geographic Region									
Asia Pacific	510	405 (79.4)	502	401 (79.9)	-0.47 [-5.44; 4.51]	0.97 [0.72; 1.32]	0.99 [0.93; 1.06]	0.853	0.636
Eastern Europe	721	452 (62.7)	718	441 (61.4)	1.27 [-3.74; 6.28]	1.06 [0.85; 1.31]	1.02 [0.94; 1.11]	0.620	
Latin and South America	316	171 (54.1)	324	195 (60.2)	-6.07 [-13.68; 1.60]	0.78 [0.57; 1.07]	0.90 [0.79; 1.03]	0.122	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	160 (66.7)	241	166 (68.9)	-2.21 [-10.55; 6.14]	0.90 [0.62; 1.32]	0.97 [0.86; 1.09]	0.604	
Western Europe	365	253 (69.3)	366	256 (69.9)	-0.63 [-7.30; 6.04]	0.97 [0.71; 1.33]	0.99 [0.90; 1.09]	0.853	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	144 (67.6)	202	138 (68.3)	-0.71 [-9.66; 8.28]	0.97 [0.64; 1.46]	0.99 [0.87; 1.13]	0.877	0.923
>30 to ≤60	882	618 (70.1)	895	630 (70.4)	-0.32 [-4.58; 3.93]	0.98 [0.80; 1.21]	1.00 [0.94; 1.06]	0.882	
>60	1021	658 (64.4)	1022	675 (66.0)	-1.60 [-5.73; 2.53]	0.93 [0.78; 1.12]	0.98 [0.92; 1.04]	0.448	
NYHA Group at Baseline									
Class I or II	1236	823 (66.6)	1267	857 (67.6)	-1.05 [-4.74; 2.63]	0.95 [0.81; 1.13]	0.98 [0.93; 1.04]	0.575	0.906
Class III or IV	914	616 (67.4)	884	602 (68.1)	-0.70 [-5.02; 3.62]	0.97 [0.79; 1.18]	0.99 [0.93; 1.05]	0.750	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	227 (69.0)	330	225 (68.2)	0.82 [-6.27; 7.90]	1.04 [0.75; 1.44]	1.01 [0.91; 1.12]	0.822	0.611
No	1823	1214 (66.6)	1820	1234 (67.8)	-1.21 [-4.26; 1.84]	0.95 [0.82; 1.09]	0.98 [0.94; 1.03]	0.437	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	332 (67.9)	507	341 (67.3)	0.64 [-5.18; 6.44]	1.03 [0.79; 1.34]	1.01 [0.93; 1.10]	0.830	0.810

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q2 (1556 - 2816)	520	353 (67.9)	493	336 (68.2)	-0.27 [-6.01; 5.48]	0.99 [0.76; 1.29]	1.00 [0.92; 1.08]	0.927	
Q3 (2816 - 5314)	511	342 (66.9)	518	360 (69.5)	-2.57 [-8.25; 3.12]	0.89 [0.68; 1.15]	0.96 [0.89; 1.05]	0.376	
Q4 (>5314)	548	353 (64.4)	523	351 (67.1)	-2.70 [-8.36; 2.99]	0.89 [0.69; 1.14]	0.96 [0.88; 1.05]	0.352	
Baseline Ejection Fraction Group 2									
<35	1719	1143 (66.5)	1734	1176 (67.8)	-1.33 [-4.46; 1.81]	0.94 [0.82; 1.09]	0.98 [0.94; 1.03]	0.406	0.525
≥35	433	298 (68.8)	417	283 (67.9)	0.96 [-5.29; 7.21]	1.05 [0.78; 1.40]	1.01 [0.93; 1.11]	0.764	
Race group									
White	1344	856 (63.7)	1353	857 (63.3)	0.35 [-3.28; 3.98]	1.02 [0.87; 1.19]	1.01 [0.95; 1.06]	0.850	0.373
Asian	500	381 (76.2)	474	368 (77.6)	-1.44 [-6.73; 3.88]	0.92 [0.68; 1.24]	0.98 [0.92; 1.05]	0.595	
Black	111	70 (63.1)	118	86 (72.9)	-9.82 [-21.75; 2.29]	0.64 [0.36; 1.11]	0.87 [0.72; 1.04]	0.115	
Other	196	133 (67.9)	206	148 (71.8)	-3.99 [-12.95; 4.99]	0.83 [0.54; 1.27]	0.94 [0.83; 1.07]	0.385	
CCSA class at Randomization									
No Angina	1843	1244 (67.5)	1850	1270 (68.6)	-1.15 [-4.16; 1.86]	0.95 [0.83; 1.09]	0.98 [0.94; 1.03]	0.454	0.491

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Angina Class 1 or 2	265	170 (64.2)	260	160 (61.5)	2.61 [-5.65; 10.85]	1.12 [0.78; 1.59]	1.04 [0.91; 1.19]	0.536	
Angina Class 3 or 4	44	27 (61.4)	41	29 (70.7)	-9.37 [-28.83; 10.94]	0.66 [0.27; 1.63]	0.87 [0.64; 1.18]	0.363	
Medical History of Diabetes Mellitus									
Yes	1047	695 (66.4)	984	678 (68.9)	-2.52 [-6.58; 1.55]	0.89 [0.74; 1.07]	0.96 [0.91; 1.02]	0.224	0.276
No	1105	746 (67.5)	1167	781 (66.9)	0.59 [-3.28; 4.44]	1.03 [0.86; 1.22]	1.01 [0.95; 1.07]	0.766	
Index Event									
HF Hospitalization within 3 Months	1439	968 (67.3)	1474	991 (67.2)	0.04 [-3.37; 3.44]	1.00 [0.86; 1.17]	1.00 [0.95; 1.05]	0.983	0.635
HF Hospitalization 3-6 Months	386	268 (69.4)	362	260 (71.8)	-2.39 [-8.90; 4.16]	0.89 [0.65; 1.22]	0.97 [0.88; 1.06]	0.472	
IV diuretic for HF (without hospitalization) within 3 Months	327	205 (62.7)	315	208 (66.0)	-3.34 [-10.71; 4.08]	0.86 [0.63; 1.19]	0.95 [0.85; 1.07]	0.377	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 34
Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Age category 2									
<75	1519	656 (43.2)	1533	652 (42.5)	0.66 [-2.86; 4.16]	1.03 [0.89; 1.19]	1.02 [0.94; 1.10]	0.715	0.179
≥75	633	285 (45.0)	618	302 (48.9)	-3.84 [-9.35; 1.69]	0.86 [0.69; 1.07]	0.92 [0.82; 1.04]	0.173	
Gender									
Male	1656	734 (44.3)	1652	731 (44.2)	0.07 [-3.31; 3.46]	1.00 [0.87; 1.15]	1.00 [0.93; 1.08]	0.966	0.397
Female	496	207 (41.7)	499	223 (44.7)	-2.96 [-9.09; 3.20]	0.89 [0.69; 1.14]	0.93 [0.81; 1.08]	0.347	
Geographic Region									
Asia Pacific	510	191 (37.5)	502	212 (42.2)	-4.78 [-10.78; 1.25]	0.82 [0.64; 1.05]	0.89 [0.76; 1.03]	0.121	0.103
Eastern Europe	721	288 (39.9)	718	261 (36.4)	3.59 [-1.43; 8.60]	1.16 [0.94; 1.44]	1.10 [0.96; 1.25]	0.161	
Latin and South America	316	130 (41.1)	324	135 (41.7)	-0.53 [-8.14; 7.10]	0.98 [0.71; 1.34]	0.99 [0.82; 1.19]	0.892	
North America	240	131 (54.6)	241	151 (62.7)	-8.07 [-16.76; 0.74]	0.72 [0.50; 1.03]	0.87 [0.75; 1.01]	0.074	
Western Europe	365	201 (55.1)	366	195 (53.3)	1.79 [-5.43; 8.99]	1.07 [0.80; 1.44]	1.03 [0.90; 1.18]	0.627	

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category									
≤30	213	112 (52.6)	202	115 (56.9)	-4.35 [-13.84; 5.24]	0.84 [0.57; 1.24]	0.92 [0.78; 1.10]	0.374	0.400
>30 to ≤60	882	422 (47.8)	895	447 (49.9)	-2.10 [-6.74; 2.55]	0.92 [0.76; 1.11]	0.96 [0.87; 1.05]	0.377	
>60	1021	392 (38.4)	1022	378 (37.0)	1.41 [-2.80; 5.61]	1.06 [0.89; 1.27]	1.04 [0.93; 1.16]	0.512	
NYHA Group at Baseline									
Class I or II	1236	515 (41.7)	1267	539 (42.5)	-0.87 [-4.74; 2.99]	0.96 [0.82; 1.13]	0.98 [0.89; 1.07]	0.658	0.858
Class III or IV	914	426 (46.6)	884	415 (46.9)	-0.34 [-4.95; 4.27]	0.99 [0.82; 1.19]	0.99 [0.90; 1.10]	0.886	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	164 (49.8)	330	147 (44.5)	5.30 [-2.32; 12.87]	1.24 [0.91; 1.68]	1.12 [0.95; 1.32]	0.174	0.096
No	1823	777 (42.6)	1820	807 (44.3)	-1.72 [-4.93; 1.50]	0.93 [0.82; 1.06]	0.96 [0.89; 1.04]	0.296	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	204 (41.7)	507	194 (38.3)	3.45 [-2.63; 9.52]	1.15 [0.90; 1.49]	1.09 [0.94; 1.27]	0.266	0.452
Q2 (1556 - 2816)	520	228 (43.8)	493	230 (46.7)	-2.81 [-8.92; 3.32]	0.89 [0.70; 1.14]	0.94 [0.82; 1.08]	0.370	
Q3 (2816 - 5314)	511	228 (44.6)	518	239 (46.1)	-1.52 [-7.59; 4.56]	0.94 [0.74; 1.20]	0.97 [0.85; 1.11]	0.624	

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q4 (>5314)	548	245 (44.7)	523	247 (47.2)	-2.52 [-8.47; 3.45]	0.90 [0.71; 1.15]	0.95 [0.83; 1.08]	0.408	
Baseline Ejection Fraction Group 2									
<35	1719	746 (43.4)	1734	764 (44.1)	-0.66 [-3.97; 2.65]	0.97 [0.85; 1.11]	0.98 [0.91; 1.06]	0.695	0.971
≥35	433	195 (45.0)	417	190 (45.6)	-0.53 [-7.21; 6.16]	0.98 [0.75; 1.28]	0.99 [0.85; 1.15]	0.877	
Race group									
White	1344	604 (44.9)	1353	585 (43.2)	1.70 [-2.04; 5.45]	1.07 [0.92; 1.25]	1.04 [0.95; 1.13]	0.373	0.298
Asian	500	168 (33.6)	474	182 (38.4)	-4.80 [-10.81; 1.23]	0.81 [0.62; 1.06]	0.88 [0.74; 1.04]	0.119	
Black	111	52 (46.8)	118	60 (50.8)	-4.00 [-16.80; 8.93]	0.85 [0.51; 1.43]	0.92 [0.71; 1.20]	0.546	
Other	196	117 (59.7)	206	127 (61.7)	-1.96 [-11.48; 7.58]	0.92 [0.62; 1.37]	0.97 [0.83; 1.13]	0.688	
CCSA class at Randomization									
No Angina	1843	805 (43.7)	1850	825 (44.6)	-0.92 [-4.12; 2.29]	0.96 [0.85; 1.10]	0.98 [0.91; 1.05]	0.575	0.892
Angina Class 1 or 2	265	116 (43.8)	260	111 (42.7)	1.08 [-7.38; 9.53]	1.05 [0.74; 1.48]	1.03 [0.84; 1.25]	0.803	
Angina Class 3 or 4	44	20 (45.5)	41	18 (43.9)	1.55 [-19.36; 22.28]	1.06 [0.45; 2.51]	1.04 [0.64; 1.66]	0.886	

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Index Event									
HF Hospitalization within 3 Months	1439	635 (44.1)	1474	640 (43.4)	0.71 [-2.89; 4.31]	1.03 [0.89; 1.19]	1.02 [0.94; 1.10]	0.700	0.428
HF Hospitalization 3-6 Months	386	175 (45.3)	362	176 (48.6)	-3.28 [-10.41; 3.87]	0.88 [0.66; 1.17]	0.93 [0.80; 1.09]	0.369	
IV diuretic for HF (without hospitalization) within 3 Months	327	131 (40.1)	315	138 (43.8)	-3.75 [-11.35; 3.89]	0.86 [0.63; 1.17]	0.91 [0.76; 1.10]	0.336	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 35
Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Age category 1									
<65	831	242 (29.1)	851	249 (29.3)	-0.14 [-4.48; 4.21]	0.99 [0.80; 1.23]	1.00 [0.86; 1.16]	0.950	0.530
≥65	1321	459 (34.7)	1300	479 (36.8)	-2.10 [-5.77; 1.57]	0.91 [0.78; 1.07]	0.94 [0.85; 1.04]	0.262	
Age category 2									
<75	1519	472 (31.1)	1533	482 (31.4)	-0.37 [-3.66; 2.92]	0.98 [0.84; 1.15]	0.99 [0.89; 1.10]	0.826	0.329
≥75	633	229 (36.2)	618	246 (39.8)	-3.63 [-8.99; 1.75]	0.86 [0.68; 1.08]	0.91 [0.79; 1.05]	0.186	
Gender									
Male	1656	544 (32.9)	1652	578 (35.0)	-2.14 [-5.36; 1.09]	0.91 [0.79; 1.05]	0.94 [0.85; 1.03]	0.194	0.275
Female	496	157 (31.7)	499	150 (30.1)	1.59 [-4.15; 7.33]	1.08 [0.82; 1.41]	1.05 [0.87; 1.27]	0.587	
Geographic Region									
Asia Pacific	510	166 (32.5)	502	160 (31.9)	0.68 [-5.08; 6.43]	1.03 [0.79; 1.34]	1.02 [0.85; 1.22]	0.818	0.871
Eastern Europe	721	217 (30.1)	718	220 (30.6)	-0.54 [-5.29; 4.21]	0.97 [0.78; 1.22]	0.98 [0.84; 1.15]	0.823	
Latin and South America	316	66 (20.9)	324	78 (24.1)	-3.19 [-9.66; 3.30]	0.83 [0.57; 1.21]	0.87 [0.65; 1.16]	0.335	

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	97 (40.4)	241	106 (44.0)	-3.57 [-12.34; 5.26]	0.86 [0.60; 1.24]	0.92 [0.75; 1.13]	0.429	
Western Europe	365	155 (42.5)	366	164 (44.8)	-2.34 [-9.51; 4.84]	0.91 [0.68; 1.22]	0.95 [0.80; 1.12]	0.523	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	97 (45.5)	202	89 (44.1)	1.48 [-8.08; 11.00]	1.06 [0.72; 1.56]	1.03 [0.83; 1.28]	0.762	0.157
>30 to ≤60	882	315 (35.7)	895	357 (39.9)	-4.17 [-8.67; 0.34]	0.84 [0.69; 1.01]	0.90 [0.79; 1.01]	0.070	
>60	1021	283 (27.7)	1022	267 (26.1)	1.59 [-2.26; 5.44]	1.08 [0.89; 1.32]	1.06 [0.92; 1.22]	0.417	
NYHA Group at Baseline									
Class I or II	1236	377 (30.5)	1267	392 (30.9)	-0.44 [-4.05; 3.18]	0.98 [0.83; 1.16]	0.99 [0.88; 1.11]	0.812	0.493
Class III or IV	914	324 (35.4)	884	336 (38.0)	-2.56 [-7.01; 1.90]	0.90 [0.74; 1.09]	0.93 [0.83; 1.05]	0.260	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	118 (35.9)	330	128 (38.8)	-2.92 [-10.28; 4.47]	0.88 [0.64; 1.21]	0.92 [0.76; 1.13]	0.438	0.650
No	1823	583 (32.0)	1820	600 (33.0)	-0.99 [-4.03; 2.05]	0.96 [0.83; 1.10]	0.97 [0.88; 1.07]	0.525	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	151 (30.9)	507	144 (28.4)	2.48 [-3.20; 8.15]	1.13 [0.86; 1.48]	1.09 [0.90; 1.32]	0.392	0.259

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q2 (1556 - 2816)	520	166 (31.9)	493	156 (31.6)	0.28 [-5.46; 6.01]	1.01 [0.78; 1.32]	1.01 [0.84; 1.21]	0.924	
Q3 (2816 - 5314)	511	168 (32.9)	518	178 (34.4)	-1.49 [-7.25; 4.29]	0.94 [0.72; 1.21]	0.96 [0.81; 1.14]	0.614	
Q4 (>5314)	548	189 (34.5)	523	210 (40.2)	-5.66 [-11.43; 0.13]	0.78 [0.61; 1.01]	0.86 [0.74; 1.00]	0.056	
Baseline Ejection Fraction Group 2									
<35	1719	560 (32.6)	1734	582 (33.6)	-0.99 [-4.12; 2.15]	0.96 [0.83; 1.10]	0.97 [0.88; 1.07]	0.538	0.689
≥35	433	141 (32.6)	417	146 (35.0)	-2.45 [-8.80; 3.91]	0.90 [0.67; 1.19]	0.93 [0.77; 1.12]	0.451	
Race group									
White	1344	472 (35.1)	1353	497 (36.7)	-1.61 [-5.23; 2.01]	0.93 [0.80; 1.09]	0.96 [0.86; 1.06]	0.382	0.874
Asian	500	147 (29.4)	474	136 (28.7)	0.71 [-5.01; 6.40]	1.03 [0.78; 1.37]	1.02 [0.84; 1.25]	0.808	
Black	111	35 (31.5)	118	41 (34.7)	-3.21 [-15.30; 9.02]	0.86 [0.50; 1.50]	0.91 [0.63; 1.31]	0.606	
Other	196	46 (23.5)	206	54 (26.2)	-2.74 [-11.18; 5.75]	0.86 [0.55; 1.36]	0.90 [0.64; 1.26]	0.525	
CCSA class at Randomization									
No Angina	1843	605 (32.8)	1850	624 (33.7)	-0.90 [-3.94; 2.14]	0.96 [0.84; 1.10]	0.97 [0.89; 1.07]	0.560	0.554

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Angina Class 1 or 2	265	85 (32.1)	260	89 (34.2)	-2.16 [-10.19; 5.90]	0.91 [0.63; 1.31]	0.94 [0.73; 1.19]	0.600	
Angina Class 3 or 4	44	11 (25.0)	41	15 (36.6)	-11.59 [-30.77; 8.13]	0.58 [0.23; 1.47]	0.68 [0.36; 1.31]	0.252	
Medical History of Diabetes Mellitus									
Yes	1047	393 (37.5)	984	371 (37.7)	-0.17 [-4.38; 4.04]	0.99 [0.83; 1.19]	1.00 [0.89; 1.11]	0.938	0.339
No	1105	308 (27.9)	1167	357 (30.6)	-2.72 [-6.45; 1.03]	0.88 [0.73; 1.05]	0.91 [0.80; 1.04]	0.155	
Index Event									
HF Hospitalization within 3 Months	1439	470 (32.7)	1474	501 (34.0)	-1.33 [-4.75; 2.10]	0.94 [0.81; 1.10]	0.96 [0.87; 1.06]	0.447	0.444
HF Hospitalization 3-6 Months	386	131 (33.9)	362	138 (38.1)	-4.18 [-11.05; 2.70]	0.83 [0.62; 1.12]	0.89 [0.74; 1.08]	0.234	
IV diuretic for HF (without hospitalization) within 3 Months	327	100 (30.6)	315	89 (28.3)	2.33 [-4.74; 9.36]	1.12 [0.80; 1.57]	1.08 [0.85; 1.38]	0.518	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 36
Analyses of Adverse Event Leading to Treatment Discontinuation for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Adverse Events leading to treatment discontinuation	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
Age category 1									
<65	831	45 (5.4)	851	34 (4.0)	1.42 [-0.61; 3.51]	1.38 [0.87; 2.17]	1.36 [0.88; 2.09]	0.171	0.143
≥65	1321	94 (7.1)	1300	100 (7.7)	-0.58 [-2.60; 1.44]	0.92 [0.69; 1.23]	0.93 [0.71; 1.21]	0.573	
Age category 2									
<75	1519	84 (5.5)	1533	87 (5.7)	-0.15 [-1.79; 1.50]	0.97 [0.71; 1.32]	0.97 [0.73; 1.30]	0.862	0.507
≥75	633	55 (8.7)	618	47 (7.6)	1.08 [-1.98; 4.16]	1.16 [0.77; 1.74]	1.14 [0.79; 1.66]	0.484	
Gender									
Male	1656	104 (6.3)	1652	103 (6.2)	0.05 [-1.62; 1.71]	1.01 [0.76; 1.34]	1.01 [0.77; 1.31]	0.957	0.660
Female	496	35 (7.1)	499	31 (6.2)	0.84 [-2.30; 4.02]	1.15 [0.70; 1.89]	1.14 [0.71; 1.81]	0.593	
Geographic Region									
Asia Pacific	510	17 (3.3)	502	16 (3.2)	0.15 [-2.15; 2.44]	1.05 [0.52; 2.10]	1.05 [0.53; 2.05]	0.896	0.875
Eastern Europe	721	38 (5.3)	718	32 (4.5)	0.81 [-1.44; 3.10]	1.19 [0.74; 1.93]	1.18 [0.75; 1.87]	0.474	
Latin and South America	316	9 (2.8)	324	13 (4.0)	-1.16 [-4.24; 1.80]	0.70 [0.30; 1.66]	0.71 [0.31; 1.64]	0.421	
North America	240	27 (11.3)	241	28 (11.6)	-0.37 [-6.17; 5.43]	0.96 [0.55; 1.69]	0.97 [0.59; 1.59]	0.899	
Western Europe	365	48 (13.2)	366	45 (12.3)	0.86 [-4.02; 5.75]	1.08 [0.70; 1.67]	1.07 [0.73; 1.56]	0.729	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	24 (11.3)	202	28 (13.9)	-2.59 [-9.16; 3.84]	0.79 [0.44; 1.41]	0.81 [0.49; 1.35]	0.426	0.543

Analyses of Adverse Event Leading to Treatment Discontinuation for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events leading to treatment discontinuation	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
>30 to ≤60	882	64 (7.3)	895	62 (6.9)	0.33 [-2.08; 2.75]	1.05 [0.73; 1.51]	1.05 [0.75; 1.47]	0.787	
>60	1021	47 (4.6)	1022	40 (3.9)	0.69 [-1.08; 2.48]	1.18 [0.77; 1.82]	1.18 [0.78; 1.78]	0.441	
NYHA Group at Baseline									
Class I or II	1236	79 (6.4)	1267	67 (5.3)	1.10 [-0.74; 2.97]	1.22 [0.87; 1.71]	1.21 [0.88; 1.66]	0.240	0.138
Class III or IV	914	59 (6.5)	884	67 (7.6)	-1.12 [-3.53; 1.25]	0.84 [0.59; 1.21]	0.85 [0.61; 1.19]	0.351	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	26 (7.9)	330	25 (7.6)	0.33 [-3.85; 4.52]	1.05 [0.59; 1.85]	1.04 [0.62; 1.77]	0.875	0.977
No	1823	113 (6.2)	1820	109 (6.0)	0.21 [-1.35; 1.77]	1.04 [0.79; 1.36]	1.03 [0.80; 1.34]	0.792	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	25 (5.1)	507	25 (4.9)	0.18 [-2.60; 2.99]	1.04 [0.59; 1.83]	1.04 [0.60; 1.78]	0.896	0.700
Q2 (1556 - 2816)	520	28 (5.4)	493	26 (5.3)	0.11 [-2.75; 2.94]	1.02 [0.59; 1.77]	1.02 [0.61; 1.72]	0.937	
Q3 (2816 - 5314)	511	39 (7.6)	518	30 (5.8)	1.84 [-1.24; 5.00]	1.34 [0.82; 2.20]	1.32 [0.83; 2.09]	0.240	
Q4 (>5314)	548	42 (7.7)	523	44 (8.4)	-0.75 [-4.08; 2.54]	0.90 [0.58; 1.40]	0.91 [0.61; 1.37]	0.652	
Baseline Ejection Fraction Group 2									
<35	1719	111 (6.5)	1734	102 (5.9)	0.57 [-1.04; 2.20]	1.10 [0.84; 1.46]	1.10 [0.85; 1.42]	0.483	0.350
≥35	433	28 (6.5)	417	32 (7.7)	-1.21 [-4.77; 2.28]	0.83 [0.49; 1.41]	0.84 [0.52; 1.37]	0.493	
Race group									
White	1344	112 (8.3)	1353	111 (8.2)	0.13 [-1.96; 2.22]	1.02 [0.77; 1.34]	1.02 [0.79; 1.31]	0.903	0.746

Analyses of Adverse Event Leading to Treatment Discontinuation for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events leading to treatment discontinuation	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Asian	500	17 (3.4)	474	13 (2.7)	0.66 [-1.61; 2.95]	1.25 [0.60; 2.60]	1.24 [0.61; 2.52]	0.554	
Black	111	6 (5.4)	118	8 (6.8)	-1.37 [-8.17; 5.40]	0.79 [0.26; 2.34]	0.80 [0.29; 2.23]	0.665	
Other	196	4 (2.0)	206	2 (1.0)	1.07 [-1.67; 4.28]	2.07 [0.41; 10.35]	2.07 [0.41; 10.35]	0.377	
CCSA class at Randomization									
No Angina	1843	119 (6.5)	1850	116 (6.3)	0.19 [-1.40; 1.77]	1.03 [0.79; 1.34]	1.03 [0.80; 1.32]	0.816	0.985
Angina Class 1 or 2	265	20 (7.5)	260	18 (6.9)	0.62 [-3.96; 5.22]	1.10 [0.57; 2.13]	1.09 [0.59; 2.01]	0.783	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	0.00 [-8.66; 8.12]	n.a.	n.a.	n.a.	
Medical History of Diabetes Mellitus									
Yes	1047	77 (7.4)	984	70 (7.1)	0.24 [-2.04; 2.51]	1.04 [0.74; 1.45]	1.03 [0.76; 1.41]	0.834	0.963
No	1105	62 (5.6)	1167	64 (5.5)	0.13 [-1.77; 2.04]	1.02 [0.72; 1.47]	1.02 [0.73; 1.44]	0.895	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

1.7 Adverse Events of Clinical Interest Endpoints by Subgroup

Table 37
Overview of Subgroup Analyses for Adverse Event of Clinical Interest Related Endpoints
Treatment by Subgroup Interaction
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**						
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 0 / >30 to ≤ 60 / >60)**	**NYHA Group at Baseline (Class I or II / Class III or IV)**	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**
Adverse Events of Clinical Interest							
Adverse Events of Clinical Interest	0.126	0.313	0.411	0.661	0.968	0.748	0.424
Serious Adverse Events of Clinical Interest	0.067	0.274	0.937	0.072	0.313	0.739	0.327
Mild Adverse Events of Clinical Interest	0.129	0.513	0.921	0.630	0.648	0.963	0.362
Moderate Adverse Events of Clinical Interest	**0.024[c]**	0.195	0.584	0.900	0.986	0.554	0.776
Severe Adverse Events of Clinical Interest	0.541	0.898	0.128	0.448	0.860	0.512	**0.037[c]**

Overview of Subgroup Analyses for Adverse Event of Clinical Interest Related Endpoints
Treatment by Subgroup Interaction
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**					
	NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**
Adverse Events of Clinical Interest						
Adverse Events of Clinical Interest	**0.039[c]**	0.759	0.661	0.608	0.229	0.608
Serious Adverse Events of Clinical Interest	**0.043[c]**	0.660	0.196	0.626	0.734	0.946
Mild Adverse Events of Clinical Interest	0.414	0.395	0.616	0.591	0.668	0.646
Moderate Adverse Events of Clinical Interest	0.204	0.892	0.637	0.899	0.103	0.695
Severe Adverse Events of Clinical Interest	0.196	0.993	0.674	0.375	0.426	0.905

a: Database Cutoff Date: 18JUN2019

b: Based on a Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if Participant has 0 event in at least one cell of the stratum.

c: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

1.7.1 Results for Subgroups with Interaction Nominal P-value < 0.05

Table 38
Analyses of Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test < 0.05
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	55 (11.2)	507	64 (12.6)	-1.38 [-5.44; 2.69]	0.88 [0.60; 1.29]	0.89 [0.64; 1.25]	0.504	0.039
Q2 (1556 - 2816)	520	86 (16.5)	493	57 (11.6)	4.98 [0.69; 9.27]	1.52 [1.06; 2.17]	1.43 [1.05; 1.95]	0.024	
Q3 (2816 - 5314)	511	74 (14.5)	518	49 (9.5)	5.02 [1.07; 9.05]	1.62 [1.10; 2.38]	1.53 [1.09; 2.15]	0.014	
Q4 (>5314)	548	62 (11.3)	523	63 (12.0)	-0.73 [-4.63; 3.13]	0.93 [0.64; 1.35]	0.94 [0.68; 1.31]	0.709	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 39
Analyses of Serious Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test < 0.05
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	13 (2.7)	507	19 (3.7)	-1.09 [-3.42; 1.17]	0.70 [0.34; 1.44]	0.71 [0.35; 1.42]	0.333	0.043
Q2 (1556 - 2816)	520	21 (4.0)	493	8 (1.6)	2.42 [0.39; 4.65]	2.55 [1.12; 5.82]	2.49 [1.11; 5.57]	0.026	
Q3 (2816 - 5314)	511	21 (4.1)	518	15 (2.9)	1.21 [-1.08; 3.61]	1.44 [0.73; 2.82]	1.42 [0.74; 2.72]	0.292	
Q4 (>5314)	548	17 (3.1)	523	22 (4.2)	-1.10 [-3.50; 1.18]	0.73 [0.38; 1.39]	0.74 [0.40; 1.37]	0.337	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 40
Analyses of Moderate Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test < 0.05
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Age category 1									
<65	831	51 (6.1)	851	37 (4.3)	1.79 [-0.35; 3.99]	1.44 [0.93; 2.22]	1.41 [0.93; 2.13]	0.101	0.024
≥65	1321	64 (4.8)	1300	81 (6.2)	-1.39 [-3.17; 0.37]	0.77 [0.55; 1.07]	0.78 [0.57; 1.07]	0.122	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 41
Analyses of Severe Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test < 0.05
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Use of Sacubitril /Valsartan at Baseline									
Yes	329	10 (3.0)	330	18 (5.5)	-2.42 [-5.76; 0.71]	0.54 [0.25; 1.20]	0.56 [0.26; 1.19]	0.130	0.037
No	1823	72 (3.9)	1820	54 (3.0)	0.98 [-0.21; 2.20]	1.34 [0.94; 1.93]	1.33 [0.94; 1.88]	0.106	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

1.7.2 Results for Subgroups with Interaction Nominal P-value ≥ 0.05 or Rule of Ten not Met

Table 42
Analyses of Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Age category 1									
<65	831	117 (14.1)	851	87 (10.2)	3.86 [0.74; 7.01]	1.44 [1.07; 1.93]	1.38 [1.06; 1.79]	0.016	0.126
≥65	1321	172 (13.0)	1300	159 (12.2)	0.79 [-1.76; 3.34]	1.07 [0.85; 1.35]	1.06 [0.87; 1.30]	0.543	
Age category 2									
<75	1519	204 (13.4)	1533	166 (10.8)	2.60 [0.29; 4.93]	1.28 [1.03; 1.59]	1.24 [1.02; 1.50]	0.028	0.313
≥75	633	85 (13.4)	618	80 (12.9)	0.48 [-3.29; 4.25]	1.04 [0.75; 1.45]	1.04 [0.78; 1.38]	0.801	
Gender									
Male	1656	225 (13.6)	1652	198 (12.0)	1.60 [-0.68; 3.88]	1.15 [0.94; 1.42]	1.13 [0.95; 1.36]	0.168	0.411
Female	496	64 (12.9)	499	48 (9.6)	3.28 [-0.65; 7.27]	1.39 [0.94; 2.07]	1.34 [0.94; 1.91]	0.103	
Geographic Region									
Asia Pacific	510	69 (13.5)	502	54 (10.8)	2.77 [-1.27; 6.84]	1.30 [0.89; 1.90]	1.26 [0.90; 1.76]	0.179	0.661
Eastern Europe	721	82 (11.4)	718	63 (8.8)	2.60 [-0.52; 5.75]	1.33 [0.94; 1.89]	1.30 [0.95; 1.77]	0.103	
Latin and South America	316	25 (7.9)	324	30 (9.3)	-1.35 [-5.80; 3.08]	0.84 [0.48; 1.47]	0.85 [0.51; 1.42]	0.544	

Analyses of Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	43 (17.9)	241	41 (17.0)	0.90 [-5.93; 7.75]	1.06 [0.66; 1.71]	1.05 [0.71; 1.55]	0.794	
Western Europe	365	70 (19.2)	366	58 (15.8)	3.33 [-2.20; 8.87]	1.26 [0.86; 1.85]	1.21 [0.88; 1.66]	0.237	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	31 (14.6)	202	25 (12.4)	2.18 [-4.51; 8.84]	1.21 [0.68; 2.12]	1.18 [0.72; 1.92]	0.517	0.968
>30 to ≤60	882	133 (15.1)	895	116 (13.0)	2.12 [-1.11; 5.37]	1.19 [0.91; 1.56]	1.16 [0.92; 1.47]	0.199	
>60	1021	121 (11.9)	1022	99 (9.7)	2.16 [-0.53; 4.87]	1.25 [0.95; 1.66]	1.22 [0.95; 1.57]	0.115	
NYHA Group at Baseline									
Class I or II	1236	159 (12.9)	1267	136 (10.7)	2.13 [-0.40; 4.68]	1.23 [0.96; 1.57]	1.20 [0.97; 1.49]	0.099	0.748
Class III or IV	914	129 (14.1)	884	110 (12.4)	1.67 [-1.48; 4.82]	1.16 [0.88; 1.52]	1.13 [0.89; 1.44]	0.297	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	51 (15.5)	330	50 (15.2)	0.35 [-5.19; 5.90]	1.03 [0.67; 1.57]	1.02 [0.71; 1.46]	0.901	0.424
No	1823	238 (13.1)	1820	196 (10.8)	2.29 [0.18; 4.40]	1.24 [1.02; 1.52]	1.21 [1.02; 1.45]	0.034	
Baseline Ejection Fraction Group 2									
<35	1719	238 (13.8)	1734	202 (11.6)	2.20 [-0.03; 4.43]	1.22 [1.00; 1.49]	1.19 [1.00; 1.42]	0.053	0.759

Analyses of Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥35	433	51 (11.8)	417	44 (10.6)	1.23 [-3.06; 5.51]	1.13 [0.74; 1.74]	1.12 [0.76; 1.63]	0.571	
Race group									
White	1344	198 (14.7)	1353	172 (12.7)	2.02 [-0.58; 4.63]	1.19 [0.95; 1.48]	1.16 [0.96; 1.40]	0.128	0.661
Asian	500	58 (11.6)	474	39 (8.2)	3.37 [-0.40; 7.18]	1.46 [0.96; 2.24]	1.41 [0.96; 2.07]	0.081	
Black	111	12 (10.8)	118	13 (11.0)	-0.21 [-8.56; 8.29]	0.98 [0.43; 2.25]	0.98 [0.47; 2.06]	0.960	
Other	196	20 (10.2)	206	22 (10.7)	-0.48 [-6.59; 5.69]	0.95 [0.50; 1.80]	0.96 [0.54; 1.69]	0.876	
CCSA class at Randomization									
No Angina	1843	250 (13.6)	1850	219 (11.8)	1.73 [-0.42; 3.88]	1.17 [0.96; 1.42]	1.15 [0.97; 1.36]	0.115	0.608
Angina Class 1 or 2	265	36 (13.6)	260	24 (9.2)	4.35 [-1.12; 9.92]	1.55 [0.89; 2.67]	1.47 [0.90; 2.40]	0.120	
Angina Class 3 or 4	44	3 (6.8)	41	3 (7.3)	-0.50 [-13.70; 12.14]	0.93 [0.18; 4.87]	0.93 [0.20; 4.36]	0.929	
Medical History of Diabetes Mellitus									
Yes	1047	147 (14.0)	984	106 (10.8)	3.27 [0.40; 6.14]	1.35 [1.04; 1.77]	1.30 [1.03; 1.65]	0.027	0.229
No	1105	142 (12.9)	1167	140 (12.0)	0.85 [-1.86; 3.59]	1.08 [0.84; 1.39]	1.07 [0.86; 1.33]	0.537	

Analyses of Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Index Event									
HF Hospitalization within 3 Months	1439	193 (13.4)	1474	159 (10.8)	2.63 [0.26; 5.01]	1.28 [1.02; 1.60]	1.24 [1.02; 1.51]	0.030	0.608
HF Hospitalization 3-6 Months	386	53 (13.7)	362	48 (13.3)	0.47 [-4.50; 5.40]	1.04 [0.68; 1.58]	1.04 [0.72; 1.49]	0.851	
IV diuretic for HF (without hospitalization) within 3 Months	327	43 (13.1)	315	39 (12.4)	0.77 [-4.47; 5.98]	1.07 [0.67; 1.70]	1.06 [0.71; 1.59]	0.771	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 43
Analyses of Serious Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
Age category 1									
<65	831	35 (4.2)	851	22 (2.6)	1.63 [-0.11; 3.45]	1.66 [0.96; 2.85]	1.63 [0.96; 2.75]	0.068	0.067
≥65	1321	39 (3.0)	1300	44 (3.4)	-0.43 [-1.81; 0.93]	0.87 [0.56; 1.35]	0.87 [0.57; 1.33]	0.528	
Age category 2									
<75	1519	56 (3.7)	1533	45 (2.9)	0.75 [-0.53; 2.05]	1.27 [0.85; 1.89]	1.26 [0.85; 1.85]	0.247	0.274
≥75	633	18 (2.8)	618	21 (3.4)	-0.55 [-2.59; 1.43]	0.83 [0.44; 1.58]	0.84 [0.45; 1.56]	0.573	
Gender									
Male	1656	61 (3.7)	1652	54 (3.3)	0.41 [-0.85; 1.69]	1.13 [0.78; 1.64]	1.13 [0.79; 1.61]	0.515	0.937
Female	496	13 (2.6)	499	12 (2.4)	0.22 [-1.84; 2.31]	1.09 [0.49; 2.42]	1.09 [0.50; 2.37]	0.828	
Geographic Region									
Asia Pacific	510	23 (4.5)	502	16 (3.2)	1.32 [-1.10; 3.83]	1.43 [0.75; 2.75]	1.41 [0.76; 2.65]	0.277	0.072
Eastern Europe	721	23 (3.2)	718	16 (2.2)	0.96 [-0.75; 2.74]	1.45 [0.76; 2.76]	1.43 [0.76; 2.69]	0.264	
Latin and South America	316	1 (0.3)	324	8 (2.5)	-2.15 [-4.52; -0.43]	0.21 [0.06; 0.79]	0.21 [0.06; 0.79]	0.021	
North America	240	10 (4.2)	241	12 (5.0)	-0.81 [-4.84; 3.13]	0.83 [0.35; 1.96]	0.84 [0.37; 1.90]	0.670	
Western Europe	365	17 (4.7)	366	14 (3.8)	0.83 [-2.20; 3.94]	1.23 [0.60; 2.53]	1.22 [0.61; 2.43]	0.577	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	6 (2.8)	202	10 (5.0)	-2.13 [-6.40; 1.72]	0.56 [0.20; 1.56]	0.57 [0.21; 1.54]	0.266	0.313
>30 to ≤60	882	38 (4.3)	895	31 (3.5)	0.84 [-0.97; 2.70]	1.25 [0.77; 2.04]	1.24 [0.78; 1.98]	0.358	

Analyses of Serious Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
>60	1021	30 (2.9)	1022	23 (2.3)	0.69 [-0.71; 2.13]	1.31 [0.76; 2.28]	1.31 [0.76; 2.23]	0.330	
NYHA Group at Baseline									
Class I or II	1236	38 (3.1)	1267	33 (2.6)	0.47 [-0.85; 1.82]	1.19 [0.74; 1.90]	1.18 [0.75; 1.87]	0.480	0.739
Class III or IV	914	36 (3.9)	884	33 (3.7)	0.21 [-1.61; 2.02]	1.06 [0.65; 1.71]	1.06 [0.66; 1.68]	0.820	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	12 (3.6)	330	15 (4.5)	-0.90 [-4.14; 2.26]	0.79 [0.37; 1.73]	0.80 [0.38; 1.69]	0.562	0.327
No	1823	62 (3.4)	1820	51 (2.8)	0.60 [-0.54; 1.75]	1.22 [0.84; 1.78]	1.21 [0.84; 1.75]	0.298	
Baseline Ejection Fraction Group 2									
<35	1719	64 (3.7)	1734	59 (3.4)	0.32 [-0.93; 1.58]	1.10 [0.77; 1.57]	1.09 [0.77; 1.55]	0.611	0.660
≥35	433	10 (2.3)	417	7 (1.7)	0.63 [-1.39; 2.73]	1.38 [0.52; 3.67]	1.38 [0.53; 3.58]	0.513	
Race group									
White	1344	50 (3.7)	1353	47 (3.5)	0.25 [-1.18; 1.68]	1.07 [0.72; 1.61]	1.07 [0.72; 1.58]	0.731	0.196
Asian	500	20 (4.0)	474	11 (2.3)	1.68 [-0.56; 4.04]	1.75 [0.83; 3.70]	1.72 [0.83; 3.56]	0.141	
Black	111	3 (2.7)	118	3 (2.5)	0.16 [-4.87; 5.42]	1.06 [0.21; 5.39]	1.06 [0.22; 5.16]	0.939	
Other	196	1 (0.5)	206	5 (2.4)	-1.92 [-5.11; 0.64]	0.27 [0.05; 1.36]	0.27 [0.05; 1.36]	0.114	
CCSA class at Randomization									
No Angina	1843	66 (3.6)	1850	60 (3.2)	0.34 [-0.84; 1.53]	1.11 [0.78; 1.58]	1.10 [0.78; 1.56]	0.572	0.626
Angina Class 1 or 2	265	8 (3.0)	260	5 (1.9)	1.10 [-1.78; 4.16]	1.59 [0.51; 4.92]	1.57 [0.52; 4.74]	0.423	
Angina Class 3 or 4	44	0 (0.0)	41	1 (2.4)	-2.44 [-12.69; 5.78]	0.13 [0.00; 6.35]	0.13 [0.00; 6.35]	0.300	

Analyses of Serious Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus									
Yes	1047	39 (3.7)	984	31 (3.2)	0.57 [-1.04; 2.20]	1.19 [0.74; 1.92]	1.18 [0.74; 1.88]	0.479	0.734
No	1105	35 (3.2)	1167	35 (3.0)	0.17 [-1.28; 1.64]	1.06 [0.66; 1.70]	1.06 [0.67; 1.68]	0.817	
Index Event									
HF Hospitalization within 3 Months	1439	52 (3.6)	1474	48 (3.3)	0.36 [-0.98; 1.71]	1.11 [0.75; 1.66]	1.11 [0.75; 1.63]	0.597	0.946
HF Hospitalization 3-6 Months	386	11 (2.8)	362	8 (2.2)	0.64 [-1.79; 3.10]	1.30 [0.52; 3.26]	1.29 [0.52; 3.17]	0.580	
IV diuretic for HF (without hospitalization) within 3 Months	327	11 (3.4)	315	10 (3.2)	0.19 [-2.78; 3.14]	1.06 [0.44; 2.54]	1.06 [0.46; 2.46]	0.893	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 44
Analyses of Mild Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Me
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Age category 1									
<65	831	48 (5.8)	851	25 (2.9)	2.84 [0.91; 4.89]	2.03 [1.24; 3.32]	1.97 [1.22; 3.16]	0.005	0.129
≥65	1321	74 (5.6)	1300	58 (4.5)	1.14 [-0.54; 2.84]	1.27 [0.89; 1.81]	1.26 [0.90; 1.76]	0.183	
Age category 2									
<75	1519	88 (5.8)	1533	57 (3.7)	2.08 [0.57; 3.62]	1.59 [1.13; 2.24]	1.56 [1.13; 2.16]	0.008	0.513
≥75	633	34 (5.4)	618	26 (4.2)	1.16 [-1.24; 3.61]	1.29 [0.77; 2.18]	1.28 [0.78; 2.10]	0.337	
Gender									
Male	1656	95 (5.7)	1652	65 (3.9)	1.80 [0.34; 3.29]	1.49 [1.08; 2.05]	1.46 [1.07; 1.98]	0.016	0.921
Female	496	27 (5.4)	499	18 (3.6)	1.84 [-0.77; 4.56]	1.54 [0.84; 2.83]	1.51 [0.84; 2.70]	0.167	
Geographic Region									
Asia Pacific	510	35 (6.9)	502	23 (4.6)	2.28 [-0.60; 5.25]	1.53 [0.89; 2.64]	1.50 [0.90; 2.50]	0.122	0.630
Eastern Europe	721	30 (4.2)	718	20 (2.8)	1.38 [-0.54; 3.37]	1.52 [0.85; 2.69]	1.49 [0.86; 2.61]	0.157	
Latin and South America	316	9 (2.8)	324	11 (3.4)	-0.55 [-3.48; 2.34]	0.83 [0.34; 2.04]	0.84 [0.35; 2.00]	0.691	

Analyses of Mild Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Me
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	19 (7.9)	241	9 (3.7)	4.18 [-0.01; 8.73]	2.22 [0.98; 5.00]	2.12 [0.98; 4.59]	0.057	
Western Europe	365	29 (7.9)	366	20 (5.5)	2.48 [-1.18; 6.26]	1.49 [0.83; 2.69]	1.45 [0.84; 2.52]	0.183	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	13 (6.1)	202	9 (4.5)	1.65 [-2.88; 6.27]	1.39 [0.58; 3.34]	1.37 [0.60; 3.13]	0.456	0.648
>30 to ≤60	882	55 (6.2)	895	42 (4.7)	1.54 [-0.58; 3.71]	1.35 [0.89; 2.04]	1.33 [0.90; 1.96]	0.154	
>60	1021	51 (5.0)	1022	29 (2.8)	2.16 [0.49; 3.91]	1.80 [1.13; 2.86]	1.76 [1.13; 2.75]	0.013	
NYHA Group at Baseline									
Class I or II	1236	73 (5.9)	1267	51 (4.0)	1.88 [0.18; 3.63]	1.50 [1.04; 2.16]	1.47 [1.03; 2.08]	0.031	0.963
Class III or IV	914	48 (5.3)	884	32 (3.6)	1.63 [-0.28; 3.59]	1.48 [0.93; 2.33]	1.45 [0.94; 2.25]	0.096	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	28 (8.5)	330	15 (4.5)	3.97 [0.20; 7.95]	1.95 [1.02; 3.73]	1.87 [1.02; 3.44]	0.043	0.362
No	1823	94 (5.2)	1820	68 (3.7)	1.42 [0.08; 2.78]	1.40 [1.02; 1.93]	1.38 [1.02; 1.87]	0.039	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	21 (4.3)	507	22 (4.3)	-0.04 [-2.65; 2.58]	0.99 [0.54; 1.82]	0.99 [0.55; 1.78]	0.972	0.414

Analyses of Mild Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Me
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q2 (1556 - 2816)	520	38 (7.3)	493	19 (3.9)	3.45 [0.64; 6.40]	1.97 [1.12; 3.46]	1.90 [1.11; 3.24]	0.019	
Q3 (2816 - 5314)	511	31 (6.1)	518	19 (3.7)	2.40 [-0.24; 5.17]	1.70 [0.95; 3.04]	1.65 [0.95; 2.89]	0.077	
Q4 (>5314)	548	27 (4.9)	523	18 (3.4)	1.49 [-0.96; 3.99]	1.45 [0.79; 2.67]	1.43 [0.80; 2.57]	0.229	
Baseline Ejection Fraction Group 2									
<35	1719	99 (5.8)	1734	64 (3.7)	2.07 [0.66; 3.51]	1.59 [1.16; 2.20]	1.56 [1.15; 2.12]	0.005	0.395
≥35	433	23 (5.3)	417	19 (4.6)	0.76 [-2.25; 3.78]	1.18 [0.63; 2.19]	1.17 [0.64; 2.11]	0.612	
Race group									
White	1344	78 (5.8)	1353	55 (4.1)	1.74 [0.11; 3.41]	1.45 [1.02; 2.07]	1.43 [1.02; 2.00]	0.038	0.616
Asian	500	29 (5.8)	474	16 (3.4)	2.42 [-0.22; 5.18]	1.76 [0.94; 3.29]	1.72 [0.95; 3.12]	0.076	
Black	111	5 (4.5)	118	2 (1.7)	2.81 [-2.06; 8.65]	2.74 [0.52; 14.40]	2.66 [0.53; 13.42]	0.237	
Other	196	9 (4.6)	206	10 (4.9)	-0.26 [-4.71; 4.23]	0.94 [0.37; 2.37]	0.95 [0.39; 2.28]	0.901	
CCSA class at Randomization									
No Angina	1843	110 (6.0)	1850	73 (3.9)	2.02 [0.63; 3.45]	1.55 [1.14; 2.09]	1.51 [1.13; 2.02]	0.005	0.591

Analyses of Mild Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Me
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Angina Class 1 or 2	265	12 (4.5)	260	9 (3.5)	1.07 [-2.47; 4.71]	1.32 [0.55; 3.19]	1.31 [0.56; 3.05]	0.534	
Angina Class 3 or 4	44	0 (0.0)	41	1 (2.4)	-2.44 [-12.69; 5.78]	0.13 [0.00; 6.35]	0.13 [0.00; 6.35]	0.300	
Medical History of Diabetes Mellitus									
Yes	1047	63 (6.0)	984	38 (3.9)	2.16 [0.27; 4.08]	1.59 [1.06; 2.41]	1.56 [1.05; 2.31]	0.027	0.668
No	1105	59 (5.3)	1167	45 (3.9)	1.48 [-0.24; 3.26]	1.41 [0.95; 2.09]	1.38 [0.95; 2.02]	0.092	
Index Event									
HF Hospitalization within 3 Months	1439	81 (5.6)	1474	53 (3.6)	2.03 [0.52; 3.60]	1.60 [1.12; 2.28]	1.57 [1.12; 2.20]	0.009	0.646
HF Hospitalization 3-6 Months	386	23 (6.0)	362	19 (5.2)	0.71 [-2.71; 4.11]	1.14 [0.61; 2.14]	1.14 [0.63; 2.05]	0.674	
IV diuretic for HF (without hospitalization) within 3 Months	327	18 (5.5)	315	11 (3.5)	2.01 [-1.28; 5.45]	1.61 [0.75; 3.47]	1.58 [0.76; 3.28]	0.224	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 45
Analyses of Moderate Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Me
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
Age category 2									
<75	1519	83 (5.5)	1533	77 (5.0)	0.44 [-1.15; 2.04]	1.09 [0.79; 1.50]	1.09 [0.80; 1.47]	0.585	0.195
≥75	633	32 (5.1)	618	41 (6.6)	-1.58 [-4.27; 1.04]	0.75 [0.47; 1.21]	0.76 [0.49; 1.19]	0.235	
Gender									
Male	1656	94 (5.7)	1652	93 (5.6)	0.05 [-1.54; 1.63]	1.01 [0.75; 1.36]	1.01 [0.76; 1.33]	0.954	0.584
Female	496	21 (4.2)	499	25 (5.0)	-0.78 [-3.49; 1.90]	0.84 [0.46; 1.52]	0.85 [0.48; 1.49]	0.560	
Geographic Region									
Asia Pacific	510	24 (4.7)	502	22 (4.4)	0.32 [-2.32; 2.98]	1.08 [0.60; 1.95]	1.07 [0.61; 1.89]	0.805	0.900
Eastern Europe	721	29 (4.0)	718	32 (4.5)	-0.43 [-2.58; 1.69]	0.90 [0.54; 1.50]	0.90 [0.55; 1.48]	0.683	
Latin and South America	316	13 (4.1)	324	17 (5.2)	-1.13 [-4.60; 2.27]	0.77 [0.37; 1.62]	0.78 [0.39; 1.59]	0.499	
North America	240	17 (7.1)	241	19 (7.9)	-0.80 [-5.70; 4.05]	0.89 [0.45; 1.76]	0.90 [0.48; 1.69]	0.739	
Western Europe	365	32 (8.8)	366	28 (7.7)	1.12 [-2.93; 5.20]	1.16 [0.68; 1.97]	1.15 [0.70; 1.86]	0.583	

Analyses of Moderate Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Me
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category									
≤30	213	10 (4.7)	202	10 (5.0)	-0.26 [-4.74; 4.12]	0.95 [0.39; 2.32]	0.95 [0.40; 2.23]	0.903	0.986
>30 to ≤60	882	54 (6.1)	895	54 (6.0)	0.09 [-2.16; 2.34]	1.02 [0.69; 1.50]	1.01 [0.70; 1.46]	0.937	
>60	1021	50 (4.9)	1022	51 (5.0)	-0.09 [-2.00; 1.81]	0.98 [0.66; 1.46]	0.98 [0.67; 1.44]	0.923	
NYHA Group at Baseline									
Class I or II	1236	66 (5.3)	1267	65 (5.1)	0.21 [-1.55; 1.98]	1.04 [0.73; 1.48]	1.04 [0.75; 1.45]	0.814	0.554
Class III or IV	914	49 (5.4)	884	53 (6.0)	-0.63 [-2.82; 1.52]	0.89 [0.60; 1.32]	0.89 [0.61; 1.30]	0.561	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	22 (6.7)	330	21 (6.4)	0.32 [-3.56; 4.23]	1.05 [0.57; 1.96]	1.05 [0.59; 1.87]	0.867	0.776
No	1823	93 (5.1)	1820	97 (5.3)	-0.23 [-1.69; 1.23]	0.95 [0.71; 1.28]	0.96 [0.73; 1.26]	0.757	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	23 (4.7)	507	27 (5.3)	-0.62 [-3.42; 2.17]	0.88 [0.50; 1.55]	0.88 [0.51; 1.52]	0.653	0.204
Q2 (1556 - 2816)	520	32 (6.2)	493	38 (7.7)	-1.55 [-4.79; 1.60]	0.79 [0.48; 1.28]	0.80 [0.51; 1.26]	0.331	
Q3 (2816 - 5314)	511	30 (5.9)	518	18 (3.5)	2.40 [-0.19; 5.12]	1.73 [0.95; 3.15]	1.69 [0.95; 2.99]	0.072	

Analyses of Moderate Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Me
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q4 (>5314)	548	25 (4.6)	523	26 (5.0)	-0.41 [-3.07; 2.20]	0.91 [0.52; 1.60]	0.92 [0.54; 1.57]	0.753	
Baseline Ejection Fraction Group 2									
<35	1719	95 (5.5)	1734	99 (5.7)	-0.18 [-1.73; 1.36]	0.97 [0.72; 1.29]	0.97 [0.74; 1.27]	0.816	0.892
≥35	433	20 (4.6)	417	19 (4.6)	0.06 [-2.87; 2.97]	1.01 [0.53; 1.93]	1.01 [0.55; 1.87]	0.965	
Race group									
White	1344	80 (6.0)	1353	83 (6.1)	-0.18 [-2.00; 1.63]	0.97 [0.71; 1.33]	0.97 [0.72; 1.31]	0.843	0.637
Asian	500	20 (4.0)	474	15 (3.2)	0.84 [-1.59; 3.29]	1.27 [0.64; 2.52]	1.26 [0.65; 2.44]	0.485	
Black	111	4 (3.6)	118	8 (6.8)	-3.18 [-9.72; 3.01]	0.51 [0.15; 1.76]	0.53 [0.16; 1.72]	0.291	
Other	196	11 (5.6)	206	12 (5.8)	-0.21 [-5.00; 4.64]	0.96 [0.41; 2.23]	0.96 [0.44; 2.13]	0.927	
CCSA class at Randomization									
No Angina	1843	100 (5.4)	1850	105 (5.7)	-0.25 [-1.74; 1.24]	0.95 [0.72; 1.26]	0.96 [0.73; 1.25]	0.740	0.899
Angina Class 1 or 2	265	13 (4.9)	260	11 (4.2)	0.67 [-3.10; 4.49]	1.17 [0.51; 2.66]	1.16 [0.53; 2.54]	0.712	
Angina Class 3 or 4	44	2 (4.5)	41	2 (4.9)	-0.33 [-12.30; 11.05]	0.93 [0.12; 6.92]	0.93 [0.14; 6.31]	0.942	

Analyses of Moderate Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Me
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
Medical History of Diabetes Mellitus									
Yes	1047	58 (5.5)	984	44 (4.5)	1.07 [-0.85; 2.99]	1.25 [0.84; 1.87]	1.24 [0.85; 1.82]	0.272	0.103
No	1105	57 (5.2)	1167	74 (6.3)	-1.18 [-3.12; 0.75]	0.80 [0.56; 1.15]	0.81 [0.58; 1.14]	0.228	
Index Event									
HF Hospitalization within 3 Months	1439	75 (5.2)	1474	73 (5.0)	0.26 [-1.35; 1.88]	1.06 [0.76; 1.47]	1.05 [0.77; 1.44]	0.750	0.695
HF Hospitalization 3-6 Months	386	24 (6.2)	362	26 (7.2)	-0.96 [-4.70; 2.67]	0.86 [0.48; 1.52]	0.87 [0.51; 1.48]	0.598	
IV diuretic for HF (without hospitalization) within 3 Months	327	16 (4.9)	315	19 (6.0)	-1.14 [-4.86; 2.47]	0.80 [0.40; 1.59]	0.81 [0.42; 1.55]	0.526	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 46
Analyses of Severe Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Me
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Age category 1									
<65	831	35 (4.2)	851	28 (3.3)	0.92 [-0.92; 2.81]	1.29 [0.78; 2.14]	1.28 [0.79; 2.08]	0.321	0.541
≥65	1321	47 (3.6)	1300	44 (3.4)	0.17 [-1.25; 1.60]	1.05 [0.69; 1.60]	1.05 [0.70; 1.57]	0.809	
Age category 2									
<75	1519	56 (3.7)	1533	49 (3.2)	0.49 [-0.82; 1.81]	1.16 [0.78; 1.71]	1.15 [0.79; 1.68]	0.458	0.898
≥75	633	26 (4.1)	618	23 (3.7)	0.39 [-1.83; 2.61]	1.11 [0.63; 1.96]	1.10 [0.64; 1.91]	0.725	
Gender									
Male	1656	63 (3.8)	1652	62 (3.8)	0.05 [-1.26; 1.37]	1.01 [0.71; 1.45]	1.01 [0.72; 1.43]	0.938	0.128
Female	496	19 (3.8)	499	10 (2.0)	1.83 [-0.28; 4.12]	1.95 [0.90; 4.23]	1.91 [0.90; 4.07]	0.093	
Geographic Region									
Asia Pacific	510	19 (3.7)	502	17 (3.4)	0.34 [-2.04; 2.73]	1.10 [0.57; 2.15]	1.10 [0.58; 2.09]	0.771	0.448
Eastern Europe	721	30 (4.2)	718	19 (2.6)	1.51 [-0.37; 3.49]	1.60 [0.89; 2.86]	1.57 [0.89; 2.77]	0.117	
Latin and South America	316	3 (0.9)	324	7 (2.2)	-1.21 [-3.56; 0.86]	0.46 [0.13; 1.59]	0.46 [0.13; 1.59]	0.217	

Analyses of Severe Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Me
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	13 (5.4)	241	14 (5.8)	-0.39 [-4.74; 3.93]	0.93 [0.43; 2.02]	0.93 [0.45; 1.94]	0.852	
Western Europe	365	17 (4.7)	366	15 (4.1)	0.56 [-2.53; 3.69]	1.14 [0.56; 2.32]	1.14 [0.58; 2.24]	0.712	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	9 (4.2)	202	9 (4.5)	-0.23 [-4.54; 3.96]	0.95 [0.37; 2.43]	0.95 [0.38; 2.34]	0.908	0.860
>30 to ≤60	882	40 (4.5)	895	34 (3.8)	0.74 [-1.14; 2.65]	1.20 [0.75; 1.92]	1.19 [0.76; 1.87]	0.438	
>60	1021	33 (3.2)	1022	26 (2.5)	0.69 [-0.79; 2.20]	1.28 [0.76; 2.16]	1.27 [0.77; 2.11]	0.354	
NYHA Group at Baseline									
Class I or II	1236	39 (3.2)	1267	39 (3.1)	0.08 [-1.31; 1.47]	1.03 [0.65; 1.61]	1.03 [0.66; 1.59]	0.912	0.512
Class III or IV	914	43 (4.7)	884	33 (3.7)	0.97 [-0.91; 2.88]	1.27 [0.80; 2.02]	1.26 [0.81; 1.96]	0.307	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	19 (3.9)	507	20 (3.9)	-0.06 [-2.56; 2.46]	0.98 [0.52; 1.87]	0.98 [0.53; 1.82]	0.962	0.196
Q2 (1556 - 2816)	520	23 (4.4)	493	11 (2.2)	2.19 [-0.03; 4.56]	2.03 [0.98; 4.21]	1.98 [0.98; 4.02]	0.058	
Q3 (2816 - 5314)	511	21 (4.1)	518	17 (3.3)	0.83 [-1.54; 3.26]	1.26 [0.66; 2.42]	1.25 [0.67; 2.35]	0.482	

Analyses of Severe Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Me
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q4 (>5314)	548	17 (3.1)	523	22 (4.2)	-1.10 [-3.50; 1.18]	0.73 [0.38; 1.39]	0.74 [0.40; 1.37]	0.337	
Baseline Ejection Fraction Group 2									
<35	1719	69 (4.0)	1734	61 (3.5)	0.50 [-0.78; 1.79]	1.15 [0.81; 1.63]	1.14 [0.81; 1.60]	0.444	0.993
≥35	433	13 (3.0)	417	11 (2.6)	0.36 [-2.01; 2.75]	1.14 [0.51; 2.58]	1.14 [0.52; 2.51]	0.749	
Race group									
White	1344	59 (4.4)	1353	54 (4.0)	0.40 [-1.13; 1.94]	1.10 [0.76; 1.61]	1.10 [0.77; 1.58]	0.605	0.674
Asian	500	16 (3.2)	474	11 (2.3)	0.88 [-1.27; 3.09]	1.39 [0.64; 3.03]	1.38 [0.65; 2.94]	0.406	
Black	111	5 (4.5)	118	3 (2.5)	1.96 [-3.32; 7.91]	1.81 [0.42; 7.75]	1.77 [0.43; 7.24]	0.426	
Other	196	2 (1.0)	206	4 (1.9)	-0.92 [-4.00; 1.92]	0.52 [0.09; 2.87]	0.53 [0.10; 2.84]	0.455	
CCSA class at Randomization									
No Angina	1843	67 (3.6)	1850	65 (3.5)	0.12 [-1.09; 1.34]	1.04 [0.73; 1.47]	1.03 [0.74; 1.45]	0.842	0.375
Angina Class 1 or 2	265	14 (5.3)	260	7 (2.7)	2.59 [-0.83; 6.30]	2.02 [0.80; 5.08]	1.96 [0.81; 4.78]	0.138	
Angina Class 3 or 4	44	1 (2.3)	41	0 (0.0)	2.27 [-6.49; 11.89]	6.90 [0.14; 348.69]	6.90 [0.14; 348.69]	0.334	

Analyses of Severe Adverse Event of Clinical Interest for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Me
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus									
Yes	1047	44 (4.2)	984	32 (3.3)	0.95 [-0.72; 2.64]	1.31 [0.82; 2.08]	1.29 [0.83; 2.02]	0.261	0.426
No	1105	38 (3.4)	1167	40 (3.4)	0.01 [-1.51; 1.55]	1.00 [0.64; 1.58]	1.00 [0.65; 1.55]	0.988	
Index Event									
HF Hospitalization within 3 Months	1439	58 (4.0)	1474	53 (3.6)	0.43 [-0.97; 1.86]	1.13 [0.77; 1.65]	1.12 [0.78; 1.62]	0.540	0.905
HF Hospitalization 3-6 Months	386	13 (3.4)	362	9 (2.5)	0.88 [-1.68; 3.50]	1.37 [0.58; 3.24]	1.35 [0.59; 3.13]	0.478	
IV diuretic for HF (without hospitalization) within 3 Months	327	11 (3.4)	315	10 (3.2)	0.19 [-2.78; 3.14]	1.06 [0.44; 2.54]	1.06 [0.46; 2.46]	0.893	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

1.8 Adverse Event by SOC and PT Endpoints by Subgroup

1.8.1 Adverse Events by SOC and PT

Table 47
Overview of Subgroup Analyses for Adverse Event Related Endpoints
Treatment by Subgroup Interaction
by System Organ Class and Preferred Term
(Incidence ≥10% or (≥1% and in at least 10 Participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**						
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 0 / >30 to ≤ 60 / >60)**	**NYHA Group at Baseline (Class I or II / Class III or IV)**	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**
Adverse Events by SOC and PT[c] - Event							
Blood and lymphatic system disorders	0.651	0.442	0.925	0.982	0.907	0.578	0.218
Anaemia	0.710	0.857	0.577	0.522	0.460	0.697	0.081
Cardiac disorders	0.088	**0.048[d]**	0.588	0.669	0.387	0.334	0.522
Cardiac failure	0.336	0.509	0.980	0.227	0.900	0.088	0.391
Cardiac failure chronic	**0.016[d]**	0.690	0.553	0.590	0.569	0.605	0.404
Ventricular tachycardia	**0.015[d]**	0.123	0.921	0.389	0.897	0.954	0.982
Gastrointestinal disorders	0.897	0.622	0.057	0.301	0.114	**0.040[d]**	0.424

Overview of Subgroup Analyses for Adverse Event Related Endpoints
Treatment by Subgroup Interaction
by System Organ Class and Preferred Term
(Incidence ≥10% or (≥1% and in at least 10 Participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**					
	NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**
Adverse Events by SOC and PT[c] - Event						
Blood and lymphatic system disorders	0.314	0.414	0.789	0.578	0.148	0.278
Anaemia	0.464	0.120	0.482	0.759	0.127	0.204
Cardiac disorders	0.655	0.193	0.875	0.684	0.069	0.183
Cardiac failure	0.831	**0.019[d]**	0.340	0.850	0.193	0.713
Cardiac failure chronic	0.109	0.230	0.474	0.432	0.496	0.722
Ventricular tachycardia	0.652	0.353	0.266	0.867	0.920	0.074
Gastrointestinal disorders	0.386	0.552	0.641	**0.032[d]**	0.840	0.763

Overview of Subgroup Analyses for Adverse Event Related Endpoints
Treatment by Subgroup Interaction
by System Organ Class and Preferred Term
(Incidence ≥10% or (≥1% and in at least 10 Participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**						
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 0 / >30 to ≤ 60 / >60)**	**NYHA Group at Baseline (Class I or II / Class III or IV)**	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**
Dyspepsia	0.090	0.637	0.166	0.529	0.247	0.508	0.752
Gastrooesophageal reflux disease	0.566	0.333	0.236	0.291	0.229	0.277	0.218
Metabolism and nutrition disorders	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Hyponatraemia	0.488	0.785	0.359	0.403	0.371	0.891	0.698
Psychiatric disorders	0.669	0.779	0.538	0.165	0.949	0.483	0.541
Respiratory, thoracic and mediastinal disorders	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Epistaxis	**0.032[d]**	0.071	0.378	0.290	**0.011[d]**	0.899	0.122

Overview of Subgroup Analyses for Adverse Event Related Endpoints
Treatment by Subgroup Interaction
by System Organ Class and Preferred Term
(Incidence ≥10% or (≥1% and in at least 10 Participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**					
	NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**
Dyspepsia	0.232	0.523	0.634	0.179	0.365	0.977
Gastrooesophageal reflux disease	0.336	0.985	0.208	0.711	0.848	0.185
Metabolism and nutrition disorders	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Hyponatraemia	0.745	0.851	0.107	0.964	0.666	0.874
Psychiatric disorders	0.610	0.572	0.954	0.080	0.421	0.850
Respiratory, thoracic and mediastinal disorders	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Epistaxis	0.320	0.649	0.844	0.636	0.992	0.395

a: Database Cutoff Date: 18JUN2019

b: Based on a Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if Participant has 0 event in at least one cell of the stratum.

c: A system organ class or specific adverse event appears on this report only if its incidence is ≥ 10% or ≥ 1% and in at least 10 patients in one or more treatment groups and p-value for main treatment effect smaller than 0.05

d: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; n.p.: not performed (subgroup analysis not performed as nominal p-value of main treatment effect greater or equal than 0.05); NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; PT: Preferred Term; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile; SOC: System Organ Class

1.8.1.1 Results for Subgroups with Interaction Nominal P-value < 0.05

Table 48
Analyses of Adverse Event for Subgroups with P-value for Interaction Test < 0.05
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Cardiac disorders									
Age category 2									
<75	1519	381 (25.1)	1533	406 (26.5)	-1.40 [-4.50; 1.70]	0.93 [0.79; 1.09]	0.95 [0.84; 1.07]	0.376	0.048
≥75	633	123 (19.4)	618	162 (26.2)	-6.78 [-11.43; -2.14]	0.68 [0.52; 0.89]	0.74 [0.60; 0.91]	0.004	
SOC: Gastrointestinal disorders									
NYHA Group at Baseline									
Class I or II	1236	302 (24.4)	1267	246 (19.4)	5.02 [1.78; 8.26]	1.34 [1.11; 1.62]	1.26 [1.08; 1.46]	0.002	0.040
Class III or IV	914	235 (25.7)	884	228 (25.8)	-0.08 [-4.13; 3.96]	1.00 [0.81; 1.23]	1.00 [0.85; 1.17]	0.969	
CCSA class at Randomization									
No Angina	1843	457 (24.8)	1850	418 (22.6)	2.20 [-0.54; 4.94]	1.13 [0.97; 1.31]	1.10 [0.98; 1.23]	0.116	0.032
Angina Class 1 or 2	265	72 (27.2)	260	44 (16.9)	10.25 [3.17; 17.29]	1.83 [1.20; 2.79]	1.61 [1.15; 2.24]	0.005	
Angina Class 3 or 4	44	8 (18.2)	41	12 (29.3)	-11.09 [-29.23; 7.18]	0.54 [0.19; 1.49]	0.62 [0.28; 1.36]	0.236	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.
h: A specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is smaller than 0.05 and rule of 10 is met
CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 49
Analyses of Adverse Event for Subgroups with P-value for Interaction Test < 0.05
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Group s)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Cardiac disorders PT[h]: Cardiac failure									
Baseline Ejection Fraction Group 2									
<35	1719	166 (9.7)	1734	182 (10.5)	-0.84 [-2.86; 1.17]	0.91 [0.73; 1.14]	0.92 [0.75; 1.12]	0.413	0.019
≥35	433	26 (6.0)	417	49 (11.8)	-5.75 [-9.71; -1.96]	0.48 [0.29; 0.79]	0.51 [0.32; 0.81]	0.004	
SOC: Cardiac disorders PT[h]: Cardiac failure chronic									
Age category 1									
<65	831	10 (1.2)	851	8 (0.9)	0.26 [-0.79; 1.37]	1.28 [0.51; 3.25]	1.28 [0.51; 3.25]	0.600	0.016
≥65	1321	7 (0.5)	1300	24 (1.8)	-1.32 [-2.26; -0.52]	0.32 [0.16; 0.66]	0.32 [0.16; 0.66]	0.002	
SOC: Cardiac disorders PT[h]: Ventricular tachycardia									
Age category 1									
<65	831	18 (2.2)	851	15 (1.8)	0.40 [-0.97; 1.82]	1.23 [0.62; 2.47]	1.23 [0.62; 2.42]	0.552	0.015
≥65	1321	17 (1.3)	1300	40 (3.1)	-1.79 [-2.99; -0.69]	0.41 [0.23; 0.73]	0.42 [0.24; 0.73]	0.002	
SOC: Respiratory, thoracic and mediastinal disorders PT[h]: Epistaxis									
Age category 1									
<65	831	12 (1.4)	851	9 (1.1)	0.39 [-0.73; 1.57]	1.37 [0.57; 3.27]	1.37 [0.58; 3.22]	0.477	0.032
≥65	1321	19 (1.4)	1300	41 (3.2)	-1.72 [-2.94; -0.59]	0.45 [0.26; 0.78]	0.46 [0.27; 0.78]	0.004	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	8 (3.8)	202	11 (5.4)	-1.69 [-6.18; 2.51]	0.68 [0.27; 1.72]	0.69 [0.28; 1.68]	0.413	0.011

Analyses of Adverse Event for Subgroups with P-value for Interaction Test < 0.05
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Group s)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
>30 to ≤60	882	8 (0.9)	895	30 (3.4)	-2.44 [-3.93; -1.16]	0.31 [0.16; 0.59]	0.31 [0.16; 0.59]	< 0.001	
>60	1021	13 (1.3)	1022	9 (0.9)	0.39 [-0.55; 1.39]	1.45 [0.62; 3.35]	1.45 [0.62; 3.35]	0.390	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

h: A specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is smaller than 0.05 and rule of 10 is met

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

1.8.1.2 Results for Subgroups with Interaction Nominal P-value ≥ 0.05

Table 50
Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Blood and lymphatic system disorders									
Age category 1									
<65	831	70 (8.4)	851	51 (6.0)	2.43 [-0.04; 4.96]	1.44 [0.99; 2.10]	1.41 [0.99; 1.99]	0.055	0.651
≥65	1321	153 (11.6)	1300	119 (9.2)	2.43 [0.09; 4.78]	1.30 [1.01; 1.67]	1.27 [1.01; 1.59]	0.042	
Age category 2									
<75	1519	147 (9.7)	1533	107 (7.0)	2.70 [0.74; 4.68]	1.43 [1.10; 1.85]	1.39 [1.09; 1.76]	0.007	0.442
≥75	633	76 (12.0)	618	63 (10.2)	1.81 [-1.69; 5.32]	1.20 [0.84; 1.71]	1.18 [0.86; 1.61]	0.309	
Gender									
Male	1656	173 (10.4)	1652	131 (7.9)	2.52 [0.55; 4.50]	1.35 [1.07; 1.72]	1.32 [1.06; 1.64]	0.013	0.925
Female	496	50 (10.1)	499	39 (7.8)	2.27 [-1.30; 5.89]	1.32 [0.85; 2.05]	1.29 [0.86; 1.92]	0.212	
Geographic Region									
Asia Pacific	510	51 (10.0)	502	36 (7.2)	2.83 [-0.64; 6.35]	1.44 [0.92; 2.25]	1.39 [0.93; 2.10]	0.111	0.982
Eastern Europe	721	78 (10.8)	718	63 (8.8)	2.04 [-1.04; 5.15]	1.26 [0.89; 1.79]	1.23 [0.90; 1.69]	0.193	
Latin and South America	316	34 (10.8)	324	24 (7.4)	3.35 [-1.12; 7.96]	1.51 [0.87; 2.60]	1.45 [0.88; 2.39]	0.143	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	25 (10.4)	241	20 (8.3)	2.12 [-3.18; 7.50]	1.28 [0.69; 2.38]	1.26 [0.72; 2.20]	0.426	
Western Europe	365	35 (9.6)	366	27 (7.4)	2.21 [-1.87; 6.37]	1.33 [0.79; 2.25]	1.30 [0.80; 2.10]	0.285	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	32 (15.0)	202	24 (11.9)	3.14 [-3.52; 9.80]	1.31 [0.74; 2.31]	1.26 [0.77; 2.07]	0.351	0.907
>30 to ≤60	882	111 (12.6)	895	90 (10.1)	2.53 [-0.42; 5.50]	1.29 [0.96; 1.73]	1.25 [0.96; 1.63]	0.093	
>60	1021	78 (7.6)	1022	56 (5.5)	2.16 [0.01; 4.35]	1.43 [1.00; 2.03]	1.39 [1.00; 1.94]	0.050	
NYHA Group at Baseline									
Class I or II	1236	116 (9.4)	1267	86 (6.8)	2.60 [0.47; 4.76]	1.42 [1.06; 1.90]	1.38 [1.06; 1.81]	0.018	0.578
Class III or IV	914	107 (11.7)	884	84 (9.5)	2.20 [-0.65; 5.07]	1.26 [0.93; 1.71]	1.23 [0.94; 1.61]	0.130	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	34 (10.3)	330	19 (5.8)	4.58 [0.43; 8.91]	1.89 [1.05; 3.38]	1.79 [1.05; 3.08]	0.034	0.218
No	1823	189 (10.4)	1820	151 (8.3)	2.07 [0.18; 3.97]	1.28 [1.02; 1.60]	1.25 [1.02; 1.53]	0.032	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	32 (6.5)	507	26 (5.1)	1.42 [-1.53; 4.44]	1.30 [0.76; 2.21]	1.28 [0.77; 2.11]	0.342	0.314

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q2 (1556 - 2816)	520	60 (11.5)	493	34 (6.9)	4.64 [1.09; 8.26]	1.76 [1.13; 2.73]	1.67 [1.12; 2.50]	0.012	
Q3 (2816 - 5314)	511	57 (11.2)	518	47 (9.1)	2.08 [-1.62; 5.83]	1.26 [0.84; 1.89]	1.23 [0.85; 1.77]	0.269	
Q4 (>5314)	548	59 (10.8)	523	56 (10.7)	0.06 [-3.70; 3.79]	1.01 [0.68; 1.48]	1.01 [0.71; 1.42]	0.975	
Baseline Ejection Fraction Group 2									
<35	1719	170 (9.9)	1734	125 (7.2)	2.68 [0.82; 4.56]	1.41 [1.11; 1.80]	1.37 [1.10; 1.71]	0.005	0.414
≥35	433	53 (12.2)	417	45 (10.8)	1.45 [-2.89; 5.79]	1.15 [0.76; 1.76]	1.13 [0.78; 1.65]	0.509	
Race group									
White	1344	131 (9.7)	1353	106 (7.8)	1.91 [-0.23; 4.07]	1.27 [0.97; 1.66]	1.24 [0.97; 1.59]	0.080	0.789
Asian	500	48 (9.6)	474	35 (7.4)	2.22 [-1.32; 5.78]	1.33 [0.85; 2.10]	1.30 [0.86; 1.97]	0.218	
Black	111	12 (10.8)	118	8 (6.8)	4.03 [-3.48; 12.03]	1.67 [0.65; 4.24]	1.59 [0.68; 3.75]	0.285	
Other	196	32 (16.3)	206	21 (10.2)	6.13 [-0.50; 12.97]	1.72 [0.95; 3.10]	1.60 [0.96; 2.68]	0.073	
CCSA class at Randomization									
No Angina	1843	188 (10.2)	1850	145 (7.8)	2.36 [0.52; 4.22]	1.34 [1.06; 1.68]	1.30 [1.06; 1.60]	0.013	0.578

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Angina Class 1 or 2	265	31 (11.7)	260	20 (7.7)	4.01 [-1.10; 9.23]	1.59 [0.88; 2.87]	1.52 [0.89; 2.60]	0.125	
Angina Class 3 or 4	44	4 (9.1)	41	5 (12.2)	-3.10 [-17.95; 11.02]	0.72 [0.18; 2.89]	0.75 [0.21; 2.59]	0.643	
Medical History of Diabetes Mellitus									
Yes	1047	128 (12.2)	984	81 (8.2)	3.99 [1.36; 6.64]	1.55 [1.16; 2.08]	1.49 [1.14; 1.93]	0.003	0.148
No	1105	95 (8.6)	1167	89 (7.6)	0.97 [-1.28; 3.25]	1.14 [0.84; 1.54]	1.13 [0.85; 1.49]	0.397	
Index Event									
HF Hospitalization within 3 Months	1439	154 (10.7)	1474	113 (7.7)	3.04 [0.94; 5.16]	1.44 [1.12; 1.86]	1.40 [1.11; 1.76]	0.005	0.278
HF Hospitalization 3-6 Months	386	34 (8.8)	362	34 (9.4)	-0.58 [-4.82; 3.58]	0.93 [0.57; 1.53]	0.94 [0.60; 1.48]	0.781	
IV diuretic for HF (without hospitalization) within 3 Months	327	35 (10.7)	315	23 (7.3)	3.40 [-1.07; 7.95]	1.52 [0.88; 2.64]	1.47 [0.89; 2.42]	0.136	
SOC: Cardiac disorders									
Age category 1									
<65	831	213 (25.6)	851	220 (25.9)	-0.22 [-4.40; 3.96]	0.99 [0.79; 1.23]	0.99 [0.84; 1.17]	0.918	0.088
≥65	1321	291 (22.0)	1300	348 (26.8)	-4.74 [-8.03; -1.45]	0.77 [0.65; 0.92]	0.82 [0.72; 0.94]	0.005	
Gender									
Male	1656	410 (24.8)	1652	454 (27.5)	-2.72 [-5.72; 0.27]	0.87 [0.74; 1.01]	0.90 [0.80; 1.01]	0.075	0.588

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Female	496	94 (19.0)	499	114 (22.8)	-3.89 [-8.95; 1.17]	0.79 [0.58; 1.07]	0.83 [0.65; 1.06]	0.132	
Geographic Region									
Asia Pacific	510	108 (21.2)	502	130 (25.9)	-4.72 [-9.95; 0.51]	0.77 [0.57; 1.03]	0.82 [0.65; 1.02]	0.078	0.669
Eastern Europe	721	182 (25.2)	718	186 (25.9)	-0.66 [-5.17; 3.85]	0.97 [0.76; 1.22]	0.97 [0.82; 1.16]	0.773	
Latin and South America	316	59 (18.7)	324	78 (24.1)	-5.40 [-11.75; 0.96]	0.72 [0.49; 1.06]	0.78 [0.57; 1.05]	0.097	
North America	240	61 (25.4)	241	66 (27.4)	-1.97 [-9.85; 5.93]	0.90 [0.60; 1.36]	0.93 [0.69; 1.25]	0.624	
Western Europe	365	94 (25.8)	366	108 (29.5)	-3.75 [-10.23; 2.74]	0.83 [0.60; 1.15]	0.87 [0.69; 1.10]	0.257	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	50 (23.5)	202	46 (22.8)	0.70 [-7.47; 8.82]	1.04 [0.66; 1.64]	1.03 [0.73; 1.46]	0.865	0.387
>30 to ≤60	882	218 (24.7)	895	266 (29.7)	-5.00 [-9.13; -0.86]	0.78 [0.63; 0.96]	0.83 [0.71; 0.97]	0.018	
>60	1021	229 (22.4)	1022	246 (24.1)	-1.64 [-5.31; 2.03]	0.91 [0.74; 1.12]	0.93 [0.80; 1.09]	0.380	
NYHA Group at Baseline									
Class I or II	1236	264 (21.4)	1267	321 (25.3)	-3.98 [-7.29; -0.66]	0.80 [0.66; 0.96]	0.84 [0.73; 0.97]	0.019	0.334

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Class III or IV	914	240 (26.3)	884	247 (27.9)	-1.68 [-5.80; 2.43]	0.92 [0.75; 1.13]	0.94 [0.81; 1.09]	0.422	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	77 (23.4)	330	94 (28.5)	-5.08 [-11.76; 1.62]	0.77 [0.54; 1.09]	0.82 [0.63; 1.07]	0.138	0.522
No	1823	427 (23.4)	1820	474 (26.0)	-2.62 [-5.42; 0.18]	0.87 [0.75; 1.01]	0.90 [0.80; 1.01]	0.067	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	107 (21.9)	507	111 (21.9)	-0.01 [-5.15; 5.14]	1.00 [0.74; 1.35]	1.00 [0.79; 1.26]	0.996	0.655
Q2 (1556 - 2816)	520	128 (24.6)	493	138 (28.0)	-3.38 [-8.81; 2.05]	0.84 [0.63; 1.11]	0.88 [0.72; 1.08]	0.223	
Q3 (2816 - 5314)	511	122 (23.9)	518	148 (28.6)	-4.70 [-10.06; 0.68]	0.78 [0.59; 1.04]	0.84 [0.68; 1.03]	0.088	
Q4 (>5314)	548	125 (22.8)	523	141 (27.0)	-4.15 [-9.34; 1.03]	0.80 [0.61; 1.06]	0.85 [0.69; 1.04]	0.117	
Baseline Ejection Fraction Group 2									
<35	1719	414 (24.1)	1734	455 (26.2)	-2.16 [-5.05; 0.74]	0.89 [0.76; 1.04]	0.92 [0.82; 1.03]	0.145	0.193
≥35	433	90 (20.8)	417	113 (27.1)	-6.31 [-12.05; -0.58]	0.71 [0.51; 0.97]	0.77 [0.60; 0.98]	0.032	
Race group									
White	1344	339 (25.2)	1353	373 (27.6)	-2.35 [-5.67; 0.98]	0.89 [0.75; 1.05]	0.91 [0.81; 1.04]	0.167	0.875

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Asian	500	99 (19.8)	474	110 (23.2)	-3.41 [-8.59; 1.76]	0.82 [0.60; 1.11]	0.85 [0.67; 1.09]	0.196	
Black	111	21 (18.9)	118	28 (23.7)	-4.81 [-15.43; 5.94]	0.75 [0.40; 1.42]	0.80 [0.48; 1.32]	0.377	
Other	196	44 (22.4)	206	57 (27.7)	-5.22 [-13.65; 3.30]	0.76 [0.48; 1.19]	0.81 [0.58; 1.14]	0.230	
CCSA class at Randomization									
No Angina	1843	433 (23.5)	1850	485 (26.2)	-2.72 [-5.51; 0.07]	0.86 [0.74; 1.00]	0.90 [0.80; 1.00]	0.056	0.684
Angina Class 1 or 2	265	61 (23.0)	260	69 (26.5)	-3.52 [-10.92; 3.88]	0.83 [0.56; 1.23]	0.87 [0.64; 1.17]	0.351	
Angina Class 3 or 4	44	10 (22.7)	41	14 (34.1)	-11.42 [-30.31; 7.88]	0.57 [0.22; 1.48]	0.67 [0.33; 1.33]	0.248	
Medical History of Diabetes Mellitus									
Yes	1047	259 (24.7)	984	248 (25.2)	-0.47 [-4.24; 3.30]	0.98 [0.80; 1.19]	0.98 [0.84; 1.14]	0.808	0.069
No	1105	245 (22.2)	1167	320 (27.4)	-5.25 [-8.79; -1.70]	0.75 [0.62; 0.91]	0.81 [0.70; 0.93]	0.004	
Index Event									
HF Hospitalization within 3 Months	1439	323 (22.4)	1474	374 (25.4)	-2.93 [-6.02; 0.17]	0.85 [0.72; 1.01]	0.88 [0.78; 1.01]	0.065	0.183
HF Hospitalization 3-6 Months	386	94 (24.4)	362	115 (31.8)	-7.42 [-13.84; -0.98]	0.69 [0.50; 0.95]	0.77 [0.61; 0.97]	0.025	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
IV diuretic for HF (without hospitalization) within 3 Months	327	87 (26.6)	315	79 (25.1)	1.53 [-5.27; 8.29]	1.08 [0.76; 1.54]	1.06 [0.82; 1.38]	0.659	
SOC: Gastrointestinal disorders									
Age category 1									
<65	831	192 (23.1)	851	175 (20.6)	2.54 [-1.41; 6.50]	1.16 [0.92; 1.46]	1.12 [0.94; 1.35]	0.208	0.897
≥65	1321	345 (26.1)	1300	299 (23.0)	3.12 [-0.18; 6.41]	1.18 [0.99; 1.41]	1.14 [0.99; 1.30]	0.064	
Age category 2									
<75	1519	366 (24.1)	1533	332 (21.7)	2.44 [-0.54; 5.42]	1.15 [0.97; 1.36]	1.11 [0.98; 1.27]	0.109	0.622
≥75	633	171 (27.0)	618	142 (23.0)	4.04 [-0.77; 8.83]	1.24 [0.96; 1.60]	1.18 [0.97; 1.43]	0.100	
Gender									
Male	1656	394 (23.8)	1652	368 (22.3)	1.52 [-1.35; 4.39]	1.09 [0.93; 1.28]	1.07 [0.94; 1.21]	0.301	0.057
Female	496	143 (28.8)	499	106 (21.2)	7.59 [2.21; 12.95]	1.50 [1.12; 2.01]	1.36 [1.09; 1.69]	0.006	
Geographic Region									
Asia Pacific	510	153 (30.0)	502	123 (24.5)	5.50 [0.01; 10.96]	1.32 [1.00; 1.74]	1.22 [1.00; 1.50]	0.050	0.301
Eastern Europe	721	169 (23.4)	718	133 (18.5)	4.92 [0.71; 9.12]	1.35 [1.04; 1.74]	1.27 [1.03; 1.55]	0.023	
Latin and South America	316	60 (19.0)	324	55 (17.0)	2.01 [-3.96; 8.01]	1.15 [0.77; 1.72]	1.12 [0.80; 1.56]	0.508	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	72 (30.0)	241	73 (30.3)	-0.29 [-8.49; 7.91]	0.99 [0.67; 1.46]	0.99 [0.75; 1.30]	0.945	
Western Europe	365	83 (22.7)	366	90 (24.6)	-1.85 [-8.02; 4.33]	0.90 [0.64; 1.27]	0.92 [0.71; 1.20]	0.556	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	52 (24.4)	202	60 (29.7)	-5.29 [-13.84; 3.27]	0.76 [0.49; 1.18]	0.82 [0.60; 1.13]	0.226	0.114
>30 to ≤60	882	235 (26.6)	895	207 (23.1)	3.52 [-0.51; 7.53]	1.21 [0.97; 1.50]	1.15 [0.98; 1.35]	0.087	
>60	1021	242 (23.7)	1022	201 (19.7)	4.03 [0.46; 7.61]	1.27 [1.03; 1.57]	1.21 [1.02; 1.42]	0.027	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	83 (25.2)	330	66 (20.0)	5.23 [-1.17; 11.62]	1.35 [0.94; 1.95]	1.26 [0.95; 1.68]	0.110	0.424
No	1823	454 (24.9)	1820	408 (22.4)	2.49 [-0.27; 5.25]	1.15 [0.98; 1.34]	1.11 [0.99; 1.25]	0.078	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	135 (27.6)	507	106 (20.9)	6.70 [1.38; 12.02]	1.44 [1.08; 1.93]	1.32 [1.06; 1.65]	0.014	0.386
Q2 (1556 - 2816)	520	129 (24.8)	493	118 (23.9)	0.87 [-4.43; 6.16]	1.05 [0.79; 1.40]	1.04 [0.83; 1.29]	0.747	
Q3 (2816 - 5314)	511	123 (24.1)	518	112 (21.6)	2.45 [-2.69; 7.59]	1.15 [0.86; 1.54]	1.11 [0.89; 1.39]	0.350	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q4 (>5314)	548	128 (23.4)	523	117 (22.4)	0.99 [-4.06; 6.02]	1.06 [0.79; 1.41]	1.04 [0.84; 1.30]	0.701	
Baseline Ejection Fraction Group 2									
<35	1719	415 (24.1)	1734	376 (21.7)	2.46 [-0.35; 5.26]	1.15 [0.98; 1.35]	1.11 [0.98; 1.26]	0.086	0.552
≥35	433	122 (28.2)	417	98 (23.5)	4.67 [-1.22; 10.54]	1.28 [0.94; 1.74]	1.20 [0.95; 1.51]	0.121	
Race group									
White	1344	325 (24.2)	1353	278 (20.5)	3.63 [0.49; 6.78]	1.23 [1.03; 1.48]	1.18 [1.02; 1.36]	0.024	0.641
Asian	500	138 (27.6)	474	115 (24.3)	3.34 [-2.18; 8.83]	1.19 [0.89; 1.59]	1.14 [0.92; 1.41]	0.236	
Black	111	28 (25.2)	118	29 (24.6)	0.65 [-10.57; 11.95]	1.04 [0.57; 1.89]	1.03 [0.65; 1.61]	0.910	
Other	196	46 (23.5)	206	52 (25.2)	-1.77 [-10.16; 6.67]	0.91 [0.58; 1.43]	0.93 [0.66; 1.31]	0.679	
Medical History of Diabetes Mellitus									
Yes	1047	264 (25.2)	984	222 (22.6)	2.65 [-1.06; 6.36]	1.16 [0.94; 1.42]	1.12 [0.96; 1.31]	0.162	0.840
No	1105	273 (24.7)	1167	252 (21.6)	3.11 [-0.36; 6.59]	1.19 [0.98; 1.45]	1.14 [0.98; 1.33]	0.079	
Index Event									
HF Hospitalization within 3 Months	1439	352 (24.5)	1474	315 (21.4)	3.09 [0.04; 6.15]	1.19 [1.00; 1.42]	1.14 [1.00; 1.31]	0.047	0.763

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
HF Hospitalization 3-6 Months	386	100 (25.9)	362	90 (24.9)	1.04 [-5.22; 7.27]	1.06 [0.76; 1.47]	1.04 [0.81; 1.33]	0.743	
IV diuretic for HF (without hospitalization) within 3 Months	327	85 (26.0)	315	69 (21.9)	4.09 [-2.54; 10.68]	1.25 [0.87; 1.80]	1.19 [0.90; 1.57]	0.226	
SOC: Psychiatric disorders									
Age category 1									
<65	831	34 (4.1)	851	43 (5.1)	-0.96 [-3.01; 1.06]	0.80 [0.51; 1.27]	0.81 [0.52; 1.26]	0.347	0.669
≥65	1321	57 (4.3)	1300	78 (6.0)	-1.69 [-3.42; 0.01]	0.71 [0.50; 1.00]	0.72 [0.52; 1.00]	0.052	
Age category 2									
<75	1519	58 (3.8)	1533	76 (5.0)	-1.14 [-2.62; 0.32]	0.76 [0.54; 1.08]	0.77 [0.55; 1.08]	0.126	0.779
≥75	633	33 (5.2)	618	45 (7.3)	-2.07 [-4.84; 0.62]	0.70 [0.44; 1.11]	0.72 [0.46; 1.11]	0.132	
Gender									
Male	1656	66 (4.0)	1652	92 (5.6)	-1.58 [-3.06; -0.13]	0.70 [0.51; 0.97]	0.72 [0.53; 0.97]	0.034	0.538
Female	496	25 (5.0)	499	29 (5.8)	-0.77 [-3.68; 2.10]	0.86 [0.50; 1.49]	0.87 [0.52; 1.46]	0.592	
Geographic Region									
Asia Pacific	510	23 (4.5)	502	31 (6.2)	-1.67 [-4.56; 1.14]	0.72 [0.41; 1.25]	0.73 [0.43; 1.23]	0.241	0.165
Eastern Europe	721	32 (4.4)	718	27 (3.8)	0.68 [-1.41; 2.80]	1.19 [0.70; 2.01]	1.18 [0.71; 1.95]	0.517	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Latin and South America	316	15 (4.7)	324	21 (6.5)	-1.73 [-5.49; 1.92]	0.72 [0.36; 1.42]	0.73 [0.38; 1.39]	0.343	
North America	240	12 (5.0)	241	19 (7.9)	-2.88 [-7.56; 1.59]	0.61 [0.29; 1.30]	0.63 [0.31; 1.28]	0.202	
Western Europe	365	9 (2.5)	366	23 (6.3)	-3.82 [-7.05; -0.90]	0.38 [0.17; 0.83]	0.39 [0.18; 0.84]	0.015	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	9 (4.2)	202	10 (5.0)	-0.73 [-5.16; 3.53]	0.85 [0.34; 2.13]	0.85 [0.35; 2.06]	0.724	0.949
>30 to ≤60	882	46 (5.2)	895	63 (7.0)	-1.82 [-4.10; 0.41]	0.73 [0.49; 1.08]	0.74 [0.51; 1.07]	0.111	
>60	1021	35 (3.4)	1022	45 (4.4)	-0.98 [-2.71; 0.72]	0.77 [0.49; 1.21]	0.78 [0.50; 1.20]	0.257	
NYHA Group at Baseline									
Class I or II	1236	47 (3.8)	1267	70 (5.5)	-1.72 [-3.41; -0.07]	0.68 [0.46; 0.99]	0.69 [0.48; 0.99]	0.043	0.483
Class III or IV	914	44 (4.8)	884	51 (5.8)	-0.96 [-3.08; 1.13]	0.83 [0.55; 1.25]	0.83 [0.56; 1.24]	0.366	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	13 (4.0)	330	21 (6.4)	-2.41 [-6.01; 1.02]	0.61 [0.30; 1.23]	0.62 [0.32; 1.22]	0.166	0.541
No	1823	78 (4.3)	1820	100 (5.5)	-1.22 [-2.64; 0.19]	0.77 [0.57; 1.04]	0.78 [0.58; 1.04]	0.090	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	22 (4.5)	507	23 (4.5)	-0.04 [-2.70; 2.64]	0.99 [0.55; 1.80]	0.99 [0.56; 1.76]	0.977	0.610
Q2 (1556 - 2816)	520	24 (4.6)	493	27 (5.5)	-0.86 [-3.68; 1.88]	0.84 [0.48; 1.47]	0.84 [0.49; 1.44]	0.531	
Q3 (2816 - 5314)	511	20 (3.9)	518	28 (5.4)	-1.49 [-4.18; 1.13]	0.71 [0.40; 1.28]	0.72 [0.41; 1.27]	0.259	
Q4 (>5314)	548	22 (4.0)	523	35 (6.7)	-2.68 [-5.52; 0.01]	0.58 [0.34; 1.01]	0.60 [0.36; 1.01]	0.054	
Baseline Ejection Fraction Group 2									
<35	1719	71 (4.1)	1734	99 (5.7)	-1.58 [-3.05; -0.14]	0.71 [0.52; 0.97]	0.72 [0.54; 0.97]	0.033	0.572
≥35	433	20 (4.6)	417	22 (5.3)	-0.66 [-3.71; 2.33]	0.87 [0.47; 1.62]	0.88 [0.49; 1.58]	0.659	
Race group									
White	1344	53 (3.9)	1353	70 (5.2)	-1.23 [-2.84; 0.35]	0.75 [0.52; 1.08]	0.76 [0.54; 1.08]	0.127	0.954
Asian	500	20 (4.0)	474	27 (5.7)	-1.70 [-4.55; 1.03]	0.69 [0.38; 1.25]	0.70 [0.40; 1.23]	0.220	
Black	111	4 (3.6)	118	7 (5.9)	-2.33 [-8.65; 3.74]	0.59 [0.17; 2.08]	0.61 [0.18; 2.02]	0.416	
Other	196	14 (7.1)	206	17 (8.3)	-1.11 [-6.53; 4.32]	0.86 [0.41; 1.79]	0.87 [0.44; 1.71]	0.677	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
CCSA class at Randomization									
No Angina	1843	71 (3.9)	1850	107 (5.8)	-1.93 [-3.34; -0.55]	0.65 [0.48; 0.89]	0.67 [0.50; 0.89]	0.007	0.080
Angina Class 1 or 2	265	19 (7.2)	260	12 (4.6)	2.55 [-1.56; 6.84]	1.60 [0.76; 3.36]	1.55 [0.77; 3.14]	0.219	
Angina Class 3 or 4	44	1 (2.3)	41	2 (4.9)	-2.61 [-14.26; 7.61]	0.45 [0.04; 5.20]	0.47 [0.04; 4.95]	0.526	
Medical History of Diabetes Mellitus									
Yes	1047	42 (4.0)	984	46 (4.7)	-0.66 [-2.49; 1.12]	0.85 [0.56; 1.31]	0.86 [0.57; 1.29]	0.464	0.421
No	1105	49 (4.4)	1167	75 (6.4)	-1.99 [-3.89; -0.13]	0.68 [0.47; 0.98]	0.69 [0.49; 0.98]	0.038	
Index Event									
HF Hospitalization within 3 Months	1439	59 (4.1)	1474	83 (5.6)	-1.53 [-3.12; 0.03]	0.72 [0.51; 1.01]	0.73 [0.53; 1.01]	0.056	0.850
HF Hospitalization 3-6 Months	386	17 (4.4)	362	22 (6.1)	-1.67 [-5.08; 1.56]	0.71 [0.37; 1.36]	0.72 [0.39; 1.34]	0.306	
IV diuretic for HF (without hospitalization) within 3 Months	327	15 (4.6)	315	16 (5.1)	-0.49 [-4.01; 2.95]	0.90 [0.44; 1.85]	0.90 [0.45; 1.80]	0.771	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1 % or ≥ 99 % in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.
h: A specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is greater than or equal to 0.05 or rule of 10 is not met
CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 51
Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Blood and lymphatic system disorders PT[h]: Anaemia									
Age category 1									
<65	831	44 (5.3)	851	30 (3.5)	1.77 [-0.20; 3.81]	1.53 [0.95; 2.46]	1.50 [0.95; 2.37]	0.079	0.710
≥65	1321	112 (8.5)	1300	82 (6.3)	2.17 [0.17; 4.20]	1.38 [1.02; 1.85]	1.34 [1.02; 1.77]	0.035	
Age category 2									
<75	1519	95 (6.3)	1533	70 (4.6)	1.69 [0.08; 3.32]	1.39 [1.02; 1.91]	1.37 [1.01; 1.85]	0.040	0.857
≥75	633	61 (9.6)	618	42 (6.8)	2.84 [-0.21; 5.94]	1.46 [0.97; 2.20]	1.42 [0.97; 2.07]	0.069	
Gender									
Male	1656	117 (7.1)	1652	87 (5.3)	1.80 [0.16; 3.46]	1.37 [1.03; 1.82]	1.34 [1.03; 1.76]	0.032	0.577
Female	496	39 (7.9)	499	25 (5.0)	2.85 [-0.20; 6.02]	1.62 [0.96; 2.72]	1.57 [0.96; 2.55]	0.069	
Geographic Region									
Asia Pacific	510	31 (6.1)	502	18 (3.6)	2.49 [-0.16; 5.27]	1.74 [0.96; 3.15]	1.70 [0.96; 2.99]	0.068	0.522
Eastern Europe	721	57 (7.9)	718	51 (7.1)	0.80 [-1.95; 3.57]	1.12 [0.76; 1.66]	1.11 [0.77; 1.60]	0.564	
Latin and South America	316	24 (7.6)	324	13 (4.0)	3.58 [-0.04; 7.46]	1.97 [0.98; 3.93]	1.89 [0.98; 3.65]	0.057	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	18 (7.5)	241	10 (4.1)	3.35 [-0.89; 7.87]	1.87 [0.85; 4.15]	1.81 [0.85; 3.83]	0.123	
Western Europe	365	26 (7.1)	366	20 (5.5)	1.66 [-1.92; 5.33]	1.33 [0.73; 2.42]	1.30 [0.74; 2.29]	0.357	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	22 (10.3)	202	19 (9.4)	0.92 [-5.00; 6.81]	1.11 [0.58; 2.12]	1.10 [0.61; 1.97]	0.753	0.460
>30 to ≤60	882	79 (9.0)	895	62 (6.9)	2.03 [-0.49; 4.59]	1.32 [0.93; 1.87]	1.29 [0.94; 1.78]	0.115	
>60	1021	53 (5.2)	1022	31 (3.0)	2.16 [0.44; 3.95]	1.75 [1.11; 2.75]	1.71 [1.11; 2.64]	0.015	
NYHA Group at Baseline									
Class I or II	1236	81 (6.6)	1267	57 (4.5)	2.05 [0.27; 3.89]	1.49 [1.05; 2.11]	1.46 [1.05; 2.03]	0.025	0.697
Class III or IV	914	75 (8.2)	884	55 (6.2)	1.98 [-0.42; 4.41]	1.35 [0.94; 1.93]	1.32 [0.94; 1.84]	0.106	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	23 (7.0)	330	9 (2.7)	4.26 [1.03; 7.84]	2.68 [1.22; 5.89]	2.56 [1.20; 5.46]	0.015	0.081
No	1823	133 (7.3)	1820	103 (5.7)	1.64 [0.04; 3.25]	1.31 [1.01; 1.71]	1.29 [1.01; 1.65]	0.046	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	21 (4.3)	507	18 (3.6)	0.74 [-1.73; 3.29]	1.22 [0.64; 2.32]	1.21 [0.65; 2.24]	0.546	0.464

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q2 (1556 - 2816)	520	41 (7.9)	493	20 (4.1)	3.83 [0.93; 6.86]	2.02 [1.17; 3.51]	1.94 [1.16; 3.27]	0.012	
Q3 (2816 - 5314)	511	40 (7.8)	518	33 (6.4)	1.46 [-1.71; 4.68]	1.25 [0.77; 2.01]	1.23 [0.79; 1.92]	0.364	
Q4 (>5314)	548	45 (8.2)	523	36 (6.9)	1.33 [-1.88; 4.55]	1.21 [0.77; 1.91]	1.19 [0.78; 1.82]	0.412	
Baseline Ejection Fraction Group 2									
<35	1719	124 (7.2)	1734	81 (4.7)	2.54 [0.97; 4.15]	1.59 [1.19; 2.12]	1.54 [1.18; 2.03]	0.002	0.120
≥35	433	32 (7.4)	417	31 (7.4)	-0.04 [-3.66; 3.54]	0.99 [0.59; 1.66]	0.99 [0.62; 1.60]	0.981	
Race group									
White	1344	93 (6.9)	1353	76 (5.6)	1.30 [-0.53; 3.16]	1.25 [0.91; 1.71]	1.23 [0.92; 1.65]	0.164	0.482
Asian	500	30 (6.0)	474	18 (3.8)	2.20 [-0.54; 5.03]	1.62 [0.89; 2.94]	1.58 [0.89; 2.80]	0.116	
Black	111	9 (8.1)	118	4 (3.4)	4.72 [-1.44; 11.75]	2.51 [0.75; 8.41]	2.39 [0.76; 7.55]	0.137	
Other	196	24 (12.2)	206	14 (6.8)	5.45 [-0.29; 11.51]	1.91 [0.96; 3.82]	1.80 [0.96; 3.38]	0.067	
CCSA class at Randomization									
No Angina	1843	129 (7.0)	1850	94 (5.1)	1.92 [0.38; 3.48]	1.41 [1.07; 1.85]	1.38 [1.06; 1.78]	0.015	0.759

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Angina Class 1 or 2	265	23 (8.7)	260	14 (5.4)	3.29 [-1.14; 7.90]	1.67 [0.84; 3.32]	1.61 [0.85; 3.06]	0.145	
Angina Class 3 or 4	44	4 (9.1)	41	4 (9.8)	-0.67 [-14.92; 13.07]	0.93 [0.22; 3.97]	0.93 [0.25; 3.48]	0.916	
Medical History of Diabetes Mellitus									
Yes	1047	95 (9.1)	984	55 (5.6)	3.48 [1.23; 5.78]	1.69 [1.19; 2.38]	1.62 [1.18; 2.24]	0.003	0.127
No	1105	61 (5.5)	1167	57 (4.9)	0.64 [-1.20; 2.50]	1.14 [0.79; 1.65]	1.13 [0.80; 1.61]	0.495	
Index Event									
HF Hospitalization within 3 Months	1439	107 (7.4)	1474	72 (4.9)	2.55 [0.81; 4.33]	1.56 [1.15; 2.13]	1.52 [1.14; 2.03]	0.004	0.204
HF Hospitalization 3-6 Months	386	25 (6.5)	362	26 (7.2)	-0.71 [-4.47; 2.97]	0.89 [0.51; 1.58]	0.90 [0.53; 1.53]	0.702	
IV diuretic for HF (without hospitalization) within 3 Months	327	24 (7.3)	315	14 (4.4)	2.90 [-0.80; 6.73]	1.70 [0.86; 3.36]	1.65 [0.87; 3.13]	0.125	
SOC: Cardiac disorders PT[h]: Cardiac failure									
Age category 1									
<65	831	78 (9.4)	851	86 (10.1)	-0.72 [-3.57; 2.14]	0.92 [0.67; 1.27]	0.93 [0.69; 1.24]	0.619	0.336
≥65	1321	114 (8.6)	1300	145 (11.2)	-2.52 [-4.83; -0.24]	0.75 [0.58; 0.97]	0.77 [0.61; 0.98]	0.031	
Age category 2									
<75	1519	137 (9.0)	1533	160 (10.4)	-1.42 [-3.53; 0.69]	0.85 [0.67; 1.08]	0.86 [0.70; 1.07]	0.187	0.509

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥75	633	55 (8.7)	618	71 (11.5)	-2.80 [-6.19; 0.54]	0.73 [0.51; 1.06]	0.76 [0.54; 1.06]	0.101	
Gender									
Male	1656	159 (9.6)	1652	191 (11.6)	-1.96 [-4.07; 0.14]	0.81 [0.65; 1.01]	0.83 [0.68; 1.01]	0.067	0.980
Female	496	33 (6.7)	499	40 (8.0)	-1.36 [-4.68; 1.92]	0.82 [0.51; 1.32]	0.83 [0.53; 1.29]	0.411	
Geographic Region									
Asia Pacific	510	44 (8.6)	502	60 (12.0)	-3.32 [-7.14; 0.42]	0.70 [0.46; 1.05]	0.72 [0.50; 1.04]	0.083	0.227
Eastern Europe	721	69 (9.6)	718	62 (8.6)	0.93 [-2.06; 3.94]	1.12 [0.78; 1.60]	1.11 [0.80; 1.54]	0.538	
Latin and South America	316	31 (9.8)	324	41 (12.7)	-2.84 [-7.82; 2.10]	0.75 [0.46; 1.23]	0.78 [0.50; 1.20]	0.257	
North America	240	8 (3.3)	241	17 (7.1)	-3.72 [-8.06; 0.27]	0.45 [0.19; 1.07]	0.47 [0.21; 1.07]	0.074	
Western Europe	365	40 (11.0)	366	51 (13.9)	-2.98 [-7.83; 1.84]	0.76 [0.49; 1.18]	0.79 [0.53; 1.16]	0.225	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	22 (10.3)	202	23 (11.4)	-1.06 [-7.25; 5.03]	0.90 [0.48; 1.66]	0.91 [0.52; 1.58]	0.729	0.900
>30 to ≤60	882	94 (10.7)	895	113 (12.6)	-1.97 [-4.97; 1.02]	0.83 [0.62; 1.10]	0.84 [0.65; 1.09]	0.197	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
>60	1021	74 (7.2)	1022	94 (9.2)	-1.95 [-4.36; 0.44]	0.77 [0.56; 1.06]	0.79 [0.59; 1.06]	0.110	
NYHA Group at Baseline									
Class I or II	1236	89 (7.2)	1267	129 (10.2)	-2.98 [-5.21; -0.78]	0.68 [0.52; 0.91]	0.71 [0.55; 0.92]	0.009	0.088
Class III or IV	914	103 (11.3)	884	102 (11.5)	-0.27 [-3.23; 2.68]	0.97 [0.73; 1.30]	0.98 [0.75; 1.26]	0.857	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	26 (7.9)	330	38 (11.5)	-3.61 [-8.26; 0.93]	0.66 [0.39; 1.11]	0.69 [0.43; 1.10]	0.120	0.391
No	1823	166 (9.1)	1820	193 (10.6)	-1.50 [-3.44; 0.44]	0.84 [0.68; 1.05]	0.86 [0.71; 1.05]	0.130	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	29 (5.9)	507	41 (8.1)	-2.16 [-5.41; 1.05]	0.72 [0.44; 1.17]	0.73 [0.46; 1.16]	0.185	0.831
Q2 (1556 - 2816)	520	51 (9.8)	493	58 (11.8)	-1.96 [-5.85; 1.88]	0.82 [0.55; 1.21]	0.83 [0.58; 1.19]	0.316	
Q3 (2816 - 5314)	511	52 (10.2)	518	57 (11.0)	-0.83 [-4.63; 2.97]	0.92 [0.62; 1.36]	0.92 [0.65; 1.32]	0.666	
Q4 (>5314)	548	53 (9.7)	523	67 (12.8)	-3.14 [-6.99; 0.65]	0.73 [0.50; 1.07]	0.75 [0.54; 1.06]	0.105	
Race group									
White	1344	127 (9.4)	1353	136 (10.1)	-0.60 [-2.85; 1.65]	0.93 [0.72; 1.20]	0.94 [0.75; 1.18]	0.598	0.340

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Asian	500	36 (7.2)	474	50 (10.5)	-3.35 [-7.03; 0.22]	0.66 [0.42; 1.03]	0.68 [0.45; 1.03]	0.068	
Black	111	5 (4.5)	118	11 (9.3)	-4.82 [-12.05; 2.01]	0.46 [0.15; 1.37]	0.48 [0.17; 1.35]	0.164	
Other	196	24 (12.2)	206	34 (16.5)	-4.26 [-11.21; 2.68]	0.71 [0.40; 1.24]	0.74 [0.46; 1.20]	0.227	
CCSA class at Randomization									
No Angina	1843	165 (9.0)	1850	200 (10.8)	-1.86 [-3.79; 0.07]	0.81 [0.65; 1.01]	0.83 [0.68; 1.01]	0.059	0.850
Angina Class 1 or 2	265	23 (8.7)	260	28 (10.8)	-2.09 [-7.32; 3.05]	0.79 [0.44; 1.41]	0.81 [0.48; 1.36]	0.420	
Angina Class 3 or 4	44	4 (9.1)	41	3 (7.3)	1.77 [-11.76; 15.12]	1.27 [0.27; 6.04]	1.24 [0.30; 5.22]	0.767	
Medical History of Diabetes Mellitus									
Yes	1047	102 (9.7)	984	102 (10.4)	-0.62 [-3.27; 2.00]	0.93 [0.70; 1.25]	0.94 [0.72; 1.22]	0.640	0.193
No	1105	90 (8.1)	1167	129 (11.1)	-2.91 [-5.34; -0.49]	0.71 [0.54; 0.95]	0.74 [0.57; 0.95]	0.020	
Index Event									
HF Hospitalization within 3 Months	1439	115 (8.0)	1474	150 (10.2)	-2.18 [-4.29; -0.10]	0.77 [0.59; 0.99]	0.79 [0.62; 0.99]	0.041	0.713
HF Hospitalization 3-6 Months	386	38 (9.8)	362	42 (11.6)	-1.76 [-6.30; 2.70]	0.83 [0.52; 1.32]	0.85 [0.56; 1.28]	0.438	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
IV diuretic for HF (without hospitalization) within 3 Months	327	39 (11.9)	315	39 (12.4)	-0.45 [-5.60; 4.65]	0.96 [0.60; 1.54]	0.96 [0.64; 1.46]	0.860	
SOC: Cardiac disorders PT[h]: Cardiac failure chronic									
Age category 2									
<75	1519	13 (0.9)	1533	23 (1.5)	-0.64 [-1.47; 0.13]	0.58 [0.30; 1.11]	0.58 [0.30; 1.11]	0.099	0.690
≥75	633	4 (0.6)	618	9 (1.5)	-0.82 [-2.19; 0.34]	0.45 [0.15; 1.34]	0.45 [0.15; 1.34]	0.151	
Gender									
Male	1656	12 (0.7)	1652	25 (1.5)	-0.79 [-1.57; -0.08]	0.49 [0.26; 0.94]	0.49 [0.26; 0.94]	0.031	0.553
Female	496	5 (1.0)	499	7 (1.4)	-0.39 [-1.98; 1.11]	0.72 [0.23; 2.27]	0.72 [0.23; 2.25]	0.570	
Geographic Region									
Asia Pacific	510	2 (0.4)	502	9 (1.8)	-1.40 [-3.03; -0.15]	0.27 [0.08; 0.89]	0.27 [0.08; 0.89]	0.032	0.590
Eastern Europe	721	9 (1.2)	718	15 (2.1)	-0.84 [-2.31; 0.52]	0.59 [0.26; 1.36]	0.60 [0.26; 1.36]	0.218	
Latin and South America	316	1 (0.3)	324	1 (0.3)	0.01 [-1.44; 1.49]	1.03 [0.06; 16.43]	1.03 [0.06; 16.43]	0.986	
North America	240	1 (0.4)	241	3 (1.2)	-0.83 [-3.23; 1.19]	0.37 [0.05; 2.62]	0.37 [0.05; 2.62]	0.318	
Western Europe	365	4 (1.1)	366	4 (1.1)	0.00 [-1.81; 1.82]	1.00 [0.25; 4.04]	1.00 [0.25; 3.98]	0.997	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category									
≤30	213	3 (1.4)	202	3 (1.5)	-0.08 [-3.03; 2.76]	0.95 [0.19; 4.75]	0.95 [0.19; 4.64]	0.948	0.569
>30 to ≤60	882	6 (0.7)	895	16 (1.8)	-1.11 [-2.28; -0.09]	0.40 [0.17; 0.94]	0.40 [0.17; 0.94]	0.035	
>60	1021	8 (0.8)	1022	13 (1.3)	-0.49 [-1.47; 0.42]	0.62 [0.26; 1.46]	0.62 [0.26; 1.46]	0.274	
NYHA Group at Baseline									
Class I or II	1236	8 (0.6)	1267	18 (1.4)	-0.77 [-1.66; 0.02]	0.47 [0.22; 1.02]	0.47 [0.22; 1.02]	0.056	0.605
Class III or IV	914	9 (1.0)	884	14 (1.6)	-0.60 [-1.76; 0.47]	0.62 [0.27; 1.42]	0.62 [0.27; 1.42]	0.259	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	3 (0.9)	330	3 (0.9)	0.00 [-1.83; 1.84]	1.00 [0.20; 5.00]	1.00 [0.20; 5.00]	0.997	0.404
No	1823	14 (0.8)	1820	29 (1.6)	-0.83 [-1.59; -0.13]	0.49 [0.27; 0.90]	0.49 [0.27; 0.90]	0.021	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	4 (0.8)	507	3 (0.6)	0.23 [-1.00; 1.56]	1.38 [0.31; 6.11]	1.38 [0.31; 6.11]	0.669	0.109
Q2 (1556 - 2816)	520	4 (0.8)	493	15 (3.0)	-2.27 [-4.27; -0.66]	0.29 [0.12; 0.72]	0.29 [0.12; 0.72]	0.008	
Q3 (2816 - 5314)	511	2 (0.4)	518	7 (1.4)	-0.96 [-2.42; 0.22]	0.33 [0.09; 1.23]	0.33 [0.09; 1.23]	0.098	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q4 (>5314)	548	7 (1.3)	523	6 (1.1)	0.13 [-1.35; 1.61]	1.11 [0.37; 3.34]	1.11 [0.38; 3.29]	0.846	
Baseline Ejection Fraction Group 2									
<35	1719	11 (0.6)	1734	26 (1.5)	-0.86 [-1.61; -0.18]	0.44 [0.23; 0.85]	0.44 [0.23; 0.85]	0.014	0.230
≥35	433	6 (1.4)	417	6 (1.4)	-0.05 [-1.88; 1.73]	0.96 [0.31; 3.01]	0.96 [0.31; 2.96]	0.948	
Race group									
White	1344	15 (1.1)	1353	23 (1.7)	-0.58 [-1.54; 0.32]	0.65 [0.34; 1.26]	0.66 [0.34; 1.25]	0.202	0.474
Asian	500	1 (0.2)	474	8 (1.7)	-1.49 [-3.12; -0.36]	0.20 [0.05; 0.73]	0.20 [0.05; 0.73]	0.015	
Black	111	0 (0.0)	118	0 (0.0)	0.00 [-3.17; 3.36]	n.a.	n.a.	n.a.	
Other	196	1 (0.5)	206	1 (0.5)	0.02 [-2.24; 2.39]	1.05 [0.07; 16.88]	1.05 [0.07; 16.88]	0.972	
CCSA class at Randomization									
No Angina	1843	13 (0.7)	1850	23 (1.2)	-0.54 [-1.23; 0.10]	0.57 [0.30; 1.10]	0.57 [0.30; 1.10]	0.096	0.432
Angina Class 1 or 2	265	4 (1.5)	260	5 (1.9)	-0.41 [-3.10; 2.14]	0.78 [0.21; 2.94]	0.78 [0.21; 2.89]	0.716	
Angina Class 3 or 4	44	0 (0.0)	41	4 (9.8)	-9.76 [-22.64; -1.23]	0.12 [0.02; 0.86]	0.12 [0.02; 0.86]	0.035	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus									
Yes	1047	8 (0.8)	984	11 (1.1)	-0.35 [-1.31; 0.52]	0.68 [0.28; 1.69]	0.68 [0.28; 1.69]	0.408	0.496
No	1105	9 (0.8)	1167	21 (1.8)	-0.99 [-2.01; -0.05]	0.47 [0.23; 0.97]	0.47 [0.23; 0.97]	0.040	
Index Event									
HF Hospitalization within 3 Months	1439	10 (0.7)	1474	22 (1.5)	-0.80 [-1.63; -0.04]	0.48 [0.24; 0.96]	0.48 [0.24; 0.96]	0.039	0.722
HF Hospitalization 3-6 Months	386	4 (1.0)	362	7 (1.9)	-0.90 [-3.02; 0.95]	0.53 [0.15; 1.83]	0.54 [0.16; 1.82]	0.316	
IV diuretic for HF (without hospitalization) within 3 Months	327	3 (0.9)	315	3 (1.0)	-0.03 [-1.95; 1.82]	0.96 [0.19; 4.80]	0.96 [0.19; 4.80]	0.963	
SOC: Cardiac disorders PT[h]: Ventricular tachycardia									
Age category 2									
<75	1519	31 (2.0)	1533	42 (2.7)	-0.70 [-1.82; 0.40]	0.74 [0.46; 1.18]	0.74 [0.47; 1.18]	0.208	0.123
≥75	633	4 (0.6)	618	13 (2.1)	-1.47 [-3.00; -0.21]	0.33 [0.13; 0.87]	0.33 [0.13; 0.87]	0.025	
Gender									
Male	1656	31 (1.9)	1652	49 (3.0)	-1.09 [-2.18; -0.05]	0.62 [0.40; 0.98]	0.63 [0.40; 0.98]	0.042	0.921
Female	496	4 (0.8)	499	6 (1.2)	-0.40 [-1.89; 1.00]	0.67 [0.19; 2.33]	0.67 [0.19; 2.33]	0.531	
Geographic Region									
Asia Pacific	510	10 (2.0)	502	10 (2.0)	-0.03 [-1.90; 1.82]	0.98 [0.41; 2.38]	0.98 [0.41; 2.34]	0.972	0.389

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Eastern Europe	721	12 (1.7)	718	16 (2.2)	-0.56 [-2.11; 0.92]	0.74 [0.35; 1.58]	0.75 [0.36; 1.57]	0.440	
Latin and South America	316	3 (0.9)	324	5 (1.5)	-0.59 [-2.73; 1.39]	0.62 [0.15; 2.49]	0.62 [0.15; 2.49]	0.499	
North America	240	1 (0.4)	241	7 (2.9)	-2.49 [-5.51; -0.26]	0.22 [0.05; 0.89]	0.22 [0.05; 0.89]	0.033	
Western Europe	365	9 (2.5)	366	17 (4.6)	-2.18 [-5.13; 0.54]	0.52 [0.23; 1.18]	0.53 [0.24; 1.18]	0.118	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	2 (0.9)	202	2 (1.0)	-0.05 [-2.70; 2.48]	0.95 [0.13; 6.78]	0.95 [0.13; 6.78]	0.958	0.897
>30 to ≤60	882	16 (1.8)	895	27 (3.0)	-1.20 [-2.72; 0.24]	0.59 [0.32; 1.11]	0.60 [0.33; 1.11]	0.103	
>60	1021	16 (1.6)	1022	24 (2.3)	-0.78 [-2.06; 0.44]	0.66 [0.35; 1.25]	0.67 [0.36; 1.25]	0.206	
NYHA Group at Baseline									
Class I or II	1236	19 (1.5)	1267	31 (2.4)	-0.91 [-2.06; 0.19]	0.62 [0.35; 1.11]	0.63 [0.36; 1.11]	0.107	0.954
Class III or IV	914	16 (1.8)	884	24 (2.7)	-0.96 [-2.43; 0.42]	0.64 [0.34; 1.21]	0.64 [0.34; 1.21]	0.169	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	9 (2.7)	330	14 (4.2)	-1.51 [-4.58; 1.40]	0.63 [0.27; 1.49]	0.64 [0.28; 1.47]	0.296	0.982

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
No	1823	26 (1.4)	1820	41 (2.3)	-0.83 [-1.74; 0.05]	0.63 [0.38; 1.03]	0.63 [0.39; 1.03]	0.066	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	5 (1.0)	507	13 (2.6)	-1.54 [-3.44; 0.13]	0.39 [0.14; 1.11]	0.40 [0.14; 1.11]	0.078	0.652
Q2 (1556 - 2816)	520	8 (1.5)	493	12 (2.4)	-0.90 [-2.84; 0.88]	0.63 [0.25; 1.55]	0.63 [0.26; 1.53]	0.310	
Q3 (2816 - 5314)	511	11 (2.2)	518	19 (3.7)	-1.52 [-3.74; 0.58]	0.58 [0.27; 1.23]	0.59 [0.28; 1.22]	0.154	
Q4 (>5314)	548	9 (1.6)	523	9 (1.7)	-0.08 [-1.79; 1.59]	0.95 [0.38; 2.42]	0.95 [0.38; 2.39]	0.920	
Baseline Ejection Fraction Group 2									
<35	1719	32 (1.9)	1734	47 (2.7)	-0.85 [-1.88; 0.15]	0.68 [0.43; 1.07]	0.69 [0.44; 1.07]	0.097	0.353
≥35	433	3 (0.7)	417	8 (1.9)	-1.23 [-3.13; 0.35]	0.38 [0.12; 1.26]	0.38 [0.12; 1.26]	0.114	
Race group									
White	1344	22 (1.6)	1353	43 (3.2)	-1.54 [-2.76; -0.39]	0.51 [0.30; 0.85]	0.52 [0.31; 0.86]	0.010	0.266
Asian	500	10 (2.0)	474	7 (1.5)	0.52 [-1.25; 2.35]	1.36 [0.51; 3.61]	1.35 [0.52; 3.53]	0.535	
Black	111	0 (0.0)	118	2 (1.7)	-1.69 [-5.98; 1.69]	0.14 [0.01; 2.29]	0.14 [0.01; 2.29]	0.169	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Other	196	3 (1.5)	206	3 (1.5)	0.07 [-2.85; 3.12]	1.05 [0.21; 5.27]	1.05 [0.21; 5.15]	0.951	
CCSA class at Randomization									
No Angina	1843	29 (1.6)	1850	46 (2.5)	-0.91 [-1.86; -0.00]	0.63 [0.39; 1.00]	0.63 [0.40; 1.00]	0.051	0.867
Angina Class 1 or 2	265	6 (2.3)	260	8 (3.1)	-0.81 [-3.97; 2.17]	0.73 [0.25; 2.13]	0.74 [0.26; 2.09]	0.565	
Angina Class 3 or 4	44	0 (0.0)	41	1 (2.4)	-2.44 [-12.69; 5.78]	0.13 [0.00; 6.35]	0.13 [0.00; 6.35]	0.300	
Medical History of Diabetes Mellitus									
Yes	1047	16 (1.5)	984	23 (2.3)	-0.81 [-2.11; 0.40]	0.65 [0.34; 1.23]	0.65 [0.35; 1.23]	0.188	0.920
No	1105	19 (1.7)	1167	32 (2.7)	-1.02 [-2.30; 0.20]	0.62 [0.35; 1.10]	0.63 [0.36; 1.10]	0.103	
Index Event									
HF Hospitalization within 3 Months	1439	25 (1.7)	1474	35 (2.4)	-0.64 [-1.71; 0.41]	0.73 [0.43; 1.22]	0.73 [0.44; 1.22]	0.228	0.074
HF Hospitalization 3-6 Months	386	5 (1.3)	362	17 (4.7)	-3.40 [-6.24; -1.05]	0.27 [0.10; 0.73]	0.28 [0.10; 0.74]	0.011	
IV diuretic for HF (without hospitalization) within 3 Months	327	5 (1.5)	315	3 (1.0)	0.58 [-1.41; 2.70]	1.60 [0.40; 6.43]	1.60 [0.40; 6.43]	0.511	
SOC: Gastrointestinal disorders PT[h]: Dyspepsia									
Age category 1									
<65	831	28 (3.4)	851	8 (0.9)	2.43 [1.10; 3.98]	3.19 [1.65; 6.17]	3.19 [1.65; 6.17]	< 0.001	0.090

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥65	1321	27 (2.0)	1300	17 (1.3)	0.74 [-0.26; 1.78]	1.57 [0.85; 2.90]	1.56 [0.86; 2.85]	0.146	
Age category 2									
<75	1519	44 (2.9)	1533	19 (1.2)	1.66 [0.67; 2.73]	2.38 [1.38; 4.09]	2.34 [1.37; 3.98]	0.002	0.637
≥75	633	11 (1.7)	618	6 (1.0)	0.77 [-0.58; 2.23]	1.77 [0.68; 4.61]	1.77 [0.68; 4.61]	0.242	
Gender									
Male	1656	36 (2.2)	1652	20 (1.2)	0.96 [0.09; 1.90]	1.81 [1.05; 3.15]	1.80 [1.04; 3.09]	0.034	0.166
Female	496	19 (3.8)	499	5 (1.0)	2.83 [1.00; 5.01]	3.94 [1.46; 10.62]	3.82 [1.44; 10.16]	0.007	
Geographic Region									
Asia Pacific	510	9 (1.8)	502	5 (1.0)	0.77 [-0.76; 2.44]	1.76 [0.61; 5.04]	1.76 [0.61; 5.04]	0.295	0.529
Eastern Europe	721	31 (4.3)	718	11 (1.5)	2.77 [1.08; 4.66]	2.89 [1.44; 5.79]	2.81 [1.42; 5.54]	0.003	
Latin and South America	316	3 (0.9)	324	1 (0.3)	0.64 [-0.86; 2.48]	2.80 [0.39; 19.98]	2.80 [0.39; 19.98]	0.304	
North America	240	8 (3.3)	241	3 (1.2)	2.09 [-0.69; 5.35]	2.74 [0.72; 10.44]	2.68 [0.72; 9.97]	0.142	
Western Europe	365	4 (1.1)	366	5 (1.4)	-0.27 [-2.20; 1.58]	0.80 [0.21; 3.00]	0.80 [0.22; 2.96]	0.741	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category									
≤30	213	1 (0.5)	202	1 (0.5)	-0.03 [-2.32; 2.16]	0.95 [0.06; 15.23]	0.95 [0.06; 15.23]	0.970	0.247
>30 to ≤60	882	19 (2.2)	895	13 (1.5)	0.70 [-0.56; 2.04]	1.49 [0.73; 3.04]	1.48 [0.74; 2.98]	0.269	
>60	1021	35 (3.4)	1022	11 (1.1)	2.35 [1.11; 3.76]	3.26 [1.65; 6.46]	3.18 [1.63; 6.24]	< 0.001	
NYHA Group at Baseline									
Class I or II	1236	30 (2.4)	1267	12 (0.9)	1.48 [0.49; 2.59]	2.45 [1.33; 4.51]	2.45 [1.33; 4.51]	0.004	0.508
Class III or IV	914	25 (2.7)	884	13 (1.5)	1.26 [-0.07; 2.69]	1.88 [0.96; 3.71]	1.86 [0.96; 3.61]	0.067	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	8 (2.4)	330	3 (0.9)	1.52 [-0.51; 3.93]	2.52 [0.77; 8.31]	2.52 [0.77; 8.31]	0.127	0.752
No	1823	47 (2.6)	1820	22 (1.2)	1.37 [0.50; 2.31]	2.16 [1.30; 3.60]	2.13 [1.29; 3.52]	0.003	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	23 (4.7)	507	7 (1.4)	3.32 [1.27; 5.72]	3.53 [1.50; 8.29]	3.41 [1.48; 7.87]	0.004	0.232
Q2 (1556 - 2816)	520	13 (2.5)	493	6 (1.2)	1.28 [-0.43; 3.16]	2.08 [0.78; 5.52]	2.05 [0.79; 5.36]	0.141	
Q3 (2816 - 5314)	511	7 (1.4)	518	8 (1.5)	-0.17 [-1.82; 1.44]	0.89 [0.32; 2.46]	0.89 [0.32; 2.43]	0.815	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q4 (>5314)	548	10 (1.8)	523	4 (0.8)	1.06 [-0.35; 2.65]	2.27 [0.79; 6.52]	2.27 [0.79; 6.52]	0.127	
Baseline Ejection Fraction Group 2									
<35	1719	40 (2.3)	1734	20 (1.2)	1.17 [0.31; 2.10]	2.04 [1.19; 3.51]	2.02 [1.18; 3.44]	0.010	0.523
≥35	433	15 (3.5)	417	5 (1.2)	2.27 [0.25; 4.58]	2.96 [1.06; 8.21]	2.89 [1.06; 7.88]	0.038	
Race group									
White	1344	40 (3.0)	1353	15 (1.1)	1.87 [0.83; 3.02]	2.74 [1.50; 4.98]	2.68 [1.49; 4.84]	0.001	0.634
Asian	500	6 (1.2)	474	5 (1.1)	0.15 [-1.39; 1.67]	1.14 [0.35; 3.76]	1.14 [0.35; 3.70]	0.830	
Black	111	5 (4.5)	118	3 (2.5)	1.96 [-3.32; 7.91]	1.81 [0.42; 7.75]	1.77 [0.43; 7.24]	0.426	
Other	196	4 (2.0)	206	2 (1.0)	1.07 [-1.67; 4.28]	2.07 [0.41; 10.35]	2.07 [0.41; 10.35]	0.377	
CCSA class at Randomization									
No Angina	1843	41 (2.2)	1850	24 (1.3)	0.93 [0.08; 1.82]	1.73 [1.04; 2.88]	1.71 [1.04; 2.83]	0.034	0.179
Angina Class 1 or 2	265	11 (4.2)	260	1 (0.4)	3.77 [1.49; 6.94]	5.38 [1.71; 16.89]	5.38 [1.71; 16.89]	0.004	
Angina Class 3 or 4	44	3 (6.8)	41	0 (0.0)	6.82 [-2.13; 18.31]	7.24 [0.73; 71.59]	7.24 [0.73; 71.59]	0.091	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus									
Yes	1047	25 (2.4)	984	8 (0.8)	1.57 [0.51; 2.78]	2.68 [1.35; 5.33]	2.68 [1.35; 5.33]	0.005	0.365
No	1105	30 (2.7)	1167	17 (1.5)	1.26 [0.09; 2.53]	1.89 [1.04; 3.44]	1.86 [1.03; 3.36]	0.038	
Index Event									
HF Hospitalization within 3 Months	1439	33 (2.3)	1474	16 (1.1)	1.21 [0.28; 2.22]	2.14 [1.17; 3.90]	2.11 [1.17; 3.82]	0.013	0.977
HF Hospitalization 3-6 Months	386	12 (3.1)	362	5 (1.4)	1.73 [-0.46; 4.14]	2.29 [0.80; 6.57]	2.25 [0.80; 6.33]	0.124	
IV diuretic for HF (without hospitalization) within 3 Months	327	10 (3.1)	315	4 (1.3)	1.79 [-0.54; 4.43]	2.45 [0.76; 7.90]	2.41 [0.76; 7.60]	0.134	
SOC: Gastrointestinal disorders PT[h]: Gastrooesophageal reflux disease									
Age category 1									
<65	831	17 (2.0)	851	8 (0.9)	1.11 [-0.06; 2.41]	2.13 [0.97; 4.68]	2.13 [0.97; 4.68]	0.061	0.566
≥65	1321	22 (1.7)	1300	7 (0.5)	1.13 [0.35; 2.03]	2.80 [1.35; 5.82]	2.80 [1.35; 5.82]	0.006	
Age category 2									
<75	1519	29 (1.9)	1533	13 (0.8)	1.06 [0.25; 1.96]	2.18 [1.19; 4.02]	2.18 [1.19; 4.02]	0.012	0.333
≥75	633	10 (1.6)	618	2 (0.3)	1.26 [0.21; 2.60]	3.75 [1.20; 11.68]	3.75 [1.20; 11.68]	0.023	
Gender									
Male	1656	25 (1.5)	1652	12 (0.7)	0.78 [0.07; 1.57]	2.03 [1.06; 3.88]	2.03 [1.06; 3.88]	0.032	0.236

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Female	496	14 (2.8)	499	3 (0.6)	2.22 [0.69; 4.15]	3.75 [1.44; 9.78]	3.75 [1.44; 9.78]	0.007	
Geographic Region									
Asia Pacific	510	19 (3.7)	502	3 (0.6)	3.13 [1.48; 5.21]	4.35 [1.87; 10.11]	4.35 [1.87; 10.11]	< 0.001	0.291
Eastern Europe	721	6 (0.8)	718	5 (0.7)	0.14 [-0.89; 1.19]	1.20 [0.37; 3.92]	1.20 [0.37; 3.92]	0.768	
Latin and South America	316	4 (1.3)	324	2 (0.6)	0.65 [-1.10; 2.66]	2.01 [0.40; 10.01]	2.01 [0.40; 10.01]	0.395	
North America	240	6 (2.5)	241	2 (0.8)	1.67 [-0.78; 4.62]	2.77 [0.69; 11.19]	2.77 [0.69; 11.19]	0.153	
Western Europe	365	4 (1.1)	366	3 (0.8)	0.28 [-1.42; 2.06]	1.34 [0.30; 5.92]	1.34 [0.30; 5.92]	0.702	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	0 (0.0)	202	2 (1.0)	-0.99 [-3.54; 0.79]	0.13 [0.01; 2.05]	0.13 [0.01; 2.05]	0.146	0.229
>30 to ≤60	882	14 (1.6)	895	5 (0.6)	1.03 [0.08; 2.15]	2.64 [1.07; 6.53]	2.64 [1.07; 6.53]	0.035	
>60	1021	24 (2.4)	1022	8 (0.8)	1.57 [0.52; 2.77]	2.76 [1.37; 5.55]	2.76 [1.37; 5.55]	0.004	
NYHA Group at Baseline									
Class I or II	1236	24 (1.9)	1267	7 (0.6)	1.39 [0.56; 2.38]	3.11 [1.53; 6.32]	3.11 [1.53; 6.32]	0.002	0.277

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Class III or IV	914	15 (1.6)	884	8 (0.9)	0.74 [-0.33; 1.89]	1.79 [0.79; 4.08]	1.79 [0.79; 4.08]	0.165	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	3 (0.9)	330	3 (0.9)	0.00 [-1.83; 1.84]	1.00 [0.20; 5.00]	1.00 [0.20; 5.00]	0.997	0.218
No	1823	36 (2.0)	1820	12 (0.7)	1.32 [0.60; 2.12]	2.75 [1.56; 4.86]	2.75 [1.56; 4.86]	< 0.001	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	14 (2.9)	507	3 (0.6)	2.27 [0.74; 4.22]	3.87 [1.48; 10.09]	3.87 [1.48; 10.09]	0.006	0.336
Q2 (1556 - 2816)	520	9 (1.7)	493	6 (1.2)	0.51 [-1.11; 2.19]	1.43 [0.51; 4.05]	1.42 [0.51; 3.97]	0.501	
Q3 (2816 - 5314)	511	9 (1.8)	518	2 (0.4)	1.38 [0.14; 2.97]	3.67 [1.12; 12.02]	3.67 [1.12; 12.02]	0.032	
Q4 (>5314)	548	5 (0.9)	523	3 (0.6)	0.34 [-0.86; 1.61]	1.58 [0.39; 6.34]	1.58 [0.39; 6.34]	0.520	
Baseline Ejection Fraction Group 2									
<35	1719	31 (1.8)	1734	12 (0.7)	1.11 [0.39; 1.92]	2.47 [1.35; 4.50]	2.47 [1.35; 4.50]	0.003	0.985
≥35	433	8 (1.8)	417	3 (0.7)	1.13 [-0.47; 2.97]	2.42 [0.74; 7.93]	2.42 [0.74; 7.93]	0.146	
Race group									
White	1344	24 (1.8)	1353	7 (0.5)	1.27 [0.49; 2.18]	3.05 [1.50; 6.20]	3.05 [1.50; 6.20]	0.002	0.208

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Asian	500	12 (2.4)	474	3 (0.6)	1.77 [0.25; 3.59]	3.20 [1.16; 8.88]	3.20 [1.16; 8.88]	0.025	
Black	111	0 (0.0)	118	3 (2.5)	-2.54 [-7.22; 0.86]	0.14 [0.01; 1.37]	0.14 [0.01; 1.37]	0.092	
Other	196	3 (1.5)	206	2 (1.0)	0.56 [-2.12; 3.55]	1.58 [0.27; 9.18]	1.58 [0.27; 9.18]	0.613	
CCSA class at Randomization									
No Angina	1843	34 (1.8)	1850	12 (0.6)	1.20 [0.50; 1.98]	2.64 [1.48; 4.73]	2.64 [1.48; 4.73]	0.001	0.711
Angina Class 1 or 2	265	4 (1.5)	260	2 (0.8)	0.74 [-1.42; 3.14]	1.92 [0.39; 9.60]	1.92 [0.39; 9.60]	0.425	
Angina Class 3 or 4	44	1 (2.3)	41	1 (2.4)	-0.17 [-10.67; 9.74]	0.93 [0.06; 15.37]	0.93 [0.06; 14.42]	0.960	
Medical History of Diabetes Mellitus									
Yes	1047	13 (1.2)	984	5 (0.5)	0.73 [-0.09; 1.66]	2.30 [0.91; 5.83]	2.30 [0.91; 5.83]	0.078	0.848
No	1105	26 (2.4)	1167	10 (0.9)	1.50 [0.49; 2.65]	2.61 [1.35; 5.04]	2.61 [1.35; 5.04]	0.004	
Index Event									
HF Hospitalization within 3 Months	1439	24 (1.7)	1474	7 (0.5)	1.19 [0.48; 2.04]	3.10 [1.53; 6.30]	3.10 [1.53; 6.30]	0.002	0.185
HF Hospitalization 3-6 Months	386	9 (2.3)	362	7 (1.9)	0.40 [-1.88; 2.68]	1.21 [0.45; 3.29]	1.21 [0.45; 3.20]	0.707	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
IV diuretic for HF (without hospitalization) within 3 Months	327	6 (1.8)	315	1 (0.3)	1.52 [-0.12; 3.67]	4.07 [0.92; 18.06]	4.07 [0.92; 18.06]	0.064	
SOC: Metabolism and nutrition disorders PT[h]: Hyponatraemia									
Age category 1									
<65	831	10 (1.2)	851	15 (1.8)	-0.56 [-1.82; 0.64]	0.68 [0.30; 1.52]	0.68 [0.31; 1.51]	0.346	0.488
≥65	1321	13 (1.0)	1300	27 (2.1)	-1.09 [-2.12; -0.16]	0.48 [0.26; 0.90]	0.48 [0.26; 0.90]	0.023	
Age category 2									
<75	1519	17 (1.1)	1533	30 (2.0)	-0.84 [-1.77; 0.04]	0.57 [0.31; 1.03]	0.57 [0.32; 1.03]	0.064	0.785
≥75	633	6 (0.9)	618	12 (1.9)	-0.99 [-2.52; 0.36]	0.50 [0.20; 1.26]	0.50 [0.20; 1.26]	0.140	
Gender									
Male	1656	17 (1.0)	1652	35 (2.1)	-1.09 [-2.00; -0.25]	0.48 [0.27; 0.86]	0.48 [0.27; 0.86]	0.014	0.359
Female	496	6 (1.2)	499	7 (1.4)	-0.19 [-1.81; 1.38]	0.86 [0.29; 2.58]	0.86 [0.29; 2.55]	0.789	
Geographic Region									
Asia Pacific	510	8 (1.6)	502	9 (1.8)	-0.22 [-1.99; 1.49]	0.87 [0.33; 2.28]	0.87 [0.34; 2.25]	0.782	0.403
Eastern Europe	721	5 (0.7)	718	10 (1.4)	-0.70 [-1.93; 0.40]	0.51 [0.18; 1.40]	0.51 [0.18; 1.40]	0.192	
Latin and South America	316	5 (1.6)	324	5 (1.5)	0.04 [-2.18; 2.29]	1.03 [0.29; 3.58]	1.03 [0.30; 3.51]	0.968	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	3 (1.3)	241	10 (4.1)	-2.90 [-6.38; 0.00]	0.29 [0.08; 1.08]	0.30 [0.08; 1.08]	0.066	
Western Europe	365	2 (0.5)	366	8 (2.2)	-1.64 [-3.77; 0.06]	0.30 [0.09; 1.04]	0.30 [0.09; 1.04]	0.057	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	3 (1.4)	202	4 (2.0)	-0.57 [-3.74; 2.33]	0.71 [0.16; 3.20]	0.71 [0.16; 3.14]	0.653	0.371
>30 to ≤60	882	7 (0.8)	895	20 (2.2)	-1.44 [-2.72; -0.33]	0.38 [0.18; 0.82]	0.38 [0.18; 0.82]	0.013	
>60	1021	13 (1.3)	1022	17 (1.7)	-0.39 [-1.51; 0.69]	0.76 [0.37; 1.58]	0.77 [0.37; 1.57]	0.465	
NYHA Group at Baseline									
Class I or II	1236	11 (0.9)	1267	20 (1.6)	-0.69 [-1.63; 0.19]	0.57 [0.28; 1.16]	0.57 [0.28; 1.16]	0.119	0.891
Class III or IV	914	12 (1.3)	884	22 (2.5)	-1.18 [-2.56; 0.09]	0.52 [0.26; 1.06]	0.53 [0.26; 1.06]	0.072	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	3 (0.9)	330	7 (2.1)	-1.21 [-3.51; 0.79]	0.45 [0.13; 1.55]	0.45 [0.13; 1.55]	0.205	0.698
No	1823	20 (1.1)	1820	35 (1.9)	-0.83 [-1.67; -0.04]	0.57 [0.33; 0.98]	0.57 [0.33; 0.98]	0.044	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	3 (0.6)	507	7 (1.4)	-0.77 [-2.28; 0.57]	0.46 [0.13; 1.61]	0.46 [0.13; 1.61]	0.225	0.745

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q2 (1556 - 2816)	520	7 (1.3)	493	8 (1.6)	-0.28 [-1.98; 1.34]	0.83 [0.30; 2.30]	0.83 [0.30; 2.27]	0.716	
Q3 (2816 - 5314)	511	4 (0.8)	518	11 (2.1)	-1.34 [-3.07; 0.14]	0.39 [0.14; 1.09]	0.39 [0.14; 1.09]	0.073	
Q4 (>5314)	548	8 (1.5)	523	15 (2.9)	-1.41 [-3.38; 0.35]	0.50 [0.21; 1.19]	0.51 [0.22; 1.19]	0.119	
Baseline Ejection Fraction Group 2									
<35	1719	18 (1.0)	1734	34 (2.0)	-0.91 [-1.78; -0.10]	0.53 [0.30; 0.94]	0.53 [0.30; 0.94]	0.030	0.851
≥35	433	5 (1.2)	417	8 (1.9)	-0.76 [-2.72; 1.00]	0.60 [0.19; 1.84]	0.60 [0.20; 1.82]	0.370	
Race group									
White	1344	8 (0.6)	1353	27 (2.0)	-1.40 [-2.35; -0.58]	0.34 [0.17; 0.65]	0.34 [0.17; 0.65]	0.001	0.107
Asian	500	8 (1.6)	474	9 (1.9)	-0.30 [-2.15; 1.47]	0.84 [0.32; 2.20]	0.84 [0.33; 2.17]	0.722	
Black	111	1 (0.9)	118	2 (1.7)	-0.79 [-5.19; 3.40]	0.54 [0.06; 5.27]	0.54 [0.06; 5.27]	0.598	
Other	196	6 (3.1)	206	4 (1.9)	1.12 [-2.23; 4.82]	1.59 [0.44; 5.74]	1.58 [0.45; 5.50]	0.475	
CCSA class at Randomization									
No Angina	1843	19 (1.0)	1850	35 (1.9)	-0.86 [-1.68; -0.09]	0.54 [0.31; 0.95]	0.54 [0.31; 0.95]	0.032	0.964

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Angina Class 1 or 2	265	4 (1.5)	260	7 (2.7)	-1.18 [-4.13; 1.47]	0.55 [0.16; 1.92]	0.56 [0.17; 1.89]	0.351	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	0.00 [-8.66; 8.12]	n.a.	n.a.	n.a.	
Medical History of Diabetes Mellitus									
Yes	1047	12 (1.1)	984	23 (2.3)	-1.19 [-2.45; -0.06]	0.48 [0.24; 0.98]	0.49 [0.25; 0.98]	0.044	0.666
No	1105	11 (1.0)	1167	19 (1.6)	-0.63 [-1.64; 0.33]	0.62 [0.30; 1.27]	0.62 [0.30; 1.27]	0.187	
Index Event									
HF Hospitalization within 3 Months	1439	16 (1.1)	1474	31 (2.1)	-0.99 [-1.97; -0.08]	0.52 [0.29; 0.96]	0.53 [0.29; 0.96]	0.037	0.874
HF Hospitalization 3-6 Months	386	4 (1.0)	362	5 (1.4)	-0.34 [-2.28; 1.43]	0.75 [0.20; 2.81]	0.75 [0.20; 2.77]	0.667	
IV diuretic for HF (without hospitalization) within 3 Months	327	3 (0.9)	315	6 (1.9)	-0.99 [-3.29; 1.00]	0.49 [0.13; 1.83]	0.49 [0.13; 1.83]	0.288	
SOC: Respiratory, thoracic and mediastinal disorders PT[h]: Epistaxis									
Age category 2									
<75	1519	22 (1.4)	1533	26 (1.7)	-0.25 [-1.17; 0.66]	0.85 [0.48; 1.51]	0.85 [0.49; 1.50]	0.583	0.071
≥75	633	9 (1.4)	618	24 (3.9)	-2.46 [-4.44; -0.72]	0.36 [0.16; 0.77]	0.37 [0.17; 0.78]	0.009	
Gender									
Male	1656	25 (1.5)	1652	36 (2.2)	-0.67 [-1.63; 0.25]	0.69 [0.41; 1.15]	0.69 [0.42; 1.15]	0.155	0.378

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Female	496	6 (1.2)	499	14 (2.8)	-1.60 [-3.58; 0.16]	0.42 [0.16; 1.11]	0.43 [0.17; 1.11]	0.082	
Geographic Region									
Asia Pacific	510	8 (1.6)	502	15 (3.0)	-1.42 [-3.48; 0.45]	0.52 [0.22; 1.23]	0.52 [0.22; 1.23]	0.137	0.290
Eastern Europe	721	7 (1.0)	718	8 (1.1)	-0.14 [-1.33; 1.01]	0.87 [0.31; 2.41]	0.87 [0.31; 2.41]	0.789	
Latin and South America	316	5 (1.6)	324	5 (1.5)	0.04 [-2.18; 2.29]	1.03 [0.29; 3.58]	1.03 [0.30; 3.51]	0.968	
North America	240	6 (2.5)	241	5 (2.1)	0.43 [-2.58; 3.53]	1.21 [0.36; 4.02]	1.20 [0.37; 3.90]	0.755	
Western Europe	365	5 (1.4)	366	17 (4.6)	-3.27 [-6.10; -0.87]	0.29 [0.10; 0.78]	0.29 [0.11; 0.79]	0.015	
NYHA Group at Baseline									
Class I or II	1236	19 (1.5)	1267	32 (2.5)	-0.99 [-2.16; 0.12]	0.60 [0.34; 1.07]	0.61 [0.35; 1.07]	0.083	0.899
Class III or IV	914	12 (1.3)	884	18 (2.0)	-0.72 [-2.02; 0.49]	0.64 [0.31; 1.34]	0.64 [0.31; 1.33]	0.235	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	2 (0.6)	330	9 (2.7)	-2.12 [-4.57; -0.20]	0.28 [0.08; 0.91]	0.28 [0.08; 0.91]	0.034	0.122
No	1823	29 (1.6)	1820	41 (2.3)	-0.66 [-1.59; 0.24]	0.70 [0.43; 1.13]	0.71 [0.44; 1.13]	0.148	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	3 (0.6)	507	9 (1.8)	-1.16 [-2.80; 0.23]	0.38 [0.12; 1.18]	0.38 [0.12; 1.18]	0.093	0.320
Q2 (1556 - 2816)	520	3 (0.6)	493	8 (1.6)	-1.05 [-2.66; 0.27]	0.38 [0.12; 1.24]	0.38 [0.12; 1.24]	0.109	
Q3 (2816 - 5314)	511	8 (1.6)	518	16 (3.1)	-1.52 [-3.57; 0.35]	0.50 [0.21; 1.18]	0.51 [0.22; 1.17]	0.113	
Q4 (>5314)	548	14 (2.6)	523	13 (2.5)	0.07 [-1.94; 2.05]	1.03 [0.48; 2.21]	1.03 [0.49; 2.17]	0.943	
Baseline Ejection Fraction Group 2									
<35	1719	27 (1.6)	1734	42 (2.4)	-0.85 [-1.83; 0.08]	0.64 [0.39; 1.05]	0.65 [0.40; 1.05]	0.076	0.649
≥35	433	4 (0.9)	417	8 (1.9)	-0.99 [-2.92; 0.68]	0.49 [0.16; 1.53]	0.49 [0.16; 1.53]	0.219	
Race group									
White	1344	19 (1.4)	1353	33 (2.4)	-1.03 [-2.13; 0.01]	0.57 [0.32; 1.01]	0.58 [0.33; 1.01]	0.056	0.844
Asian	500	7 (1.4)	474	12 (2.5)	-1.13 [-3.13; 0.66]	0.55 [0.21; 1.40]	0.55 [0.22; 1.39]	0.209	
Black	111	1 (0.9)	118	1 (0.8)	0.05 [-3.84; 4.17]	1.06 [0.07; 17.13]	1.06 [0.07; 17.13]	0.965	
Other	196	4 (2.0)	206	4 (1.9)	0.10 [-3.11; 3.42]	1.05 [0.26; 4.27]	1.05 [0.27; 4.14]	0.943	

Analyses of Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
CCSA class at Randomization									
No Angina	1843	25 (1.4)	1850	43 (2.3)	-0.97 [-1.88; -0.10]	0.58 [0.35; 0.95]	0.58 [0.36; 0.95]	0.031	0.636
Angina Class 1 or 2	265	6 (2.3)	260	6 (2.3)	-0.04 [-2.96; 2.84]	0.98 [0.31; 3.08]	0.98 [0.32; 3.00]	0.973	
Angina Class 3 or 4	44	0 (0.0)	41	1 (2.4)	-2.44 [-12.69; 5.78]	0.13 [0.00; 6.35]	0.13 [0.00; 6.35]	0.300	
Medical History of Diabetes Mellitus									
Yes	1047	17 (1.6)	984	26 (2.6)	-1.02 [-2.38; 0.24]	0.61 [0.33; 1.13]	0.61 [0.34; 1.13]	0.115	0.992
No	1105	14 (1.3)	1167	24 (2.1)	-0.79 [-1.91; 0.28]	0.61 [0.31; 1.19]	0.62 [0.32; 1.18]	0.147	
Index Event									
HF Hospitalization within 3 Months	1439	22 (1.5)	1474	30 (2.0)	-0.51 [-1.51; 0.47]	0.75 [0.43; 1.30]	0.75 [0.44; 1.30]	0.304	0.395
HF Hospitalization 3-6 Months	386	7 (1.8)	362	13 (3.6)	-1.78 [-4.44; 0.58]	0.50 [0.20; 1.26]	0.50 [0.20; 1.25]	0.140	
IV diuretic for HF (without hospitalization) within 3 Months	327	2 (0.6)	315	7 (2.2)	-1.61 [-3.98; 0.26]	0.31 [0.08; 1.16]	0.31 [0.08; 1.16]	0.083	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1 % or ≥ 99 % in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.
h: A specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is greater than or equal to 0.05 or rule of 10 is not met
CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

1.8.2 Serious Adverse Events by SOC and PT

Table 52
Overview of Subgroup Analyses for Serious Adverse Event Related Endpoints
Treatment by Subgroup Interaction
by System Organ Class and Preferred Term
(Incidence ≥5% or (≥1% and in at least 10 Participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**						
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 0 / >30 to ≤ 60 / >60)**	**NYHA Group at Baseline (Class I or II / Class III or IV)**	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**
Serious Adverse Events by SOC and PT[c] - Event							
Blood and lymphatic system disorders	0.452	0.097	0.662	0.833	0.289	0.415	0.210
Cardiac disorders	**0.039[d]**	0.604	0.241	0.971	0.181	0.934	0.408
Atrial fibrillation	0.346	0.115	0.152	0.517	0.471	0.452	0.387
Cardiac failure	0.230	0.785	0.665	0.147	0.955	0.443	0.902

Overview of Subgroup Analyses for Serious Adverse Event Related Endpoints
Treatment by Subgroup Interaction
by System Organ Class and Preferred Term
(Incidence ≥5% or (≥1% and in at least 10 Participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**					
	NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**
Serious Adverse Events by SOC and PT[c] - Event						
Blood and lymphatic system disorders	0.502	0.412	0.808	0.425	0.638	0.483
Cardiac disorders	0.694	0.858	0.997	**0.045[d]**	0.366	0.503
Atrial fibrillation	0.154	0.717	0.915	0.454	0.124	0.792
Cardiac failure	0.447	0.684	0.641	0.759	0.975	0.595

a: Database Cutoff Date: 18JUN2019

b: Based on a Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if Participant has 0 event in at least one cell of the stratum.

c: A system organ class or specific adverse event appears on this report only if its incidence is ≥ 5% or ≥ 1% and in at least 10 patients in one or more treatment groups and p-value for main treatment effect smaller than 0.05

d: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; PT: Preferred Term; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile; SOC: System Organ Class

1.8.2.1 Results for Subgroups with Interaction Nominal P-value < 0.05

Table 53
Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test < 0.05
(Incidence ≥ 5% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Cardiac disorders									
Age category 1									
<65	831	76 (9.1)	851	87 (10.2)	-1.08 [-3.93; 1.77]	0.88 [0.64; 1.22]	0.89 [0.67; 1.20]	0.455	0.039
≥65	1321	93 (7.0)	1300	153 (11.8)	-4.73 [-6.99; -2.51]	0.57 [0.43; 0.74]	0.60 [0.47; 0.77]	< 0.001	
CCSA class at Randomization									
No Angina	1843	141 (7.7)	1850	204 (11.0)	-3.38 [-5.27; -1.51]	0.67 [0.53; 0.84]	0.69 [0.57; 0.85]	< 0.001	0.045
Angina Class 1 or 2	265	27 (10.2)	260	28 (10.8)	-0.58 [-5.95; 4.75]	0.94 [0.54; 1.64]	0.95 [0.57; 1.56]	0.828	
Angina Class 3 or 4	44	1 (2.3)	41	8 (19.5)	-17.24 [-32.21; -4.86]	0.10 [0.01; 0.81]	0.12 [0.02; 0.89]	0.038	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

h: A specific adverse event appears on this report only if its incidence ≥ 5% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main

treatment effect is smaller than 0.05 and p-value for interaction test is smaller than 0.05 and rule of 10 is met
CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

1.8.2.2 Results for Subgroups with Interaction Nominal P-value ≥ 0.05

Table 54
Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	Vericiguat		Placebo		Vericiguat vs. Placebo				
Serious Adverse Events	N[b]	Participants with Event n (%)	N[b]	Participants with Event n (%)	Risk Difference [95 %-CI][c]	Odds Ratio [95 %-CI][d]	Relative Risk [95 %-CI][e]	p-Value[e,f]	p-Value for Interaction Test[g]
SOC: Blood and lymphatic system disorders									
Age category 1									
<65	831	11 (1.3)	851	4 (0.5)	0.85 [-0.05; 1.94]	2.63 [0.95; 7.26]	2.63 [0.95; 7.26]	0.063	0.452
≥65	1321	28 (2.1)	1300	16 (1.2)	0.89 [-0.10; 1.94]	1.74 [0.94; 3.23]	1.72 [0.94; 3.17]	0.080	
Age category 2									
<75	1519	26 (1.7)	1533	9 (0.6)	1.12 [0.39; 1.97]	2.70 [1.38; 5.25]	2.70 [1.38; 5.25]	0.004	0.097
≥75	633	13 (2.1)	618	11 (1.8)	0.27 [-1.34; 1.91]	1.16 [0.51; 2.60]	1.15 [0.52; 2.56]	0.724	
Gender									
Male	1656	33 (2.0)	1652	16 (1.0)	1.02 [0.21; 1.91]	2.02 [1.15; 3.55]	2.02 [1.15; 3.55]	0.015	0.662
Female	496	6 (1.2)	499	4 (0.8)	0.41 [-0.98; 1.91]	1.51 [0.43; 5.23]	1.51 [0.43; 5.23]	0.519	
Geographic Region									
Asia Pacific	510	8 (1.6)	502	5 (1.0)	0.57 [-0.93; 2.19]	1.57 [0.53; 4.69]	1.57 [0.53; 4.69]	0.419	0.833
Eastern Europe	721	12 (1.7)	718	7 (1.0)	0.69 [-0.54; 2.02]	1.70 [0.69; 4.19]	1.70 [0.69; 4.19]	0.252	
Latin and South America	316	2 (0.6)	324	2 (0.6)	0.02 [-1.66; 1.73]	1.03 [0.14; 7.31]	1.03 [0.14; 7.31]	0.980	

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	7 (2.9)	241	3 (1.2)	1.67 [-1.05; 4.81]	2.38 [0.61; 9.33]	2.34 [0.61; 8.95]	0.213	
Western Europe	365	10 (2.7)	366	3 (0.8)	1.92 [0.00; 4.25]	3.00 [1.00; 8.97]	3.00 [1.00; 8.97]	0.050	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	5 (2.3)	202	4 (2.0)	0.37 [-2.92; 3.66]	1.19 [0.31; 4.50]	1.19 [0.32; 4.35]	0.798	0.289
>30 to ≤60	882	18 (2.0)	895	12 (1.3)	0.70 [-0.53; 2.01]	1.53 [0.73; 3.20]	1.52 [0.74; 3.14]	0.256	
>60	1021	15 (1.5)	1022	4 (0.4)	1.08 [0.27; 2.06]	3.22 [1.30; 7.94]	3.22 [1.30; 7.94]	0.011	
NYHA Group at Baseline									
Class I or II	1236	27 (2.2)	1267	12 (0.9)	1.24 [0.28; 2.31]	2.24 [1.19; 4.22]	2.24 [1.19; 4.22]	0.012	0.415
Class III or IV	914	12 (1.3)	884	8 (0.9)	0.41 [-0.62; 1.48]	1.45 [0.60; 3.50]	1.45 [0.60; 3.50]	0.410	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	6 (1.8)	330	1 (0.3)	1.52 [-0.06; 3.66]	4.24 [0.96; 18.79]	4.24 [0.96; 18.79]	0.057	0.210
No	1823	33 (1.8)	1820	19 (1.0)	0.77 [-0.00; 1.59]	1.75 [0.99; 3.08]	1.73 [0.99; 3.04]	0.054	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	6 (1.2)	507	1 (0.2)	1.03 [-0.01; 2.48]	4.37 [0.99; 19.31]	4.37 [0.99; 19.31]	0.052	0.502

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q2 (1556 - 2816)	520	8 (1.5)	493	6 (1.2)	0.32 [-1.27; 1.94]	1.27 [0.44; 3.68]	1.26 [0.44; 3.62]	0.662	
Q3 (2816 - 5314)	511	10 (2.0)	518	7 (1.4)	0.61 [-1.05; 2.37]	1.46 [0.55; 3.86]	1.45 [0.56; 3.77]	0.449	
Q4 (>5314)	548	12 (2.2)	523	6 (1.1)	1.04 [-0.56; 2.78]	1.93 [0.72; 5.18]	1.91 [0.72; 5.05]	0.193	
Baseline Ejection Fraction Group 2									
<35	1719	29 (1.7)	1734	13 (0.7)	0.94 [0.22; 1.74]	2.18 [1.19; 4.01]	2.18 [1.19; 4.01]	0.012	0.412
≥35	433	10 (2.3)	417	7 (1.7)	0.63 [-1.39; 2.73]	1.38 [0.52; 3.67]	1.38 [0.53; 3.58]	0.513	
Race group									
White	1344	27 (2.0)	1353	14 (1.0)	0.97 [0.05; 1.97]	1.96 [1.02; 3.76]	1.94 [1.02; 3.69]	0.043	0.808
Asian	500	7 (1.4)	474	5 (1.1)	0.35 [-1.21; 1.94]	1.33 [0.42; 4.23]	1.33 [0.42; 4.15]	0.627	
Black	111	2 (1.8)	118	0 (0.0)	1.80 [-1.39; 6.35]	7.94 [0.49; 127.91]	7.94 [0.49; 127.91]	0.144	
Other	196	3 (1.5)	206	1 (0.5)	1.05 [-1.32; 3.98]	2.88 [0.40; 20.62]	2.88 [0.40; 20.62]	0.292	
CCSA class at Randomization									
No Angina	1843	34 (1.8)	1850	18 (1.0)	0.87 [0.12; 1.68]	1.87 [1.08; 3.24]	1.87 [1.08; 3.24]	0.025	0.425

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Angina Class 1 or 2	265	5 (1.9)	260	1 (0.4)	1.50 [-0.44; 4.00]	3.77 [0.76; 18.82]	3.77 [0.76; 18.82]	0.106	
Angina Class 3 or 4	44	0 (0.0)	41	1 (2.4)	-2.44 [-12.69; 5.78]	0.13 [0.00; 6.35]	0.13 [0.00; 6.35]	0.300	
Medical History of Diabetes Mellitus									
Yes	1047	22 (2.1)	984	12 (1.2)	0.88 [-0.25; 2.07]	1.74 [0.86; 3.53]	1.72 [0.86; 3.46]	0.127	0.638
No	1105	17 (1.5)	1167	8 (0.7)	0.85 [-0.01; 1.84]	2.19 [0.99; 4.82]	2.19 [0.99; 4.82]	0.051	
Index Event									
HF Hospitalization within 3 Months	1439	24 (1.7)	1474	14 (0.9)	0.72 [-0.11; 1.61]	1.75 [0.92; 3.31]	1.75 [0.92; 3.31]	0.088	0.483
HF Hospitalization 3-6 Months	386	9 (2.3)	362	5 (1.4)	0.95 [-1.14; 3.17]	1.70 [0.57; 5.13]	1.69 [0.57; 4.99]	0.344	
IV diuretic for HF (without hospitalization) within 3 Months	327	6 (1.8)	315	1 (0.3)	1.52 [-0.12; 3.67]	4.07 [0.92; 18.06]	4.07 [0.92; 18.06]	0.064	
SOC: Cardiac disorders									
Age category 2									
<75	1519	126 (8.3)	1533	175 (11.4)	-3.12 [-5.25; -1.01]	0.70 [0.55; 0.89]	0.73 [0.58; 0.90]	0.004	0.604
≥75	633	43 (6.8)	618	65 (10.5)	-3.72 [-6.92; -0.62]	0.62 [0.41; 0.93]	0.65 [0.45; 0.93]	0.020	
Gender									
Male	1656	141 (8.5)	1652	189 (11.4)	-2.93 [-4.98; -0.89]	0.72 [0.57; 0.91]	0.74 [0.60; 0.92]	0.005	0.241

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Female	496	28 (5.6)	499	51 (10.2)	-4.58 [-8.04; -1.24]	0.53 [0.33; 0.85]	0.55 [0.35; 0.86]	0.009	
Geographic Region									
Asia Pacific	510	36 (7.1)	502	56 (11.2)	-4.10 [-7.73; -0.56]	0.60 [0.39; 0.94]	0.63 [0.42; 0.94]	0.025	0.971
Eastern Europe	721	54 (7.5)	718	72 (10.0)	-2.54 [-5.51; 0.39]	0.73 [0.50; 1.05]	0.75 [0.53; 1.05]	0.090	
Latin and South America	316	21 (6.6)	324	33 (10.2)	-3.54 [-7.98; 0.79]	0.63 [0.35; 1.11]	0.65 [0.39; 1.10]	0.111	
North America	240	19 (7.9)	241	26 (10.8)	-2.87 [-8.26; 2.41]	0.71 [0.38; 1.32]	0.73 [0.42; 1.29]	0.282	
Western Europe	365	39 (10.7)	366	53 (14.5)	-3.80 [-8.68; 1.03]	0.71 [0.45; 1.10]	0.74 [0.50; 1.09]	0.124	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	18 (8.5)	202	16 (7.9)	0.53 [-4.97; 5.98]	1.07 [0.53; 2.17]	1.07 [0.56; 2.03]	0.844	0.181
>30 to ≤60	882	75 (8.5)	895	124 (13.9)	-5.35 [-8.31; -2.44]	0.58 [0.43; 0.78]	0.61 [0.47; 0.80]	< 0.001	
>60	1021	74 (7.2)	1022	93 (9.1)	-1.85 [-4.26; 0.53]	0.78 [0.57; 1.07]	0.80 [0.59; 1.07]	0.128	
NYHA Group at Baseline									
Class I or II	1236	94 (7.6)	1267	138 (10.9)	-3.29 [-5.57; -1.02]	0.67 [0.51; 0.89]	0.70 [0.54; 0.90]	0.005	0.934

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Class III or IV	914	75 (8.2)	884	102 (11.5)	-3.33 [-6.13; -0.58]	0.69 [0.50; 0.94]	0.71 [0.54; 0.94]	0.018	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	26 (7.9)	330	44 (13.3)	-5.43 [-10.25; -0.74]	0.56 [0.33; 0.93]	0.59 [0.37; 0.94]	0.026	0.408
No	1823	143 (7.8)	1820	196 (10.8)	-2.93 [-4.83; -1.04]	0.71 [0.56; 0.88]	0.73 [0.59; 0.89]	0.003	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	31 (6.3)	507	50 (9.9)	-3.52 [-6.99; -0.13]	0.62 [0.39; 0.99]	0.64 [0.42; 0.99]	0.044	0.694
Q2 (1556 - 2816)	520	38 (7.3)	493	57 (11.6)	-4.25 [-7.96; -0.67]	0.60 [0.39; 0.93]	0.63 [0.43; 0.93]	0.022	
Q3 (2816 - 5314)	511	47 (9.2)	518	56 (10.8)	-1.61 [-5.33; 2.08]	0.84 [0.56; 1.26]	0.85 [0.59; 1.23]	0.389	
Q4 (>5314)	548	44 (8.0)	523	61 (11.7)	-3.63 [-7.29; -0.07]	0.66 [0.44; 0.99]	0.69 [0.48; 1.00]	0.047	
Baseline Ejection Fraction Group 2									
<35	1719	141 (8.2)	1734	200 (11.5)	-3.33 [-5.33; -1.35]	0.69 [0.55; 0.86]	0.71 [0.58; 0.87]	0.001	0.858
≥35	433	28 (6.5)	417	40 (9.6)	-3.13 [-6.91; 0.53]	0.65 [0.39; 1.08]	0.67 [0.42; 1.07]	0.096	
Race group									
White	1344	112 (8.3)	1353	161 (11.9)	-3.57 [-5.86; -1.30]	0.67 [0.52; 0.87]	0.70 [0.56; 0.88]	0.002	0.997

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (Incidence ≥ 1% and in at least 10 participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Asian	500	31 (6.2)	474	43 (9.1)	-2.87 [-6.33; 0.47]	0.66 [0.41; 1.07]	0.68 [0.44; 1.07]	0.093	
Black	111	10 (9.0)	118	14 (11.9)	-2.86 [-11.13; 5.40]	0.74 [0.31; 1.73]	0.76 [0.35; 1.64]	0.483	
Other	196	15 (7.7)	206	22 (10.7)	-3.03 [-8.87; 2.75]	0.69 [0.35; 1.38]	0.72 [0.38; 1.34]	0.297	
Medical History of Diabetes Mellitus									
Yes	1047	92 (8.8)	984	113 (11.5)	-2.70 [-5.36; -0.07]	0.74 [0.56; 0.99]	0.77 [0.59; 0.99]	0.045	0.366
No	1105	77 (7.0)	1167	127 (10.9)	-3.91 [-6.28; -1.58]	0.61 [0.46; 0.82]	0.64 [0.49; 0.84]	0.001	
Index Event									
HF Hospitalization within 3 Months	1439	121 (8.4)	1474	172 (11.7)	-3.26 [-5.46; -1.08]	0.69 [0.54; 0.89]	0.72 [0.58; 0.90]	0.004	0.503
HF Hospitalization 3-6 Months	386	29 (7.5)	362	47 (13.0)	-5.47 [-9.97; -1.15]	0.54 [0.33; 0.89]	0.58 [0.37; 0.90]	0.015	
IV diuretic for HF (without hospitalization) within 3 Months	327	19 (5.8)	315	21 (6.7)	-0.86 [-4.78; 2.98]	0.86 [0.46; 1.64]	0.87 [0.48; 1.59]	0.654	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1 % or ≥ 99 % in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.
h: A specific adverse event appears on this report only if its incidence ≥ 5% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is greater than or equal to 0.05 or rule of 10 is not met
CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 55
Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Cardiac disorders PT[h]: Atrial fibrillation									
Age category 1									
<65	831	5 (0.6)	851	10 (1.2)	-0.57 [-1.62; 0.37]	0.52 [0.19; 1.44]	0.52 [0.19; 1.44]	0.211	0.346
≥65	1321	4 (0.3)	1300	16 (1.2)	-0.93 [-1.72; -0.29]	0.29 [0.12; 0.71]	0.29 [0.12; 0.71]	0.006	
Age category 2									
<75	1519	9 (0.6)	1533	17 (1.1)	-0.52 [-1.24; 0.15]	0.54 [0.25; 1.17]	0.54 [0.25; 1.17]	0.121	0.115
≥75	633	0 (0.0)	618	9 (1.5)	-1.46 [-2.75; -0.77]	0.13 [0.04; 0.48]	0.13 [0.04; 0.48]	0.002	
Gender									
Male	1656	8 (0.5)	1652	17 (1.0)	-0.55 [-1.21; 0.05]	0.48 [0.22; 1.06]	0.48 [0.22; 1.06]	0.070	0.152
Female	496	1 (0.2)	499	9 (1.8)	-1.60 [-3.21; -0.46]	0.20 [0.06; 0.70]	0.20 [0.06; 0.70]	0.011	
Geographic Region									
Asia Pacific	510	3 (0.6)	502	4 (0.8)	-0.21 [-1.51; 1.01]	0.74 [0.17; 3.26]	0.74 [0.17; 3.26]	0.689	0.517
Eastern Europe	721	1 (0.1)	718	10 (1.4)	-1.25 [-2.42; -0.44]	0.19 [0.06; 0.63]	0.19 [0.06; 0.63]	0.006	
Latin and South America	316	0 (0.0)	324	1 (0.3)	-0.31 [-1.73; 0.90]	0.14 [0.00; 6.99]	0.14 [0.00; 6.99]	0.323	

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	2 (0.8)	241	2 (0.8)	0.00 [-2.23; 2.25]	1.00 [0.14; 7.17]	1.00 [0.14; 7.17]	0.997	
Western Europe	365	3 (0.8)	366	9 (2.5)	-1.64 [-3.88; 0.24]	0.36 [0.12; 1.14]	0.36 [0.12; 1.14]	0.082	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	0 (0.0)	202	2 (1.0)	-0.99 [-3.54; 0.79]	0.13 [0.01; 2.05]	0.13 [0.01; 2.05]	0.146	0.471
>30 to ≤60	882	4 (0.5)	895	16 (1.8)	-1.33 [-2.48; -0.39]	0.30 [0.12; 0.73]	0.30 [0.12; 0.73]	0.008	
>60	1021	5 (0.5)	1022	8 (0.8)	-0.29 [-1.11; 0.45]	0.63 [0.21; 1.87]	0.63 [0.21; 1.87]	0.405	
NYHA Group at Baseline									
Class I or II	1236	6 (0.5)	1267	14 (1.1)	-0.62 [-1.42; 0.09]	0.46 [0.19; 1.10]	0.46 [0.19; 1.10]	0.082	0.452
Class III or IV	914	3 (0.3)	884	12 (1.4)	-1.03 [-2.07; -0.21]	0.29 [0.10; 0.80]	0.29 [0.10; 0.80]	0.016	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	0 (0.0)	330	4 (1.2)	-1.21 [-3.08; -0.05]	0.13 [0.02; 0.96]	0.13 [0.02; 0.96]	0.045	0.387
No	1823	9 (0.5)	1820	22 (1.2)	-0.72 [-1.38; -0.13]	0.43 [0.21; 0.87]	0.43 [0.21; 0.87]	0.019	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	4 (0.8)	507	3 (0.6)	0.23 [-1.00; 1.56]	1.38 [0.31; 6.11]	1.38 [0.31; 6.11]	0.669	0.154

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q2 (1556 - 2816)	520	1 (0.2)	493	8 (1.6)	-1.43 [-3.00; -0.35]	0.20 [0.05; 0.73]	0.20 [0.05; 0.73]	0.015	
Q3 (2816 - 5314)	511	3 (0.6)	518	8 (1.5)	-0.96 [-2.50; 0.36]	0.40 [0.12; 1.33]	0.40 [0.12; 1.33]	0.136	
Q4 (>5314)	548	1 (0.2)	523	6 (1.1)	-0.96 [-2.32; 0.00]	0.23 [0.05; 1.00]	0.23 [0.05; 1.00]	0.050	
Baseline Ejection Fraction Group 2									
<35	1719	8 (0.5)	1734	22 (1.3)	-0.80 [-1.50; -0.20]	0.39 [0.19; 0.81]	0.39 [0.19; 0.81]	0.011	0.717
≥35	433	1 (0.2)	417	4 (1.0)	-0.73 [-2.24; 0.43]	0.29 [0.05; 1.67]	0.29 [0.05; 1.67]	0.165	
Race group									
White	1344	7 (0.5)	1353	21 (1.6)	-1.03 [-1.90; -0.29]	0.37 [0.17; 0.77]	0.37 [0.17; 0.77]	0.008	0.915
Asian	500	2 (0.4)	474	3 (0.6)	-0.23 [-1.49; 0.88]	0.63 [0.11; 3.68]	0.63 [0.11; 3.68]	0.611	
Black	111	0 (0.0)	118	1 (0.8)	-0.85 [-4.66; 2.53]	0.14 [0.00; 7.25]	0.14 [0.00; 7.25]	0.332	
Other	196	0 (0.0)	206	1 (0.5)	-0.49 [-2.70; 1.45]	0.14 [0.00; 7.17]	0.14 [0.00; 7.17]	0.329	
CCSA class at Randomization									
No Angina	1843	7 (0.4)	1850	24 (1.3)	-0.92 [-1.58; -0.35]	0.33 [0.16; 0.67]	0.33 [0.16; 0.67]	0.002	0.454

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Angina Class 1 or 2	265	2 (0.8)	260	2 (0.8)	-0.01 [-2.09; 2.02]	0.98 [0.14; 7.00]	0.98 [0.14; 7.00]	0.985	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	0.00 [-8.66; 8.12]	n.a.	n.a.	n.a.	
Medical History of Diabetes Mellitus									
Yes	1047	7 (0.7)	984	12 (1.2)	-0.55 [-1.52; 0.31]	0.55 [0.22; 1.36]	0.55 [0.22; 1.36]	0.198	0.124
No	1105	2 (0.2)	1167	14 (1.2)	-1.02 [-1.84; -0.39]	0.23 [0.09; 0.62]	0.23 [0.09; 0.62]	0.004	
Index Event									
HF Hospitalization within 3 Months	1439	6 (0.4)	1474	15 (1.0)	-0.60 [-1.30; 0.02]	0.43 [0.18; 1.02]	0.43 [0.18; 1.02]	0.055	0.792
HF Hospitalization 3-6 Months	386	2 (0.5)	362	6 (1.7)	-1.14 [-3.11; 0.42]	0.34 [0.08; 1.37]	0.34 [0.08; 1.37]	0.130	
IV diuretic for HF (without hospitalization) within 3 Months	327	1 (0.3)	315	5 (1.6)	-1.28 [-3.39; 0.29]	0.25 [0.05; 1.25]	0.25 [0.05; 1.25]	0.092	
SOC: Cardiac disorders PT[h]: Cardiac failure									
Age category 1									
<65	831	27 (3.2)	851	32 (3.8)	-0.51 [-2.32; 1.29]	0.86 [0.51; 1.45]	0.86 [0.52; 1.43]	0.569	0.230
≥65	1321	40 (3.0)	1300	67 (5.2)	-2.13 [-3.69; -0.62]	0.57 [0.39; 0.86]	0.59 [0.40; 0.86]	0.007	
Age category 2									
<75	1519	47 (3.1)	1533	72 (4.7)	-1.60 [-3.01; -0.23]	0.65 [0.45; 0.94]	0.66 [0.46; 0.94]	0.023	0.785

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥75	633	20 (3.2)	618	27 (4.4)	-1.21 [-3.43; 0.93]	0.71 [0.40; 1.29]	0.72 [0.41; 1.28]	0.263	
Gender									
Male	1656	56 (3.4)	1652	80 (4.8)	-1.46 [-2.85; -0.11]	0.69 [0.49; 0.97]	0.70 [0.50; 0.98]	0.035	0.665
Female	496	11 (2.2)	499	19 (3.8)	-1.59 [-3.90; 0.57]	0.57 [0.27; 1.22]	0.58 [0.28; 1.21]	0.148	
Geographic Region									
Asia Pacific	510	16 (3.1)	502	29 (5.8)	-2.64 [-5.35; -0.10]	0.53 [0.28; 0.99]	0.54 [0.30; 0.99]	0.045	0.147
Eastern Europe	721	24 (3.3)	718	20 (2.8)	0.54 [-1.28; 2.41]	1.20 [0.66; 2.20]	1.20 [0.67; 2.14]	0.550	
Latin and South America	316	12 (3.8)	324	17 (5.2)	-1.45 [-4.88; 1.88]	0.71 [0.33; 1.52]	0.72 [0.35; 1.49]	0.380	
North America	240	2 (0.8)	241	8 (3.3)	-2.49 [-5.69; 0.08]	0.30 [0.08; 1.03]	0.30 [0.08; 1.03]	0.056	
Western Europe	365	13 (3.6)	366	25 (6.8)	-3.27 [-6.70; -0.05]	0.50 [0.25; 1.00]	0.52 [0.27; 1.00]	0.051	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	6 (2.8)	202	9 (4.5)	-1.64 [-5.78; 2.15]	0.62 [0.22; 1.78]	0.63 [0.23; 1.74]	0.376	0.955
>30 to ≤60	882	35 (4.0)	895	54 (6.0)	-2.07 [-4.15; -0.04]	0.64 [0.42; 1.00]	0.66 [0.43; 1.00]	0.048	

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
>60	1021	25 (2.4)	1022	35 (3.4)	-0.98 [-2.50; 0.50]	0.71 [0.42; 1.19]	0.71 [0.43; 1.19]	0.194	
NYHA Group at Baseline									
Class I or II	1236	35 (2.8)	1267	59 (4.7)	-1.82 [-3.36; -0.34]	0.60 [0.39; 0.91]	0.61 [0.40; 0.92]	0.018	0.443
Class III or IV	914	32 (3.5)	884	40 (4.5)	-1.02 [-2.91; 0.80]	0.77 [0.48; 1.23]	0.77 [0.49; 1.22]	0.270	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	11 (3.3)	330	17 (5.2)	-1.81 [-5.13; 1.35]	0.64 [0.29; 1.38]	0.65 [0.31; 1.36]	0.254	0.902
No	1823	56 (3.1)	1820	82 (4.5)	-1.43 [-2.70; -0.20]	0.67 [0.48; 0.95]	0.68 [0.49; 0.95]	0.024	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	12 (2.5)	507	21 (4.1)	-1.69 [-4.07; 0.57]	0.58 [0.28; 1.20]	0.59 [0.29; 1.19]	0.142	0.447
Q2 (1556 - 2816)	520	16 (3.1)	493	27 (5.5)	-2.40 [-5.08; 0.09]	0.55 [0.29; 1.03]	0.56 [0.31; 1.03]	0.062	
Q3 (2816 - 5314)	511	21 (4.1)	518	20 (3.9)	0.25 [-2.22; 2.74]	1.07 [0.57; 1.99]	1.06 [0.58; 1.94]	0.839	
Q4 (>5314)	548	17 (3.1)	523	25 (4.8)	-1.68 [-4.17; 0.67]	0.64 [0.34; 1.20]	0.65 [0.35; 1.19]	0.161	
Baseline Ejection Fraction Group 2									
<35	1719	56 (3.3)	1734	81 (4.7)	-1.41 [-2.74; -0.11]	0.69 [0.49; 0.97]	0.70 [0.50; 0.97]	0.034	0.684

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥35	433	11 (2.5)	417	18 (4.3)	-1.78 [-4.45; 0.70]	0.58 [0.27; 1.24]	0.59 [0.28; 1.23]	0.159	
Race group									
White	1344	43 (3.2)	1353	59 (4.4)	-1.16 [-2.64; 0.28]	0.72 [0.49; 1.08]	0.73 [0.50; 1.08]	0.116	0.641
Asian	500	12 (2.4)	474	24 (5.1)	-2.66 [-5.27; -0.30]	0.46 [0.23; 0.93]	0.47 [0.24; 0.94]	0.032	
Black	111	4 (3.6)	118	4 (3.4)	0.21 [-5.29; 5.95]	1.07 [0.26; 4.37]	1.06 [0.27; 4.15]	0.930	
Other	196	8 (4.1)	206	12 (5.8)	-1.74 [-6.34; 2.74]	0.69 [0.28; 1.72]	0.70 [0.29; 1.68]	0.425	
CCSA class at Randomization									
No Angina	1843	56 (3.0)	1850	86 (4.6)	-1.61 [-2.88; -0.37]	0.64 [0.46; 0.91]	0.65 [0.47; 0.91]	0.012	0.759
Angina Class 1 or 2	265	10 (3.8)	260	11 (4.2)	-0.46 [-4.10; 3.10]	0.89 [0.37; 2.13]	0.89 [0.39; 2.06]	0.789	
Angina Class 3 or 4	44	1 (2.3)	41	2 (4.9)	-2.61 [-14.26; 7.61]	0.45 [0.04; 5.20]	0.47 [0.04; 4.95]	0.526	
Medical History of Diabetes Mellitus									
Yes	1047	36 (3.4)	984	50 (5.1)	-1.64 [-3.47; 0.11]	0.67 [0.43; 1.03]	0.68 [0.44; 1.03]	0.068	0.975
No	1105	31 (2.8)	1167	49 (4.2)	-1.39 [-2.95; 0.13]	0.66 [0.42; 1.04]	0.67 [0.43; 1.04]	0.074	

Analyses of Serious Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Index Event									
HF Hospitalization within 3 Months	1439	45 (3.1)	1474	71 (4.8)	-1.69 [-3.14; -0.27]	0.64 [0.44; 0.93]	0.65 [0.45; 0.94]	0.021	0.595
HF Hospitalization 3-6 Months	386	14 (3.6)	362	21 (5.8)	-2.17 [-5.45; 0.89]	0.61 [0.31; 1.22]	0.63 [0.32; 1.21]	0.164	
IV diuretic for HF (without hospitalization) within 3 Months	327	8 (2.4)	315	7 (2.2)	0.22 [-2.37; 2.81]	1.10 [0.40; 3.08]	1.10 [0.40; 3.00]	0.851	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1 % or ≥ 99 % in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

h: A specific adverse event appears on this report only if its incidence ≥ 5% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is greater than or equal to 0.05 or rule of 10 is not met

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

1.8.3 Adverse Events by severity by SOC and PT

Table 56
Overview of Subgroup Analyses for Mild Adverse Event Related Endpoints
Treatment by Subgroup Interaction
by System Organ Class and Preferred Term
(Incidence ≥10% or (≥1% and in at least 10 Participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**						
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 0 / >30 to ≤ 60 / >60)**	**NYHA Group at Baseline (Class I or II / Class III or IV)**	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**
Mild Adverse Events by SOC and PT[c] - Event							
Blood and lymphatic system disorders	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Anaemia	0.159	0.685	0.888	0.788	**0.033[d]**	0.940	0.159
Gastrointestinal disorders	0.200	0.982	**0.031[d]**	0.481	0.351	**0.042[d]**	0.944
Dyspepsia	0.380	0.704	0.177	0.598	0.251	0.602	0.630
Gastrooesophageal reflux disease	0.111	0.862	0.203	0.337	0.210	0.147	0.562
Infections and infestations	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Influenza	0.370	0.495	0.286	0.569	0.313	0.519	0.285

Overview of Subgroup Analyses for Mild Adverse Event Related Endpoints
Treatment by Subgroup Interaction
by System Organ Class and Preferred Term
(Incidence ≥10% or (≥1% and in at least 10 Participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**					
	NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**
Mild Adverse Events by SOC and PT[c] - Event						
Blood and lymphatic system disorders	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Anaemia	0.097	0.990	0.858	0.790	0.522	0.799
Gastrointestinal disorders	0.780	0.383	0.720	0.063	0.823	0.970
Dyspepsia	0.418	0.659	0.961	0.330	0.563	0.930
Gastrooesophageal reflux disease	0.457	0.998	**0.043[d]**	0.515	0.609	0.402
Infections and infestations	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Influenza	0.723	0.406	0.347	0.312	0.485	0.416

Overview of Subgroup Analyses for Mild Adverse Event Related Endpoints
Treatment by Subgroup Interaction
by System Organ Class and Preferred Term
(Incidence ≥10% or (≥1% and in at least 10 Participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**						
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 0 / >30 to ≤ 60 / >60)**	**NYHA Group at Baseline (Class I or II / Class III or IV)**	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**
Respiratory, thoracic and mediastinal disorders	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Epistaxis	**0.024[d]**	0.141	0.633	0.662	**0.024[d]**	0.868	0.139
Vascular disorders	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Hypotension	**0.040[d]**	0.321	0.868	0.528	0.725	0.414	0.346

Overview of Subgroup Analyses for Mild Adverse Event Related Endpoints
Treatment by Subgroup Interaction
by System Organ Class and Preferred Term
(Incidence ≥10% or (≥1% and in at least 10 Participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**					
	NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**
Respiratory, thoracic and mediastinal disorders	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Epistaxis	0.286	0.299	0.823	0.863	0.946	0.499
Vascular disorders	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Hypotension	0.904	0.440	0.570	0.942	0.648	0.481

a: Database Cutoff Date: 18JUN2019

b: Based on a Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if Participant has 0 event in at least one cell of the stratum.

c: A system organ class or specific adverse event appears on this report only if its incidence is ≥ 10% or ≥ 1% and in at least 10 patients in one or more treatment groups and p-value for main treatment effect smaller than 0.05

d: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; n.p.: not performed (subgroup analysis not performed as nominal p-value of main treatment effect greater or equal than 0.05); NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; PT: Preferred Term; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile; SOC: System Organ Class

Table 57
Overview of Subgroup Analyses for Moderate Adverse Event Related Endpoints
Treatment by Subgroup Interaction
by System Organ Class and Preferred Term
(Incidence ≥10% or (≥1% and in at least 10 Participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**						
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 0 / >30 to ≤ 60 / >60)**	**NYHA Group at Baseline (Class I or II / Class III or IV)**	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**
Moderate Adverse Events by SOC and PT[c] - Event							
Gastrointestinal disorders	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Vomiting	**0.031[d]**	0.074	0.235	0.606	0.148	0.081	0.293
Infections and infestations	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Bronchitis	0.583	0.987	0.482	0.317	0.224	0.330	0.286
Injury, poisoning and procedural complications	**< 0.001[d]**	0.375	0.608	0.550	0.739	**0.010[d]**	0.969
Respiratory, thoracic and mediastinal disorders	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Chronic obstructive pulmonary disease	0.781	0.634	0.380	0.465	0.647	**0.015[d]**	0.737

Overview of Subgroup Analyses for Moderate Adverse Event Related Endpoints
Treatment by Subgroup Interaction
by System Organ Class and Preferred Term
(Incidence ≥10% or (≥1% and in at least 10 Participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**					
	NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**
Moderate Adverse Events by SOC and PT[c] - Event						
Gastrointestinal disorders	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Vomiting	0.361	0.996	0.959	0.489	0.655	0.898
Infections and infestations	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Bronchitis	0.647	0.804	0.993	0.521	0.240	0.334
Injury, poisoning and procedural complications	**0.022[d]**	0.464	0.053	0.418	0.407	0.172
Respiratory, thoracic and mediastinal disorders	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.
Chronic obstructive pulmonary disease	0.296	0.698	0.698	0.309	0.959	0.820

a: Database Cutoff Date: 18JUN2019

b: Based on a Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if Participant has 0 event in at least one cell of the stratum.

c: A system organ class or specific adverse event appears on this report only if its incidence is ≥ 10% or ≥ 1% and in at least 10 patients in one or more treatment groups and p-value for main treatment effect smaller than 0.05

d: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; n.p.: not performed (subgroup analysis not performed as nominal p-value of main treatment effect greater or equal than 0.05); NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; PT: Preferred Term; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile; SOC: System Organ Class

Table 58
Overview of Subgroup Analyses for Severe Adverse Event Related Endpoints
Treatment by Subgroup Interaction
by System Organ Class and Preferred Term
(Incidence ≥5% or (≥1% and in at least 10 Participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**						
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 0 / >30 to ≤ 60 / >60)**	**NYHA Group at Baseline (Class I or II / Class III or IV)**	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**
Severe Adverse Events by SOC and PT[c] - Event							
Blood and lymphatic system disorders	0.639	**0.048[d]**	0.845	0.547	0.096	0.093	0.671
Anaemia	0.660	0.455	0.350	0.329	0.403	0.203	0.653
Cardiac disorders	0.171	0.634	0.790	0.484	0.255	0.259	0.156
Atrial fibrillation	0.179	0.090	0.460	0.502	0.431	0.561	0.335
Metabolism and nutrition disorders	0.519	0.252	0.232	0.186	0.306	0.788	0.985
Musculoskeletal and connective tissue disorders	0.082	0.139	0.747	0.729	0.814	0.955	0.463

Overview of Subgroup Analyses for Severe Adverse Event Related Endpoints
Treatment by Subgroup Interaction
by System Organ Class and Preferred Term
(Incidence ≥5% or (≥1% and in at least 10 Participants) in One or More Treatment Groups)
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**					
	NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**
Severe Adverse Events by SOC and PT[c] - Event						
Blood and lymphatic system disorders	0.420	0.521	0.540	0.422	0.285	0.953
Anaemia	0.257	0.521	0.755	0.917	0.430	0.840
Cardiac disorders	0.936	0.679	0.853	0.249	0.481	0.544
Atrial fibrillation	0.124	0.596	0.805	0.162	0.478	0.427
Metabolism and nutrition disorders	0.531	0.934	0.470	0.574	0.949	0.595
Musculoskeletal and connective tissue disorders	0.666	0.172	0.756	0.913	0.133	0.291

a: Database Cutoff Date: 18JUN2019

b: Based on a Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if Participant has 0 event in at least one cell of the stratum.

c: A system organ class or specific adverse event appears on this report only if its incidence is ≥ 5% or ≥ 1% and in at least 10 patients in one or more treatment groups and p-value for main treatment effect smaller than 0.05

d: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; PT: Preferred Term; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile; SOC: System Organ Class

1.8.3.1 Results for Subgroups with Interaction Nominal P-value < 0.05

Table 59
Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test < 0.05
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	Vericiguat		Placebo		Vericiguat vs. Placebo				
Mild Adverse Events	N[b]	Participants with Event n (%)	N[b]	Participants with Event n (%)	Risk Difference [95 %-CI][c]	Odds Ratio [95 %-CI][d]	Relative Risk [95 %-CI][e]	p-Value[e,f]	p-Value for Interaction Test[g]
SOC: Gastrointestinal disorders									
Gender									
Male	1656	278 (16.8)	1652	261 (15.8)	0.99 [-1.53; 3.51]	1.08 [0.89; 1.29]	1.06 [0.91; 1.24]	0.442	0.031
Female	496	108 (21.8)	499	73 (14.6)	7.14 [2.36; 11.95]	1.62 [1.17; 2.25]	1.49 [1.14; 1.95]	0.004	
NYHA Group at Baseline									
Class I or II	1236	227 (18.4)	1267	178 (14.0)	4.32 [1.43; 7.21]	1.38 [1.11; 1.71]	1.31 [1.09; 1.56]	0.004	0.042
Class III or IV	914	159 (17.4)	884	156 (17.6)	-0.25 [-3.78; 3.27]	0.98 [0.77; 1.25]	0.99 [0.81; 1.20]	0.889	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

h: A specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is smaller than 0.05 and rule of 10 is met

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 60
Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test < 0.05
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
SOC: Blood and lymphatic system disorders PT[h]: Anaemia									
eGFR (mL/min/1.73 m^2) Category									
≤30	213	7 (3.3)	202	13 (6.4)	-3.15 [-7.80; 1.05]	0.49 [0.19; 1.26]	0.51 [0.21; 1.25]	0.143	0.033
>30 to ≤60	882	43 (4.9)	895	32 (3.6)	1.30 [-0.58; 3.24]	1.38 [0.87; 2.21]	1.36 [0.87; 2.13]	0.175	
>60	1021	38 (3.7)	1022	19 (1.9)	1.86 [0.45; 3.38]	2.04 [1.17; 3.56]	2.00 [1.16; 3.45]	0.012	
SOC: Gastrointestinal disorders PT[h]: Gastrooesophageal reflux disease									
Race group									
White	1344	15 (1.1)	1353	1 (0.1)	1.04 [0.54; 1.77]	5.85 [2.19; 15.63]	5.85 [2.19; 15.63]	< 0.001	0.043
Asian	500	12 (2.4)	474	0 (0.0)	2.40 [1.38; 4.15]	7.17 [2.30; 22.39]	7.17 [2.30; 22.39]	< 0.001	
Black	111	0 (0.0)	118	3 (2.5)	-2.54 [-7.22; 0.86]	0.14 [0.01; 1.37]	0.14 [0.01; 1.37]	0.092	
Other	196	2 (1.0)	206	1 (0.5)	0.53 [-1.77; 3.21]	2.06 [0.21; 19.89]	2.06 [0.21; 19.89]	0.534	
SOC: Respiratory, thoracic and mediastinal disorders PT[h]: Epistaxis									
Age category 1									
<65	831	9 (1.1)	851	7 (0.8)	0.26 [-0.74; 1.32]	1.32 [0.49; 3.53]	1.32 [0.49; 3.53]	0.582	0.024
≥65	1321	11 (0.8)	1300	32 (2.5)	-1.63 [-2.70; -0.69]	0.36 [0.20; 0.67]	0.36 [0.20; 0.67]	0.001	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test < 0.05
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category									
≤30	213	6 (2.8)	202	7 (3.5)	-0.65 [-4.51; 3.01]	0.81 [0.27; 2.44]	0.81 [0.28; 2.38]	0.705	0.024
>30 to ≤60	882	5 (0.6)	895	25 (2.8)	-2.23 [-3.58; -1.11]	0.26 [0.13; 0.54]	0.26 [0.13; 0.54]	< 0.001	
>60	1021	8 (0.8)	1022	7 (0.7)	0.10 [-0.72; 0.94]	1.14 [0.41; 3.16]	1.14 [0.41; 3.16]	0.794	
SOC: Vascular disorders PT[h]: Hypotension									
Age category 1									
<65	831	91 (11.0)	851	58 (6.8)	4.14 [1.43; 6.91]	1.68 [1.19; 2.37]	1.61 [1.17; 2.20]	0.003	0.040
≥65	1321	123 (9.3)	1300	114 (8.8)	0.54 [-1.66; 2.75]	1.07 [0.82; 1.40]	1.06 [0.83; 1.35]	0.629	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

h: A specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is smaller than 0.05 and rule of 10 is met

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 61
Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test < 0.05
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
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Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
SOC: Injury, poisoning and procedural complications									
Age category 1									
<65	831	27 (3.2)	851	16 (1.9)	1.37 [-0.15; 2.99]	1.75 [0.94; 3.28]	1.73 [0.94; 3.18]	0.079	< 0.001
≥65	1321	38 (2.9)	1300	76 (5.8)	-2.97 [-4.59; -1.43]	0.48 [0.32; 0.71]	0.49 [0.34; 0.72]	< 0.001	
NYHA Group at Baseline									
Class I or II	1236	44 (3.6)	1267	45 (3.6)	0.01 [-1.47; 1.49]	1.00 [0.66; 1.53]	1.00 [0.67; 1.51]	0.991	0.010
Class III or IV	914	21 (2.3)	884	47 (5.3)	-3.02 [-4.90; -1.28]	0.42 [0.25; 0.71]	0.43 [0.26; 0.72]	0.001	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	11 (2.2)	507	14 (2.8)	-0.51 [-2.60; 1.54]	0.81 [0.36; 1.80]	0.81 [0.37; 1.78]	0.606	0.022
Q2 (1556 - 2816)	520	22 (4.2)	493	19 (3.9)	0.38 [-2.15; 2.89]	1.10 [0.59; 2.06]	1.10 [0.60; 2.00]	0.761	
Q3 (2816 - 5314)	511	16 (3.1)	518	16 (3.1)	0.04 [-2.18; 2.28]	1.01 [0.50; 2.05]	1.01 [0.51; 2.01]	0.969	
Q4 (>5314)	548	15 (2.7)	523	41 (7.8)	-5.10 [-7.97; -2.50]	0.33 [0.18; 0.61]	0.35 [0.20; 0.62]	< 0.001	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

h: A specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is smaller than 0.05 and rule of 10 is met
CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 62
Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test < 0.05
(Incidence ≥ 10% or (≥ 1% and in at least 10 participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Gastrointestinal disorders PT[h]: Vomiting									
Age category 1									
<65	831	14 (1.7)	851	2 (0.2)	1.45 [0.60; 2.60]	4.65 [1.74; 12.46]	4.65 [1.74; 12.46]	0.002	0.031
≥65	1321	10 (0.8)	1300	8 (0.6)	0.14 [-0.54; 0.85]	1.23 [0.49; 3.11]	1.23 [0.49; 3.11]	0.661	
SOC: Respiratory, thoracic and mediastinal disorders PT[h]: Chronic obstructive pulmonary disease									
NYHA Group at Baseline									
Class I or II	1236	8 (0.6)	1267	9 (0.7)	-0.06 [-0.78; 0.65]	0.91 [0.35; 2.36]	0.91 [0.35; 2.36]	0.848	0.015
Class III or IV	914	17 (1.9)	884	3 (0.3)	1.52 [0.62; 2.66]	3.98 [1.65; 9.61]	3.98 [1.65; 9.61]	0.002	

a: Database Cutoff Date: 18JUN2019
b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%
c: Based on Unstratified Miettinen & Nurminen method.
d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum
e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum
f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.
h: A specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is smaller than 0.05 and rule of 10 is met
CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 63
Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test < 0.05
(Incidence ≥ 5% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Blood and lymphatic system disorders									
Age category 2									
<75	1519	26 (1.7)	1533	9 (0.6)	1.12 [0.39; 1.97]	2.70 [1.38; 5.25]	2.70 [1.38; 5.25]	0.004	0.048
≥75	633	12 (1.9)	618	12 (1.9)	-0.05 [-1.68; 1.57]	0.98 [0.44; 2.19]	0.98 [0.44; 2.16]	0.953	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

h: A specific adverse event appears on this report only if its incidence ≥ 5% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is smaller than 0.05 and rule of 10 is met

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

1.8.3.2 Results for Subgroups with Interaction Nominal P-value ≥ 0.05

Table 64
Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥10% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Gastrointestinal disorders									
Age category 1									
<65	831	134 (16.1)	851	133 (15.6)	0.50 [-3.00; 4.01]	1.04 [0.80; 1.35]	1.03 [0.83; 1.29]	0.781	0.200
≥65	1321	252 (19.1)	1300	201 (15.5)	3.61 [0.72; 6.51]	1.29 [1.05; 1.58]	1.23 [1.04; 1.46]	0.015	
Age category 2									
<75	1519	267 (17.6)	1533	233 (15.2)	2.38 [-0.25; 5.01]	1.19 [0.98; 1.44]	1.16 [0.98; 1.36]	0.076	0.982
≥75	633	119 (18.8)	618	101 (16.3)	2.46 [-1.77; 6.68]	1.19 [0.89; 1.59]	1.15 [0.90; 1.46]	0.255	
Geographic Region									
Asia Pacific	510	124 (24.3)	502	107 (21.3)	3.00 [-2.18; 8.17]	1.19 [0.88; 1.59]	1.14 [0.91; 1.43]	0.256	0.481
Eastern Europe	721	128 (17.8)	718	93 (13.0)	4.80 [1.08; 8.54]	1.45 [1.09; 1.94]	1.37 [1.07; 1.75]	0.012	
Latin and South America	316	32 (10.1)	324	34 (10.5)	-0.37 [-5.16; 4.43]	0.96 [0.58; 1.60]	0.97 [0.61; 1.52]	0.879	
North America	240	50 (20.8)	241	47 (19.5)	1.33 [-5.88; 8.54]	1.09 [0.70; 1.70]	1.07 [0.75; 1.52]	0.716	
Western Europe	365	52 (14.2)	366	53 (14.5)	-0.23 [-5.36; 4.89]	0.98 [0.65; 1.48]	0.98 [0.69; 1.40]	0.928	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥10% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category									
≤30	213	40 (18.8)	202	42 (20.8)	-2.01 [-9.76; 5.68]	0.88 [0.54; 1.43]	0.90 [0.61; 1.33]	0.607	0.351
>30 to ≤60	882	157 (17.8)	895	142 (15.9)	1.93 [-1.55; 5.43]	1.15 [0.90; 1.47]	1.12 [0.91; 1.38]	0.276	
>60	1021	183 (17.9)	1022	147 (14.4)	3.54 [0.35; 6.74]	1.30 [1.03; 1.65]	1.25 [1.02; 1.52]	0.030	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	56 (17.0)	330	48 (14.5)	2.48 [-3.12; 8.09]	1.21 [0.79; 1.83]	1.17 [0.82; 1.67]	0.384	0.944
No	1823	330 (18.1)	1820	286 (15.7)	2.39 [-0.05; 4.83]	1.19 [1.00; 1.41]	1.15 [1.00; 1.33]	0.055	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	94 (19.2)	507	85 (16.8)	2.46 [-2.32; 7.26]	1.18 [0.85; 1.63]	1.15 [0.88; 1.50]	0.313	0.780
Q2 (1556 - 2816)	520	94 (18.1)	493	80 (16.2)	1.85 [-2.82; 6.50]	1.14 [0.82; 1.58]	1.11 [0.85; 1.46]	0.436	
Q3 (2816 - 5314)	511	89 (17.4)	518	69 (13.3)	4.10 [-0.31; 8.54]	1.37 [0.98; 1.93]	1.31 [0.98; 1.75]	0.070	
Q4 (>5314)	548	95 (17.3)	523	85 (16.3)	1.08 [-3.42; 5.57]	1.08 [0.78; 1.49]	1.07 [0.82; 1.39]	0.636	
Baseline Ejection Fraction Group 2									
<35	1719	294 (17.1)	1734	265 (15.3)	1.82 [-0.64; 4.28]	1.14 [0.95; 1.37]	1.12 [0.96; 1.30]	0.147	0.383

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥10% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥35	433	92 (21.2)	417	69 (16.5)	4.70 [-0.58; 9.97]	1.36 [0.96; 1.92]	1.28 [0.97; 1.70]	0.082	
Race group									
White	1344	223 (16.6)	1353	182 (13.5)	3.14 [0.44; 5.85]	1.28 [1.04; 1.58]	1.23 [1.03; 1.48]	0.023	0.720
Asian	500	115 (23.0)	474	102 (21.5)	1.48 [-3.77; 6.70]	1.09 [0.81; 1.47]	1.07 [0.84; 1.35]	0.579	
Black	111	21 (18.9)	118	21 (17.8)	1.12 [-9.00; 11.37]	1.08 [0.55; 2.11]	1.06 [0.62; 1.84]	0.826	
Other	196	27 (13.8)	206	29 (14.1)	-0.30 [-7.15; 6.61]	0.98 [0.55; 1.72]	0.98 [0.60; 1.59]	0.930	
CCSA class at Randomization									
No Angina	1843	330 (17.9)	1850	297 (16.1)	1.85 [-0.57; 4.28]	1.14 [0.96; 1.35]	1.12 [0.97; 1.29]	0.134	0.063
Angina Class 1 or 2	265	52 (19.6)	260	30 (11.5)	8.08 [1.90; 14.34]	1.87 [1.15; 3.04]	1.70 [1.12; 2.58]	0.012	
Angina Class 3 or 4	44	4 (9.1)	41	7 (17.1)	-7.98 [-23.70; 6.89]	0.49 [0.13; 1.80]	0.53 [0.17; 1.69]	0.284	
Medical History of Diabetes Mellitus									
Yes	1047	184 (17.6)	984	152 (15.4)	2.13 [-1.11; 5.36]	1.17 [0.92; 1.48]	1.14 [0.93; 1.38]	0.198	0.823
No	1105	202 (18.3)	1167	182 (15.6)	2.68 [-0.40; 5.79]	1.21 [0.97; 1.51]	1.17 [0.98; 1.41]	0.088	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥10% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Index Event									
HF Hospitalization within 3 Months	1439	253 (17.6)	1474	223 (15.1)	2.45 [-0.23; 5.15]	1.20 [0.98; 1.46]	1.16 [0.99; 1.37]	0.074	0.970
HF Hospitalization 3-6 Months	386	70 (18.1)	362	59 (16.3)	1.84 [-3.62; 7.26]	1.14 [0.78; 1.66]	1.11 [0.81; 1.53]	0.507	
IV diuretic for HF (without hospitalization) within 3 Months	327	63 (19.3)	315	52 (16.5)	2.76 [-3.21; 8.71]	1.21 [0.81; 1.81]	1.17 [0.84; 1.63]	0.363	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1 % or ≥ 99 % in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

h: A specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is greater than or equal to 0.05 or rule of 10 is not met

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 65
Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Blood and lymphatic system disorders PT[h]: Anaemia									
Age category 1									
<65	831	32 (3.9)	851	17 (2.0)	1.85 [0.25; 3.58]	1.96 [1.08; 3.57]	1.93 [1.08; 3.44]	0.027	0.159
≥65	1321	56 (4.2)	1300	47 (3.6)	0.62 [-0.88; 2.14]	1.18 [0.79; 1.75]	1.17 [0.80; 1.71]	0.412	
Age category 2									
<75	1519	53 (3.5)	1533	41 (2.7)	0.81 [-0.42; 2.08]	1.32 [0.87; 1.99]	1.30 [0.87; 1.95]	0.194	0.685
≥75	633	35 (5.5)	618	23 (3.7)	1.81 [-0.54; 4.23]	1.51 [0.88; 2.59]	1.49 [0.89; 2.48]	0.131	
Gender									
Male	1656	63 (3.8)	1652	45 (2.7)	1.08 [-0.13; 2.32]	1.41 [0.96; 2.08]	1.40 [0.96; 2.03]	0.082	0.888
Female	496	25 (5.0)	499	19 (3.8)	1.23 [-1.37; 3.92]	1.34 [0.73; 2.47]	1.32 [0.74; 2.37]	0.346	
Geographic Region									
Asia Pacific	510	21 (4.1)	502	13 (2.6)	1.53 [-0.73; 3.90]	1.62 [0.80; 3.26]	1.59 [0.81; 3.14]	0.182	0.788
Eastern Europe	721	37 (5.1)	718	25 (3.5)	1.65 [-0.46; 3.83]	1.50 [0.89; 2.52]	1.47 [0.90; 2.42]	0.126	
Latin and South America	316	13 (4.1)	324	10 (3.1)	1.03 [-1.98; 4.18]	1.35 [0.58; 3.12]	1.33 [0.59; 3.00]	0.487	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	8 (3.3)	241	5 (2.1)	1.26 [-1.86; 4.62]	1.63 [0.52; 5.05]	1.61 [0.53; 4.84]	0.399	
Western Europe	365	9 (2.5)	366	11 (3.0)	-0.54 [-3.13; 1.98]	0.82 [0.33; 1.99]	0.82 [0.34; 1.96]	0.655	
NYHA Group at Baseline									
Class I or II	1236	45 (3.6)	1267	34 (2.7)	0.96 [-0.42; 2.38]	1.37 [0.87; 2.15]	1.36 [0.88; 2.10]	0.173	0.940
Class III or IV	914	43 (4.7)	884	30 (3.4)	1.31 [-0.53; 3.19]	1.41 [0.87; 2.26]	1.39 [0.88; 2.19]	0.161	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	15 (4.6)	330	6 (1.8)	2.74 [0.06; 5.78]	2.58 [0.99; 6.73]	2.51 [0.99; 6.38]	0.054	0.159
No	1823	73 (4.0)	1820	58 (3.2)	0.82 [-0.40; 2.05]	1.27 [0.89; 1.80]	1.26 [0.90; 1.76]	0.186	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	10 (2.0)	507	15 (3.0)	-0.91 [-3.02; 1.11]	0.68 [0.30; 1.54]	0.69 [0.31; 1.52]	0.360	0.097
Q2 (1556 - 2816)	520	28 (5.4)	493	11 (2.2)	3.15 [0.83; 5.68]	2.49 [1.23; 5.07]	2.41 [1.21; 4.79]	0.012	
Q3 (2816 - 5314)	511	21 (4.1)	518	15 (2.9)	1.21 [-1.08; 3.61]	1.44 [0.73; 2.82]	1.42 [0.74; 2.72]	0.292	
Q4 (>5314)	548	23 (4.2)	523	20 (3.8)	0.37 [-2.07; 2.81]	1.10 [0.60; 2.03]	1.10 [0.61; 1.97]	0.756	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Baseline Ejection Fraction Group 2									
<35	1719	68 (4.0)	1734	50 (2.9)	1.07 [-0.14; 2.32]	1.39 [0.96; 2.01]	1.37 [0.96; 1.96]	0.084	0.990
≥35	433	20 (4.6)	417	14 (3.4)	1.26 [-1.45; 4.04]	1.39 [0.69; 2.80]	1.38 [0.70; 2.69]	0.350	
Race group									
White	1344	47 (3.5)	1353	38 (2.8)	0.69 [-0.64; 2.05]	1.25 [0.81; 1.94]	1.25 [0.82; 1.90]	0.307	0.858
Asian	500	21 (4.2)	474	13 (2.7)	1.46 [-0.90; 3.90]	1.55 [0.77; 3.14]	1.53 [0.78; 3.02]	0.219	
Black	111	6 (5.4)	118	3 (2.5)	2.86 [-2.55; 9.09]	2.19 [0.53; 8.98]	2.13 [0.54; 8.30]	0.278	
Other	196	14 (7.1)	206	10 (4.9)	2.29 [-2.48; 7.35]	1.51 [0.65; 3.48]	1.47 [0.67; 3.23]	0.336	
CCSA class at Randomization									
No Angina	1843	72 (3.9)	1850	54 (2.9)	0.99 [-0.19; 2.19]	1.35 [0.94; 1.94]	1.34 [0.95; 1.89]	0.100	0.790
Angina Class 1 or 2	265	13 (4.9)	260	9 (3.5)	1.44 [-2.14; 5.17]	1.44 [0.60; 3.43]	1.42 [0.62; 3.26]	0.412	
Angina Class 3 or 4	44	3 (6.8)	41	1 (2.4)	4.38 [-6.67; 16.25]	2.93 [0.29; 29.33]	2.80 [0.30; 25.81]	0.365	
Medical History of Diabetes Mellitus									
Yes	1047	51 (4.9)	984	32 (3.3)	1.62 [-0.11; 3.38]	1.52 [0.97; 2.39]	1.50 [0.97; 2.31]	0.068	0.522

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
No	1105	37 (3.3)	1167	32 (2.7)	0.61 [-0.82; 2.08]	1.23 [0.76; 1.99]	1.22 [0.77; 1.95]	0.401	
Index Event									
HF Hospitalization within 3 Months	1439	60 (4.2)	1474	42 (2.8)	1.32 [-0.02; 2.70]	1.48 [0.99; 2.22]	1.46 [0.99; 2.16]	0.054	0.799
HF Hospitalization 3-6 Months	386	14 (3.6)	362	12 (3.3)	0.31 [-2.49; 3.08]	1.10 [0.50; 2.41]	1.09 [0.51; 2.33]	0.816	
IV diuretic for HF (without hospitalization) within 3 Months	327	14 (4.3)	315	10 (3.2)	1.11 [-1.97; 4.26]	1.36 [0.60; 3.12]	1.35 [0.61; 2.99]	0.462	
SOC: Gastrointestinal disorders PT[h]: Dyspepsia									
Age category 1									
<65	831	18 (2.2)	851	8 (0.9)	1.23 [0.05; 2.56]	2.24 [1.03; 4.85]	2.24 [1.03; 4.85]	0.042	0.380
≥65	1321	22 (1.7)	1300	15 (1.2)	0.51 [-0.41; 1.48]	1.45 [0.75; 2.81]	1.44 [0.75; 2.77]	0.270	
Age category 2									
<75	1519	31 (2.0)	1533	17 (1.1)	0.93 [0.05; 1.88]	1.86 [1.02; 3.37]	1.84 [1.02; 3.31]	0.042	0.704
≥75	633	9 (1.4)	618	6 (1.0)	0.45 [-0.85; 1.83]	1.46 [0.53; 4.05]	1.46 [0.53; 4.05]	0.464	
Gender									
Male	1656	25 (1.5)	1652	18 (1.1)	0.42 [-0.37; 1.24]	1.39 [0.76; 2.56]	1.39 [0.76; 2.53]	0.288	0.177
Female	496	15 (3.0)	499	5 (1.0)	2.02 [0.31; 4.04]	3.08 [1.11; 8.54]	3.02 [1.11; 8.24]	0.031	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Geographic Region									
Asia Pacific	510	9 (1.8)	502	4 (0.8)	0.97 [-0.49; 2.62]	2.14 [0.72; 6.40]	2.14 [0.72; 6.40]	0.172	0.598
Eastern Europe	721	19 (2.6)	718	10 (1.4)	1.24 [-0.22; 2.84]	1.92 [0.88; 4.15]	1.89 [0.89; 4.04]	0.099	
Latin and South America	316	3 (0.9)	324	1 (0.3)	0.64 [-0.86; 2.48]	2.80 [0.39; 19.98]	2.80 [0.39; 19.98]	0.304	
North America	240	6 (2.5)	241	3 (1.2)	1.26 [-1.41; 4.26]	2.03 [0.50; 8.23]	2.01 [0.51; 7.94]	0.320	
Western Europe	365	3 (0.8)	366	5 (1.4)	-0.54 [-2.44; 1.19]	0.61 [0.15; 2.44]	0.61 [0.15; 2.44]	0.480	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	1 (0.5)	202	1 (0.5)	-0.03 [-2.32; 2.16]	0.95 [0.06; 15.23]	0.95 [0.06; 15.23]	0.970	0.251
>30 to ≤60	882	13 (1.5)	895	12 (1.3)	0.13 [-1.03; 1.32]	1.10 [0.50; 2.43]	1.10 [0.50; 2.40]	0.812	
>60	1021	26 (2.5)	1022	10 (1.0)	1.57 [0.45; 2.83]	2.47 [1.28; 4.78]	2.47 [1.28; 4.78]	0.007	
NYHA Group at Baseline									
Class I or II	1236	23 (1.9)	1267	12 (0.9)	0.91 [-0.01; 1.93]	1.94 [1.00; 3.78]	1.94 [1.00; 3.78]	0.052	0.602
Class III or IV	914	17 (1.9)	884	11 (1.2)	0.62 [-0.57; 1.85]	1.50 [0.70; 3.23]	1.49 [0.70; 3.17]	0.295	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Use of Sacubitril /Valsartan at Baseline									
Yes	329	7 (2.1)	330	3 (0.9)	1.22 [-0.78; 3.53]	2.26 [0.65; 7.86]	2.26 [0.65; 7.86]	0.201	0.630
No	1823	33 (1.8)	1820	20 (1.1)	0.71 [-0.07; 1.54]	1.66 [0.95; 2.90]	1.65 [0.95; 2.86]	0.076	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	16 (3.3)	507	7 (1.4)	1.89 [0.03; 4.02]	2.42 [0.99; 5.93]	2.37 [0.98; 5.71]	0.054	0.418
Q2 (1556 - 2816)	520	9 (1.7)	493	6 (1.2)	0.51 [-1.11; 2.19]	1.43 [0.51; 4.05]	1.42 [0.51; 3.97]	0.501	
Q3 (2816 - 5314)	511	6 (1.2)	518	7 (1.4)	-0.18 [-1.73; 1.35]	0.87 [0.29; 2.60]	0.87 [0.29; 2.57]	0.799	
Q4 (>5314)	548	9 (1.6)	523	3 (0.6)	1.07 [-0.23; 2.59]	2.62 [0.84; 8.18]	2.62 [0.84; 8.18]	0.097	
Baseline Ejection Fraction Group 2									
<35	1719	29 (1.7)	1734	18 (1.0)	0.65 [-0.13; 1.47]	1.64 [0.91; 2.96]	1.63 [0.91; 2.92]	0.103	0.659
≥35	433	11 (2.5)	417	5 (1.2)	1.34 [-0.55; 3.44]	2.15 [0.74; 6.24]	2.12 [0.74; 6.05]	0.160	
Race group									
White	1344	27 (2.0)	1353	14 (1.0)	0.97 [0.05; 1.97]	1.96 [1.02; 3.76]	1.94 [1.02; 3.69]	0.043	0.961
Asian	500	6 (1.2)	474	4 (0.8)	0.36 [-1.09; 1.85]	1.42 [0.41; 4.93]	1.42 [0.41; 4.93]	0.582	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Black	111	4 (3.6)	118	3 (2.5)	1.06 [-4.10; 6.69]	1.43 [0.31; 6.55]	1.42 [0.32; 6.19]	0.643	
Other	196	3 (1.5)	206	2 (1.0)	0.56 [-2.12; 3.55]	1.58 [0.27; 9.18]	1.58 [0.27; 9.18]	0.613	
CCSA class at Randomization									
No Angina	1843	32 (1.7)	1850	22 (1.2)	0.55 [-0.24; 1.36]	1.47 [0.85; 2.54]	1.46 [0.85; 2.50]	0.169	0.330
Angina Class 1 or 2	265	8 (3.0)	260	1 (0.4)	2.63 [0.53; 5.51]	4.76 [1.28; 17.77]	4.76 [1.28; 17.77]	0.020	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	0.00 [-8.66; 8.12]	n.a.	n.a.	n.a.	
Medical History of Diabetes Mellitus									
Yes	1047	18 (1.7)	984	8 (0.8)	0.91 [-0.08; 1.98]	2.05 [0.94; 4.44]	2.05 [0.94; 4.44]	0.070	0.563
No	1105	22 (2.0)	1167	15 (1.3)	0.71 [-0.35; 1.84]	1.56 [0.81; 3.02]	1.55 [0.81; 2.97]	0.188	
Index Event									
HF Hospitalization within 3 Months	1439	24 (1.7)	1474	15 (1.0)	0.65 [-0.19; 1.55]	1.65 [0.86; 3.16]	1.64 [0.86; 3.11]	0.131	0.930
HF Hospitalization 3-6 Months	386	9 (2.3)	362	4 (1.1)	1.23 [-0.76; 3.41]	2.14 [0.65; 7.00]	2.11 [0.66; 6.79]	0.211	
IV diuretic for HF (without hospitalization) within 3 Months	327	7 (2.1)	315	4 (1.3)	0.87 [-1.34; 3.24]	1.70 [0.49; 5.87]	1.69 [0.50; 5.70]	0.401	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Gastrointestinal disorders PT[h]: Gastrooesophageal reflux disease									
Age category 1									
<65	831	12 (1.4)	851	4 (0.5)	0.97 [0.05; 2.09]	2.81 [1.05; 7.52]	2.81 [1.05; 7.52]	0.040	0.111
≥65	1321	17 (1.3)	1300	1 (0.1)	1.21 [0.67; 1.98]	5.89 [2.33; 14.88]	5.89 [2.33; 14.88]	< 0.001	
Age category 2									
<75	1519	22 (1.4)	1533	4 (0.3)	1.19 [0.58; 1.95]	4.08 [1.88; 8.82]	4.08 [1.88; 8.82]	< 0.001	0.862
≥75	633	7 (1.1)	618	1 (0.2)	0.94 [0.08; 2.12]	4.41 [1.10; 17.72]	4.41 [1.10; 17.72]	0.036	
Gender									
Male	1656	18 (1.1)	1652	5 (0.3)	0.78 [0.24; 1.44]	3.11 [1.37; 7.07]	3.11 [1.37; 7.07]	0.007	0.203
Female	496	11 (2.2)	499	0 (0.0)	2.22 [1.24; 3.93]	7.59 [2.31; 24.89]	7.59 [2.31; 24.89]	< 0.001	
Geographic Region									
Asia Pacific	510	15 (2.9)	502	0 (0.0)	2.94 [1.79; 4.80]	7.48 [2.70; 20.73]	7.48 [2.70; 20.73]	< 0.001	0.337
Eastern Europe	721	5 (0.7)	718	2 (0.3)	0.41 [-0.39; 1.37]	2.36 [0.53; 10.39]	2.36 [0.53; 10.39]	0.258	
Latin and South America	316	2 (0.6)	324	2 (0.6)	0.02 [-1.66; 1.73]	1.03 [0.14; 7.31]	1.03 [0.14; 7.31]	0.980	
North America	240	4 (1.7)	241	1 (0.4)	1.25 [-0.81; 3.84]	3.37 [0.58; 19.58]	3.37 [0.58; 19.58]	0.176	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Western Europe	365	3 (0.8)	366	0 (0.0)	0.82 [-0.22; 2.39]	7.45 [0.77; 71.85]	7.45 [0.77; 71.85]	0.082	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	0 (0.0)	202	0 (0.0)	0.00 [-1.87; 1.78]	n.a.	n.a.	n.a.	0.210
>30 to ≤60	882	10 (1.1)	895	4 (0.4)	0.69 [-0.15; 1.68]	2.41 [0.84; 6.89]	2.41 [0.84; 6.89]	0.102	
>60	1021	18 (1.8)	1022	1 (0.1)	1.67 [0.95; 2.68]	6.09 [2.47; 15.02]	6.09 [2.47; 15.02]	< 0.001	
NYHA Group at Baseline									
Class I or II	1236	21 (1.7)	1267	2 (0.2)	1.54 [0.87; 2.44]	5.43 [2.39; 12.34]	5.43 [2.39; 12.34]	< 0.001	0.147
Class III or IV	914	8 (0.9)	884	3 (0.3)	0.54 [-0.22; 1.42]	2.41 [0.74; 7.90]	2.41 [0.74; 7.90]	0.145	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	3 (0.9)	330	1 (0.3)	0.61 [-0.87; 2.38]	2.74 [0.38; 19.53]	2.74 [0.38; 19.53]	0.315	0.562
No	1823	26 (1.4)	1820	4 (0.2)	1.21 [0.67; 1.88]	4.38 [2.13; 8.98]	4.38 [2.13; 8.98]	< 0.001	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	10 (2.0)	507	1 (0.2)	1.85 [0.68; 3.55]	5.42 [1.65; 17.78]	5.42 [1.65; 17.78]	0.005	0.457
Q2 (1556 - 2816)	520	6 (1.2)	493	3 (0.6)	0.55 [-0.75; 1.96]	1.86 [0.50; 6.90]	1.86 [0.50; 6.90]	0.355	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
Q3 (2816 - 5314)	511	6 (1.2)	518	0 (0.0)	1.17 [0.43; 2.54]	7.57 [1.52; 37.63]	7.57 [1.52; 37.63]	0.013	
Q4 (>5314)	548	5 (0.9)	523	1 (0.2)	0.72 [-0.25; 1.95]	3.65 [0.73; 18.14]	3.65 [0.73; 18.14]	0.114	
Baseline Ejection Fraction Group 2									
<35	1719	23 (1.3)	1734	4 (0.2)	1.11 [0.56; 1.79]	4.17 [1.95; 8.88]	4.17 [1.95; 8.88]	< 0.001	0.998
≥35	433	6 (1.4)	417	1 (0.2)	1.15 [-0.10; 2.78]	4.06 [0.92; 17.97]	4.06 [0.92; 17.97]	0.065	
CCSA class at Randomization									
No Angina	1843	26 (1.4)	1850	4 (0.2)	1.19 [0.66; 1.86]	4.40 [2.15; 9.03]	4.40 [2.15; 9.03]	< 0.001	0.515
Angina Class 1 or 2	265	2 (0.8)	260	1 (0.4)	0.37 [-1.46; 2.37]	1.92 [0.20; 18.50]	1.92 [0.20; 18.50]	0.574	
Angina Class 3 or 4	44	1 (2.3)	41	0 (0.0)	2.27 [-6.49; 11.89]	6.90 [0.14; 348.69]	6.90 [0.14; 348.69]	0.334	
Medical History of Diabetes Mellitus									
Yes	1047	9 (0.9)	984	2 (0.2)	0.66 [0.02; 1.45]	3.38 [1.03; 11.06]	3.38 [1.03; 11.06]	0.044	0.609
No	1105	20 (1.8)	1167	3 (0.3)	1.55 [0.79; 2.55]	4.71 [2.07; 10.70]	4.71 [2.07; 10.70]	< 0.001	
Index Event									
HF Hospitalization within 3 Months	1439	20 (1.4)	1474	2 (0.1)	1.25 [0.69; 2.02]	5.33 [2.30; 12.32]	5.33 [2.30; 12.32]	< 0.001	0.402

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
HF Hospitalization 3-6 Months	386	5 (1.3)	362	2 (0.6)	0.74 [-0.84; 2.51]	2.23 [0.50; 9.86]	2.23 [0.50; 9.86]	0.292	
IV diuretic for HF (without hospitalization) within 3 Months	327	4 (1.2)	315	1 (0.3)	0.91 [-0.66; 2.82]	3.22 [0.56; 18.71]	3.22 [0.56; 18.71]	0.192	
SOC: Infections and infestations PT[h]: Influenza									
Age category 1									
<65	831	20 (2.4)	851	10 (1.2)	1.23 [-0.04; 2.64]	2.07 [0.96; 4.46]	2.05 [0.96; 4.35]	0.062	0.370
≥65	1321	30 (2.3)	1300	22 (1.7)	0.58 [-0.51; 1.70]	1.35 [0.77; 2.35]	1.34 [0.78; 2.31]	0.290	
Age category 2									
<75	1519	36 (2.4)	1533	21 (1.4)	1.00 [0.04; 2.02]	1.75 [1.02; 3.01]	1.73 [1.01; 2.95]	0.044	0.495
≥75	633	14 (2.2)	618	11 (1.8)	0.43 [-1.20; 2.10]	1.25 [0.56; 2.77]	1.24 [0.57; 2.72]	0.586	
Gender									
Male	1656	41 (2.5)	1652	23 (1.4)	1.08 [0.15; 2.07]	1.80 [1.07; 3.01]	1.78 [1.07; 2.95]	0.026	0.286
Female	496	9 (1.8)	499	9 (1.8)	0.01 [-1.80; 1.83]	1.01 [0.40; 2.56]	1.01 [0.40; 2.51]	0.990	
Geographic Region									
Asia Pacific	510	12 (2.4)	502	10 (2.0)	0.36 [-1.55; 2.31]	1.19 [0.51; 2.77]	1.18 [0.51; 2.71]	0.694	0.569
Eastern Europe	721	15 (2.1)	718	10 (1.4)	0.69 [-0.71; 2.17]	1.50 [0.67; 3.37]	1.49 [0.68; 3.30]	0.322	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Latin and South America	316	14 (4.4)	324	5 (1.5)	2.89 [0.28; 5.93]	2.96 [1.05; 8.31]	2.87 [1.05; 7.88]	0.041	
North America	240	1 (0.4)	241	2 (0.8)	-0.41 [-2.60; 1.57]	0.51 [0.05; 4.97]	0.51 [0.05; 4.97]	0.565	
Western Europe	365	8 (2.2)	366	5 (1.4)	0.83 [-1.24; 3.07]	1.62 [0.52; 4.99]	1.60 [0.53; 4.86]	0.403	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	3 (1.4)	202	5 (2.5)	-1.07 [-4.43; 1.90]	0.56 [0.13; 2.39]	0.57 [0.14; 2.35]	0.436	0.313
>30 to ≤60	882	22 (2.5)	895	12 (1.3)	1.15 [-0.13; 2.55]	1.88 [0.93; 3.83]	1.86 [0.93; 3.74]	0.081	
>60	1021	25 (2.4)	1022	15 (1.5)	0.98 [-0.23; 2.27]	1.69 [0.88; 3.22]	1.67 [0.88; 3.15]	0.114	
NYHA Group at Baseline									
Class I or II	1236	34 (2.8)	1267	20 (1.6)	1.17 [0.03; 2.39]	1.76 [1.01; 3.08]	1.74 [1.01; 3.01]	0.046	0.519
Class III or IV	914	16 (1.8)	884	12 (1.4)	0.39 [-0.81; 1.62]	1.29 [0.61; 2.75]	1.29 [0.61; 2.71]	0.502	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	4 (1.2)	330	5 (1.5)	-0.30 [-2.43; 1.75]	0.80 [0.21; 3.01]	0.80 [0.22; 2.96]	0.741	0.285
No	1823	46 (2.5)	1820	27 (1.5)	1.04 [0.13; 1.99]	1.72 [1.06; 2.78]	1.70 [1.06; 2.72]	0.027	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	14 (2.9)	507	10 (2.0)	0.89 [-1.08; 3.00]	1.46 [0.64; 3.33]	1.45 [0.65; 3.24]	0.362	0.723
Q2 (1556 - 2816)	520	16 (3.1)	493	7 (1.4)	1.66 [-0.20; 3.69]	2.20 [0.90; 5.40]	2.17 [0.90; 5.22]	0.085	
Q3 (2816 - 5314)	511	8 (1.6)	518	6 (1.2)	0.41 [-1.13; 2.04]	1.36 [0.47; 3.94]	1.35 [0.47; 3.87]	0.574	
Q4 (>5314)	548	10 (1.8)	523	9 (1.7)	0.10 [-1.63; 1.82]	1.06 [0.43; 2.63]	1.06 [0.43; 2.59]	0.897	
Baseline Ejection Fraction Group 2									
<35	1719	45 (2.6)	1734	27 (1.6)	1.06 [0.11; 2.06]	1.70 [1.05; 2.75]	1.68 [1.05; 2.70]	0.031	0.406
≥35	433	5 (1.2)	417	5 (1.2)	-0.04 [-1.76; 1.63]	0.96 [0.28; 3.35]	0.96 [0.28; 3.30]	0.952	
Race group									
White	1344	32 (2.4)	1353	17 (1.3)	1.12 [0.12; 2.20]	1.92 [1.06; 3.47]	1.89 [1.06; 3.40]	0.032	0.347
Asian	500	11 (2.2)	474	10 (2.1)	0.09 [-1.89; 2.05]	1.04 [0.44; 2.48]	1.04 [0.45; 2.43]	0.923	
Black	111	0 (0.0)	118	2 (1.7)	-1.69 [-5.98; 1.69]	0.14 [0.01; 2.29]	0.14 [0.01; 2.29]	0.169	
Other	196	7 (3.6)	206	3 (1.5)	2.12 [-1.10; 5.91]	2.51 [0.64; 9.83]	2.45 [0.64; 9.35]	0.189	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
CCSA class at Randomization									
No Angina	1843	48 (2.6)	1850	30 (1.6)	0.98 [0.06; 1.95]	1.62 [1.02; 2.57]	1.61 [1.02; 2.52]	0.040	0.312
Angina Class 1 or 2	265	0 (0.0)	260	2 (0.8)	-0.77 [-2.76; 0.67]	0.13 [0.01; 2.12]	0.13 [0.01; 2.12]	0.153	
Angina Class 3 or 4	44	2 (4.5)	41	0 (0.0)	4.55 [-4.31; 15.22]	7.06 [0.43; 115.04]	7.06 [0.43; 115.04]	0.170	
Medical History of Diabetes Mellitus									
Yes	1047	21 (2.0)	984	15 (1.5)	0.48 [-0.71; 1.69]	1.32 [0.68; 2.58]	1.32 [0.68; 2.54]	0.413	0.485
No	1105	29 (2.6)	1167	17 (1.5)	1.17 [0.01; 2.42]	1.82 [1.00; 3.34]	1.80 [1.00; 3.26]	0.052	
Index Event									
HF Hospitalization within 3 Months	1439	33 (2.3)	1474	21 (1.4)	0.87 [-0.11; 1.91]	1.62 [0.94; 2.82]	1.61 [0.94; 2.77]	0.085	0.416
HF Hospitalization 3-6 Months	386	12 (3.1)	362	5 (1.4)	1.73 [-0.46; 4.14]	2.29 [0.80; 6.57]	2.25 [0.80; 6.33]	0.124	
IV diuretic for HF (without hospitalization) within 3 Months	327	5 (1.5)	315	6 (1.9)	-0.38 [-2.75; 1.87]	0.80 [0.24; 2.65]	0.80 [0.25; 2.60]	0.714	
SOC: Respiratory, thoracic and mediastinal disorders PT[h]: Epistaxis									
Age category 2									
<75	1519	14 (0.9)	1533	20 (1.3)	-0.38 [-1.18; 0.38]	0.71 [0.36; 1.39]	0.71 [0.36; 1.39]	0.314	0.141
≥75	633	6 (0.9)	618	19 (3.1)	-2.13 [-3.91; -0.62]	0.34 [0.15; 0.75]	0.34 [0.15; 0.75]	0.007	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Gender									
Male	1656	16 (1.0)	1652	29 (1.8)	-0.79 [-1.64; 0.00]	0.56 [0.31; 1.00]	0.56 [0.31; 1.00]	0.050	0.633
Female	496	4 (0.8)	499	10 (2.0)	-1.20 [-2.94; 0.31]	0.42 [0.15; 1.21]	0.42 [0.15; 1.21]	0.109	
Geographic Region									
Asia Pacific	510	4 (0.8)	502	13 (2.6)	-1.81 [-3.69; -0.25]	0.34 [0.13; 0.87]	0.34 [0.13; 0.87]	0.026	0.662
Eastern Europe	721	6 (0.8)	718	7 (1.0)	-0.14 [-1.27; 0.95]	0.85 [0.29; 2.54]	0.85 [0.29; 2.54]	0.775	
Latin and South America	316	2 (0.6)	324	4 (1.2)	-0.60 [-2.57; 1.18]	0.52 [0.11; 2.61]	0.52 [0.11; 2.61]	0.430	
North America	240	4 (1.7)	241	5 (2.1)	-0.41 [-3.31; 2.39]	0.80 [0.21; 3.02]	0.80 [0.22; 2.96]	0.742	
Western Europe	365	4 (1.1)	366	10 (2.7)	-1.64 [-3.99; 0.40]	0.39 [0.12; 1.27]	0.40 [0.13; 1.27]	0.120	
NYHA Group at Baseline									
Class I or II	1236	13 (1.1)	1267	25 (2.0)	-0.92 [-1.95; 0.04]	0.53 [0.27; 1.04]	0.53 [0.27; 1.04]	0.064	0.868
Class III or IV	914	7 (0.8)	884	14 (1.6)	-0.82 [-1.96; 0.19]	0.49 [0.21; 1.16]	0.49 [0.21; 1.16]	0.107	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	1 (0.3)	330	7 (2.1)	-1.82 [-4.05; -0.19]	0.22 [0.05; 0.89]	0.22 [0.05; 0.89]	0.033	0.139

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
No	1823	19 (1.0)	1820	32 (1.8)	-0.72 [-1.53; 0.05]	0.59 [0.33; 1.04]	0.59 [0.34; 1.04]	0.069	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	2 (0.4)	507	8 (1.6)	-1.17 [-2.72; 0.09]	0.31 [0.09; 1.07]	0.31 [0.09; 1.07]	0.064	0.286
Q2 (1556 - 2816)	520	3 (0.6)	493	6 (1.2)	-0.64 [-2.12; 0.62]	0.48 [0.13; 1.80]	0.48 [0.13; 1.80]	0.278	
Q3 (2816 - 5314)	511	3 (0.6)	518	11 (2.1)	-1.54 [-3.24; -0.14]	0.32 [0.11; 0.91]	0.32 [0.11; 0.91]	0.033	
Q4 (>5314)	548	10 (1.8)	523	10 (1.9)	-0.09 [-1.87; 1.65]	0.95 [0.39; 2.31]	0.95 [0.40; 2.27]	0.916	
Baseline Ejection Fraction Group 2									
<35	1719	19 (1.1)	1734	34 (2.0)	-0.86 [-1.73; -0.04]	0.56 [0.32; 0.98]	0.56 [0.32; 0.98]	0.044	0.299
≥35	433	1 (0.2)	417	5 (1.2)	-0.97 [-2.57; 0.22]	0.25 [0.05; 1.25]	0.25 [0.05; 1.25]	0.092	
Race group									
White	1344	13 (1.0)	1353	24 (1.8)	-0.81 [-1.76; 0.08]	0.55 [0.29; 1.05]	0.55 [0.29; 1.05]	0.072	0.823
Asian	500	4 (0.8)	474	11 (2.3)	-1.52 [-3.40; 0.03]	0.37 [0.13; 1.02]	0.37 [0.13; 1.02]	0.054	
Black	111	1 (0.9)	118	1 (0.8)	0.05 [-3.84; 4.17]	1.06 [0.07; 17.13]	1.06 [0.07; 17.13]	0.965	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Other	196	2 (1.0)	206	3 (1.5)	-0.44 [-3.30; 2.35]	0.70 [0.12; 4.22]	0.70 [0.12; 4.15]	0.695	
CCSA class at Randomization									
No Angina	1843	16 (0.9)	1850	33 (1.8)	-0.92 [-1.71; -0.18]	0.50 [0.28; 0.87]	0.50 [0.28; 0.87]	0.015	0.863
Angina Class 1 or 2	265	4 (1.5)	260	6 (2.3)	-0.80 [-3.62; 1.80]	0.65 [0.18; 2.33]	0.65 [0.19; 2.29]	0.507	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	0.00 [-8.66; 8.12]	n.a.	n.a.	n.a.	
Medical History of Diabetes Mellitus									
Yes	1047	10 (1.0)	984	18 (1.8)	-0.87 [-2.02; 0.15]	0.53 [0.25; 1.11]	0.53 [0.25; 1.11]	0.091	0.946
No	1105	10 (0.9)	1167	21 (1.8)	-0.89 [-1.93; 0.06]	0.51 [0.25; 1.05]	0.51 [0.25; 1.05]	0.066	
Index Event									
HF Hospitalization within 3 Months	1439	13 (0.9)	1474	20 (1.4)	-0.45 [-1.28; 0.33]	0.67 [0.34; 1.33]	0.67 [0.34; 1.33]	0.248	0.499
HF Hospitalization 3-6 Months	386	5 (1.3)	362	13 (3.6)	-2.30 [-4.90; -0.11]	0.35 [0.12; 1.00]	0.36 [0.13; 1.00]	0.050	
IV diuretic for HF (without hospitalization) within 3 Months	327	2 (0.6)	315	6 (1.9)	-1.29 [-3.55; 0.53]	0.35 [0.09; 1.41]	0.35 [0.09; 1.41]	0.140	
SOC: Vascular disorders PT[h]: Hypotension									
Age category 2									
<75	1519	156 (10.3)	1533	119 (7.8)	2.51 [0.48; 4.56]	1.36 [1.06; 1.75]	1.32 [1.05; 1.66]	0.016	0.321

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥75	633	58 (9.2)	618	53 (8.6)	0.59 [-2.60; 3.77]	1.08 [0.73; 1.59]	1.07 [0.75; 1.52]	0.715	
Gender									
Male	1656	166 (10.0)	1652	132 (8.0)	2.03 [0.08; 4.00]	1.28 [1.01; 1.63]	1.25 [1.01; 1.56]	0.042	0.868
Female	496	48 (9.7)	499	40 (8.0)	1.66 [-1.90; 5.26]	1.23 [0.79; 1.91]	1.21 [0.81; 1.80]	0.357	
Geographic Region									
Asia Pacific	510	54 (10.6)	502	49 (9.8)	0.83 [-2.94; 4.60]	1.09 [0.73; 1.65]	1.08 [0.75; 1.57]	0.664	0.528
Eastern Europe	721	64 (8.9)	718	46 (6.4)	2.47 [-0.28; 5.27]	1.42 [0.96; 2.11]	1.39 [0.96; 1.99]	0.080	
Latin and South America	316	17 (5.4)	324	19 (5.9)	-0.48 [-4.20; 3.23]	0.91 [0.47; 1.79]	0.92 [0.49; 1.73]	0.790	
North America	240	35 (14.6)	241	21 (8.7)	5.87 [0.13; 11.76]	1.79 [1.01; 3.17]	1.67 [1.00; 2.79]	0.048	
Western Europe	365	44 (12.1)	366	37 (10.1)	1.95 [-2.65; 6.58]	1.22 [0.77; 1.94]	1.19 [0.79; 1.80]	0.403	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	22 (10.3)	202	13 (6.4)	3.89 [-1.53; 9.46]	1.67 [0.82; 3.42]	1.60 [0.83; 3.10]	0.159	0.725
>30 to ≤60	882	96 (10.9)	895	81 (9.1)	1.83 [-0.96; 4.65]	1.23 [0.90; 1.68]	1.20 [0.91; 1.59]	0.198	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
>60	1021	93 (9.1)	1022	76 (7.4)	1.67 [-0.72; 4.09]	1.25 [0.91; 1.71]	1.22 [0.92; 1.64]	0.171	
NYHA Group at Baseline									
Class I or II	1236	113 (9.1)	1267	100 (7.9)	1.25 [-0.94; 3.46]	1.17 [0.89; 1.56]	1.16 [0.90; 1.50]	0.263	0.414
Class III or IV	914	101 (11.1)	884	72 (8.1)	2.91 [0.18; 5.65]	1.40 [1.02; 1.92]	1.36 [1.02; 1.81]	0.038	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	51 (15.5)	330	35 (10.6)	4.90 [-0.26; 10.12]	1.55 [0.98; 2.45]	1.46 [0.98; 2.19]	0.064	0.346
No	1823	163 (8.9)	1820	137 (7.5)	1.41 [-0.37; 3.21]	1.21 [0.95; 1.53]	1.19 [0.96; 1.48]	0.121	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	38 (7.8)	507	30 (5.9)	1.85 [-1.30; 5.10]	1.34 [0.82; 2.20]	1.31 [0.83; 2.09]	0.248	0.904
Q2 (1556 - 2816)	520	54 (10.4)	493	40 (8.1)	2.27 [-1.33; 5.89]	1.31 [0.85; 2.02]	1.28 [0.87; 1.89]	0.215	
Q3 (2816 - 5314)	511	57 (11.2)	518	53 (10.2)	0.92 [-2.88; 4.75]	1.10 [0.74; 1.64]	1.09 [0.77; 1.55]	0.632	
Q4 (>5314)	548	55 (10.0)	523	41 (7.8)	2.20 [-1.25; 5.66]	1.31 [0.86; 2.00]	1.28 [0.87; 1.88]	0.210	
Baseline Ejection Fraction Group 2									
<35	1719	180 (10.5)	1734	141 (8.1)	2.34 [0.40; 4.29]	1.32 [1.05; 1.67]	1.29 [1.04; 1.59]	0.018	0.440

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥35	433	34 (7.9)	417	31 (7.4)	0.42 [-3.24; 4.06]	1.06 [0.64; 1.76]	1.06 [0.66; 1.69]	0.819	
Race group									
White	1344	135 (10.0)	1353	98 (7.2)	2.80 [0.68; 4.95]	1.43 [1.09; 1.88]	1.39 [1.08; 1.78]	0.010	0.570
Asian	500	48 (9.6)	474	44 (9.3)	0.32 [-3.42; 4.03]	1.04 [0.68; 1.60]	1.03 [0.70; 1.53]	0.866	
Black	111	12 (10.8)	118	12 (10.2)	0.64 [-7.57; 9.04]	1.07 [0.46; 2.49]	1.06 [0.50; 2.27]	0.874	
Other	196	18 (9.2)	206	18 (8.7)	0.45 [-5.28; 6.27]	1.06 [0.53; 2.09]	1.05 [0.56; 1.96]	0.876	
CCSA class at Randomization									
No Angina	1843	191 (10.4)	1850	155 (8.4)	1.99 [0.11; 3.88]	1.26 [1.01; 1.58]	1.24 [1.01; 1.51]	0.039	0.942
Angina Class 1 or 2	265	21 (7.9)	260	16 (6.2)	1.77 [-2.72; 6.34]	1.31 [0.67; 2.58]	1.29 [0.69; 2.41]	0.430	
Angina Class 3 or 4	44	2 (4.5)	41	1 (2.4)	2.11 [-8.66; 13.13]	1.90 [0.17; 21.84]	1.86 [0.18; 19.79]	0.606	
Medical History of Diabetes Mellitus									
Yes	1047	101 (9.6)	984	80 (8.1)	1.52 [-0.97; 4.01]	1.21 [0.89; 1.64]	1.19 [0.90; 1.57]	0.231	0.648
No	1105	113 (10.2)	1167	92 (7.9)	2.34 [-0.01; 4.74]	1.33 [1.00; 1.78]	1.30 [1.00; 1.69]	0.052	

Analyses of Mild Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Index Event									
HF Hospitalization within 3 Months	1439	142 (9.9)	1474	114 (7.7)	2.13 [0.08; 4.21]	1.31 [1.01; 1.69]	1.28 [1.01; 1.61]	0.043	0.481
HF Hospitalization 3-6 Months	386	37 (9.6)	362	35 (9.7)	-0.08 [-4.41; 4.19]	0.99 [0.61; 1.61]	0.99 [0.64; 1.54]	0.969	
IV diuretic for HF (without hospitalization) within 3 Months	327	35 (10.7)	315	23 (7.3)	3.40 [-1.07; 7.95]	1.52 [0.88; 2.64]	1.47 [0.89; 2.42]	0.136	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1 % or ≥ 99 % in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

h: A specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is greater than or equal to 0.05 or rule of 10 is not met

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 66
Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥10% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Injury, poisoning and procedural complications									
Age category 2									
<75	1519	42 (2.8)	1533	54 (3.5)	-0.76 [-2.03; 0.49]	0.78 [0.52; 1.17]	0.78 [0.53; 1.17]	0.232	0.375
≥75	633	23 (3.6)	618	38 (6.1)	-2.52 [-5.02; -0.13]	0.58 [0.34; 0.98]	0.59 [0.36; 0.98]	0.041	
Gender									
Male	1656	45 (2.7)	1652	67 (4.1)	-1.34 [-2.61; -0.11]	0.66 [0.45; 0.97]	0.67 [0.46; 0.97]	0.035	0.608
Female	496	20 (4.0)	499	25 (5.0)	-0.98 [-3.67; 1.66]	0.80 [0.44; 1.45]	0.80 [0.45; 1.43]	0.459	
Geographic Region									
Asia Pacific	510	18 (3.5)	502	18 (3.6)	-0.06 [-2.45; 2.32]	0.98 [0.51; 1.91]	0.98 [0.52; 1.87]	0.961	0.550
Eastern Europe	721	16 (2.2)	718	21 (2.9)	-0.71 [-2.44; 0.97]	0.75 [0.39; 1.46]	0.76 [0.40; 1.44]	0.399	
Latin and South America	316	3 (0.9)	324	10 (3.1)	-2.14 [-4.76; 0.06]	0.34 [0.11; 1.03]	0.34 [0.11; 1.03]	0.056	
North America	240	10 (4.2)	241	16 (6.6)	-2.47 [-6.83; 1.67]	0.61 [0.27; 1.38]	0.63 [0.29; 1.35]	0.235	
Western Europe	365	18 (4.9)	366	27 (7.4)	-2.45 [-6.10; 1.08]	0.65 [0.35; 1.20]	0.67 [0.37; 1.19]	0.172	

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥10% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category									
≤30	213	7 (3.3)	202	11 (5.4)	-2.16 [-6.60; 1.91]	0.59 [0.22; 1.55]	0.60 [0.24; 1.53]	0.286	0.739
>30 to ≤60	882	31 (3.5)	895	49 (5.5)	-1.96 [-3.95; -0.03]	0.63 [0.40; 1.00]	0.64 [0.41; 1.00]	0.048	
>60	1021	26 (2.5)	1022	32 (3.1)	-0.58 [-2.08; 0.88]	0.81 [0.48; 1.37]	0.81 [0.49; 1.35]	0.427	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	9 (2.7)	330	13 (3.9)	-1.20 [-4.21; 1.66]	0.69 [0.29; 1.63]	0.69 [0.30; 1.60]	0.393	0.969
No	1823	56 (3.1)	1820	79 (4.3)	-1.27 [-2.52; -0.04]	0.70 [0.49; 0.99]	0.71 [0.51; 0.99]	0.044	
Baseline Ejection Fraction Group 2									
<35	1719	51 (3.0)	1734	77 (4.4)	-1.47 [-2.76; -0.22]	0.66 [0.46; 0.94]	0.67 [0.47; 0.95]	0.023	0.464
≥35	433	14 (3.2)	417	15 (3.6)	-0.36 [-2.97; 2.18]	0.90 [0.43; 1.88]	0.90 [0.44; 1.84]	0.770	
Race group									
White	1344	44 (3.3)	1353	63 (4.7)	-1.38 [-2.89; 0.09]	0.69 [0.47; 1.03]	0.70 [0.48; 1.03]	0.067	0.053
Asian	500	15 (3.0)	474	13 (2.7)	0.26 [-1.97; 2.47]	1.10 [0.52; 2.33]	1.09 [0.53; 2.27]	0.810	
Black	111	4 (3.6)	118	3 (2.5)	1.06 [-4.10; 6.69]	1.43 [0.31; 6.55]	1.42 [0.32; 6.19]	0.643	

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥10% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Other	196	2 (1.0)	206	13 (6.3)	-5.29 [-9.61; -1.85]	0.15 [0.03; 0.69]	0.16 [0.04; 0.71]	0.016	
CCSA class at Randomization									
No Angina	1843	53 (2.9)	1850	81 (4.4)	-1.50 [-2.74; -0.30]	0.65 [0.45; 0.92]	0.66 [0.47; 0.92]	0.015	0.418
Angina Class 1 or 2	265	11 (4.2)	260	9 (3.5)	0.69 [-2.80; 4.24]	1.21 [0.49; 2.96]	1.20 [0.51; 2.85]	0.680	
Angina Class 3 or 4	44	1 (2.3)	41	2 (4.9)	-2.61 [-14.26; 7.61]	0.45 [0.04; 5.20]	0.47 [0.04; 4.95]	0.526	
Medical History of Diabetes Mellitus									
Yes	1047	38 (3.6)	984	45 (4.6)	-0.94 [-2.73; 0.79]	0.79 [0.51; 1.22]	0.79 [0.52; 1.21]	0.284	0.407
No	1105	27 (2.4)	1167	47 (4.0)	-1.58 [-3.09; -0.13]	0.60 [0.37; 0.97]	0.61 [0.38; 0.97]	0.036	
Index Event									
HF Hospitalization within 3 Months	1439	46 (3.2)	1474	57 (3.9)	-0.67 [-2.04; 0.68]	0.82 [0.55; 1.22]	0.83 [0.56; 1.21]	0.328	0.172
HF Hospitalization 3-6 Months	386	10 (2.6)	362	24 (6.6)	-4.04 [-7.35; -1.10]	0.37 [0.18; 0.79]	0.39 [0.19; 0.81]	0.011	
IV diuretic for HF (without hospitalization) within 3 Months	327	9 (2.8)	315	11 (3.5)	-0.74 [-3.71; 2.10]	0.78 [0.32; 1.91]	0.79 [0.33; 1.88]	0.591	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1 % or ≥ 99 % in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

h: A specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is greater than or equal to 0.05 or rule of 10 is not met

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 67
Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Gastrointestinal disorders PT[h]: Vomiting									
Age category 2									
<75	1519	21 (1.4)	1533	6 (0.4)	0.99 [0.35; 1.75]	3.10 [1.45; 6.60]	3.10 [1.45; 6.60]	0.003	0.074
≥75	633	3 (0.5)	618	4 (0.6)	-0.17 [-1.23; 0.81]	0.73 [0.17; 3.24]	0.73 [0.17; 3.24]	0.681	
Gender									
Male	1656	15 (0.9)	1652	4 (0.2)	0.66 [0.17; 1.27]	3.20 [1.30; 7.87]	3.20 [1.30; 7.87]	0.012	0.235
Female	496	9 (1.8)	499	6 (1.2)	0.61 [-1.01; 2.35]	1.52 [0.54; 4.30]	1.51 [0.54; 4.21]	0.432	
Geographic Region									
Asia Pacific	510	6 (1.2)	502	1 (0.2)	0.98 [-0.06; 2.37]	4.14 [0.94; 18.31]	4.14 [0.94; 18.31]	0.061	0.606
Eastern Europe	721	8 (1.1)	718	4 (0.6)	0.55 [-0.45; 1.68]	1.95 [0.63; 6.07]	1.95 [0.63; 6.07]	0.249	
Latin and South America	316	1 (0.3)	324	2 (0.6)	-0.30 [-1.94; 1.21]	0.53 [0.05; 5.07]	0.53 [0.05; 5.07]	0.578	
North America	240	6 (2.5)	241	3 (1.2)	1.26 [-1.41; 4.26]	2.03 [0.50; 8.23]	2.01 [0.51; 7.94]	0.320	
Western Europe	365	3 (0.8)	366	0 (0.0)	0.82 [-0.22; 2.39]	7.45 [0.77; 71.85]	7.45 [0.77; 71.85]	0.082	

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	5 (2.3)	202	0 (0.0)	2.35 [0.46; 5.38]	7.15 [1.23; 41.66]	7.15 [1.23; 41.66]	0.029	0.148
>30 to ≤60	882	9 (1.0)	895	8 (0.9)	0.13 [-0.86; 1.14]	1.14 [0.44; 2.97]	1.14 [0.44; 2.97]	0.784	
>60	1021	10 (1.0)	1022	2 (0.2)	0.78 [0.15; 1.62]	3.82 [1.23; 11.90]	3.82 [1.23; 11.90]	0.020	
NYHA Group at Baseline									
Class I or II	1236	12 (1.0)	1267	2 (0.2)	0.81 [0.27; 1.55]	4.31 [1.51; 12.32]	4.31 [1.51; 12.32]	0.006	0.081
Class III or IV	914	12 (1.3)	884	8 (0.9)	0.41 [-0.62; 1.48]	1.45 [0.60; 3.50]	1.45 [0.60; 3.50]	0.410	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	6 (1.8)	330	1 (0.3)	1.52 [-0.06; 3.66]	4.24 [0.96; 18.79]	4.24 [0.96; 18.79]	0.057	0.293
No	1823	18 (1.0)	1820	9 (0.5)	0.49 [-0.07; 1.11]	1.95 [0.92; 4.17]	1.95 [0.92; 4.17]	0.083	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	5 (1.0)	507	1 (0.2)	0.83 [-0.19; 2.20]	3.96 [0.80; 19.72]	3.96 [0.80; 19.72]	0.093	0.361
Q2 (1556 - 2816)	520	2 (0.4)	493	1 (0.2)	0.18 [-0.79; 1.21]	1.85 [0.19; 17.84]	1.85 [0.19; 17.84]	0.595	
Q3 (2816 - 5314)	511	9 (1.8)	518	2 (0.4)	1.38 [0.14; 2.97]	3.67 [1.12; 12.02]	3.67 [1.12; 12.02]	0.032	

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q4 (>5314)	548	7 (1.3)	523	6 (1.1)	0.13 [-1.35; 1.61]	1.11 [0.37; 3.34]	1.11 [0.38; 3.29]	0.846	
Baseline Ejection Fraction Group 2									
<35	1719	19 (1.1)	1734	8 (0.5)	0.64 [0.06; 1.31]	2.29 [1.08; 4.89]	2.29 [1.08; 4.89]	0.032	0.996
≥35	433	5 (1.2)	417	2 (0.5)	0.68 [-0.70; 2.25]	2.28 [0.52; 10.10]	2.28 [0.52; 10.10]	0.277	
Race group									
White	1344	17 (1.3)	1353	7 (0.5)	0.75 [0.04; 1.55]	2.33 [1.04; 5.21]	2.33 [1.04; 5.21]	0.039	0.959
Asian	500	3 (0.6)	474	1 (0.2)	0.39 [-0.64; 1.56]	2.59 [0.36; 18.43]	2.59 [0.36; 18.43]	0.343	
Black	111	1 (0.9)	118	0 (0.0)	0.90 [-2.28; 4.94]	7.87 [0.16; 397.35]	7.87 [0.16; 397.35]	0.303	
Other	196	3 (1.5)	206	2 (1.0)	0.56 [-2.12; 3.55]	1.58 [0.27; 9.18]	1.58 [0.27; 9.18]	0.613	
CCSA class at Randomization									
No Angina	1843	20 (1.1)	1850	7 (0.4)	0.71 [0.17; 1.33]	2.65 [1.24; 5.64]	2.65 [1.24; 5.64]	0.012	0.489
Angina Class 1 or 2	265	3 (1.1)	260	3 (1.2)	-0.02 [-2.34; 2.26]	0.98 [0.20; 4.91]	0.98 [0.20; 4.82]	0.981	
Angina Class 3 or 4	44	1 (2.3)	41	0 (0.0)	2.27 [-6.49; 11.89]	6.90 [0.14; 348.69]	6.90 [0.14; 348.69]	0.334	

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
Medical History of Diabetes Mellitus									
Yes	1047	21 (2.0)	984	8 (0.8)	1.19 [0.17; 2.32]	2.33 [1.12; 4.86]	2.33 [1.12; 4.86]	0.024	0.655
No	1105	3 (0.3)	1167	2 (0.2)	0.10 [-0.38; 0.64]	1.58 [0.27; 9.12]	1.58 [0.27; 9.12]	0.611	
Index Event									
HF Hospitalization within 3 Months	1439	18 (1.3)	1474	8 (0.5)	0.71 [0.03; 1.48]	2.23 [1.03; 4.82]	2.23 [1.03; 4.82]	0.042	0.898
HF Hospitalization 3-6 Months	386	4 (1.0)	362	1 (0.3)	0.76 [-0.60; 2.39]	3.14 [0.54; 18.21]	3.14 [0.54; 18.21]	0.203	
IV diuretic for HF (without hospitalization) within 3 Months	327	2 (0.6)	315	1 (0.3)	0.29 [-1.22; 1.92]	1.88 [0.19; 18.15]	1.88 [0.19; 18.15]	0.585	
SOC: Infections and infestations PT[h]: Bronchitis									
Age category 1									
<65	831	13 (1.6)	851	19 (2.2)	-0.67 [-2.07; 0.68]	0.70 [0.34; 1.42]	0.70 [0.35; 1.41]	0.319	0.583
≥65	1321	13 (1.0)	1300	24 (1.8)	-0.86 [-1.85; 0.04]	0.54 [0.28; 1.03]	0.54 [0.28; 1.03]	0.061	
Age category 2									
<75	1519	18 (1.2)	1533	30 (2.0)	-0.77 [-1.71; 0.12]	0.60 [0.33; 1.08]	0.61 [0.34; 1.08]	0.090	0.987
≥75	633	8 (1.3)	618	13 (2.1)	-0.84 [-2.44; 0.63]	0.60 [0.25; 1.45]	0.60 [0.25; 1.44]	0.253	
Gender									
Male	1656	18 (1.1)	1652	33 (2.0)	-0.91 [-1.81; -0.07]	0.54 [0.30; 0.96]	0.54 [0.31; 0.96]	0.036	0.482

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Female	496	8 (1.6)	499	10 (2.0)	-0.39 [-2.23; 1.39]	0.80 [0.31; 2.05]	0.80 [0.32; 2.02]	0.644	
Geographic Region									
Asia Pacific	510	4 (0.8)	502	5 (1.0)	-0.21 [-1.62; 1.12]	0.79 [0.21; 2.92]	0.79 [0.21; 2.92]	0.720	0.317
Eastern Europe	721	11 (1.5)	718	9 (1.3)	0.27 [-1.02; 1.60]	1.22 [0.50; 2.96]	1.22 [0.51; 2.92]	0.660	
Latin and South America	316	3 (0.9)	324	6 (1.9)	-0.90 [-3.15; 1.12]	0.52 [0.14; 1.94]	0.52 [0.14; 1.94]	0.333	
North America	240	4 (1.7)	241	11 (4.6)	-2.90 [-6.53; 0.24]	0.35 [0.11; 1.13]	0.37 [0.12; 1.13]	0.081	
Western Europe	365	4 (1.1)	366	12 (3.3)	-2.18 [-4.68; -0.07]	0.33 [0.10; 1.02]	0.33 [0.11; 1.03]	0.056	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	1 (0.5)	202	7 (3.5)	-3.00 [-6.57; -0.45]	0.21 [0.05; 0.83]	0.21 [0.05; 0.83]	0.027	0.224
>30 to ≤60	882	12 (1.4)	895	19 (2.1)	-0.76 [-2.08; 0.48]	0.64 [0.31; 1.32]	0.64 [0.31; 1.31]	0.224	
>60	1021	12 (1.2)	1022	17 (1.7)	-0.49 [-1.60; 0.57]	0.70 [0.33; 1.48]	0.71 [0.34; 1.47]	0.354	
NYHA Group at Baseline									
Class I or II	1236	11 (0.9)	1267	24 (1.9)	-1.00 [-2.01; -0.09]	0.48 [0.25; 0.94]	0.48 [0.25; 0.94]	0.032	0.330

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Class III or IV	914	15 (1.6)	884	19 (2.1)	-0.51 [-1.86; 0.79]	0.76 [0.38; 1.50]	0.76 [0.39; 1.49]	0.430	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	7 (2.1)	330	7 (2.1)	0.01 [-2.45; 2.47]	1.00 [0.35; 2.89]	1.00 [0.36; 2.83]	0.995	0.286
No	1823	19 (1.0)	1820	36 (2.0)	-0.94 [-1.78; -0.15]	0.52 [0.30; 0.91]	0.53 [0.30; 0.92]	0.023	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	10 (2.0)	507	11 (2.2)	-0.12 [-2.05; 1.81]	0.94 [0.40; 2.24]	0.94 [0.40; 2.20]	0.891	0.647
Q2 (1556 - 2816)	520	6 (1.2)	493	12 (2.4)	-1.28 [-3.18; 0.38]	0.47 [0.17; 1.26]	0.47 [0.18; 1.25]	0.132	
Q3 (2816 - 5314)	511	5 (1.0)	518	9 (1.7)	-0.76 [-2.41; 0.75]	0.57 [0.20; 1.63]	0.57 [0.20; 1.63]	0.294	
Q4 (>5314)	548	4 (0.7)	523	9 (1.7)	-0.99 [-2.59; 0.37]	0.44 [0.15; 1.31]	0.44 [0.15; 1.31]	0.139	
Baseline Ejection Fraction Group 2									
<35	1719	21 (1.2)	1734	34 (2.0)	-0.74 [-1.62; 0.10]	0.62 [0.36; 1.07]	0.62 [0.36; 1.07]	0.086	0.804
≥35	433	5 (1.2)	417	9 (2.2)	-1.00 [-3.03; 0.80]	0.53 [0.18; 1.59]	0.54 [0.18; 1.58]	0.259	
Race group									
White	1344	20 (1.5)	1353	34 (2.5)	-1.02 [-2.14; 0.03]	0.59 [0.34; 1.02]	0.59 [0.34; 1.02]	0.061	0.993

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Asian	500	3 (0.6)	474	4 (0.8)	-0.24 [-1.62; 1.01]	0.71 [0.16; 3.14]	0.71 [0.16; 3.14]	0.653	
Black	111	1 (0.9)	118	2 (1.7)	-0.79 [-5.19; 3.40]	0.54 [0.06; 5.27]	0.54 [0.06; 5.27]	0.598	
Other	196	2 (1.0)	206	3 (1.5)	-0.44 [-3.30; 2.35]	0.70 [0.12; 4.22]	0.70 [0.12; 4.15]	0.695	
CCSA class at Randomization									
No Angina	1843	23 (1.2)	1850	37 (2.0)	-0.75 [-1.61; 0.07]	0.62 [0.37; 1.05]	0.62 [0.37; 1.05]	0.073	0.521
Angina Class 1 or 2	265	2 (0.8)	260	6 (2.3)	-1.55 [-4.28; 0.68]	0.36 [0.09; 1.44]	0.36 [0.09; 1.44]	0.147	
Angina Class 3 or 4	44	1 (2.3)	41	0 (0.0)	2.27 [-6.49; 11.89]	6.90 [0.14; 348.69]	6.90 [0.14; 348.69]	0.334	
Medical History of Diabetes Mellitus									
Yes	1047	16 (1.5)	984	19 (1.9)	-0.40 [-1.62; 0.76]	0.79 [0.40; 1.54]	0.79 [0.41; 1.53]	0.487	0.240
No	1105	10 (0.9)	1167	24 (2.1)	-1.15 [-2.23; -0.16]	0.46 [0.23; 0.90]	0.46 [0.23; 0.90]	0.024	
Index Event									
HF Hospitalization within 3 Months	1439	18 (1.3)	1474	23 (1.6)	-0.31 [-1.21; 0.57]	0.80 [0.43; 1.49]	0.80 [0.43; 1.48]	0.479	0.334
HF Hospitalization 3-6 Months	386	4 (1.0)	362	9 (2.5)	-1.45 [-3.74; 0.48]	0.41 [0.13; 1.35]	0.42 [0.13; 1.34]	0.142	

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
IV diuretic for HF (without hospitalization) within 3 Months	327	4 (1.2)	315	11 (3.5)	-2.27 [-5.07; 0.08]	0.34 [0.11; 1.09]	0.35 [0.11; 1.09]	0.070	
SOC: Respiratory, thoracic and mediastinal disorders PT[h]: Chronic obstructive pulmonary disease									
Age category 1									
<65	831	9 (1.1)	851	5 (0.6)	0.50 [-0.42; 1.53]	1.82 [0.64; 5.22]	1.82 [0.64; 5.22]	0.264	0.781
≥65	1321	16 (1.2)	1300	7 (0.5)	0.67 [-0.05; 1.48]	2.17 [0.95; 4.92]	2.17 [0.95; 4.92]	0.065	
Age category 2									
<75	1519	19 (1.3)	1533	10 (0.7)	0.60 [-0.10; 1.36]	1.89 [0.91; 3.92]	1.89 [0.91; 3.92]	0.088	0.634
≥75	633	6 (0.9)	618	2 (0.3)	0.62 [-0.33; 1.77]	2.67 [0.66; 10.71]	2.67 [0.66; 10.71]	0.166	
Gender									
Male	1656	22 (1.3)	1652	12 (0.7)	0.60 [-0.09; 1.35]	1.81 [0.92; 3.55]	1.81 [0.92; 3.55]	0.086	0.380
Female	496	3 (0.6)	499	0 (0.0)	0.60 [-0.16; 1.76]	7.46 [0.77; 71.92]	7.46 [0.77; 71.92]	0.082	
Geographic Region									
Asia Pacific	510	3 (0.6)	502	3 (0.6)	-0.01 [-1.22; 1.19]	0.98 [0.20; 4.90]	0.98 [0.20; 4.90]	0.985	0.465
Eastern Europe	721	9 (1.2)	718	5 (0.7)	0.55 [-0.53; 1.74]	1.77 [0.62; 5.08]	1.77 [0.62; 5.08]	0.286	
Latin and South America	316	4 (1.3)	324	1 (0.3)	0.96 [-0.58; 2.94]	3.43 [0.59; 19.92]	3.43 [0.59; 19.92]	0.169	

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	2 (0.8)	241	2 (0.8)	0.00 [-2.23; 2.25]	1.00 [0.14; 7.17]	1.00 [0.14; 7.17]	0.997	
Western Europe	365	7 (1.9)	366	1 (0.3)	1.64 [0.18; 3.67]	4.56 [1.13; 18.35]	4.56 [1.13; 18.35]	0.033	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	1 (0.5)	202	1 (0.5)	-0.03 [-2.32; 2.16]	0.95 [0.06; 15.23]	0.95 [0.06; 15.23]	0.970	0.647
>30 to ≤60	882	12 (1.4)	895	7 (0.8)	0.58 [-0.42; 1.67]	1.73 [0.70; 4.26]	1.73 [0.70; 4.26]	0.236	
>60	1021	12 (1.2)	1022	4 (0.4)	0.78 [0.02; 1.70]	2.74 [1.03; 7.33]	2.74 [1.03; 7.33]	0.044	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	5 (1.5)	330	3 (0.9)	0.61 [-1.30; 2.71]	1.66 [0.41; 6.70]	1.66 [0.41; 6.70]	0.474	0.737
No	1823	20 (1.1)	1820	9 (0.5)	0.60 [0.03; 1.25]	2.14 [1.03; 4.45]	2.14 [1.03; 4.45]	0.041	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	10 (2.0)	507	2 (0.4)	1.65 [0.35; 3.37]	4.00 [1.28; 12.47]	4.00 [1.28; 12.47]	0.017	0.296
Q2 (1556 - 2816)	520	5 (1.0)	493	3 (0.6)	0.35 [-0.92; 1.70]	1.57 [0.39; 6.30]	1.57 [0.39; 6.30]	0.526	
Q3 (2816 - 5314)	511	6 (1.2)	518	6 (1.2)	0.02 [-1.47; 1.52]	1.01 [0.32; 3.16]	1.01 [0.33; 3.12]	0.981	

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q4 (>5314)	548	4 (0.7)	523	1 (0.2)	0.54 [-0.41; 1.69]	3.18 [0.55; 18.45]	3.18 [0.55; 18.45]	0.196	
Baseline Ejection Fraction Group 2									
<35	1719	16 (0.9)	1734	7 (0.4)	0.53 [-0.02; 1.15]	2.22 [0.98; 5.03]	2.22 [0.98; 5.03]	0.057	0.698
≥35	433	9 (2.1)	417	5 (1.2)	0.88 [-0.95; 2.85]	1.75 [0.58; 5.26]	1.73 [0.59; 5.13]	0.320	
Race group									
White	1344	18 (1.3)	1353	7 (0.5)	0.82 [0.11; 1.65]	2.45 [1.11; 5.38]	2.45 [1.11; 5.38]	0.026	0.698
Asian	500	3 (0.6)	474	3 (0.6)	-0.03 [-1.31; 1.19]	0.95 [0.19; 4.72]	0.95 [0.19; 4.72]	0.948	
Black	111	1 (0.9)	118	0 (0.0)	0.90 [-2.28; 4.94]	7.87 [0.16; 397.35]	7.87 [0.16; 397.35]	0.303	
Other	196	3 (1.5)	206	2 (1.0)	0.56 [-2.12; 3.55]	1.58 [0.27; 9.18]	1.58 [0.27; 9.18]	0.613	
CCSA class at Randomization									
No Angina	1843	20 (1.1)	1850	8 (0.4)	0.65 [0.10; 1.28]	2.38 [1.13; 5.01]	2.38 [1.13; 5.01]	0.022	0.309
Angina Class 1 or 2	265	3 (1.1)	260	4 (1.5)	-0.41 [-2.89; 1.92]	0.73 [0.16; 3.31]	0.74 [0.17; 3.26]	0.686	
Angina Class 3 or 4	44	2 (4.5)	41	0 (0.0)	4.55 [-4.31; 15.22]	7.06 [0.43; 115.04]	7.06 [0.43; 115.04]	0.170	

Analyses of Moderate Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 10% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus									
Yes	1047	13 (1.2)	984	6 (0.6)	0.63 [-0.23; 1.58]	1.98 [0.80; 4.88]	1.98 [0.80; 4.88]	0.139	0.959
No	1105	12 (1.1)	1167	6 (0.5)	0.57 [-0.17; 1.43]	2.07 [0.82; 5.23]	2.07 [0.82; 5.23]	0.124	
Index Event									
HF Hospitalization within 3 Months	1439	15 (1.0)	1474	8 (0.5)	0.50 [-0.15; 1.23]	1.89 [0.83; 4.30]	1.89 [0.83; 4.30]	0.128	0.820
HF Hospitalization 3-6 Months	386	6 (1.6)	362	3 (0.8)	0.73 [-1.03; 2.63]	1.84 [0.49; 6.85]	1.84 [0.49; 6.85]	0.363	
IV diuretic for HF (without hospitalization) within 3 Months	327	4 (1.2)	315	1 (0.3)	0.91 [-0.66; 2.82]	3.22 [0.56; 18.71]	3.22 [0.56; 18.71]	0.192	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1 % or ≥ 99 % in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

h: A specific adverse event appears on this report only if its incidence ≥ 10% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main

treatment effect is smaller than 0.05 and p-value for interaction test is greater than or equal to 0.05 or rule of 10 is not met
CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 68
Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Blood and lymphatic system disorders									
Age category 1									
<65	831	9 (1.1)	851	4 (0.5)	0.61 [-0.26; 1.63]	2.22 [0.75; 6.62]	2.22 [0.75; 6.62]	0.151	0.639
≥65	1321	29 (2.2)	1300	17 (1.3)	0.89 [-0.12; 1.96]	1.69 [0.93; 3.10]	1.68 [0.93; 3.04]	0.087	
Gender									
Male	1656	30 (1.8)	1652	17 (1.0)	0.78 [-0.03; 1.64]	1.77 [0.97; 3.23]	1.76 [0.97; 3.18]	0.061	0.845
Female	496	8 (1.6)	499	4 (0.8)	0.81 [-0.63; 2.44]	1.97 [0.63; 6.16]	1.97 [0.63; 6.16]	0.241	
Geographic Region									
Asia Pacific	510	7 (1.4)	502	3 (0.6)	0.77 [-0.54; 2.28]	2.21 [0.64; 7.66]	2.21 [0.64; 7.66]	0.213	0.547
Eastern Europe	721	10 (1.4)	718	10 (1.4)	-0.01 [-1.32; 1.31]	1.00 [0.41; 2.41]	1.00 [0.42; 2.38]	0.993	
Latin and South America	316	3 (0.9)	324	1 (0.3)	0.64 [-0.86; 2.48]	2.80 [0.39; 19.98]	2.80 [0.39; 19.98]	0.304	
North America	240	7 (2.9)	241	2 (0.8)	2.09 [-0.42; 5.17]	3.11 [0.83; 11.61]	3.11 [0.83; 11.61]	0.092	
Western Europe	365	11 (3.0)	366	5 (1.4)	1.65 [-0.53; 4.11]	2.24 [0.77; 6.52]	2.21 [0.77; 6.29]	0.139	

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category									
≤30	213	5 (2.3)	202	4 (2.0)	0.37 [-2.92; 3.66]	1.19 [0.31; 4.50]	1.19 [0.32; 4.35]	0.798	0.096
>30 to ≤60	882	17 (1.9)	895	14 (1.6)	0.36 [-0.90; 1.67]	1.24 [0.61; 2.52]	1.23 [0.61; 2.48]	0.560	
>60	1021	15 (1.5)	1022	3 (0.3)	1.18 [0.41; 2.15]	3.84 [1.52; 9.71]	3.84 [1.52; 9.71]	0.004	
NYHA Group at Baseline									
Class I or II	1236	26 (2.1)	1267	10 (0.8)	1.31 [0.40; 2.35]	2.53 [1.31; 4.88]	2.53 [1.31; 4.88]	0.006	0.093
Class III or IV	914	12 (1.3)	884	11 (1.2)	0.07 [-1.05; 1.18]	1.06 [0.46; 2.41]	1.06 [0.47; 2.38]	0.897	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	5 (1.5)	330	2 (0.6)	0.91 [-0.84; 2.98]	2.38 [0.54; 10.55]	2.38 [0.54; 10.55]	0.253	0.671
No	1823	33 (1.8)	1820	19 (1.0)	0.77 [-0.00; 1.59]	1.75 [0.99; 3.08]	1.73 [0.99; 3.04]	0.054	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	6 (1.2)	507	0 (0.0)	1.23 [0.47; 2.65]	7.75 [1.56; 38.54]	7.75 [1.56; 38.54]	0.012	0.420
Q2 (1556 - 2816)	520	8 (1.5)	493	6 (1.2)	0.32 [-1.27; 1.94]	1.27 [0.44; 3.68]	1.26 [0.44; 3.62]	0.662	
Q3 (2816 - 5314)	511	9 (1.8)	518	8 (1.5)	0.22 [-1.47; 1.95]	1.14 [0.44; 2.99]	1.14 [0.44; 2.93]	0.785	

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q4 (>5314)	548	13 (2.4)	523	7 (1.3)	1.03 [-0.65; 2.84]	1.79 [0.71; 4.53]	1.77 [0.71; 4.41]	0.218	
Baseline Ejection Fraction Group 2									
<35	1719	28 (1.6)	1734	14 (0.8)	0.82 [0.09; 1.62]	1.98 [1.08; 3.64]	1.98 [1.08; 3.64]	0.028	0.521
≥35	433	10 (2.3)	417	7 (1.7)	0.63 [-1.39; 2.73]	1.38 [0.52; 3.67]	1.38 [0.53; 3.58]	0.513	
Race group									
White	1344	26 (1.9)	1353	18 (1.3)	0.60 [-0.37; 1.62]	1.46 [0.80; 2.68]	1.45 [0.80; 2.64]	0.218	0.540
Asian	500	6 (1.2)	474	3 (0.6)	0.57 [-0.78; 2.04]	1.86 [0.50; 6.90]	1.86 [0.50; 6.90]	0.355	
Black	111	2 (1.8)	118	0 (0.0)	1.80 [-1.39; 6.35]	7.94 [0.49; 127.91]	7.94 [0.49; 127.91]	0.144	
Other	196	4 (2.0)	206	0 (0.0)	2.04 [0.19; 5.13]	7.90 [1.10; 56.51]	7.90 [1.10; 56.51]	0.040	
CCSA class at Randomization									
No Angina	1843	33 (1.8)	1850	16 (0.9)	0.93 [0.19; 1.72]	2.03 [1.15; 3.56]	2.03 [1.15; 3.56]	0.014	0.422
Angina Class 1 or 2	265	5 (1.9)	260	4 (1.5)	0.35 [-2.23; 3.00]	1.23 [0.33; 4.64]	1.23 [0.33; 4.52]	0.759	
Angina Class 3 or 4	44	0 (0.0)	41	1 (2.4)	-2.44 [-12.69; 5.78]	0.13 [0.00; 6.35]	0.13 [0.00; 6.35]	0.300	

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus									
Yes	1047	21 (2.0)	984	14 (1.4)	0.58 [-0.58; 1.78]	1.42 [0.72; 2.80]	1.41 [0.72; 2.76]	0.316	0.285
No	1105	17 (1.5)	1167	7 (0.6)	0.94 [0.10; 1.91]	2.45 [1.10; 5.49]	2.45 [1.10; 5.49]	0.029	
Index Event									
HF Hospitalization within 3 Months	1439	24 (1.7)	1474	13 (0.9)	0.79 [-0.03; 1.68]	1.87 [0.98; 3.58]	1.87 [0.98; 3.58]	0.058	0.953
HF Hospitalization 3-6 Months	386	10 (2.6)	362	6 (1.7)	0.93 [-1.29; 3.25]	1.58 [0.57; 4.39]	1.56 [0.57; 4.26]	0.382	
IV diuretic for HF (without hospitalization) within 3 Months	327	4 (1.2)	315	2 (0.6)	0.59 [-1.19; 2.55]	1.89 [0.38; 9.41]	1.89 [0.38; 9.41]	0.439	
SOC: Cardiac disorders									
Age category 1									
<65	831	74 (8.9)	851	85 (10.0)	-1.08 [-3.90; 1.73]	0.88 [0.63; 1.22]	0.89 [0.66; 1.20]	0.448	0.171
≥65	1321	99 (7.5)	1300	143 (11.0)	-3.51 [-5.75; -1.30]	0.66 [0.50; 0.86]	0.68 [0.53; 0.87]	0.002	
Age category 2									
<75	1519	130 (8.6)	1533	168 (11.0)	-2.40 [-4.52; -0.30]	0.76 [0.60; 0.97]	0.78 [0.63; 0.97]	0.026	0.634
≥75	633	43 (6.8)	618	60 (9.7)	-2.92 [-6.04; 0.13]	0.68 [0.45; 1.02]	0.70 [0.48; 1.02]	0.062	
Gender									
Male	1656	141 (8.5)	1652	183 (11.1)	-2.56 [-4.60; -0.54]	0.75 [0.59; 0.94]	0.77 [0.62; 0.95]	0.014	0.790

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Female	496	32 (6.5)	499	45 (9.0)	-2.57 [-5.97; 0.77]	0.70 [0.43; 1.11]	0.72 [0.46; 1.11]	0.132	
Geographic Region									
Asia Pacific	510	34 (6.7)	502	52 (10.4)	-3.69 [-7.23; -0.26]	0.62 [0.39; 0.97]	0.64 [0.43; 0.97]	0.037	0.484
Eastern Europe	721	62 (8.6)	718	68 (9.5)	-0.87 [-3.87; 2.11]	0.90 [0.63; 1.29]	0.91 [0.65; 1.26]	0.564	
Latin and South America	316	17 (5.4)	324	33 (10.2)	-4.81 [-9.13; -0.67]	0.50 [0.27; 0.92]	0.53 [0.30; 0.93]	0.027	
North America	240	22 (9.2)	241	27 (11.2)	-2.04 [-7.60; 3.46]	0.80 [0.44; 1.45]	0.82 [0.48; 1.40]	0.461	
Western Europe	365	38 (10.4)	366	48 (13.1)	-2.70 [-7.45; 2.00]	0.77 [0.49; 1.21]	0.79 [0.53; 1.18]	0.258	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	19 (8.9)	202	16 (7.9)	1.00 [-4.55; 6.52]	1.14 [0.57; 2.28]	1.13 [0.60; 2.13]	0.714	0.255
>30 to ≤60	882	79 (9.0)	895	117 (13.1)	-4.12 [-7.05; -1.21]	0.65 [0.48; 0.88]	0.69 [0.52; 0.90]	0.006	
>60	1021	75 (7.3)	1022	87 (8.5)	-1.17 [-3.54; 1.19]	0.85 [0.62; 1.18]	0.86 [0.64; 1.16]	0.330	
NYHA Group at Baseline									
Class I or II	1236	85 (6.9)	1267	128 (10.1)	-3.23 [-5.43; -1.05]	0.66 [0.49; 0.87]	0.68 [0.52; 0.89]	0.004	0.259

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
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Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Class III or IV	914	88 (9.6)	884	100 (11.3)	-1.68 [-4.55; 1.15]	0.84 [0.62; 1.13]	0.85 [0.65; 1.12]	0.244	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	26 (7.9)	330	46 (13.9)	-6.04 [-10.91; -1.29]	0.53 [0.32; 0.88]	0.57 [0.36; 0.89]	0.015	0.156
No	1823	147 (8.1)	1820	182 (10.0)	-1.94 [-3.81; -0.08]	0.79 [0.63; 0.99]	0.81 [0.66; 0.99]	0.042	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	31 (6.3)	507	46 (9.1)	-2.73 [-6.12; 0.60]	0.68 [0.42; 1.09]	0.70 [0.45; 1.08]	0.109	0.936
Q2 (1556 - 2816)	520	39 (7.5)	493	51 (10.3)	-2.84 [-6.46; 0.67]	0.70 [0.45; 1.09]	0.73 [0.49; 1.08]	0.114	
Q3 (2816 - 5314)	511	46 (9.0)	518	60 (11.6)	-2.58 [-6.35; 1.15]	0.76 [0.50; 1.13]	0.78 [0.54; 1.12]	0.175	
Q4 (>5314)	548	48 (8.8)	523	55 (10.5)	-1.76 [-5.37; 1.79]	0.82 [0.54; 1.23]	0.83 [0.58; 1.20]	0.330	
Baseline Ejection Fraction Group 2									
<35	1719	145 (8.4)	1734	189 (10.9)	-2.46 [-4.45; -0.49]	0.75 [0.60; 0.95]	0.77 [0.63; 0.95]	0.015	0.679
≥35	433	28 (6.5)	417	39 (9.4)	-2.89 [-6.65; 0.75]	0.67 [0.40; 1.11]	0.69 [0.43; 1.10]	0.121	
Race group									
White	1344	121 (9.0)	1353	157 (11.6)	-2.60 [-4.91; -0.31]	0.75 [0.59; 0.97]	0.78 [0.62; 0.97]	0.027	0.853

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Asian	500	29 (5.8)	474	40 (8.4)	-2.64 [-6.00; 0.60]	0.67 [0.41; 1.10]	0.69 [0.43; 1.09]	0.111	
Black	111	10 (9.0)	118	11 (9.3)	-0.31 [-8.14; 7.65]	0.96 [0.39; 2.37]	0.97 [0.43; 2.19]	0.935	
Other	196	12 (6.1)	206	20 (9.7)	-3.59 [-9.12; 1.80]	0.61 [0.29; 1.28]	0.63 [0.32; 1.26]	0.189	
CCSA class at Randomization									
No Angina	1843	145 (7.9)	1850	197 (10.6)	-2.78 [-4.66; -0.92]	0.72 [0.57; 0.90]	0.74 [0.60; 0.91]	0.004	0.249
Angina Class 1 or 2	265	26 (9.8)	260	25 (9.6)	0.20 [-5.00; 5.37]	1.02 [0.57; 1.82]	1.02 [0.61; 1.72]	0.940	
Angina Class 3 or 4	44	2 (4.5)	41	6 (14.6)	-10.09 [-24.72; 2.80]	0.28 [0.05; 1.46]	0.31 [0.07; 1.45]	0.137	
Medical History of Diabetes Mellitus									
Yes	1047	93 (8.9)	984	108 (11.0)	-2.09 [-4.73; 0.51]	0.79 [0.59; 1.06]	0.81 [0.62; 1.05]	0.115	0.481
No	1105	80 (7.2)	1167	120 (10.3)	-3.04 [-5.38; -0.72]	0.68 [0.51; 0.92]	0.70 [0.54; 0.92]	0.011	
Index Event									
HF Hospitalization within 3 Months	1439	127 (8.8)	1474	162 (11.0)	-2.16 [-4.35; 0.01]	0.78 [0.61; 1.00]	0.80 [0.64; 1.00]	0.051	0.544
HF Hospitalization 3-6 Months	386	30 (7.8)	362	46 (12.7)	-4.94 [-9.43; -0.61]	0.58 [0.36; 0.94]	0.61 [0.40; 0.95]	0.027	

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
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(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
IV diuretic for HF (without hospitalization) within 3 Months	327	16 (4.9)	315	20 (6.3)	-1.46 [-5.23; 2.18]	0.76 [0.39; 1.49]	0.77 [0.41; 1.46]	0.424	
SOC: Metabolism and nutrition disorders									
Age category 1									
<65	831	21 (2.5)	851	34 (4.0)	-1.47 [-3.25; 0.24]	0.62 [0.36; 1.08]	0.63 [0.37; 1.08]	0.094	0.519
≥65	1321	44 (3.3)	1300	55 (4.2)	-0.90 [-2.40; 0.57]	0.78 [0.52; 1.17]	0.79 [0.53; 1.16]	0.228	
Age category 2									
<75	1519	46 (3.0)	1533	56 (3.7)	-0.62 [-1.93; 0.66]	0.82 [0.55; 1.22]	0.83 [0.56; 1.22]	0.338	0.252
≥75	633	19 (3.0)	618	33 (5.3)	-2.34 [-4.69; -0.13]	0.55 [0.31; 0.98]	0.56 [0.32; 0.98]	0.041	
Gender									
Male	1656	45 (2.7)	1652	69 (4.2)	-1.46 [-2.74; -0.22]	0.64 [0.44; 0.94]	0.65 [0.45; 0.94]	0.023	0.232
Female	496	20 (4.0)	499	20 (4.0)	0.02 [-2.51; 2.56]	1.01 [0.53; 1.89]	1.01 [0.55; 1.85]	0.984	
Geographic Region									
Asia Pacific	510	22 (4.3)	502	24 (4.8)	-0.47 [-3.14; 2.17]	0.90 [0.50; 1.62]	0.90 [0.51; 1.59]	0.721	0.186
Eastern Europe	721	19 (2.6)	718	22 (3.1)	-0.43 [-2.23; 1.34]	0.86 [0.46; 1.60]	0.86 [0.47; 1.58]	0.625	
Latin and South America	316	6 (1.9)	324	6 (1.9)	0.05 [-2.32; 2.46]	1.03 [0.33; 3.21]	1.03 [0.33; 3.15]	0.965	

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	13 (5.4)	241	18 (7.5)	-2.05 [-6.70; 2.45]	0.71 [0.34; 1.48]	0.73 [0.36; 1.45]	0.362	
Western Europe	365	5 (1.4)	366	19 (5.2)	-3.82 [-6.75; -1.34]	0.25 [0.09; 0.69]	0.26 [0.10; 0.70]	0.007	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	8 (3.8)	202	16 (7.9)	-4.16 [-9.16; 0.35]	0.45 [0.19; 1.08]	0.47 [0.21; 1.08]	0.077	0.306
>30 to ≤60	882	30 (3.4)	895	45 (5.0)	-1.63 [-3.56; 0.25]	0.67 [0.42; 1.07]	0.68 [0.43; 1.06]	0.090	
>60	1021	27 (2.6)	1022	28 (2.7)	-0.10 [-1.54; 1.35]	0.96 [0.56; 1.65]	0.97 [0.57; 1.63]	0.894	
NYHA Group at Baseline									
Class I or II	1236	34 (2.8)	1267	46 (3.6)	-0.88 [-2.30; 0.51]	0.75 [0.48; 1.18]	0.76 [0.49; 1.17]	0.213	0.788
Class III or IV	914	31 (3.4)	884	43 (4.9)	-1.47 [-3.39; 0.37]	0.69 [0.43; 1.10]	0.70 [0.44; 1.10]	0.118	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	11 (3.3)	330	15 (4.5)	-1.20 [-4.41; 1.89]	0.73 [0.33; 1.61]	0.74 [0.34; 1.58]	0.430	0.985
No	1823	54 (3.0)	1820	74 (4.1)	-1.10 [-2.33; 0.09]	0.72 [0.50; 1.03]	0.73 [0.52; 1.03]	0.072	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	12 (2.5)	507	13 (2.6)	-0.11 [-2.18; 1.97]	0.96 [0.43; 2.12]	0.96 [0.44; 2.08]	0.912	0.531

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q2 (1556 - 2816)	520	18 (3.5)	493	25 (5.1)	-1.61 [-4.26; 0.90]	0.67 [0.36; 1.25]	0.68 [0.38; 1.24]	0.207	
Q3 (2816 - 5314)	511	18 (3.5)	518	20 (3.9)	-0.34 [-2.75; 2.05]	0.91 [0.48; 1.74]	0.91 [0.49; 1.70]	0.774	
Q4 (>5314)	548	16 (2.9)	523	29 (5.5)	-2.63 [-5.21; -0.23]	0.51 [0.27; 0.95]	0.53 [0.29; 0.96]	0.036	
Baseline Ejection Fraction Group 2									
<35	1719	51 (3.0)	1734	71 (4.1)	-1.13 [-2.39; 0.11]	0.72 [0.50; 1.03]	0.72 [0.51; 1.03]	0.074	0.934
≥35	433	14 (3.2)	417	18 (4.3)	-1.08 [-3.83; 1.55]	0.74 [0.36; 1.51]	0.75 [0.38; 1.49]	0.409	
Race group									
White	1344	34 (2.5)	1353	53 (3.9)	-1.39 [-2.77; -0.05]	0.64 [0.41; 0.99]	0.65 [0.42; 0.99]	0.043	0.470
Asian	500	21 (4.2)	474	24 (5.1)	-0.86 [-3.64; 1.83]	0.82 [0.45; 1.50]	0.83 [0.47; 1.47]	0.522	
Black	111	3 (2.7)	118	7 (5.9)	-3.23 [-9.43; 2.48]	0.44 [0.11; 1.75]	0.46 [0.12; 1.72]	0.246	
Other	196	7 (3.6)	206	5 (2.4)	1.14 [-2.46; 5.06]	1.49 [0.46; 4.77]	1.47 [0.47; 4.56]	0.503	
CCSA class at Randomization									
No Angina	1843	56 (3.0)	1850	72 (3.9)	-0.85 [-2.06; 0.33]	0.77 [0.54; 1.10]	0.78 [0.55; 1.10]	0.157	0.574

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Angina Class 1 or 2	265	8 (3.0)	260	16 (6.2)	-3.13 [-7.09; 0.47]	0.47 [0.20; 1.13]	0.49 [0.21; 1.13]	0.093	
Angina Class 3 or 4	44	1 (2.3)	41	1 (2.4)	-0.17 [-10.67; 9.74]	0.93 [0.06; 15.37]	0.93 [0.06; 14.42]	0.960	
Medical History of Diabetes Mellitus									
Yes	1047	46 (4.4)	984	61 (6.2)	-1.81 [-3.82; 0.14]	0.70 [0.47; 1.03]	0.71 [0.49; 1.03]	0.070	0.949
No	1105	19 (1.7)	1167	28 (2.4)	-0.68 [-1.90; 0.51]	0.71 [0.40; 1.28]	0.72 [0.40; 1.28]	0.258	
Index Event									
HF Hospitalization within 3 Months	1439	36 (2.5)	1474	58 (3.9)	-1.43 [-2.76; -0.15]	0.63 [0.41; 0.96]	0.64 [0.42; 0.96]	0.030	0.595
HF Hospitalization 3-6 Months	386	20 (5.2)	362	22 (6.1)	-0.90 [-4.37; 2.47]	0.84 [0.45; 1.58]	0.85 [0.47; 1.54]	0.595	
IV diuretic for HF (without hospitalization) within 3 Months	327	9 (2.8)	315	9 (2.9)	-0.10 [-2.92; 2.65]	0.96 [0.38; 2.46]	0.96 [0.39; 2.40]	0.936	
SOC: Musculoskeletal and connective tissue disorders									
Age category 1									
<65	831	3 (0.4)	851	13 (1.5)	-1.17 [-2.28; -0.27]	0.29 [0.11; 0.78]	0.29 [0.11; 0.78]	0.014	0.082
≥65	1321	19 (1.4)	1300	25 (1.9)	-0.48 [-1.53; 0.52]	0.74 [0.41; 1.36]	0.75 [0.41; 1.35]	0.336	
Age category 2									
<75	1519	10 (0.7)	1533	25 (1.6)	-0.97 [-1.80; -0.23]	0.42 [0.22; 0.83]	0.42 [0.22; 0.83]	0.012	0.139

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥75	633	12 (1.9)	618	13 (2.1)	-0.21 [-1.88; 1.43]	0.90 [0.41; 1.99]	0.90 [0.41; 1.96]	0.793	
Gender									
Male	1656	16 (1.0)	1652	29 (1.8)	-0.79 [-1.64; 0.00]	0.56 [0.31; 1.00]	0.56 [0.31; 1.00]	0.050	0.747
Female	496	6 (1.2)	499	9 (1.8)	-0.59 [-2.33; 1.03]	0.67 [0.24; 1.89]	0.67 [0.24; 1.87]	0.445	
Geographic Region									
Asia Pacific	510	6 (1.2)	502	6 (1.2)	-0.02 [-1.55; 1.50]	0.98 [0.32; 3.07]	0.98 [0.32; 3.03]	0.978	0.729
Eastern Europe	721	3 (0.4)	718	4 (0.6)	-0.14 [-1.06; 0.72]	0.75 [0.17; 3.30]	0.75 [0.17; 3.30]	0.701	
Latin and South America	316	2 (0.6)	324	3 (0.9)	-0.29 [-2.13; 1.45]	0.69 [0.12; 3.98]	0.69 [0.12; 3.98]	0.674	
North America	240	2 (0.8)	241	7 (2.9)	-2.07 [-5.15; 0.44]	0.32 [0.09; 1.21]	0.32 [0.09; 1.21]	0.094	
Western Europe	365	9 (2.5)	366	18 (4.9)	-2.45 [-5.45; 0.30]	0.49 [0.22; 1.10]	0.50 [0.23; 1.10]	0.086	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	2 (0.9)	202	5 (2.5)	-1.54 [-4.84; 1.19]	0.40 [0.09; 1.77]	0.40 [0.09; 1.77]	0.225	0.814
>30 to ≤60	882	15 (1.7)	895	26 (2.9)	-1.20 [-2.70; 0.20]	0.58 [0.30; 1.10]	0.59 [0.31; 1.10]	0.095	

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
>60	1021	5 (0.5)	1022	7 (0.7)	-0.20 [-0.98; 0.54]	0.72 [0.23; 2.23]	0.72 [0.23; 2.23]	0.564	
NYHA Group at Baseline									
Class I or II	1236	12 (1.0)	1267	21 (1.7)	-0.69 [-1.65; 0.22]	0.59 [0.30; 1.17]	0.59 [0.30; 1.17]	0.132	0.955
Class III or IV	914	10 (1.1)	884	17 (1.9)	-0.83 [-2.08; 0.31]	0.56 [0.26; 1.24]	0.57 [0.26; 1.24]	0.154	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	4 (1.2)	330	10 (3.0)	-1.81 [-4.42; 0.44]	0.39 [0.12; 1.27]	0.40 [0.13; 1.27]	0.119	0.463
No	1823	18 (1.0)	1820	28 (1.5)	-0.55 [-1.32; 0.18]	0.64 [0.36; 1.15]	0.64 [0.36; 1.15]	0.136	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	5 (1.0)	507	11 (2.2)	-1.15 [-2.94; 0.47]	0.47 [0.16; 1.35]	0.47 [0.16; 1.35]	0.160	0.666
Q2 (1556 - 2816)	520	6 (1.2)	493	7 (1.4)	-0.27 [-1.88; 1.26]	0.81 [0.27; 2.43]	0.81 [0.28; 2.40]	0.707	
Q3 (2816 - 5314)	511	7 (1.4)	518	10 (1.9)	-0.56 [-2.31; 1.11]	0.71 [0.27; 1.87]	0.71 [0.27; 1.85]	0.483	
Q4 (>5314)	548	3 (0.5)	523	9 (1.7)	-1.17 [-2.75; 0.10]	0.35 [0.11; 1.08]	0.35 [0.11; 1.08]	0.068	
Baseline Ejection Fraction Group 2									
<35	1719	15 (0.9)	1734	32 (1.8)	-0.97 [-1.80; -0.21]	0.48 [0.27; 0.86]	0.48 [0.27; 0.86]	0.014	0.172

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥35	433	7 (1.6)	417	6 (1.4)	0.18 [-1.68; 2.04]	1.13 [0.38; 3.38]	1.12 [0.38; 3.32]	0.833	
Race group									
White	1344	15 (1.1)	1353	28 (2.1)	-0.95 [-1.97; -0.01]	0.53 [0.28; 1.00]	0.54 [0.29; 1.01]	0.052	0.756
Asian	500	5 (1.0)	474	6 (1.3)	-0.27 [-1.85; 1.22]	0.79 [0.24; 2.59]	0.79 [0.24; 2.59]	0.695	
Black	111	0 (0.0)	118	2 (1.7)	-1.69 [-5.98; 1.69]	0.14 [0.01; 2.29]	0.14 [0.01; 2.29]	0.169	
Other	196	2 (1.0)	206	2 (1.0)	0.05 [-2.57; 2.78]	1.05 [0.15; 7.52]	1.05 [0.15; 7.52]	0.960	
CCSA class at Randomization									
No Angina	1843	21 (1.1)	1850	35 (1.9)	-0.75 [-1.59; 0.04]	0.60 [0.35; 1.03]	0.60 [0.35; 1.03]	0.064	0.913
Angina Class 1 or 2	265	1 (0.4)	260	3 (1.2)	-0.78 [-3.00; 1.06]	0.36 [0.05; 2.56]	0.36 [0.05; 2.56]	0.307	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	0.00 [-8.66; 8.12]	n.a.	n.a.	n.a.	
Medical History of Diabetes Mellitus									
Yes	1047	9 (0.9)	984	22 (2.2)	-1.38 [-2.59; -0.33]	0.40 [0.20; 0.81]	0.40 [0.20; 0.81]	0.011	0.133
No	1105	13 (1.2)	1167	16 (1.4)	-0.19 [-1.17; 0.78]	0.86 [0.41; 1.79]	0.86 [0.41; 1.78]	0.680	

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥5% or (Incidence ≥1% and in at least 10 Participants) in One or More Groups)
for System Organ Classes
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Index Event									
HF Hospitalization within 3 Months	1439	13 (0.9)	1474	28 (1.9)	-1.00 [-1.92; -0.15]	0.49 [0.26; 0.90]	0.49 [0.26; 0.90]	0.023	0.291
HF Hospitalization 3-6 Months	386	5 (1.3)	362	8 (2.2)	-0.91 [-3.16; 1.08]	0.58 [0.19; 1.79]	0.59 [0.19; 1.78]	0.345	
IV diuretic for HF (without hospitalization) within 3 Months	327	4 (1.2)	315	2 (0.6)	0.59 [-1.19; 2.55]	1.89 [0.38; 9.41]	1.89 [0.38; 9.41]	0.439	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1 % or ≥ 99 % in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

h: A specific adverse event appears on this report only if its incidence ≥ 5% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is greater than or equal to 0.05 or rule of 10 is not met

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

Table 69
Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
SOC: Blood and lymphatic system disorders PT[h]: Anaemia									
Age category 1									
<65	831	4 (0.5)	851	3 (0.4)	0.13 [-0.61; 0.92]	1.36 [0.31; 6.02]	1.36 [0.31; 6.02]	0.682	0.660
≥65	1321	24 (1.8)	1300	12 (0.9)	0.89 [0.00; 1.86]	1.93 [1.00; 3.73]	1.93 [1.00; 3.73]	0.049	
Age category 2									
<75	1519	18 (1.2)	1533	8 (0.5)	0.66 [0.01; 1.40]	2.19 [1.01; 4.74]	2.19 [1.01; 4.74]	0.046	0.455
≥75	633	10 (1.6)	618	7 (1.1)	0.45 [-0.93; 1.89]	1.40 [0.53; 3.70]	1.39 [0.53; 3.64]	0.497	
Gender									
Male	1656	21 (1.3)	1652	13 (0.8)	0.48 [-0.22; 1.23]	1.60 [0.82; 3.15]	1.60 [0.82; 3.15]	0.170	0.350
Female	496	7 (1.4)	499	2 (0.4)	1.01 [-0.21; 2.53]	3.08 [0.83; 11.45]	3.08 [0.83; 11.45]	0.092	
Geographic Region									
Asia Pacific	510	4 (0.8)	502	2 (0.4)	0.39 [-0.74; 1.65]	1.92 [0.39; 9.57]	1.92 [0.39; 9.57]	0.424	0.329
Eastern Europe	721	7 (1.0)	718	9 (1.3)	-0.28 [-1.51; 0.89]	0.77 [0.29; 2.07]	0.77 [0.29; 2.07]	0.609	
Latin and South America	316	1 (0.3)	324	0 (0.0)	0.32 [-0.86; 1.77]	7.58 [0.15; 382.05]	7.58 [0.15; 382.05]	0.311	

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	6 (2.5)	241	1 (0.4)	2.09 [-0.08; 4.98]	4.27 [0.96; 18.95]	4.27 [0.96; 18.95]	0.056	
Western Europe	365	10 (2.7)	366	3 (0.8)	1.92 [0.00; 4.25]	3.00 [1.00; 8.97]	3.00 [1.00; 8.97]	0.050	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	4 (1.9)	202	4 (2.0)	-0.10 [-3.33; 3.01]	0.95 [0.23; 3.84]	0.95 [0.24; 3.74]	0.940	0.403
>30 to ≤60	882	13 (1.5)	895	8 (0.9)	0.58 [-0.46; 1.71]	1.64 [0.70; 3.88]	1.64 [0.70; 3.88]	0.258	
>60	1021	10 (1.0)	1022	3 (0.3)	0.69 [-0.00; 1.53]	2.96 [0.99; 8.80]	2.96 [0.99; 8.80]	0.051	
NYHA Group at Baseline									
Class I or II	1236	20 (1.6)	1267	8 (0.6)	0.99 [0.17; 1.92]	2.44 [1.16; 5.14]	2.44 [1.16; 5.14]	0.019	0.203
Class III or IV	914	8 (0.9)	884	7 (0.8)	0.08 [-0.85; 1.02]	1.11 [0.40; 3.06]	1.11 [0.40; 3.06]	0.846	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	3 (0.9)	330	1 (0.3)	0.61 [-0.87; 2.38]	2.74 [0.38; 19.53]	2.74 [0.38; 19.53]	0.315	0.653
No	1823	25 (1.4)	1820	14 (0.8)	0.60 [-0.07; 1.32]	1.77 [0.94; 3.32]	1.77 [0.94; 3.32]	0.077	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	5 (1.0)	507	0 (0.0)	1.02 [0.27; 2.37]	7.73 [1.33; 44.79]	7.73 [1.33; 44.79]	0.023	0.257

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q2 (1556 - 2816)	520	5 (1.0)	493	6 (1.2)	-0.26 [-1.78; 1.17]	0.79 [0.24; 2.59]	0.79 [0.24; 2.59]	0.695	
Q3 (2816 - 5314)	511	7 (1.4)	518	6 (1.2)	0.21 [-1.30; 1.78]	1.19 [0.40; 3.55]	1.18 [0.40; 3.49]	0.762	
Q4 (>5314)	548	9 (1.6)	523	3 (0.6)	1.07 [-0.23; 2.59]	2.62 [0.84; 8.18]	2.62 [0.84; 8.18]	0.097	
Baseline Ejection Fraction Group 2									
<35	1719	21 (1.2)	1734	10 (0.6)	0.64 [0.02; 1.34]	2.06 [1.02; 4.19]	2.06 [1.02; 4.19]	0.045	0.521
≥35	433	7 (1.6)	417	5 (1.2)	0.42 [-1.35; 2.25]	1.35 [0.43; 4.30]	1.35 [0.43; 4.21]	0.607	
Race group									
White	1344	21 (1.6)	1353	13 (1.0)	0.60 [-0.25; 1.52]	1.62 [0.82; 3.19]	1.62 [0.82; 3.19]	0.161	0.755
Asian	500	3 (0.6)	474	2 (0.4)	0.18 [-0.99; 1.38]	1.42 [0.24; 8.21]	1.42 [0.24; 8.21]	0.698	
Black	111	2 (1.8)	118	0 (0.0)	1.80 [-1.39; 6.35]	7.94 [0.49; 127.91]	7.94 [0.49; 127.91]	0.144	
Other	196	2 (1.0)	206	0 (0.0)	1.02 [-0.82; 3.65]	7.82 [0.49; 125.50]	7.82 [0.49; 125.50]	0.147	
CCSA class at Randomization									
No Angina	1843	23 (1.2)	1850	12 (0.6)	0.60 [-0.03; 1.28]	1.89 [0.97; 3.68]	1.89 [0.97; 3.68]	0.060	0.917

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Angina Class 1 or 2	265	5 (1.9)	260	3 (1.2)	0.73 [-1.68; 3.33]	1.65 [0.39; 6.97]	1.64 [0.39; 6.77]	0.498	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	0.00 [-8.66; 8.12]	n.a.	n.a.	n.a.	
Medical History of Diabetes Mellitus									
Yes	1047	16 (1.5)	984	10 (1.0)	0.51 [-0.51; 1.57]	1.51 [0.68; 3.35]	1.50 [0.69; 3.30]	0.309	0.430
No	1105	12 (1.1)	1167	5 (0.4)	0.66 [-0.06; 1.51]	2.42 [0.93; 6.29]	2.42 [0.93; 6.29]	0.069	
Index Event									
HF Hospitalization within 3 Months	1439	17 (1.2)	1474	8 (0.5)	0.64 [-0.03; 1.40]	2.12 [0.96; 4.65]	2.12 [0.96; 4.65]	0.062	0.840
HF Hospitalization 3-6 Months	386	8 (2.1)	362	5 (1.4)	0.69 [-1.37; 2.83]	1.51 [0.49; 4.66]	1.50 [0.50; 4.54]	0.473	
IV diuretic for HF (without hospitalization) within 3 Months	327	3 (0.9)	315	2 (0.6)	0.28 [-1.47; 2.10]	1.44 [0.25; 8.36]	1.44 [0.25; 8.36]	0.684	
SOC: Cardiac disorders PT[h]: Atrial fibrillation									
Age category 1									
<65	831	7 (0.8)	851	11 (1.3)	-0.45 [-1.56; 0.59]	0.65 [0.26; 1.65]	0.65 [0.26; 1.65]	0.370	0.179
≥65	1321	4 (0.3)	1300	16 (1.2)	-0.93 [-1.72; -0.29]	0.29 [0.12; 0.71]	0.29 [0.12; 0.71]	0.006	
Age category 2									
<75	1519	10 (0.7)	1533	18 (1.2)	-0.52 [-1.26; 0.17]	0.57 [0.27; 1.19]	0.57 [0.27; 1.19]	0.135	0.090

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥75	633	1 (0.2)	618	9 (1.5)	-1.30 [-2.60; -0.39]	0.19 [0.06; 0.68]	0.19 [0.06; 0.68]	0.010	
Gender									
Male	1656	9 (0.5)	1652	19 (1.2)	-0.61 [-1.30; 0.02]	0.49 [0.23; 1.02]	0.49 [0.23; 1.02]	0.057	0.460
Female	496	2 (0.4)	499	8 (1.6)	-1.20 [-2.78; 0.05]	0.30 [0.09; 1.04]	0.30 [0.09; 1.04]	0.058	
Geographic Region									
Asia Pacific	510	3 (0.6)	502	3 (0.6)	-0.01 [-1.22; 1.19]	0.98 [0.20; 4.90]	0.98 [0.20; 4.90]	0.985	0.502
Eastern Europe	721	2 (0.3)	718	11 (1.5)	-1.25 [-2.48; -0.33]	0.25 [0.08; 0.73]	0.25 [0.08; 0.73]	0.012	
Latin and South America	316	1 (0.3)	324	2 (0.6)	-0.30 [-1.94; 1.21]	0.53 [0.05; 5.07]	0.53 [0.05; 5.07]	0.578	
North America	240	3 (1.3)	241	4 (1.7)	-0.41 [-3.09; 2.15]	0.75 [0.17; 3.39]	0.75 [0.17; 3.33]	0.708	
Western Europe	365	2 (0.5)	366	7 (1.9)	-1.36 [-3.41; 0.29]	0.33 [0.09; 1.21]	0.33 [0.09; 1.21]	0.095	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	0 (0.0)	202	2 (1.0)	-0.99 [-3.54; 0.79]	0.13 [0.01; 2.05]	0.13 [0.01; 2.05]	0.146	0.431
>30 to ≤60	882	5 (0.6)	895	16 (1.8)	-1.22 [-2.38; -0.24]	0.35 [0.15; 0.83]	0.35 [0.15; 0.83]	0.017	

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
>60	1021	6 (0.6)	1022	8 (0.8)	-0.20 [-1.02; 0.59]	0.75 [0.26; 2.15]	0.75 [0.26; 2.15]	0.593	
NYHA Group at Baseline									
Class I or II	1236	4 (0.3)	1267	13 (1.0)	-0.70 [-1.46; -0.07]	0.35 [0.14; 0.92]	0.35 [0.14; 0.92]	0.032	0.561
Class III or IV	914	7 (0.8)	884	14 (1.6)	-0.82 [-1.96; 0.19]	0.49 [0.21; 1.16]	0.49 [0.21; 1.16]	0.107	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	0 (0.0)	330	4 (1.2)	-1.21 [-3.08; -0.05]	0.13 [0.02; 0.96]	0.13 [0.02; 0.96]	0.045	0.335
No	1823	11 (0.6)	1820	23 (1.3)	-0.66 [-1.35; -0.04]	0.49 [0.25; 0.96]	0.49 [0.25; 0.96]	0.038	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	4 (0.8)	507	2 (0.4)	0.42 [-0.70; 1.73]	2.03 [0.41; 10.09]	2.03 [0.41; 10.09]	0.388	0.124
Q2 (1556 - 2816)	520	2 (0.4)	493	11 (2.2)	-1.85 [-3.61; -0.53]	0.23 [0.08; 0.70]	0.23 [0.08; 0.70]	0.009	
Q3 (2816 - 5314)	511	2 (0.4)	518	7 (1.4)	-0.96 [-2.42; 0.22]	0.33 [0.09; 1.23]	0.33 [0.09; 1.23]	0.098	
Q4 (>5314)	548	3 (0.5)	523	5 (1.0)	-0.41 [-1.73; 0.76]	0.58 [0.14; 2.32]	0.58 [0.14; 2.32]	0.438	
Baseline Ejection Fraction Group 2									
<35	1719	10 (0.6)	1734	23 (1.3)	-0.74 [-1.46; -0.10]	0.46 [0.23; 0.90]	0.46 [0.23; 0.90]	0.025	0.596

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥35	433	1 (0.2)	417	4 (1.0)	-0.73 [-2.24; 0.43]	0.29 [0.05; 1.67]	0.29 [0.05; 1.67]	0.165	
Race group									
White	1344	9 (0.7)	1353	22 (1.6)	-0.96 [-1.85; -0.16]	0.43 [0.21; 0.88]	0.43 [0.21; 0.88]	0.020	0.805
Asian	500	2 (0.4)	474	2 (0.4)	-0.02 [-1.17; 1.07]	0.95 [0.13; 6.75]	0.95 [0.13; 6.75]	0.957	
Black	111	0 (0.0)	118	1 (0.8)	-0.85 [-4.66; 2.53]	0.14 [0.00; 7.25]	0.14 [0.00; 7.25]	0.332	
Other	196	0 (0.0)	206	2 (1.0)	-0.97 [-3.47; 0.97]	0.14 [0.01; 2.27]	0.14 [0.01; 2.27]	0.167	
CCSA class at Randomization									
No Angina	1843	8 (0.4)	1850	26 (1.4)	-0.97 [-1.66; -0.38]	0.34 [0.18; 0.68]	0.34 [0.18; 0.68]	0.002	0.162
Angina Class 1 or 2	265	3 (1.1)	260	1 (0.4)	0.75 [-1.12; 2.94]	2.68 [0.38; 19.15]	2.68 [0.38; 19.15]	0.325	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	0.00 [-8.66; 8.12]	n.a.	n.a.	n.a.	
Medical History of Diabetes Mellitus									
Yes	1047	7 (0.7)	984	13 (1.3)	-0.65 [-1.65; 0.22]	0.51 [0.21; 1.24]	0.51 [0.21; 1.24]	0.137	0.478
No	1105	4 (0.4)	1167	14 (1.2)	-0.84 [-1.68; -0.12]	0.34 [0.14; 0.87]	0.34 [0.14; 0.87]	0.024	

Analyses of Severe Adverse Event for Subgroups with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
(Incidence ≥ 5% or (≥ 1% and in at least 10 Participants) in One or More Groups)
for Preferred Terms
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Index Event									
HF Hospitalization within 3 Months	1439	10 (0.7)	1474	18 (1.2)	-0.53 [-1.30; 0.20]	0.58 [0.27; 1.21]	0.58 [0.27; 1.21]	0.146	0.427
HF Hospitalization 3-6 Months	386	1 (0.3)	362	6 (1.7)	-1.40 [-3.34; -0.02]	0.22 [0.05; 0.98]	0.22 [0.05; 0.98]	0.047	
IV diuretic for HF (without hospitalization) within 3 Months	327	0 (0.0)	315	3 (1.0)	-0.95 [-2.76; 0.22]	0.13 [0.01; 1.25]	0.13 [0.01; 1.25]	0.077	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1 % or ≥ 99 % in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1 % or ≥ 99 % in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

h: A specific adverse event appears on this report only if its incidence ≥ 5% or (incidence ≥ 1% and in at least 10 Participants) in one or more groups and p-value of main treatment effect is smaller than 0.05 and p-value for interaction test is greater than or equal to 0.05 or rule of 10 is not met

CI: Confidence Interval; n.a.: Not Applicable (when estimation not possible).

1.9 Adverse Events of Clinical Interest by Category Endpoints by Subgroup

1.9.1 ECI by Category

Table 70
Overview of Subgroup Analyses for Adverse Event of Clinical Interest Related Endpoints
Treatment by Subgroup Interaction
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**						
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 0 / >30 to ≤ 60 / >60)**	**NYHA Group at Baseline (Class I or II / Class III or IV)**	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**
Adverse Events of Clinical Interest by ECI Category							
Hepatic ECI	0.753	0.785	0.265	0.454	0.095	**0.031[c]**	0.521
Symptomatic Hypotension	**0.046[c]**	0.441	0.511	0.878	0.852	0.849	0.831
Syncope	0.903	0.654	0.749	0.314	0.625	0.306	0.584

Overview of Subgroup Analyses for Adverse Event of Clinical Interest Related Endpoints
Treatment by Subgroup Interaction
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**					
	NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**
Adverse Events of Clinical Interest by ECI Category						
Hepatic ECI	0.295	0.491	0.551	0.657	0.926	0.233
Symptomatic Hypotension	0.148	0.729	0.868	0.651	0.167	0.466
Syncope	0.654	0.908	0.450	0.275	0.721	0.973

a: Database Cutoff Date: 18JUN2019

b: Based on a Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if Participant has 0 event in at least one cell of the stratum.

c: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; ECI: Adverse Events of Clinical Interest; eGFR: Estimated glomerular filtration rate; HF: Heart failure; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

1.9.1.1 Results for Subgroups with Interaction Nominal P-value < 0.05

Table 71
Analyses of Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test < 0.05
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Category: Hepatic ECI									
NYHA Group at Baseline									
Class I or II	1236	10 (0.8)	1267	10 (0.8)	0.02 [-0.73; 0.78]	1.03 [0.43; 2.47]	1.03 [0.43; 2.47]	0.956	0.031
Class III or IV	914	12 (1.3)	884	2 (0.2)	1.09 [0.32; 2.08]	4.08 [1.42; 11.67]	4.08 [1.42; 11.67]	0.009	
Category: Symptomatic Hypotension									
Age category 1									
<65	831	77 (9.3)	851	53 (6.2)	3.04 [0.49; 5.65]	1.54 [1.07; 2.21]	1.49 [1.06; 2.08]	0.021	0.046
≥65	1321	120 (9.1)	1300	121 (9.3)	-0.22 [-2.45; 2.00]	0.97 [0.75; 1.27]	0.98 [0.77; 1.24]	0.843	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; ECI: Events of Clinical Interest; n.a.: Not Applicable (when estimation not possible).

1.9.1.2 Results for Subgroups with Interaction Nominal P-value ≥ 0.05

Table 72
Analyses of Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Category: Hepatic ECI									
Age category 1									
<65	831	12 (1.4)	851	6 (0.7)	0.74 [-0.27; 1.88]	2.01 [0.79; 5.09]	2.01 [0.79; 5.09]	0.141	0.753
≥65	1321	10 (0.8)	1300	6 (0.5)	0.30 [-0.34; 0.98]	1.63 [0.61; 4.35]	1.63 [0.61; 4.35]	0.332	
Age category 2									
<75	1519	19 (1.3)	1533	10 (0.7)	0.60 [-0.10; 1.36]	1.89 [0.91; 3.92]	1.89 [0.91; 3.92]	0.088	0.785
≥75	633	3 (0.5)	618	2 (0.3)	0.15 [-0.75; 1.10]	1.46 [0.25; 8.44]	1.46 [0.25; 8.44]	0.674	
Gender									
Male	1656	17 (1.0)	1652	11 (0.7)	0.36 [-0.28; 1.04]	1.54 [0.73; 3.23]	1.54 [0.73; 3.23]	0.258	0.265
Female	496	5 (1.0)	499	1 (0.2)	0.81 [-0.22; 2.16]	3.84 [0.77; 19.12]	3.84 [0.77; 19.12]	0.100	
Geographic Region									
Asia Pacific	510	11 (2.2)	502	3 (0.6)	1.56 [0.14; 3.29]	3.13 [1.09; 8.99]	3.13 [1.09; 8.99]	0.034	0.454
Eastern Europe	721	7 (1.0)	718	4 (0.6)	0.41 [-0.57; 1.50]	1.72 [0.53; 5.65]	1.72 [0.53; 5.65]	0.368	
Latin and South America	316	1 (0.3)	324	2 (0.6)	-0.30 [-1.94; 1.21]	0.53 [0.05; 5.07]	0.53 [0.05; 5.07]	0.578	

Analyses of Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	2 (0.8)	241	1 (0.4)	0.42 [-1.55; 2.62]	1.96 [0.20; 18.95]	1.96 [0.20; 18.95]	0.560	
Western Europe	365	1 (0.3)	366	2 (0.5)	-0.27 [-1.73; 1.04]	0.51 [0.05; 4.96]	0.51 [0.05; 4.96]	0.565	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	0 (0.0)	202	1 (0.5)	-0.50 [-2.75; 1.29]	0.13 [0.00; 6.47]	0.13 [0.00; 6.47]	0.304	0.095
>30 to ≤60	882	6 (0.7)	895	7 (0.8)	-0.10 [-1.01; 0.79]	0.87 [0.29; 2.59]	0.87 [0.29; 2.59]	0.801	
>60	1021	16 (1.6)	1022	4 (0.4)	1.18 [0.36; 2.18]	3.36 [1.39; 8.11]	3.36 [1.39; 8.11]	0.007	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	2 (0.6)	330	2 (0.6)	0.00 [-1.64; 1.65]	1.00 [0.14; 7.15]	1.00 [0.14; 7.15]	0.998	0.521
No	1823	20 (1.1)	1820	10 (0.5)	0.55 [-0.04; 1.20]	1.95 [0.95; 4.01]	1.95 [0.95; 4.01]	0.067	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	2 (0.4)	507	4 (0.8)	-0.38 [-1.65; 0.77]	0.53 [0.11; 2.64]	0.53 [0.11; 2.64]	0.439	0.295
Q2 (1556 - 2816)	520	6 (1.2)	493	2 (0.4)	0.75 [-0.44; 2.14]	2.60 [0.65; 10.44]	2.60 [0.65; 10.44]	0.179	
Q3 (2816 - 5314)	511	6 (1.2)	518	4 (0.8)	0.40 [-0.94; 1.86]	1.52 [0.44; 5.27]	1.52 [0.44; 5.27]	0.511	

Analyses of Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q4 (>5314)	548	8 (1.5)	523	2 (0.4)	1.08 [-0.09; 2.52]	3.20 [0.92; 11.12]	3.20 [0.92; 11.12]	0.067	
Baseline Ejection Fraction Group 2									
<35	1719	20 (1.2)	1734	10 (0.6)	0.59 [-0.03; 1.27]	1.98 [0.96; 4.05]	1.98 [0.96; 4.05]	0.063	0.491
≥35	433	2 (0.5)	417	2 (0.5)	-0.02 [-1.32; 1.24]	0.96 [0.14; 6.86]	0.96 [0.14; 6.86]	0.970	
Race group									
White	1344	10 (0.7)	1353	9 (0.7)	0.08 [-0.60; 0.78]	1.12 [0.45; 2.76]	1.12 [0.45; 2.76]	0.807	0.551
Asian	500	11 (2.2)	474	3 (0.6)	1.57 [0.08; 3.34]	3.02 [1.05; 8.67]	3.02 [1.05; 8.67]	0.040	
Black	111	1 (0.9)	118	0 (0.0)	0.90 [-2.28; 4.94]	7.87 [0.16; 397.35]	7.87 [0.16; 397.35]	0.303	
Other	196	0 (0.0)	206	0 (0.0)	0.00 [-1.84; 1.93]	n.a.	n.a.	n.a.	
CCSA class at Randomization									
No Angina	1843	17 (0.9)	1850	11 (0.6)	0.33 [-0.25; 0.94]	1.55 [0.73; 3.25]	1.55 [0.73; 3.25]	0.251	0.657
Angina Class 1 or 2	265	5 (1.9)	260	1 (0.4)	1.50 [-0.44; 4.00]	3.77 [0.76; 18.82]	3.77 [0.76; 18.82]	0.106	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	0.00 [-8.66; 8.12]	n.a.	n.a.	n.a.	

Analyses of Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus									
Yes	1047	12 (1.1)	984	6 (0.6)	0.54 [-0.31; 1.46]	1.84 [0.73; 4.66]	1.84 [0.73; 4.66]	0.198	0.926
No	1105	10 (0.9)	1167	6 (0.5)	0.39 [-0.33; 1.20]	1.75 [0.65; 4.68]	1.75 [0.65; 4.68]	0.266	
Index Event									
HF Hospitalization within 3 Months	1439	13 (0.9)	1474	7 (0.5)	0.43 [-0.19; 1.12]	1.87 [0.78; 4.52]	1.87 [0.78; 4.52]	0.161	0.233
HF Hospitalization 3-6 Months	386	6 (1.6)	362	1 (0.3)	1.28 [-0.14; 3.11]	3.96 [0.89; 17.55]	3.96 [0.89; 17.55]	0.070	
IV diuretic for HF (without hospitalization) within 3 Months	327	3 (0.9)	315	4 (1.3)	-0.35 [-2.41; 1.55]	0.72 [0.16; 3.20]	0.72 [0.16; 3.20]	0.668	
Category: Symptomatic Hypotension									
Age category 2									
<75	1519	137 (9.0)	1533	116 (7.6)	1.45 [-0.51; 3.43]	1.21 [0.94; 1.57]	1.19 [0.94; 1.51]	0.146	0.441
≥75	633	60 (9.5)	618	58 (9.4)	0.09 [-3.18; 3.36]	1.01 [0.69; 1.48]	1.01 [0.72; 1.42]	0.955	
Gender									
Male	1656	150 (9.1)	1652	137 (8.3)	0.76 [-1.16; 2.69]	1.10 [0.86; 1.40]	1.09 [0.88; 1.36]	0.435	0.511
Female	496	47 (9.5)	499	37 (7.4)	2.06 [-1.42; 5.60]	1.31 [0.83; 2.05]	1.28 [0.85; 1.93]	0.244	
Geographic Region									
Asia Pacific	510	47 (9.2)	502	37 (7.4)	1.85 [-1.58; 5.31]	1.28 [0.81; 2.00]	1.25 [0.83; 1.89]	0.289	0.878

Analyses of Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Eastern Europe	721	48 (6.7)	718	46 (6.4)	0.25 [-2.34; 2.85]	1.04 [0.69; 1.58]	1.04 [0.70; 1.54]	0.847	
Latin and South America	316	19 (6.0)	324	21 (6.5)	-0.47 [-4.35; 3.41]	0.92 [0.49; 1.75]	0.93 [0.51; 1.69]	0.807	
North America	240	36 (15.0)	241	28 (11.6)	3.38 [-2.74; 9.57]	1.34 [0.79; 2.28]	1.29 [0.81; 2.05]	0.277	
Western Europe	365	47 (12.9)	366	42 (11.5)	1.40 [-3.38; 6.21]	1.14 [0.73; 1.78]	1.12 [0.76; 1.66]	0.563	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	24 (11.3)	202	17 (8.4)	2.85 [-3.01; 8.76]	1.38 [0.72; 2.66]	1.34 [0.74; 2.42]	0.333	0.852
>30 to ≤60	882	94 (10.7)	895	86 (9.6)	1.05 [-1.77; 3.88]	1.12 [0.82; 1.53]	1.11 [0.84; 1.46]	0.464	
>60	1021	76 (7.4)	1022	66 (6.5)	0.99 [-1.23; 3.22]	1.16 [0.83; 1.64]	1.15 [0.84; 1.58]	0.382	
NYHA Group at Baseline									
Class I or II	1236	105 (8.5)	1267	94 (7.4)	1.08 [-1.05; 3.22]	1.16 [0.87; 1.55]	1.15 [0.88; 1.50]	0.320	0.849
Class III or IV	914	91 (10.0)	884	80 (9.0)	0.91 [-1.82; 3.64]	1.11 [0.81; 1.52]	1.10 [0.83; 1.46]	0.513	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	41 (12.5)	330	38 (11.5)	0.95 [-4.07; 5.98]	1.09 [0.68; 1.75]	1.08 [0.72; 1.64]	0.708	0.831

Analyses of Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
No	1823	156 (8.6)	1820	136 (7.5)	1.08 [-0.68; 2.86]	1.16 [0.91; 1.47]	1.15 [0.92; 1.43]	0.228	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	37 (7.6)	507	42 (8.3)	-0.72 [-4.13; 2.70]	0.91 [0.57; 1.44]	0.91 [0.60; 1.40]	0.675	0.148
Q2 (1556 - 2816)	520	59 (11.3)	493	41 (8.3)	3.03 [-0.66; 6.74]	1.41 [0.93; 2.15]	1.36 [0.93; 1.99]	0.108	
Q3 (2816 - 5314)	511	49 (9.6)	518	33 (6.4)	3.22 [-0.09; 6.63]	1.56 [0.98; 2.47]	1.51 [0.98; 2.30]	0.059	
Q4 (>5314)	548	42 (7.7)	523	46 (8.8)	-1.13 [-4.50; 2.18]	0.86 [0.56; 1.33]	0.87 [0.58; 1.30]	0.501	
Baseline Ejection Fraction Group 2									
<35	1719	162 (9.4)	1734	142 (8.2)	1.23 [-0.66; 3.14]	1.17 [0.92; 1.48]	1.15 [0.93; 1.43]	0.201	0.729
≥35	433	35 (8.1)	417	32 (7.7)	0.41 [-3.29; 4.10]	1.06 [0.64; 1.74]	1.05 [0.66; 1.67]	0.825	
Race group									
White	1344	132 (9.8)	1353	120 (8.9)	0.95 [-1.25; 3.16]	1.12 [0.86; 1.45]	1.11 [0.88; 1.40]	0.396	0.868
Asian	500	37 (7.4)	474	26 (5.5)	1.91 [-1.21; 5.08]	1.38 [0.82; 2.31]	1.35 [0.83; 2.19]	0.227	
Black	111	9 (8.1)	118	10 (8.5)	-0.37 [-7.91; 7.30]	0.95 [0.37; 2.44]	0.96 [0.40; 2.27]	0.920	

Analyses of Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Other	196	18 (9.2)	206	18 (8.7)	0.45 [-5.28; 6.27]	1.06 [0.53; 2.09]	1.05 [0.56; 1.96]	0.876	
CCSA class at Randomization									
No Angina	1843	179 (9.7)	1850	155 (8.4)	1.33 [-0.52; 3.20]	1.18 [0.94; 1.47]	1.16 [0.94; 1.42]	0.158	0.651
Angina Class 1 or 2	265	16 (6.0)	260	18 (6.9)	-0.89 [-5.31; 3.46]	0.86 [0.43; 1.73]	0.87 [0.45; 1.67]	0.681	
Angina Class 3 or 4	44	2 (4.5)	41	1 (2.4)	2.11 [-8.66; 13.13]	1.90 [0.17; 21.84]	1.86 [0.18; 19.79]	0.606	
Medical History of Diabetes Mellitus									
Yes	1047	103 (9.8)	984	74 (7.5)	2.32 [-0.14; 4.78]	1.34 [0.98; 1.83]	1.31 [0.98; 1.74]	0.065	0.167
No	1105	94 (8.5)	1167	100 (8.6)	-0.06 [-2.37; 2.26]	0.99 [0.74; 1.33]	0.99 [0.76; 1.30]	0.958	
Index Event									
HF Hospitalization within 3 Months	1439	137 (9.5)	1474	115 (7.8)	1.72 [-0.33; 3.78]	1.24 [0.96; 1.61]	1.22 [0.96; 1.55]	0.100	0.466
HF Hospitalization 3-6 Months	386	31 (8.0)	362	33 (9.1)	-1.08 [-5.23; 2.97]	0.87 [0.52; 1.45]	0.88 [0.55; 1.41]	0.596	
IV diuretic for HF (without hospitalization) within 3 Months	327	29 (8.9)	315	26 (8.3)	0.61 [-3.82; 5.04]	1.08 [0.62; 1.88]	1.07 [0.65; 1.78]	0.781	
Category: Syncope									
Age category 1									
<65	831	36 (4.3)	851	32 (3.8)	0.57 [-1.34; 2.52]	1.16 [0.71; 1.88]	1.15 [0.72; 1.84]	0.552	0.903

Analyses of Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥65	1321	53 (4.0)	1300	47 (3.6)	0.40 [-1.09; 1.89]	1.11 [0.75; 1.66]	1.11 [0.75; 1.63]	0.596	
Age category 2									
<75	1519	63 (4.1)	1533	54 (3.5)	0.62 [-0.75; 2.02]	1.19 [0.82; 1.72]	1.18 [0.82; 1.68]	0.369	0.654
≥75	633	26 (4.1)	618	25 (4.0)	0.06 [-2.20; 2.32]	1.02 [0.58; 1.78]	1.02 [0.59; 1.74]	0.956	
Gender									
Male	1656	76 (4.6)	1652	66 (4.0)	0.59 [-0.80; 2.00]	1.16 [0.83; 1.62]	1.15 [0.83; 1.59]	0.400	0.749
Female	496	13 (2.6)	499	13 (2.6)	0.02 [-2.09; 2.13]	1.01 [0.46; 2.19]	1.01 [0.47; 2.15]	0.988	
Geographic Region									
Asia Pacific	510	16 (3.1)	502	17 (3.4)	-0.25 [-2.56; 2.03]	0.92 [0.46; 1.85]	0.93 [0.47; 1.81]	0.823	0.314
Eastern Europe	721	30 (4.2)	718	17 (2.4)	1.79 [-0.05; 3.74]	1.79 [0.98; 3.28]	1.76 [0.98; 3.16]	0.059	
Latin and South America	316	5 (1.6)	324	9 (2.8)	-1.20 [-3.81; 1.22]	0.56 [0.19; 1.70]	0.57 [0.19; 1.68]	0.308	
North America	240	10 (4.2)	241	12 (5.0)	-0.81 [-4.84; 3.13]	0.83 [0.35; 1.96]	0.84 [0.37; 1.90]	0.670	
Western Europe	365	28 (7.7)	366	24 (6.6)	1.11 [-2.69; 4.96]	1.18 [0.67; 2.08]	1.17 [0.69; 1.98]	0.559	

Analyses of Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category									
≤30	213	8 (3.8)	202	9 (4.5)	-0.70 [-4.95; 3.37]	0.84 [0.32; 2.21]	0.84 [0.33; 2.14]	0.720	0.625
>30 to ≤60	882	43 (4.9)	895	33 (3.7)	1.19 [-0.71; 3.13]	1.34 [0.84; 2.13]	1.32 [0.85; 2.06]	0.218	
>60	1021	37 (3.6)	1022	35 (3.4)	0.20 [-1.43; 1.84]	1.06 [0.66; 1.70]	1.06 [0.67; 1.67]	0.807	
NYHA Group at Baseline									
Class I or II	1236	54 (4.4)	1267	43 (3.4)	0.98 [-0.55; 2.53]	1.30 [0.86; 1.96]	1.29 [0.87; 1.91]	0.208	0.306
Class III or IV	914	35 (3.8)	884	36 (4.1)	-0.24 [-2.10; 1.59]	0.94 [0.58; 1.51]	0.94 [0.60; 1.48]	0.791	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	13 (4.0)	330	14 (4.2)	-0.29 [-3.50; 2.90]	0.93 [0.43; 2.01]	0.93 [0.44; 1.95]	0.851	0.584
No	1823	76 (4.2)	1820	65 (3.6)	0.60 [-0.66; 1.87]	1.17 [0.84; 1.65]	1.17 [0.84; 1.62]	0.350	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	20 (4.1)	507	23 (4.5)	-0.45 [-3.06; 2.17]	0.90 [0.49; 1.66]	0.90 [0.50; 1.62]	0.729	0.654
Q2 (1556 - 2816)	520	24 (4.6)	493	18 (3.7)	0.96 [-1.56; 3.52]	1.28 [0.68; 2.38]	1.26 [0.69; 2.30]	0.443	
Q3 (2816 - 5314)	511	23 (4.5)	518	16 (3.1)	1.41 [-0.96; 3.90]	1.48 [0.77; 2.83]	1.46 [0.78; 2.73]	0.239	

Analyses of Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q4 (>5314)	548	19 (3.5)	523	19 (3.6)	-0.17 [-2.50; 2.12]	0.95 [0.50; 1.82]	0.95 [0.51; 1.78]	0.883	
Baseline Ejection Fraction Group 2									
<35	1719	72 (4.2)	1734	65 (3.7)	0.44 [-0.87; 1.76]	1.12 [0.80; 1.58]	1.12 [0.80; 1.55]	0.508	0.908
≥35	433	17 (3.9)	417	14 (3.4)	0.57 [-2.07; 3.23]	1.18 [0.57; 2.42]	1.17 [0.58; 2.34]	0.659	
Race group									
White	1344	70 (5.2)	1353	58 (4.3)	0.92 [-0.69; 2.56]	1.23 [0.86; 1.75]	1.21 [0.87; 1.71]	0.261	0.450
Asian	500	14 (2.8)	474	12 (2.5)	0.27 [-1.89; 2.42]	1.11 [0.51; 2.42]	1.11 [0.52; 2.37]	0.795	
Black	111	3 (2.7)	118	3 (2.5)	0.16 [-4.87; 5.42]	1.06 [0.21; 5.39]	1.06 [0.22; 5.16]	0.939	
Other	196	2 (1.0)	206	6 (2.9)	-1.89 [-5.32; 1.07]	0.34 [0.07; 1.72]	0.35 [0.07; 1.72]	0.196	
CCSA class at Randomization									
No Angina	1843	72 (3.9)	1850	69 (3.7)	0.18 [-1.07; 1.43]	1.05 [0.75; 1.47]	1.05 [0.76; 1.45]	0.779	0.275
Angina Class 1 or 2	265	16 (6.0)	260	8 (3.1)	2.96 [-0.66; 6.87]	2.02 [0.85; 4.81]	1.96 [0.85; 4.51]	0.112	
Angina Class 3 or 4	44	1 (2.3)	41	2 (4.9)	-2.61 [-14.26; 7.61]	0.45 [0.04; 5.20]	0.47 [0.04; 4.95]	0.526	

Analyses of Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus									
Yes	1047	41 (3.9)	984	32 (3.3)	0.66 [-0.98; 2.32]	1.21 [0.76; 1.94]	1.20 [0.76; 1.90]	0.423	0.721
No	1105	48 (4.3)	1167	47 (4.0)	0.32 [-1.35; 2.01]	1.08 [0.72; 1.63]	1.08 [0.73; 1.60]	0.706	
Index Event									
HF Hospitalization within 3 Months	1439	57 (4.0)	1474	51 (3.5)	0.50 [-0.88; 1.91]	1.15 [0.78; 1.69]	1.14 [0.79; 1.66]	0.475	0.973
HF Hospitalization 3-6 Months	386	19 (4.9)	362	17 (4.7)	0.23 [-2.99; 3.40]	1.05 [0.54; 2.05]	1.05 [0.55; 1.98]	0.885	
IV diuretic for HF (without hospitalization) within 3 Months	327	13 (4.0)	315	11 (3.5)	0.48 [-2.63; 3.61]	1.14 [0.50; 2.59]	1.14 [0.52; 2.50]	0.747	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; ECI: Events of Clinical Interest; n.a.: Not Applicable (when estimation not possible).

1.9.2 Serious ECI by Category

Table 73
Overview of Subgroup Analyses for Serious Adverse Event of Clinical Interest Related Endpoints
Treatment by Subgroup Interaction
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**						
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 0 / >30 to ≤ 60 / >60)**	**NYHA Group at Baseline (Class I or II / Class III or IV)**	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**
Serious Adverse Events of Clinical Interest by ECI Category							
Hepatic ECI	0.304	0.871	0.372	n.c.	0.072	**0.049[c]**	0.346
Symptomatic Hypotension	**0.037[c]**	0.267	0.990	0.480	0.687	0.675	0.958
Syncope	0.779	0.665	0.160	0.519	**0.034[c]**	0.121	0.635

Overview of Subgroup Analyses for Serious Adverse Event of Clinical Interest Related Endpoints
Treatment by Subgroup Interaction
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**					
	NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**
Serious Adverse Events of Clinical Interest by ECI Category						
Hepatic ECI	n.c.	0.864	0.532	0.785	0.860	0.974
Symptomatic Hypotension	0.083	0.866	0.587	0.976	0.867	0.701
Syncope	0.209	0.513	0.155	0.689	0.918	0.962

a: Database Cutoff Date: 18JUN2019

b: Based on a Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if Participant has 0 event in at least one cell of the stratum.

c: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; ECI: Adverse Events of Clinical Interest; eGFR: Estimated glomerular filtration rate; HF: Heart failure; n.c.: not calculated. At least 10 subjects per subgroup and at least 10 events in one of the subgroups necessary; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

1.9.2.1 Results for Subgroups with Interaction Nominal P-value < 0.05

Table 74
Analyses of Serious Adverse Event of Clinical Interest for Subgroups;with P-value for Interaction Test < 0.05
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Category: Hepatic ECI									
NYHA Group at Baseline									
Class I or II	1236	5 (0.4)	1267	5 (0.4)	0.01 [-0.56; 0.59]	1.03 [0.30; 3.55]	1.03 [0.30; 3.55]	0.969	0.049
Class III or IV	914	9 (1.0)	884	1 (0.1)	0.87 [0.24; 1.76]	4.83 [1.39; 16.74]	4.83 [1.39; 16.74]	0.013	
Category: Symptomatic Hypotension									
Age category 1									
<65	831	14 (1.7)	851	9 (1.1)	0.63 [-0.52; 1.87]	1.60 [0.69; 3.72]	1.59 [0.69; 3.66]	0.273	0.037
≥65	1321	12 (0.9)	1300	23 (1.8)	-0.86 [-1.82; 0.02]	0.52 [0.27; 1.01]	0.52 [0.27; 1.01]	0.055	
Category: Syncope									
eGFR (mL/min/1.73 m^2) Category									
≤30	213	0 (0.0)	202	6 (3.0)	-2.97 [-6.33; -1.17]	0.12 [0.02; 0.63]	0.12 [0.02; 0.63]	0.011	0.034
>30 to ≤60	882	25 (2.8)	895	11 (1.2)	1.61 [0.31; 3.05]	2.34 [1.15; 4.79]	2.31 [1.14; 4.66]	0.020	
>60	1021	14 (1.4)	1022	14 (1.4)	0.00 [-1.07; 1.07]	1.00 [0.47; 2.11]	1.00 [0.48; 2.09]	0.998	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤

1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; ECI: Events of Clinical Interest; n.a.: Not Applicable (when estimation not possible).

1.9.2.2 Results for Subgroups with Interaction Nominal P-value ≥ 0.05

Table 75
Analyses of Serious Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Category: Hepatic ECI									
Age category 1									
<65	831	8 (1.0)	851	2 (0.2)	0.73 [-0.01; 1.68]	3.42 [0.99; 11.86]	3.42 [0.99; 11.86]	0.052	0.304
≥65	1321	6 (0.5)	1300	4 (0.3)	0.15 [-0.39; 0.72]	1.47 [0.42; 5.09]	1.47 [0.42; 5.09]	0.543	
Age category 2									
<75	1519	12 (0.8)	1533	5 (0.3)	0.46 [-0.07; 1.09]	2.31 [0.89; 5.99]	2.31 [0.89; 5.99]	0.085	0.871
≥75	633	2 (0.3)	618	1 (0.2)	0.15 [-0.62; 1.00]	1.90 [0.20; 18.34]	1.90 [0.20; 18.34]	0.577	
Gender									
Male	1656	9 (0.5)	1652	5 (0.3)	0.24 [-0.23; 0.76]	1.77 [0.62; 5.06]	1.77 [0.62; 5.06]	0.286	0.372
Female	496	5 (1.0)	499	1 (0.2)	0.81 [-0.22; 2.16]	3.84 [0.77; 19.12]	3.84 [0.77; 19.12]	0.100	
Geographic Region									
Asia Pacific	510	8 (1.6)	502	1 (0.2)	n.a.	n.a.	n.a.	n.a.	n.a.
Eastern Europe	721	4 (0.6)	718	1 (0.1)	n.a.	n.a.	n.a.	n.a.	
Latin and South America	316	0 (0.0)	324	1 (0.3)	n.a.	n.a.	n.a.	n.a.	

Analyses of Serious Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	1 (0.4)	241	1 (0.4)	n.a.	n.a.	n.a.	n.a.	
Western Europe	365	1 (0.3)	366	2 (0.5)	n.a.	n.a.	n.a.	n.a.	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	0 (0.0)	202	1 (0.5)	-0.50 [-2.75; 1.29]	0.13 [0.00; 6.47]	0.13 [0.00; 6.47]	0.304	0.072
>30 to ≤60	882	3 (0.3)	895	4 (0.4)	-0.11 [-0.84; 0.60]	0.76 [0.17; 3.36]	0.76 [0.17; 3.36]	0.719	
>60	1021	11 (1.1)	1022	1 (0.1)	0.98 [0.39; 1.83]	5.35 [1.72; 16.63]	5.35 [1.72; 16.63]	0.004	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	2 (0.6)	330	2 (0.6)	0.00 [-1.64; 1.65]	1.00 [0.14; 7.15]	1.00 [0.14; 7.15]	0.998	0.346
No	1823	12 (0.7)	1820	4 (0.2)	0.44 [0.01; 0.95]	2.73 [1.02; 7.28]	2.73 [1.02; 7.28]	0.045	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	1 (0.2)	507	2 (0.4)	n.a.	n.a.	n.a.	n.a.	n.a.
Q2 (1556 - 2816)	520	2 (0.4)	493	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Q3 (2816 - 5314)	511	4 (0.8)	518	3 (0.6)	n.a.	n.a.	n.a.	n.a.	

Analyses of Serious Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q4 (>5314)	548	7 (1.3)	523	1 (0.2)	n.a.	n.a.	n.a.	n.a.	
Baseline Ejection Fraction Group 2									
<35	1719	12 (0.7)	1734	5 (0.3)	0.41 [-0.06; 0.96]	2.31 [0.89; 5.98]	2.31 [0.89; 5.98]	0.085	0.864
≥35	433	2 (0.5)	417	1 (0.2)	0.22 [-0.92; 1.45]	1.88 [0.19; 18.12]	1.88 [0.19; 18.12]	0.585	
Race group									
White	1344	6 (0.4)	1353	5 (0.4)	0.08 [-0.47; 0.64]	1.21 [0.37; 3.95]	1.21 [0.37; 3.95]	0.754	0.532
Asian	500	8 (1.6)	474	1 (0.2)	1.39 [0.25; 2.94]	4.55 [1.23; 16.92]	4.55 [1.23; 16.92]	0.024	
Black	111	0 (0.0)	118	0 (0.0)	0.00 [-3.17; 3.36]	n.a.	n.a.	n.a.	
Other	196	0 (0.0)	206	0 (0.0)	0.00 [-1.84; 1.93]	n.a.	n.a.	n.a.	
CCSA class at Randomization									
No Angina	1843	12 (0.7)	1850	6 (0.3)	0.33 [-0.14; 0.85]	1.96 [0.78; 4.95]	1.96 [0.78; 4.95]	0.154	0.785
Angina Class 1 or 2	265	2 (0.8)	260	0 (0.0)	0.75 [-0.71; 2.71]	7.28 [0.45; 116.69]	7.28 [0.45; 116.69]	0.161	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	0.00 [-8.66; 8.12]	n.a.	n.a.	n.a.	

Analyses of Serious Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus									
Yes	1047	8 (0.8)	984	3 (0.3)	0.46 [-0.22; 1.23]	2.34 [0.72; 7.67]	2.34 [0.72; 7.67]	0.159	0.860
No	1105	6 (0.5)	1167	3 (0.3)	0.29 [-0.28; 0.95]	2.06 [0.56; 7.64]	2.06 [0.56; 7.64]	0.278	
Index Event									
HF Hospitalization within 3 Months	1439	9 (0.6)	1474	4 (0.3)	0.35 [-0.15; 0.94]	2.22 [0.75; 6.59]	2.22 [0.75; 6.59]	0.152	0.974
HF Hospitalization 3-6 Months	386	3 (0.8)	362	1 (0.3)	0.50 [-0.84; 2.02]	2.56 [0.36; 18.27]	2.56 [0.36; 18.27]	0.348	
IV diuretic for HF (without hospitalization) within 3 Months	327	2 (0.6)	315	1 (0.3)	0.29 [-1.22; 1.92]	1.88 [0.19; 18.15]	1.88 [0.19; 18.15]	0.585	
Category: Symptomatic Hypotension									
Age category 2									
<75	1519	21 (1.4)	1533	22 (1.4)	-0.05 [-0.92; 0.82]	0.96 [0.53; 1.76]	0.96 [0.53; 1.74]	0.902	0.267
≥75	633	5 (0.8)	618	10 (1.6)	-0.83 [-2.25; 0.43]	0.50 [0.18; 1.38]	0.50 [0.18; 1.38]	0.179	
Gender									
Male	1656	22 (1.3)	1652	27 (1.6)	-0.31 [-1.17; 0.54]	0.81 [0.46; 1.43]	0.81 [0.46; 1.42]	0.467	0.990
Female	496	4 (0.8)	499	5 (1.0)	-0.20 [-1.62; 1.17]	0.80 [0.22; 2.99]	0.80 [0.22; 2.99]	0.745	
Geographic Region									
Asia Pacific	510	6 (1.2)	502	9 (1.8)	-0.62 [-2.33; 0.98]	0.65 [0.23; 1.85]	0.66 [0.24; 1.83]	0.421	0.480

Analyses of Serious Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Eastern Europe	721	8 (1.1)	718	7 (1.0)	0.13 [-1.02; 1.32]	1.14 [0.41; 3.15]	1.14 [0.41; 3.15]	0.802	
Latin and South America	316	0 (0.0)	324	5 (1.5)	-1.54 [-3.56; -0.33]	0.14 [0.02; 0.80]	0.14 [0.02; 0.80]	0.027	
North America	240	7 (2.9)	241	5 (2.1)	0.84 [-2.22; 4.08]	1.42 [0.44; 4.53]	1.41 [0.45; 4.37]	0.556	
Western Europe	365	5 (1.4)	366	6 (1.6)	-0.27 [-2.33; 1.73]	0.83 [0.25; 2.76]	0.84 [0.26; 2.71]	0.765	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	6 (2.8)	202	4 (2.0)	0.84 [-2.51; 4.29]	1.43 [0.40; 5.16]	1.42 [0.41; 4.97]	0.581	0.687
>30 to ≤60	882	13 (1.5)	895	17 (1.9)	-0.43 [-1.71; 0.82]	0.77 [0.37; 1.60]	0.78 [0.38; 1.59]	0.488	
>60	1021	7 (0.7)	1022	9 (0.9)	-0.20 [-1.06; 0.63]	0.78 [0.29; 2.08]	0.78 [0.29; 2.08]	0.617	
NYHA Group at Baseline									
Class I or II	1236	12 (1.0)	1267	17 (1.3)	-0.37 [-1.28; 0.50]	0.72 [0.35; 1.50]	0.72 [0.35; 1.50]	0.386	0.675
Class III or IV	914	14 (1.5)	884	15 (1.7)	-0.17 [-1.42; 1.05]	0.90 [0.43; 1.88]	0.90 [0.44; 1.86]	0.781	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	5 (1.5)	330	6 (1.8)	-0.30 [-2.58; 1.92]	0.83 [0.25; 2.76]	0.84 [0.26; 2.71]	0.765	0.958

Analyses of Serious Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
No	1823	21 (1.2)	1820	26 (1.4)	-0.28 [-1.05; 0.47]	0.80 [0.45; 1.43]	0.81 [0.46; 1.43]	0.460	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	5 (1.0)	507	8 (1.6)	-0.56 [-2.19; 0.98]	0.64 [0.21; 1.98]	0.65 [0.21; 1.97]	0.444	0.083
Q2 (1556 - 2816)	520	9 (1.7)	493	5 (1.0)	0.72 [-0.83; 2.37]	1.72 [0.57; 5.17]	1.71 [0.58; 5.06]	0.335	
Q3 (2816 - 5314)	511	8 (1.6)	518	6 (1.2)	0.41 [-1.13; 2.04]	1.36 [0.47; 3.94]	1.35 [0.47; 3.87]	0.574	
Q4 (>5314)	548	3 (0.5)	523	11 (2.1)	-1.56 [-3.24; -0.22]	0.30 [0.10; 0.86]	0.30 [0.10; 0.86]	0.025	
Baseline Ejection Fraction Group 2									
<35	1719	23 (1.3)	1734	28 (1.6)	-0.28 [-1.12; 0.55]	0.83 [0.47; 1.44]	0.83 [0.48; 1.43]	0.501	0.866
≥35	433	3 (0.7)	417	4 (1.0)	-0.27 [-1.83; 1.17]	0.72 [0.16; 3.19]	0.72 [0.16; 3.19]	0.668	
Race group									
White	1344	17 (1.3)	1353	22 (1.6)	-0.36 [-1.32; 0.57]	0.78 [0.41; 1.47]	0.78 [0.41; 1.46]	0.433	0.587
Asian	500	5 (1.0)	474	7 (1.5)	-0.48 [-2.13; 1.03]	0.68 [0.22; 2.11]	0.68 [0.22; 2.11]	0.500	
Black	111	3 (2.7)	118	1 (0.8)	1.86 [-2.23; 6.91]	2.93 [0.41; 21.12]	2.93 [0.41; 21.12]	0.285	

Analyses of Serious Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Other	196	1 (0.5)	206	2 (1.0)	-0.46 [-3.02; 1.95]	0.54 [0.06; 5.20]	0.54 [0.06; 5.20]	0.592	
CCSA class at Randomization									
No Angina	1843	24 (1.3)	1850	30 (1.6)	-0.32 [-1.13; 0.47]	0.80 [0.47; 1.37]	0.80 [0.47; 1.37]	0.420	0.976
Angina Class 1 or 2	265	2 (0.8)	260	2 (0.8)	-0.01 [-2.09; 2.02]	0.98 [0.14; 7.00]	0.98 [0.14; 7.00]	0.985	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	0.00 [-8.66; 8.12]	n.a.	n.a.	n.a.	
Medical History of Diabetes Mellitus									
Yes	1047	14 (1.3)	984	17 (1.7)	-0.39 [-1.55; 0.71]	0.77 [0.38; 1.57]	0.77 [0.38; 1.56]	0.474	0.867
No	1105	12 (1.1)	1167	15 (1.3)	-0.20 [-1.15; 0.75]	0.84 [0.39; 1.81]	0.84 [0.40; 1.80]	0.662	
Index Event									
HF Hospitalization within 3 Months	1439	20 (1.4)	1474	25 (1.7)	-0.31 [-1.24; 0.62]	0.82 [0.45; 1.48]	0.82 [0.46; 1.47]	0.504	0.701
HF Hospitalization 3-6 Months	386	4 (1.0)	362	3 (0.8)	0.21 [-1.49; 1.91]	1.25 [0.28; 5.54]	1.25 [0.28; 5.54]	0.768	
IV diuretic for HF (without hospitalization) within 3 Months	327	2 (0.6)	315	4 (1.3)	-0.66 [-2.68; 1.08]	0.49 [0.10; 2.45]	0.49 [0.10; 2.45]	0.387	
Category: Syncope									
Age category 1									
<65	831	16 (1.9)	851	12 (1.4)	0.52 [-0.75; 1.85]	1.37 [0.65; 2.92]	1.37 [0.65; 2.87]	0.411	0.779

Analyses of Serious Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥65	1321	23 (1.7)	1300	19 (1.5)	0.28 [-0.71; 1.29]	1.19 [0.65; 2.20]	1.19 [0.65; 2.18]	0.569	
Age category 2									
<75	1519	28 (1.8)	1533	21 (1.4)	0.47 [-0.43; 1.41]	1.35 [0.76; 2.39]	1.35 [0.77; 2.36]	0.300	0.665
≥75	633	11 (1.7)	618	10 (1.6)	0.12 [-1.42; 1.66]	1.08 [0.45; 2.55]	1.07 [0.46; 2.51]	0.869	
Gender									
Male	1656	35 (2.1)	1652	24 (1.5)	0.66 [-0.25; 1.61]	1.46 [0.87; 2.47]	1.45 [0.87; 2.43]	0.154	0.160
Female	496	4 (0.8)	499	7 (1.4)	-0.60 [-2.16; 0.83]	0.58 [0.18; 1.90]	0.58 [0.18; 1.90]	0.369	
Geographic Region									
Asia Pacific	510	11 (2.2)	502	6 (1.2)	0.96 [-0.69; 2.77]	1.82 [0.67; 4.97]	1.80 [0.67; 4.84]	0.241	0.519
Eastern Europe	721	11 (1.5)	718	8 (1.1)	0.41 [-0.84; 1.73]	1.37 [0.55; 3.44]	1.37 [0.55; 3.38]	0.496	
Latin and South America	316	1 (0.3)	324	3 (0.9)	-0.61 [-2.41; 0.93]	0.38 [0.05; 2.68]	0.38 [0.05; 2.68]	0.328	
North America	240	4 (1.7)	241	6 (2.5)	-0.82 [-3.87; 2.03]	0.66 [0.18; 2.38]	0.67 [0.19; 2.34]	0.530	
Western Europe	365	12 (3.3)	366	8 (2.2)	1.10 [-1.37; 3.73]	1.52 [0.61; 3.77]	1.50 [0.62; 3.64]	0.365	

Analyses of Serious Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
NYHA Group at Baseline									
Class I or II	1236	23 (1.9)	1267	13 (1.0)	0.83 [-0.10; 1.85]	1.83 [0.92; 3.63]	1.81 [0.92; 3.56]	0.084	0.121
Class III or IV	914	16 (1.8)	884	18 (2.0)	-0.29 [-1.63; 1.02]	0.86 [0.43; 1.69]	0.86 [0.44; 1.68]	0.657	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	7 (2.1)	330	7 (2.1)	0.01 [-2.45; 2.47]	1.00 [0.35; 2.89]	1.00 [0.36; 2.83]	0.995	0.635
No	1823	32 (1.8)	1820	24 (1.3)	0.44 [-0.37; 1.27]	1.34 [0.78; 2.28]	1.33 [0.79; 2.25]	0.286	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	9 (1.8)	507	11 (2.2)	-0.33 [-2.23; 1.55]	0.85 [0.35; 2.06]	0.85 [0.35; 2.03]	0.712	0.209
Q2 (1556 - 2816)	520	10 (1.9)	493	3 (0.6)	1.31 [-0.09; 2.97]	2.82 [0.94; 8.42]	2.82 [0.94; 8.42]	0.063	
Q3 (2816 - 5314)	511	10 (2.0)	518	6 (1.2)	0.80 [-0.79; 2.54]	1.70 [0.61; 4.72]	1.69 [0.62; 4.61]	0.306	
Q4 (>5314)	548	9 (1.6)	523	11 (2.1)	-0.46 [-2.27; 1.25]	0.78 [0.32; 1.89]	0.78 [0.33; 1.87]	0.579	
Baseline Ejection Fraction Group 2									
<35	1719	33 (1.9)	1734	28 (1.6)	0.30 [-0.59; 1.22]	1.19 [0.72; 1.98]	1.19 [0.72; 1.96]	0.497	0.513
≥35	433	6 (1.4)	417	3 (0.7)	0.67 [-0.87; 2.36]	1.89 [0.51; 7.02]	1.89 [0.51; 7.02]	0.343	

Analyses of Serious Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Race group									
White	1344	30 (2.2)	1353	22 (1.6)	0.61 [-0.45; 1.70]	1.38 [0.79; 2.41]	1.37 [0.80; 2.37]	0.254	0.155
Asian	500	9 (1.8)	474	3 (0.6)	1.17 [-0.26; 2.83]	2.61 [0.83; 8.14]	2.61 [0.83; 8.14]	0.099	
Black	111	0 (0.0)	118	2 (1.7)	-1.69 [-5.98; 1.69]	0.14 [0.01; 2.29]	0.14 [0.01; 2.29]	0.169	
Other	196	0 (0.0)	206	4 (1.9)	-1.94 [-4.89; 0.00]	0.14 [0.02; 1.00]	0.14 [0.02; 1.00]	0.050	
CCSA class at Randomization									
No Angina	1843	35 (1.9)	1850	27 (1.5)	0.44 [-0.40; 1.30]	1.31 [0.79; 2.17]	1.30 [0.79; 2.14]	0.300	0.689
Angina Class 1 or 2	265	4 (1.5)	260	3 (1.2)	0.36 [-2.01; 2.81]	1.31 [0.29; 5.92]	1.31 [0.30; 5.79]	0.723	
Angina Class 3 or 4	44	0 (0.0)	41	1 (2.4)	-2.44 [-12.69; 5.78]	0.13 [0.00; 6.35]	0.13 [0.00; 6.35]	0.300	
Medical History of Diabetes Mellitus									
Yes	1047	17 (1.6)	984	13 (1.3)	0.30 [-0.80; 1.41]	1.23 [0.60; 2.55]	1.23 [0.60; 2.52]	0.573	0.918
No	1105	22 (2.0)	1167	18 (1.5)	0.45 [-0.66; 1.61]	1.30 [0.69; 2.43]	1.29 [0.70; 2.39]	0.418	
Index Event									
HF Hospitalization within 3 Months	1439	27 (1.9)	1474	21 (1.4)	0.45 [-0.49; 1.43]	1.32 [0.74; 2.35]	1.32 [0.75; 2.32]	0.340	0.962

Analyses of Serious Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Serious Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
HF Hospitalization 3-6 Months	386	5 (1.3)	362	4 (1.1)	0.19 [-1.66; 2.03]	1.17 [0.31; 4.41]	1.17 [0.32; 4.33]	0.812	
IV diuretic for HF (without hospitalization) within 3 Months	327	7 (2.1)	315	6 (1.9)	0.24 [-2.21; 2.69]	1.13 [0.37; 3.39]	1.12 [0.38; 3.31]	0.832	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; ECI: Events of Clinical Interest; n.a.: Not Applicable (when estimation not possible).

1.9.3 ECI by severity by Category

Table 76
Overview of Subgroup Analyses for Mild Adverse Event of Clinical Interest Related Endpoints
Treatment by Subgroup Interaction
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**						
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 0 / >30 to ≤ 60 / >60)**	**NYHA Group at Baseline (Class I or II / Class III or IV)**	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**
Mild Adverse Events of Clinical Interest by ECI Category							
Hepatic ECI	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Symptomatic Hypotension	0.212	0.812	0.833	0.980	0.560	0.651	0.654
Syncope	0.222	0.382	0.758	0.537	0.339	0.615	0.381

Overview of Subgroup Analyses for Mild Adverse Event of Clinical Interest Related Endpoints
Treatment by Subgroup Interaction
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**					
	NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**
Mild Adverse Events of Clinical Interest by ECI Category						
Hepatic ECI	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Symptomatic Hypotension	0.423	0.756	0.736	0.463	0.197	0.393
Syncope	0.100	0.242	0.688	0.978	0.211	0.709

a: Database Cutoff Date: 18JUN2019

b: Based on a Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if Participant has 0 event in at least one cell of the stratum.

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; ECI: Adverse Events of Clinical Interest; eGFR: Estimated glomerular filtration rate; HF: Heart failure; n.c.: not calculated. At least 10 subjects per subgroup and at least 10 events in one of the subgroups necessary; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

Table 77
Overview of Subgroup Analyses for Moderate Adverse Event of Clinical Interest Related Endpoints
Treatment by Subgroup Interaction
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**						
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 0 / >30 to ≤ 60 / >60)**	**NYHA Group at Baseline (Class I or II / Class III or IV)**	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**
Moderate Adverse Events of Clinical Interest by ECI Category							
Hepatic ECI	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Symptomatic Hypotension	**0.005[c]**	0.397	0.752	0.800	0.884	0.886	0.637
Syncope	0.823	0.597	0.149	0.384	> 0.999	0.506	0.860

Overview of Subgroup Analyses for Moderate Adverse Event of Clinical Interest Related Endpoints
Treatment by Subgroup Interaction
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**					
	NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**
Moderate Adverse Events of Clinical Interest by ECI Category						
Hepatic ECI	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Symptomatic Hypotension	0.527	0.892	0.702	0.558	**0.046[c]**	0.383
Syncope	0.481	0.458	0.984	0.532	0.806	0.996

a: Database Cutoff Date: 18JUN2019

b: Based on a Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if Participant has 0 event in at least one cell of the stratum.

c: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; ECI: Adverse Events of Clinical Interest; eGFR: Estimated glomerular filtration rate; HF: Heart failure; n.c.: not calculated. At least 10 subjects per subgroup and at least 10 events in one of the subgroups necessary; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

Table 78
Overview of Subgroup Analyses for Severe Adverse Event of Clinical Interest Related Endpoints
Treatment by Subgroup Interaction
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**						
	Age category 1 (<65 / ≥65)	**Age category 2 (<75 / ≥75)**	**Gender (Male / Female)**	**Geographic Region (Asia Pacific / Eastern Europe / Latin and South America / North America / Western Europe)**	**eGFR (mL/min/ 1.73 m^2) Category (≤ 0 / >30 to ≤ 60 / >60)**	**NYHA Group at Baseline (Class I or II / Class III or IV)**	**Use of Sacubitril /Valsartan at Baseline (Yes / No)**
Severe Adverse Events of Clinical Interest by ECI Category							
Hepatic ECI	0.247	0.825	0.423	n.c.	0.060	**0.037[c]**	0.311
Symptomatic Hypotension	0.753	0.866	0.412	0.402	0.171	0.489	0.339
Syncope	0.965	0.909	0.354	0.515	**0.048[c]**	0.477	0.245

Overview of Subgroup Analyses for Severe Adverse Event of Clinical Interest Related Endpoints
Treatment by Subgroup Interaction
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001[a]	**P-Values of Treatment by Subgroup Interaction Tests[b]**					
	NT-pro BNP (pg/mL) Baseline Grp: Central Lab (Q1 (≤ 1556) / Q2 (1556 - 2816) / Q3 (2816 - 5314) / Q4 (>5314))	**Baseline Ejection Fraction Group 2 (<35% / ≥35%)**	**Race group (White / Asian / Black / Other)**	**CCSA class at Randomization (No Angina / Angina Class 1 or 2 / Angina Class 3 or 4)**	**Medical History of Diabetes Mellitus (Yes / No)**	**Index Event (HF Hospitalization 3-6 Months / HF Hospitalization within 3 Months / IV diuretic for HF (without hospitalization) within 3 Months)**
Severe Adverse Events of Clinical Interest by ECI Category						
Hepatic ECI	n.c.	0.818	0.524	0.667	0.765	0.972
Symptomatic Hypotension	0.106	0.803	0.078	0.995	0.713	0.314
Syncope	0.357	0.673	0.410	0.496	0.076	0.872

a: Database Cutoff Date: 18JUN2019

b: Based on a Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if Participant has 0 event in at least one cell of the stratum.

c: p-value of interaction smaller than 0.05

CCSA: Canadian Cardiovascular Society Functional Classification of Angina; ECI: Adverse Events of Clinical Interest; eGFR: Estimated glomerular filtration rate; HF: Heart failure; n.c.: not calculated. At least 10 subjects per subgroup and at least 10 events in one of the subgroups necessary; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; Q1: First quartile; Q2: Second quartile; Q3: Third quartile; Q4: Fourth quartile

1.9.3.1 Results for Subgroups with Interaction Nominal P-value < 0.05

Table 79
Analyses of Moderate Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test < 0.05
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	Vericiguat		Placebo		Vericiguat vs. Placebo				p-Value for Interaction Test[g]
Moderate Adverse Events of Clinical Interest	N[b]	Participants with Event n (%)	N[b]	Participants with Event n (%)	Risk Difference [95 %-CI][c]	Odds Ratio [95 %-CI][d]	Relative Risk [95 %-CI][e]	p-Value[e,f]	
Category: Symptomatic Hypotension									
Age category 1									
<65	831	36 (4.3)	851	22 (2.6)	1.75 [0.00; 3.59]	1.71 [1.00; 2.93]	1.68 [0.99; 2.82]	0.052	0.005
≥65	1321	46 (3.5)	1300	67 (5.2)	-1.67 [-3.27; -0.12]	0.66 [0.45; 0.97]	0.68 [0.47; 0.98]	0.036	
Medical History of Diabetes Mellitus									
Yes	1047	43 (4.1)	984	31 (3.2)	0.96 [-0.69; 2.62]	1.32 [0.82; 2.11]	1.30 [0.83; 2.05]	0.252	0.046
No	1105	39 (3.5)	1167	58 (5.0)	-1.44 [-3.14; 0.23]	0.70 [0.46; 1.06]	0.71 [0.48; 1.06]	0.091	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; ECI: Events of Clinical Interest; n.a.: Not Applicable (when estimation not possible).

Table 80
Analyses of Severe Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test < 0.05
by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Category: Hepatic ECI									
NYHA Group at Baseline									
Class I or II	1236	5 (0.4)	1267	5 (0.4)	0.01 [-0.56; 0.59]	1.03 [0.30; 3.55]	1.03 [0.30; 3.55]	0.969	0.037
Class III or IV	914	10 (1.1)	884	1 (0.1)	0.98 [0.33; 1.90]	5.01 [1.53; 16.41]	5.01 [1.53; 16.41]	0.008	
Category: Syncope									
eGFR (mL/min/1.73 m^2) Category									
≤30	213	0 (0.0)	202	4 (2.0)	-1.98 [-4.99; -0.19]	0.13 [0.02; 0.90]	0.13 [0.02; 0.90]	0.039	0.048
>30 to ≤60	882	26 (2.9)	895	11 (1.2)	1.72 [0.41; 3.18]	2.44 [1.20; 4.97]	2.40 [1.19; 4.82]	0.014	
>60	1021	15 (1.5)	1022	15 (1.5)	0.00 [-1.10; 1.11]	1.00 [0.49; 2.06]	1.00 [0.49; 2.04]	0.998	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; ECI: Events of Clinical Interest; n.a.: Not Applicable (when estimation not possible).

1.9.3.2 Results for Subgroups with Interaction Nominal P-value ≥ 0.05

Table 81
Analyses of Mild Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Category: Hepatic ECI									
Age category 1									
<65	831	1 (0.1)	851	2 (0.2)	n.a.	n.a.	n.a.	n.a.	n.a.
≥65	1321	1 (0.1)	1300	1 (0.1)	n.a.	n.a.	n.a.	n.a.	
Age category 2									
<75	1519	1 (0.1)	1533	3 (0.2)	n.a.	n.a.	n.a.	n.a.	n.a.
≥75	633	1 (0.2)	618	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Gender									
Male	1656	2 (0.1)	1652	3 (0.2)	n.a.	n.a.	n.a.	n.a.	n.a.
Female	496	0 (0.0)	499	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Geographic Region									
Asia Pacific	510	1 (0.2)	502	1 (0.2)	n.a.	n.a.	n.a.	n.a.	n.a.
Eastern Europe	721	1 (0.1)	718	1 (0.1)	n.a.	n.a.	n.a.	n.a.	
Latin and South America	316	0 (0.0)	324	1 (0.3)	n.a.	n.a.	n.a.	n.a.	

Analyses of Mild Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	0 (0.0)	241	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Western Europe	365	0 (0.0)	366	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	0 (0.0)	202	0 (0.0)	n.a.	n.a.	n.a.	n.a.	n.a.
>30 to ≤60	882	1 (0.1)	895	1 (0.1)	n.a.	n.a.	n.a.	n.a.	
>60	1021	1 (0.1)	1022	2 (0.2)	n.a.	n.a.	n.a.	n.a.	
NYHA Group at Baseline									
Class I or II	1236	1 (0.1)	1267	3 (0.2)	n.a.	n.a.	n.a.	n.a.	n.a.
Class III or IV	914	1 (0.1)	884	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	0 (0.0)	330	0 (0.0)	n.a.	n.a.	n.a.	n.a.	n.a.
No	1823	2 (0.1)	1820	3 (0.2)	n.a.	n.a.	n.a.	n.a.	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	0 (0.0)	507	2 (0.4)	n.a.	n.a.	n.a.	n.a.	n.a.

Analyses of Mild Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q2 (1556 - 2816)	520	1 (0.2)	493	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Q3 (2816 - 5314)	511	0 (0.0)	518	1 (0.2)	n.a.	n.a.	n.a.	n.a.	
Q4 (>5314)	548	1 (0.2)	523	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Baseline Ejection Fraction Group 2									
<35	1719	2 (0.1)	1734	3 (0.2)	n.a.	n.a.	n.a.	n.a.	n.a.
≥35	433	0 (0.0)	417	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Race group									
White	1344	1 (0.1)	1353	2 (0.1)	n.a.	n.a.	n.a.	n.a.	n.a.
Asian	500	1 (0.2)	474	1 (0.2)	n.a.	n.a.	n.a.	n.a.	
Black	111	0 (0.0)	118	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Other	196	0 (0.0)	206	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
CCSA class at Randomization									
No Angina	1843	1 (0.1)	1850	3 (0.2)	n.a.	n.a.	n.a.	n.a.	n.a.

Analyses of Mild Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Angina Class 1 or 2	265	1 (0.4)	260	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Medical History of Diabetes Mellitus									
Yes	1047	0 (0.0)	984	1 (0.1)	n.a.	n.a.	n.a.	n.a.	n.a.
No	1105	2 (0.2)	1167	2 (0.2)	n.a.	n.a.	n.a.	n.a.	
Index Event									
HF Hospitalization within 3 Months	1439	1 (0.1)	1474	2 (0.1)	n.a.	n.a.	n.a.	n.a.	n.a.
HF Hospitalization 3-6 Months	386	1 (0.3)	362	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
IV diuretic for HF (without hospitalization) within 3 Months	327	0 (0.0)	315	1 (0.3)	n.a.	n.a.	n.a.	n.a.	
Category: Symptomatic Hypotension									
Age category 1									
<65	831	38 (4.6)	851	19 (2.2)	2.34 [0.63; 4.18]	2.10 [1.20; 3.67]	2.05 [1.19; 3.52]	0.010	0.212
≥65	1321	63 (4.8)	1300	46 (3.5)	1.23 [-0.30; 2.79]	1.37 [0.93; 2.01]	1.35 [0.93; 1.96]	0.116	
Age category 2									
<75	1519	74 (4.9)	1533	47 (3.1)	1.81 [0.43; 3.23]	1.62 [1.12; 2.35]	1.59 [1.11; 2.27]	0.011	0.812

Analyses of Mild Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥75	633	27 (4.3)	618	18 (2.9)	1.35 [-0.74; 3.52]	1.49 [0.81; 2.73]	1.46 [0.82; 2.63]	0.202	
Gender									
Male	1656	78 (4.7)	1652	51 (3.1)	1.62 [0.31; 2.98]	1.55 [1.08; 2.22]	1.53 [1.08; 2.16]	0.017	0.833
Female	496	23 (4.6)	499	14 (2.8)	1.83 [-0.55; 4.35]	1.68 [0.86; 3.31]	1.65 [0.86; 3.17]	0.131	
Geographic Region									
Asia Pacific	510	29 (5.7)	502	18 (3.6)	2.10 [-0.51; 4.82]	1.62 [0.89; 2.96]	1.59 [0.89; 2.82]	0.116	0.980
Eastern Europe	721	25 (3.5)	718	17 (2.4)	1.10 [-0.67; 2.94]	1.48 [0.79; 2.77]	1.46 [0.80; 2.69]	0.218	
Latin and South America	316	7 (2.2)	324	6 (1.9)	0.36 [-2.05; 2.88]	1.20 [0.40; 3.61]	1.20 [0.41; 3.52]	0.745	
North America	240	16 (6.7)	241	9 (3.7)	2.93 [-1.11; 7.26]	1.84 [0.80; 4.25]	1.79 [0.80; 3.96]	0.154	
Western Europe	365	24 (6.6)	366	15 (4.1)	2.48 [-0.82; 5.93]	1.65 [0.85; 3.19]	1.60 [0.86; 3.01]	0.140	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	8 (3.8)	202	7 (3.5)	0.29 [-3.69; 4.23]	1.09 [0.39; 3.05]	1.08 [0.40; 2.93]	0.874	0.560
>30 to ≤60	882	48 (5.4)	895	33 (3.7)	1.76 [-0.19; 3.77]	1.50 [0.96; 2.37]	1.48 [0.96; 2.28]	0.078	

Analyses of Mild Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
>60	1021	42 (4.1)	1022	22 (2.2)	1.96 [0.46; 3.55]	1.95 [1.16; 3.29]	1.91 [1.15; 3.18]	0.013	
NYHA Group at Baseline									
Class I or II	1236	59 (4.8)	1267	37 (2.9)	1.85 [0.35; 3.42]	1.67 [1.10; 2.53]	1.63 [1.09; 2.45]	0.017	0.651
Class III or IV	914	41 (4.5)	884	28 (3.2)	1.32 [-0.47; 3.15]	1.44 [0.88; 2.34]	1.42 [0.88; 2.27]	0.148	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	26 (7.9)	330	15 (4.5)	3.36 [-0.35; 7.26]	1.80 [0.94; 3.47]	1.74 [0.94; 3.22]	0.079	0.654
No	1823	75 (4.1)	1820	50 (2.7)	1.37 [0.19; 2.58]	1.52 [1.06; 2.19]	1.50 [1.05; 2.13]	0.025	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	19 (3.9)	507	15 (3.0)	0.93 [-1.39; 3.34]	1.33 [0.67; 2.64]	1.31 [0.68; 2.55]	0.422	0.423
Q2 (1556 - 2816)	520	32 (6.2)	493	18 (3.7)	2.50 [-0.17; 5.28]	1.73 [0.96; 3.13]	1.69 [0.96; 2.96]	0.070	
Q3 (2816 - 5314)	511	26 (5.1)	518	11 (2.1)	2.96 [0.72; 5.44]	2.47 [1.21; 5.06]	2.40 [1.20; 4.80]	0.014	
Q4 (>5314)	548	19 (3.5)	523	16 (3.1)	0.41 [-1.82; 2.64]	1.14 [0.58; 2.24]	1.13 [0.59; 2.18]	0.708	
Baseline Ejection Fraction Group 2									
<35	1719	82 (4.8)	1734	52 (3.0)	1.77 [0.49; 3.10]	1.62 [1.14; 2.31]	1.59 [1.13; 2.24]	0.008	0.756

Analyses of Mild Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥35	433	19 (4.4)	417	13 (3.1)	1.27 [-1.37; 3.99]	1.43 [0.70; 2.93]	1.41 [0.70; 2.81]	0.333	
Race group									
White	1344	65 (4.8)	1353	44 (3.3)	1.58 [0.10; 3.11]	1.51 [1.02; 2.23]	1.49 [1.02; 2.16]	0.038	0.736
Asian	500	23 (4.6)	474	11 (2.3)	2.28 [-0.03; 4.74]	2.03 [0.98; 4.21]	1.98 [0.98; 4.02]	0.058	
Black	111	4 (3.6)	118	2 (1.7)	1.91 [-2.83; 7.43]	2.17 [0.39; 12.08]	2.13 [0.40; 11.38]	0.378	
Other	196	8 (4.1)	206	8 (3.9)	0.20 [-3.93; 4.44]	1.05 [0.39; 2.86]	1.05 [0.40; 2.75]	0.919	
CCSA class at Randomization									
No Angina	1843	93 (5.0)	1850	57 (3.1)	1.97 [0.70; 3.27]	1.67 [1.19; 2.34]	1.64 [1.19; 2.26]	0.003	0.463
Angina Class 1 or 2	265	8 (3.0)	260	7 (2.7)	0.33 [-2.81; 3.49]	1.13 [0.40; 3.15]	1.12 [0.41; 3.05]	0.822	
Angina Class 3 or 4	44	0 (0.0)	41	1 (2.4)	-2.44 [-12.69; 5.78]	0.13 [0.00; 6.35]	0.13 [0.00; 6.35]	0.300	
Medical History of Diabetes Mellitus									
Yes	1047	55 (5.3)	984	27 (2.7)	2.51 [0.82; 4.27]	1.97 [1.23; 3.14]	1.91 [1.22; 3.01]	0.005	0.197
No	1105	46 (4.2)	1167	38 (3.3)	0.91 [-0.66; 2.52]	1.29 [0.83; 2.00]	1.28 [0.84; 1.95]	0.254	

Analyses of Mild Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Index Event									
HF Hospitalization within 3 Months	1439	66 (4.6)	1474	42 (2.8)	1.74 [0.37; 3.16]	1.64 [1.11; 2.43]	1.61 [1.10; 2.35]	0.014	0.393
HF Hospitalization 3-6 Months	386	17 (4.4)	362	15 (4.1)	0.26 [-2.80; 3.28]	1.07 [0.52; 2.17]	1.06 [0.54; 2.10]	0.860	
IV diuretic for HF (without hospitalization) within 3 Months	327	18 (5.5)	315	8 (2.5)	2.96 [-0.09; 6.29]	2.24 [0.96; 5.22]	2.17 [0.96; 4.91]	0.064	
Category: Syncope									
Age category 1									
<65	831	10 (1.2)	851	5 (0.6)	0.62 [-0.32; 1.68]	2.01 [0.73; 5.54]	2.01 [0.73; 5.54]	0.179	0.222
≥65	1321	12 (0.9)	1300	13 (1.0)	-0.09 [-0.90; 0.70]	0.91 [0.41; 2.00]	0.91 [0.41; 2.00]	0.809	
Age category 2									
<75	1519	15 (1.0)	1533	10 (0.7)	0.34 [-0.33; 1.04]	1.51 [0.69; 3.32]	1.51 [0.69; 3.32]	0.304	0.382
≥75	633	7 (1.1)	618	8 (1.3)	-0.19 [-1.56; 1.13]	0.85 [0.31; 2.37]	0.85 [0.31; 2.34]	0.759	
Gender									
Male	1656	18 (1.1)	1652	14 (0.8)	0.24 [-0.45; 0.96]	1.28 [0.64; 2.58]	1.28 [0.64; 2.58]	0.482	0.758
Female	496	4 (0.8)	499	4 (0.8)	0.00 [-1.33; 1.35]	1.01 [0.25; 4.04]	1.01 [0.25; 4.04]	0.993	
Geographic Region									
Asia Pacific	510	6 (1.2)	502	4 (0.8)	0.38 [-1.00; 1.84]	1.47 [0.42; 5.12]	1.47 [0.42; 5.12]	0.542	0.537

Analyses of Mild Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Eastern Europe	721	4 (0.6)	718	3 (0.4)	0.14 [-0.73; 1.05]	1.33 [0.30; 5.86]	1.33 [0.30; 5.86]	0.709	
Latin and South America	316	2 (0.6)	324	4 (1.2)	-0.60 [-2.57; 1.18]	0.52 [0.11; 2.61]	0.52 [0.11; 2.61]	0.430	
North America	240	4 (1.7)	241	0 (0.0)	1.67 [0.08; 4.21]	7.51 [1.05; 53.67]	7.51 [1.05; 53.67]	0.044	
Western Europe	365	6 (1.6)	366	7 (1.9)	-0.27 [-2.45; 1.86]	0.86 [0.29; 2.58]	0.86 [0.29; 2.53]	0.784	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	6 (2.8)	202	3 (1.5)	1.33 [-1.80; 4.72]	1.92 [0.47; 7.79]	1.90 [0.48; 7.48]	0.361	0.339
>30 to ≤60	882	7 (0.8)	895	10 (1.1)	-0.32 [-1.34; 0.65]	0.71 [0.27; 1.85]	0.71 [0.27; 1.85]	0.484	
>60	1021	9 (0.9)	1022	5 (0.5)	0.39 [-0.37; 1.23]	1.78 [0.62; 5.09]	1.78 [0.62; 5.09]	0.283	
NYHA Group at Baseline									
Class I or II	1236	16 (1.3)	1267	12 (0.9)	0.35 [-0.51; 1.25]	1.37 [0.65; 2.88]	1.37 [0.65; 2.88]	0.409	0.615
Class III or IV	914	6 (0.7)	884	6 (0.7)	-0.02 [-0.89; 0.83]	0.97 [0.31; 3.01]	0.97 [0.31; 3.01]	0.954	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	3 (0.9)	330	1 (0.3)	0.61 [-0.87; 2.38]	2.74 [0.38; 19.53]	2.74 [0.38; 19.53]	0.315	0.381

Analyses of Mild Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
No	1823	19 (1.0)	1820	17 (0.9)	0.11 [-0.56; 0.79]	1.12 [0.58; 2.15]	1.12 [0.58; 2.15]	0.741	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	2 (0.4)	507	6 (1.2)	-0.77 [-2.20; 0.43]	0.38 [0.09; 1.52]	0.38 [0.09; 1.52]	0.171	0.100
Q2 (1556 - 2816)	520	6 (1.2)	493	1 (0.2)	0.95 [-0.10; 2.32]	3.99 [0.90; 17.65]	3.99 [0.90; 17.65]	0.068	
Q3 (2816 - 5314)	511	6 (1.2)	518	7 (1.4)	-0.18 [-1.73; 1.35]	0.87 [0.29; 2.60]	0.87 [0.29; 2.57]	0.799	
Q4 (>5314)	548	7 (1.3)	523	4 (0.8)	0.51 [-0.82; 1.94]	1.65 [0.50; 5.43]	1.65 [0.50; 5.43]	0.406	
Baseline Ejection Fraction Group 2									
<35	1719	18 (1.0)	1734	12 (0.7)	0.36 [-0.28; 1.03]	1.51 [0.74; 3.10]	1.51 [0.74; 3.10]	0.261	0.242
≥35	433	4 (0.9)	417	6 (1.4)	-0.52 [-2.29; 1.09]	0.64 [0.18; 2.23]	0.64 [0.18; 2.23]	0.487	
Race group									
White	1344	15 (1.1)	1353	11 (0.8)	0.30 [-0.47; 1.11]	1.37 [0.63; 2.97]	1.37 [0.63; 2.97]	0.421	0.688
Asian	500	5 (1.0)	474	4 (0.8)	0.16 [-1.27; 1.58]	1.19 [0.32; 4.41]	1.19 [0.32; 4.41]	0.799	
Black	111	1 (0.9)	118	0 (0.0)	0.90 [-2.28; 4.94]	7.87 [0.16; 397.35]	7.87 [0.16; 397.35]	0.303	

Analyses of Mild Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Mild Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Other	196	1 (0.5)	206	3 (1.5)	-0.95 [-3.75; 1.51]	0.38 [0.05; 2.75]	0.38 [0.05; 2.75]	0.340	
CCSA class at Randomization									
No Angina	1843	19 (1.0)	1850	16 (0.9)	0.17 [-0.48; 0.83]	1.19 [0.61; 2.32]	1.19 [0.61; 2.32]	0.603	0.978
Angina Class 1 or 2	265	3 (1.1)	260	2 (0.8)	0.36 [-1.75; 2.60]	1.47 [0.25; 8.53]	1.47 [0.25; 8.53]	0.669	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	0.00 [-8.66; 8.12]	n.a.	n.a.	n.a.	
Medical History of Diabetes Mellitus									
Yes	1047	11 (1.1)	984	12 (1.2)	-0.17 [-1.18; 0.80]	0.86 [0.38; 1.96]	0.86 [0.38; 1.94]	0.719	0.211
No	1105	11 (1.0)	1167	6 (0.5)	0.48 [-0.25; 1.32]	1.91 [0.74; 4.96]	1.91 [0.74; 4.96]	0.183	
Index Event									
HF Hospitalization within 3 Months	1439	15 (1.0)	1474	12 (0.8)	0.23 [-0.50; 0.99]	1.28 [0.60; 2.74]	1.28 [0.60; 2.74]	0.520	0.709
HF Hospitalization 3-6 Months	386	6 (1.6)	362	4 (1.1)	0.45 [-1.44; 2.39]	1.41 [0.40; 5.05]	1.41 [0.40; 4.94]	0.595	
IV diuretic for HF (without hospitalization) within 3 Months	327	1 (0.3)	315	2 (0.6)	-0.33 [-2.01; 1.13]	0.49 [0.05; 4.76]	0.49 [0.05; 4.76]	0.541	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤

1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; ECI: Events of Clinical Interest; n.a.: Not Applicable (when estimation not possible).

Table 82
Analyses of Moderate Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Category: Hepatic ECI									
Age category 1									
<65	831	3 (0.4)	851	2 (0.2)	n.a.	n.a.	n.a.	n.a.	n.a.
≥65	1321	3 (0.2)	1300	1 (0.1)	n.a.	n.a.	n.a.	n.a.	
Age category 2									
<75	1519	6 (0.4)	1533	2 (0.1)	n.a.	n.a.	n.a.	n.a.	n.a.
≥75	633	0 (0.0)	618	1 (0.2)	n.a.	n.a.	n.a.	n.a.	
Gender									
Male	1656	6 (0.4)	1652	3 (0.2)	n.a.	n.a.	n.a.	n.a.	n.a.
Female	496	0 (0.0)	499	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Geographic Region									
Asia Pacific	510	3 (0.6)	502	1 (0.2)	n.a.	n.a.	n.a.	n.a.	n.a.
Eastern Europe	721	2 (0.3)	718	2 (0.3)	n.a.	n.a.	n.a.	n.a.	
Latin and South America	316	1 (0.3)	324	0 (0.0)	n.a.	n.a.	n.a.	n.a.	

Analyses of Moderate Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	0 (0.0)	241	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Western Europe	365	0 (0.0)	366	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	0 (0.0)	202	0 (0.0)	n.a.	n.a.	n.a.	n.a.	n.a.
>30 to ≤60	882	2 (0.2)	895	2 (0.2)	n.a.	n.a.	n.a.	n.a.	
>60	1021	4 (0.4)	1022	1 (0.1)	n.a.	n.a.	n.a.	n.a.	
NYHA Group at Baseline									
Class I or II	1236	4 (0.3)	1267	2 (0.2)	n.a.	n.a.	n.a.	n.a.	n.a.
Class III or IV	914	2 (0.2)	884	1 (0.1)	n.a.	n.a.	n.a.	n.a.	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	0 (0.0)	330	0 (0.0)	n.a.	n.a.	n.a.	n.a.	n.a.
No	1823	6 (0.3)	1820	3 (0.2)	n.a.	n.a.	n.a.	n.a.	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	0 (0.0)	507	0 (0.0)	n.a.	n.a.	n.a.	n.a.	n.a.

Analyses of Moderate Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q2 (1556 - 2816)	520	3 (0.6)	493	2 (0.4)	n.a.	n.a.	n.a.	n.a.	
Q3 (2816 - 5314)	511	2 (0.4)	518	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Q4 (>5314)	548	1 (0.2)	523	1 (0.2)	n.a.	n.a.	n.a.	n.a.	
Baseline Ejection Fraction Group 2									
<35	1719	6 (0.3)	1734	2 (0.1)	n.a.	n.a.	n.a.	n.a.	n.a.
≥35	433	0 (0.0)	417	1 (0.2)	n.a.	n.a.	n.a.	n.a.	
Race group									
White	1344	3 (0.2)	1353	2 (0.1)	n.a.	n.a.	n.a.	n.a.	n.a.
Asian	500	3 (0.6)	474	1 (0.2)	n.a.	n.a.	n.a.	n.a.	
Black	111	0 (0.0)	118	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Other	196	0 (0.0)	206	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
CCSA class at Randomization									
No Angina	1843	5 (0.3)	1850	2 (0.1)	n.a.	n.a.	n.a.	n.a.	n.a.

Analyses of Moderate Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
Angina Class 1 or 2	265	1 (0.4)	260	1 (0.4)	n.a.	n.a.	n.a.	n.a.	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Medical History of Diabetes Mellitus									
Yes	1047	4 (0.4)	984	2 (0.2)	n.a.	n.a.	n.a.	n.a.	n.a.
No	1105	2 (0.2)	1167	1 (0.1)	n.a.	n.a.	n.a.	n.a.	
Index Event									
HF Hospitalization within 3 Months	1439	2 (0.1)	1474	1 (0.1)	n.a.	n.a.	n.a.	n.a.	n.a.
HF Hospitalization 3-6 Months	386	2 (0.5)	362	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
IV diuretic for HF (without hospitalization) within 3 Months	327	2 (0.6)	315	2 (0.6)	n.a.	n.a.	n.a.	n.a.	
Category: Symptomatic Hypotension									
Age category 2									
<75	1519	55 (3.6)	1533	55 (3.6)	0.03 [-1.31; 1.38]	1.01 [0.69; 1.48]	1.01 [0.70; 1.46]	0.961	0.397
≥75	633	27 (4.3)	618	34 (5.5)	-1.24 [-3.72; 1.18]	0.77 [0.46; 1.28]	0.78 [0.47; 1.27]	0.312	
Gender									
Male	1656	63 (3.8)	1652	70 (4.2)	-0.43 [-1.79; 0.92]	0.89 [0.63; 1.27]	0.90 [0.64; 1.25]	0.526	0.752

Analyses of Moderate Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Female	496	19 (3.8)	499	19 (3.8)	0.02 [-2.46; 2.51]	1.01 [0.53; 1.92]	1.01 [0.54; 1.88]	0.985	
Geographic Region									
Asia Pacific	510	18 (3.5)	502	18 (3.6)	-0.06 [-2.45; 2.32]	0.98 [0.51; 1.91]	0.98 [0.52; 1.87]	0.961	0.800
Eastern Europe	721	17 (2.4)	718	24 (3.3)	-0.98 [-2.81; 0.77]	0.70 [0.37; 1.31]	0.71 [0.38; 1.30]	0.264	
Latin and South America	316	10 (3.2)	324	13 (4.0)	-0.85 [-3.96; 2.19]	0.78 [0.34; 1.81]	0.79 [0.35; 1.77]	0.566	
North America	240	16 (6.7)	241	13 (5.4)	1.27 [-3.13; 5.79]	1.25 [0.59; 2.66]	1.24 [0.61; 2.51]	0.559	
Western Europe	365	21 (5.8)	366	21 (5.7)	0.02 [-3.47; 3.51]	1.00 [0.54; 1.87]	1.00 [0.56; 1.80]	0.993	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	8 (3.8)	202	8 (4.0)	-0.20 [-4.32; 3.80]	0.95 [0.35; 2.57]	0.95 [0.36; 2.48]	0.914	0.884
>30 to ≤60	882	42 (4.8)	895	42 (4.7)	0.07 [-1.94; 2.08]	1.02 [0.66; 1.57]	1.01 [0.67; 1.54]	0.945	
>60	1021	32 (3.1)	1022	37 (3.6)	-0.49 [-2.10; 1.11]	0.86 [0.53; 1.39]	0.87 [0.54; 1.38]	0.543	
NYHA Group at Baseline									
Class I or II	1236	44 (3.6)	1267	50 (3.9)	-0.39 [-1.90; 1.13]	0.90 [0.59; 1.36]	0.90 [0.61; 1.34]	0.611	0.886

Analyses of Moderate Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Class III or IV	914	38 (4.2)	884	39 (4.4)	-0.25 [-2.18; 1.65]	0.94 [0.60; 1.48]	0.94 [0.61; 1.46]	0.790	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	16 (4.9)	330	15 (4.5)	0.32 [-3.06; 3.72]	1.07 [0.52; 2.21]	1.07 [0.54; 2.13]	0.847	0.637
No	1823	66 (3.6)	1820	74 (4.1)	-0.45 [-1.71; 0.81]	0.89 [0.63; 1.24]	0.89 [0.64; 1.23]	0.485	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	16 (3.3)	507	20 (3.9)	-0.67 [-3.10; 1.73]	0.82 [0.42; 1.61]	0.83 [0.43; 1.58]	0.570	0.527
Q2 (1556 - 2816)	520	21 (4.0)	493	26 (5.3)	-1.24 [-3.97; 1.39]	0.76 [0.42; 1.36]	0.77 [0.44; 1.34]	0.352	
Q3 (2816 - 5314)	511	21 (4.1)	518	15 (2.9)	1.21 [-1.08; 3.61]	1.44 [0.73; 2.82]	1.42 [0.74; 2.72]	0.292	
Q4 (>5314)	548	20 (3.6)	523	20 (3.8)	-0.17 [-2.56; 2.17]	0.95 [0.51; 1.79]	0.95 [0.52; 1.75]	0.880	
Baseline Ejection Fraction Group 2									
<35	1719	67 (3.9)	1734	74 (4.3)	-0.37 [-1.71; 0.96]	0.91 [0.65; 1.27]	0.91 [0.66; 1.26]	0.583	0.892
≥35	433	15 (3.5)	417	15 (3.6)	-0.13 [-2.77; 2.46]	0.96 [0.46; 1.99]	0.96 [0.48; 1.95]	0.916	
Race group									
White	1344	55 (4.1)	1353	59 (4.4)	-0.27 [-1.81; 1.27]	0.94 [0.64; 1.36]	0.94 [0.66; 1.34]	0.729	0.702

Analyses of Moderate Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Asian	500	14 (2.8)	474	12 (2.5)	0.27 [-1.89; 2.42]	1.11 [0.51; 2.42]	1.11 [0.52; 2.37]	0.795	
Black	111	3 (2.7)	118	7 (5.9)	-3.23 [-9.43; 2.48]	0.44 [0.11; 1.75]	0.46 [0.12; 1.72]	0.246	
Other	196	10 (5.1)	206	11 (5.3)	-0.24 [-4.86; 4.44]	0.95 [0.40; 2.30]	0.96 [0.42; 2.20]	0.915	
CCSA class at Randomization									
No Angina	1843	72 (3.9)	1850	81 (4.4)	-0.47 [-1.77; 0.82]	0.89 [0.64; 1.23]	0.89 [0.65; 1.22]	0.472	0.558
Angina Class 1 or 2	265	8 (3.0)	260	8 (3.1)	-0.06 [-3.31; 3.16]	0.98 [0.36; 2.65]	0.98 [0.37; 2.58]	0.969	
Angina Class 3 or 4	44	2 (4.5)	41	0 (0.0)	4.55 [-4.31; 15.22]	7.06 [0.43; 115.04]	7.06 [0.43; 115.04]	0.170	
Index Event									
HF Hospitalization within 3 Months	1439	59 (4.1)	1474	57 (3.9)	0.23 [-1.20; 1.68]	1.06 [0.73; 1.54]	1.06 [0.74; 1.51]	0.748	0.383
HF Hospitalization 3-6 Months	386	14 (3.6)	362	20 (5.5)	-1.90 [-5.13; 1.13]	0.64 [0.32; 1.29]	0.66 [0.34; 1.28]	0.217	
IV diuretic for HF (without hospitalization) within 3 Months	327	9 (2.8)	315	12 (3.8)	-1.06 [-4.11; 1.82]	0.71 [0.30; 1.72]	0.72 [0.31; 1.69]	0.454	
Category: Syncope									
Age category 1									
<65	831	12 (1.4)	851	14 (1.6)	-0.20 [-1.46; 1.05]	0.88 [0.40; 1.91]	0.88 [0.41; 1.89]	0.738	0.823

Analyses of Moderate Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
≥65	1321	18 (1.4)	1300	18 (1.4)	-0.02 [-0.96; 0.91]	0.98 [0.51; 1.90]	0.98 [0.51; 1.88]	0.961	
Age category 2									
<75	1519	24 (1.6)	1533	24 (1.6)	0.01 [-0.90; 0.93]	1.01 [0.57; 1.79]	1.01 [0.58; 1.77]	0.974	0.597
≥75	633	6 (0.9)	618	8 (1.3)	-0.35 [-1.70; 0.92]	0.73 [0.26; 2.10]	0.73 [0.26; 2.10]	0.560	
Gender									
Male	1656	28 (1.7)	1652	26 (1.6)	0.12 [-0.77; 1.01]	1.08 [0.63; 1.84]	1.07 [0.63; 1.82]	0.791	0.149
Female	496	2 (0.4)	499	6 (1.2)	-0.80 [-2.24; 0.39]	0.37 [0.09; 1.48]	0.37 [0.09; 1.48]	0.158	
Geographic Region									
Asia Pacific	510	3 (0.6)	502	5 (1.0)	-0.41 [-1.79; 0.84]	0.59 [0.15; 2.39]	0.59 [0.15; 2.39]	0.464	0.384
Eastern Europe	721	10 (1.4)	718	7 (1.0)	0.41 [-0.78; 1.67]	1.42 [0.55; 3.70]	1.42 [0.55; 3.70]	0.470	
Latin and South America	316	2 (0.6)	324	4 (1.2)	-0.60 [-2.57; 1.18]	0.52 [0.11; 2.61]	0.52 [0.11; 2.61]	0.430	
North America	240	2 (0.8)	241	6 (2.5)	-1.66 [-4.60; 0.79]	0.36 [0.09; 1.47]	0.36 [0.09; 1.47]	0.156	
Western Europe	365	13 (3.6)	366	10 (2.7)	0.83 [-1.83; 3.59]	1.31 [0.57; 3.04]	1.30 [0.58; 2.93]	0.522	

Analyses of Moderate Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
eGFR (mL/min/1.73 m^2) Category									
≤30	213	2 (0.9)	202	2 (1.0)	-0.05 [-2.70; 2.48]	0.95 [0.13; 6.78]	0.95 [0.13; 6.78]	0.958	1.000
>30 to ≤60	882	12 (1.4)	895	13 (1.5)	-0.09 [-1.27; 1.08]	0.94 [0.42; 2.06]	0.94 [0.43; 2.04]	0.869	
>60	1021	15 (1.5)	1022	16 (1.6)	-0.10 [-1.22; 1.02]	0.94 [0.46; 1.91]	0.94 [0.47; 1.89]	0.859	
NYHA Group at Baseline									
Class I or II	1236	18 (1.5)	1267	17 (1.3)	0.11 [-0.84; 1.09]	1.09 [0.56; 2.12]	1.09 [0.56; 2.10]	0.807	0.506
Class III or IV	914	12 (1.3)	884	15 (1.7)	-0.38 [-1.61; 0.79]	0.77 [0.36; 1.66]	0.77 [0.36; 1.64]	0.505	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	6 (1.8)	330	7 (2.1)	-0.30 [-2.72; 2.06]	0.86 [0.28; 2.58]	0.86 [0.29; 2.53]	0.784	0.860
No	1823	24 (1.3)	1820	25 (1.4)	-0.06 [-0.83; 0.72]	0.96 [0.55; 1.68]	0.96 [0.55; 1.67]	0.881	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	9 (1.8)	507	8 (1.6)	0.26 [-1.47; 2.07]	1.17 [0.45; 3.06]	1.17 [0.45; 3.00]	0.749	0.481
Q2 (1556 - 2816)	520	8 (1.5)	493	13 (2.6)	-1.10 [-3.09; 0.71]	0.58 [0.24; 1.40]	0.58 [0.24; 1.40]	0.226	
Q3 (2816 - 5314)	511	7 (1.4)	518	4 (0.8)	0.60 [-0.77; 2.12]	1.76 [0.54; 5.77]	1.76 [0.54; 5.77]	0.352	

Analyses of Moderate Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q4 (>5314)	548	5 (0.9)	523	5 (1.0)	-0.04 [-1.41; 1.28]	0.95 [0.27; 3.31]	0.95 [0.27; 3.31]	0.941	
Baseline Ejection Fraction Group 2									
<35	1719	24 (1.4)	1734	28 (1.6)	-0.22 [-1.06; 0.62]	0.86 [0.50; 1.49]	0.86 [0.50; 1.49]	0.598	0.458
≥35	433	6 (1.4)	417	4 (1.0)	0.43 [-1.22; 2.15]	1.44 [0.41; 5.02]	1.44 [0.41; 5.02]	0.565	
Race group									
White	1344	25 (1.9)	1353	26 (1.9)	-0.06 [-1.13; 1.00]	0.97 [0.56; 1.68]	0.97 [0.56; 1.67]	0.907	0.984
Asian	500	3 (0.6)	474	4 (0.8)	-0.24 [-1.62; 1.01]	0.71 [0.16; 3.14]	0.71 [0.16; 3.14]	0.653	
Black	111	1 (0.9)	118	1 (0.8)	0.05 [-3.84; 4.17]	1.06 [0.07; 17.13]	1.06 [0.07; 17.13]	0.965	
Other	196	1 (0.5)	206	1 (0.5)	0.02 [-2.24; 2.39]	1.05 [0.07; 16.88]	1.05 [0.07; 16.88]	0.972	
CCSA class at Randomization									
No Angina	1843	25 (1.4)	1850	26 (1.4)	-0.05 [-0.83; 0.73]	0.96 [0.56; 1.68]	0.97 [0.56; 1.66]	0.899	0.532
Angina Class 1 or 2	265	5 (1.9)	260	4 (1.5)	0.35 [-2.23; 3.00]	1.23 [0.33; 4.64]	1.23 [0.33; 4.52]	0.759	
Angina Class 3 or 4	44	0 (0.0)	41	2 (4.9)	-4.88 [-16.23; 3.45]	0.12 [0.01; 2.00]	0.12 [0.01; 2.00]	0.141	

Analyses of Moderate Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				**p-Value for Interaction Test[g]**
Moderate Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	
Medical History of Diabetes Mellitus									
Yes	1047	13 (1.2)	984	12 (1.2)	0.02 [-1.01; 1.04]	1.02 [0.46; 2.24]	1.02 [0.47; 2.22]	0.964	0.806
No	1105	17 (1.5)	1167	20 (1.7)	-0.18 [-1.26; 0.92]	0.90 [0.47; 1.72]	0.90 [0.47; 1.70]	0.742	
Index Event									
HF Hospitalization within 3 Months	1439	16 (1.1)	1474	18 (1.2)	-0.11 [-0.93; 0.71]	0.91 [0.46; 1.79]	0.91 [0.47; 1.78]	0.784	0.996
HF Hospitalization 3-6 Months	386	8 (2.1)	362	8 (2.2)	-0.14 [-2.47; 2.11]	0.94 [0.35; 2.52]	0.94 [0.36; 2.47]	0.897	
IV diuretic for HF (without hospitalization) within 3 Months	327	6 (1.8)	315	6 (1.9)	-0.07 [-2.48; 2.28]	0.96 [0.31; 3.02]	0.96 [0.31; 2.96]	0.948	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; ECI: Events of Clinical Interest; n.a.: Not Applicable (when estimation not possible).

Table 83
Analyses of Severe Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Category: Hepatic ECI									
Age category 1									
<65	831	9 (1.1)	851	2 (0.2)	0.85 [0.09; 1.84]	3.69 [1.13; 12.06]	3.69 [1.13; 12.06]	0.031	0.247
≥65	1321	6 (0.5)	1300	4 (0.3)	0.15 [-0.39; 0.72]	1.47 [0.42; 5.09]	1.47 [0.42; 5.09]	0.543	
Age category 2									
<75	1519	13 (0.9)	1533	5 (0.3)	0.53 [-0.02; 1.17]	2.47 [0.98; 6.23]	2.47 [0.98; 6.23]	0.056	0.825
≥75	633	2 (0.3)	618	1 (0.2)	0.15 [-0.62; 1.00]	1.90 [0.20; 18.34]	1.90 [0.20; 18.34]	0.577	
Gender									
Male	1656	10 (0.6)	1652	5 (0.3)	0.30 [-0.18; 0.84]	1.95 [0.71; 5.37]	1.95 [0.71; 5.37]	0.197	0.423
Female	496	5 (1.0)	499	1 (0.2)	0.81 [-0.22; 2.16]	3.84 [0.77; 19.12]	3.84 [0.77; 19.12]	0.100	
Geographic Region									
Asia Pacific	510	8 (1.6)	502	1 (0.2)	n.a.	n.a.	n.a.	n.a.	n.a.
Eastern Europe	721	4 (0.6)	718	1 (0.1)	n.a.	n.a.	n.a.	n.a.	
Latin and South America	316	0 (0.0)	324	1 (0.3)	n.a.	n.a.	n.a.	n.a.	

Analyses of Severe Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	2 (0.8)	241	1 (0.4)	n.a.	n.a.	n.a.	n.a.	
Western Europe	365	1 (0.3)	366	2 (0.5)	n.a.	n.a.	n.a.	n.a.	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	0 (0.0)	202	1 (0.5)	-0.50 [-2.75; 1.29]	0.13 [0.00; 6.47]	0.13 [0.00; 6.47]	0.304	0.060
>30 to ≤60	882	3 (0.3)	895	4 (0.4)	-0.11 [-0.84; 0.60]	0.76 [0.17; 3.36]	0.76 [0.17; 3.36]	0.719	
>60	1021	12 (1.2)	1022	1 (0.1)	1.08 [0.47; 1.96]	5.49 [1.85; 16.34]	5.49 [1.85; 16.34]	0.002	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	2 (0.6)	330	2 (0.6)	0.00 [-1.64; 1.65]	1.00 [0.14; 7.15]	1.00 [0.14; 7.15]	0.998	0.311
No	1823	13 (0.7)	1820	4 (0.2)	0.49 [0.06; 1.02]	2.89 [1.12; 7.50]	2.89 [1.12; 7.50]	0.029	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	2 (0.4)	507	2 (0.4)	n.a.	n.a.	n.a.	n.a.	n.a.
Q2 (1556 - 2816)	520	2 (0.4)	493	0 (0.0)	n.a.	n.a.	n.a.	n.a.	
Q3 (2816 - 5314)	511	4 (0.8)	518	3 (0.6)	n.a.	n.a.	n.a.	n.a.	

Analyses of Severe Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Q4 (>5314)	548	7 (1.3)	523	1 (0.2)	n.a.	n.a.	n.a.	n.a.	
Baseline Ejection Fraction Group 2									
<35	1719	13 (0.8)	1734	5 (0.3)	0.47 [-0.01; 1.03]	2.46 [0.98; 6.22]	2.46 [0.98; 6.22]	0.056	0.818
≥35	433	2 (0.5)	417	1 (0.2)	0.22 [-0.92; 1.45]	1.88 [0.19; 18.12]	1.88 [0.19; 18.12]	0.585	
Race group									
White	1344	6 (0.4)	1353	5 (0.4)	0.08 [-0.47; 0.64]	1.21 [0.37; 3.95]	1.21 [0.37; 3.95]	0.754	0.524
Asian	500	8 (1.6)	474	1 (0.2)	1.39 [0.25; 2.94]	4.55 [1.23; 16.92]	4.55 [1.23; 16.92]	0.024	
Black	111	1 (0.9)	118	0 (0.0)	0.90 [-2.28; 4.94]	7.87 [0.16; 397.35]	7.87 [0.16; 397.35]	0.303	
Other	196	0 (0.0)	206	0 (0.0)	0.00 [-1.84; 1.93]	n.a.	n.a.	n.a.	
CCSA class at Randomization									
No Angina	1843	12 (0.7)	1850	6 (0.3)	0.33 [-0.14; 0.85]	1.96 [0.78; 4.95]	1.96 [0.78; 4.95]	0.154	0.667
Angina Class 1 or 2	265	3 (1.1)	260	0 (0.0)	1.13 [-0.33; 3.28]	7.31 [0.76; 70.55]	7.31 [0.76; 70.55]	0.086	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	0.00 [-8.66; 8.12]	n.a.	n.a.	n.a.	

Analyses of Severe Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Medical History of Diabetes Mellitus									
Yes	1047	9 (0.9)	984	3 (0.3)	0.55 [-0.13; 1.36]	2.57 [0.83; 8.00]	2.57 [0.83; 8.00]	0.103	0.765
No	1105	6 (0.5)	1167	3 (0.3)	0.29 [-0.28; 0.95]	2.06 [0.56; 7.64]	2.06 [0.56; 7.64]	0.278	
Index Event									
HF Hospitalization within 3 Months	1439	10 (0.7)	1474	4 (0.3)	0.42 [-0.09; 1.03]	2.42 [0.85; 6.93]	2.42 [0.85; 6.93]	0.098	0.972
HF Hospitalization 3-6 Months	386	3 (0.8)	362	1 (0.3)	0.50 [-0.84; 2.02]	2.56 [0.36; 18.27]	2.56 [0.36; 18.27]	0.348	
IV diuretic for HF (without hospitalization) within 3 Months	327	2 (0.6)	315	1 (0.3)	0.29 [-1.22; 1.92]	1.88 [0.19; 18.15]	1.88 [0.19; 18.15]	0.585	
Category: Symptomatic Hypotension									
Age category 1									
<65	831	11 (1.3)	851	13 (1.5)	-0.20 [-1.43; 1.00]	0.86 [0.39; 1.94]	0.87 [0.39; 1.92]	0.725	0.753
≥65	1321	18 (1.4)	1300	24 (1.8)	-0.48 [-1.51; 0.50]	0.73 [0.40; 1.36]	0.74 [0.40; 1.35]	0.326	
Age category 2									
<75	1519	18 (1.2)	1533	24 (1.6)	-0.38 [-1.25; 0.47]	0.75 [0.41; 1.40]	0.76 [0.41; 1.39]	0.368	0.866
≥75	633	11 (1.7)	618	13 (2.1)	-0.37 [-2.02; 1.23]	0.82 [0.37; 1.85]	0.83 [0.37; 1.83]	0.638	
Gender									
Male	1656	22 (1.3)	1652	31 (1.9)	-0.55 [-1.45; 0.32]	0.70 [0.41; 1.22]	0.71 [0.41; 1.22]	0.212	0.412

Analyses of Severe Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Female	496	7 (1.4)	499	6 (1.2)	0.21 [-1.36; 1.83]	1.18 [0.39; 3.52]	1.17 [0.40; 3.47]	0.772	
Geographic Region									
Asia Pacific	510	2 (0.4)	502	8 (1.6)	-1.20 [-2.77; 0.02]	0.29 [0.08; 1.02]	0.29 [0.08; 1.02]	0.053	0.402
Eastern Europe	721	9 (1.2)	718	10 (1.4)	-0.14 [-1.44; 1.13]	0.89 [0.36; 2.22]	0.90 [0.37; 2.19]	0.810	
Latin and South America	316	2 (0.6)	324	4 (1.2)	-0.60 [-2.57; 1.18]	0.52 [0.11; 2.61]	0.52 [0.11; 2.61]	0.430	
North America	240	9 (3.8)	241	7 (2.9)	0.85 [-2.60; 4.43]	1.30 [0.48; 3.56]	1.29 [0.49; 3.41]	0.606	
Western Europe	365	7 (1.9)	366	8 (2.2)	-0.27 [-2.57; 1.99]	0.88 [0.31; 2.44]	0.88 [0.32; 2.39]	0.798	
eGFR (mL/min/1.73 m^2) Category									
≤30	213	9 (4.2)	202	4 (2.0)	2.25 [-1.29; 6.11]	2.18 [0.66; 7.21]	2.13 [0.67; 6.82]	0.201	0.171
>30 to ≤60	882	13 (1.5)	895	21 (2.3)	-0.87 [-2.24; 0.42]	0.62 [0.31; 1.25]	0.63 [0.32; 1.25]	0.184	
>60	1021	7 (0.7)	1022	10 (1.0)	-0.29 [-1.19; 0.55]	0.70 [0.27; 1.82]	0.70 [0.27; 1.82]	0.466	
NYHA Group at Baseline									
Class I or II	1236	12 (1.0)	1267	19 (1.5)	-0.53 [-1.46; 0.36]	0.65 [0.32; 1.32]	0.65 [0.32; 1.32]	0.232	0.489

Analyses of Severe Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Class III or IV	914	17 (1.9)	884	18 (2.0)	-0.18 [-1.53; 1.15]	0.91 [0.47; 1.78]	0.91 [0.47; 1.76]	0.787	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	5 (1.5)	330	10 (3.0)	-1.51 [-4.15; 0.86]	0.49 [0.17; 1.46]	0.50 [0.17; 1.45]	0.203	0.339
No	1823	24 (1.3)	1820	27 (1.5)	-0.17 [-0.96; 0.62]	0.89 [0.51; 1.54]	0.89 [0.51; 1.53]	0.668	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	7 (1.4)	507	10 (2.0)	-0.54 [-2.34; 1.19]	0.72 [0.27; 1.91]	0.73 [0.28; 1.89]	0.512	0.106
Q2 (1556 - 2816)	520	11 (2.1)	493	6 (1.2)	0.90 [-0.77; 2.68]	1.75 [0.64; 4.78]	1.74 [0.65; 4.66]	0.272	
Q3 (2816 - 5314)	511	7 (1.4)	518	9 (1.7)	-0.37 [-2.07; 1.28]	0.79 [0.29; 2.13]	0.79 [0.30; 2.10]	0.635	
Q4 (>5314)	548	3 (0.5)	523	11 (2.1)	-1.56 [-3.24; -0.22]	0.30 [0.10; 0.86]	0.30 [0.10; 0.86]	0.025	
Baseline Ejection Fraction Group 2									
<35	1719	24 (1.4)	1734	30 (1.7)	-0.33 [-1.20; 0.51]	0.80 [0.47; 1.38]	0.81 [0.47; 1.37]	0.430	0.803
≥35	433	5 (1.2)	417	7 (1.7)	-0.52 [-2.41; 1.21]	0.68 [0.22; 2.17]	0.69 [0.22; 2.15]	0.520	
Race group									
White	1344	22 (1.6)	1353	29 (2.1)	-0.51 [-1.58; 0.54]	0.76 [0.43; 1.33]	0.76 [0.44; 1.32]	0.336	0.078

Analyses of Severe Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Asian	500	1 (0.2)	474	6 (1.3)	-1.07 [-2.56; -0.01]	0.22 [0.05; 0.99]	0.22 [0.05; 0.99]	0.049	
Black	111	4 (3.6)	118	1 (0.8)	2.76 [-1.44; 8.17]	3.61 [0.62; 21.21]	3.61 [0.62; 21.21]	0.155	
Other	196	2 (1.0)	206	1 (0.5)	0.53 [-1.77; 3.21]	2.06 [0.21; 19.89]	2.06 [0.21; 19.89]	0.534	
CCSA class at Randomization									
No Angina	1843	26 (1.4)	1850	33 (1.8)	-0.37 [-1.22; 0.45]	0.79 [0.47; 1.32]	0.79 [0.47; 1.32]	0.367	0.995
Angina Class 1 or 2	265	3 (1.1)	260	4 (1.5)	-0.41 [-2.89; 1.92]	0.73 [0.16; 3.31]	0.74 [0.17; 3.26]	0.686	
Angina Class 3 or 4	44	0 (0.0)	41	0 (0.0)	0.00 [-8.66; 8.12]	n.a.	n.a.	n.a.	
Medical History of Diabetes Mellitus									
Yes	1047	16 (1.5)	984	21 (2.1)	-0.61 [-1.87; 0.58]	0.71 [0.37; 1.37]	0.72 [0.38; 1.36]	0.310	0.713
No	1105	13 (1.2)	1167	16 (1.4)	-0.19 [-1.17; 0.78]	0.86 [0.41; 1.79]	0.86 [0.41; 1.78]	0.680	
Index Event									
HF Hospitalization within 3 Months	1439	22 (1.5)	1474	28 (1.9)	-0.37 [-1.35; 0.60]	0.80 [0.46; 1.41]	0.80 [0.46; 1.40]	0.442	0.314
HF Hospitalization 3-6 Months	386	5 (1.3)	362	3 (0.8)	0.47 [-1.26; 2.27]	1.55 [0.39; 6.26]	1.55 [0.39; 6.26]	0.536	

Analyses of Severe Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
IV diuretic for HF (without hospitalization) within 3 Months	327	2 (0.6)	315	6 (1.9)	-1.29 [-3.55; 0.53]	0.35 [0.09; 1.41]	0.35 [0.09; 1.41]	0.140	
Category: Syncope									
Age category 1									
<65	831	17 (2.0)	851	13 (1.5)	0.52 [-0.79; 1.89]	1.35 [0.65; 2.79]	1.34 [0.65; 2.74]	0.424	0.965
≥65	1321	24 (1.8)	1300	18 (1.4)	0.43 [-0.55; 1.45]	1.32 [0.71; 2.44]	1.31 [0.72; 2.41]	0.380	
Age category 2									
<75	1519	28 (1.8)	1533	21 (1.4)	0.47 [-0.43; 1.41]	1.35 [0.76; 2.39]	1.35 [0.77; 2.36]	0.300	0.909
≥75	633	13 (2.1)	618	10 (1.6)	0.44 [-1.14; 2.05]	1.27 [0.55; 2.93]	1.27 [0.56; 2.87]	0.567	
Gender									
Male	1656	34 (2.1)	1652	28 (1.7)	0.36 [-0.58; 1.32]	1.22 [0.73; 2.01]	1.21 [0.74; 1.99]	0.448	0.354
Female	496	7 (1.4)	499	3 (0.6)	0.81 [-0.52; 2.35]	2.26 [0.65; 7.84]	2.26 [0.65; 7.84]	0.200	
Geographic Region									
Asia Pacific	510	9 (1.8)	502	8 (1.6)	0.17 [-1.56; 1.92]	1.11 [0.42; 2.90]	1.11 [0.43; 2.85]	0.832	0.515
Eastern Europe	721	17 (2.4)	718	8 (1.1)	1.24 [-0.12; 2.75]	2.14 [0.92; 5.00]	2.12 [0.92; 4.87]	0.078	
Latin and South America	316	1 (0.3)	324	2 (0.6)	-0.30 [-1.94; 1.21]	0.53 [0.05; 5.07]	0.53 [0.05; 5.07]	0.578	

Analyses of Severe Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
North America	240	4 (1.7)	241	6 (2.5)	-0.82 [-3.87; 2.03]	0.66 [0.18; 2.38]	0.67 [0.19; 2.34]	0.530	
Western Europe	365	10 (2.7)	366	7 (1.9)	0.83 [-1.50; 3.29]	1.44 [0.54; 3.84]	1.43 [0.55; 3.72]	0.461	
NYHA Group at Baseline									
Class I or II	1236	24 (1.9)	1267	16 (1.3)	0.68 [-0.32; 1.74]	1.55 [0.82; 2.93]	1.54 [0.82; 2.88]	0.179	0.477
Class III or IV	914	17 (1.9)	884	15 (1.7)	0.16 [-1.12; 1.45]	1.10 [0.54; 2.21]	1.10 [0.55; 2.18]	0.794	
Use of Sacubitril /Valsartan at Baseline									
Yes	329	4 (1.2)	330	6 (1.8)	-0.60 [-2.84; 1.49]	0.66 [0.19; 2.38]	0.67 [0.19; 2.35]	0.530	0.245
No	1823	37 (2.0)	1820	25 (1.4)	0.66 [-0.19; 1.54]	1.49 [0.89; 2.48]	1.48 [0.89; 2.44]	0.128	
NT-pro BNP (pg/mL) Baseline Grp: Central Lab									
Q1 (≤1556)	489	11 (2.2)	507	9 (1.8)	0.47 [-1.37; 2.41]	1.27 [0.52; 3.10]	1.27 [0.53; 3.03]	0.595	0.357
Q2 (1556 - 2816)	520	11 (2.1)	493	5 (1.0)	1.10 [-0.50; 2.86]	2.11 [0.73; 6.11]	2.09 [0.73; 5.96]	0.170	
Q3 (2816 - 5314)	511	11 (2.2)	518	6 (1.2)	0.99 [-0.62; 2.79]	1.88 [0.69; 5.11]	1.86 [0.69; 4.99]	0.219	
Q4 (>5314)	548	7 (1.3)	523	10 (1.9)	-0.63 [-2.35; 0.95]	0.66 [0.25; 1.76]	0.67 [0.26; 1.74]	0.409	

Analyses of Severe Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
Baseline Ejection Fraction Group 2									
<35	1719	34 (2.0)	1734	27 (1.6)	0.42 [-0.47; 1.34]	1.28 [0.77; 2.12]	1.27 [0.77; 2.10]	0.349	0.673
≥35	433	7 (1.6)	417	4 (1.0)	0.66 [-1.02; 2.46]	1.67 [0.51; 5.49]	1.67 [0.51; 5.49]	0.397	
Race group									
White	1344	33 (2.5)	1353	22 (1.6)	0.83 [-0.25; 1.95]	1.52 [0.88; 2.63]	1.51 [0.89; 2.58]	0.130	0.410
Asian	500	7 (1.4)	474	4 (0.8)	0.56 [-0.92; 2.12]	1.64 [0.50; 5.40]	1.64 [0.50; 5.40]	0.412	
Black	111	1 (0.9)	118	2 (1.7)	-0.79 [-5.19; 3.40]	0.54 [0.06; 5.27]	0.54 [0.06; 5.27]	0.598	
Other	196	0 (0.0)	206	3 (1.5)	-1.46 [-4.20; 0.48]	0.14 [0.01; 1.36]	0.14 [0.01; 1.36]	0.090	
CCSA class at Randomization									
No Angina	1843	32 (1.7)	1850	28 (1.5)	0.22 [-0.61; 1.07]	1.15 [0.69; 1.92]	1.15 [0.69; 1.90]	0.593	0.496
Angina Class 1 or 2	265	8 (3.0)	260	3 (1.2)	1.87 [-0.70; 4.84]	2.67 [0.70; 10.16]	2.62 [0.70; 9.75]	0.152	
Angina Class 3 or 4	44	1 (2.3)	41	0 (0.0)	2.27 [-6.49; 11.89]	6.90 [0.14; 348.69]	6.90 [0.14; 348.69]	0.334	
Medical History of Diabetes Mellitus									
Yes	1047	20 (1.9)	984	8 (0.8)	1.10 [0.09; 2.21]	2.24 [1.06; 4.72]	2.24 [1.06; 4.72]	0.034	0.076

Analyses of Severe Adverse Event of Clinical Interest for Subgroups; with P-value for Interaction Test ≥ 0.05 or Rule of 10 Not Met by ECI Category
(All-Subjects-as-Treated Population)
Participants with Screening Ejection Fraction < 40%

Study: MK-1242-001	**Vericiguat**		**Placebo**		**Vericiguat vs. Placebo**				
Severe Adverse Events of Clinical Interest	**N[b]**	**Participants with Event n (%)**	**N[b]**	**Participants with Event n (%)**	**Risk Difference [95 %-CI][c]**	**Odds Ratio [95 %-CI][d]**	**Relative Risk [95 %-CI][e]**	**p-Value[e,f]**	**p-Value for Interaction Test[g]**
No	1105	21 (1.9)	1167	23 (2.0)	-0.07 [-1.24; 1.11]	0.96 [0.53; 1.75]	0.96 [0.54; 1.73]	0.903	
Index Event									
HF Hospitalization within 3 Months	1439	27 (1.9)	1474	21 (1.4)	0.45 [-0.49; 1.43]	1.32 [0.74; 2.35]	1.32 [0.75; 2.32]	0.340	0.872
HF Hospitalization 3-6 Months	386	7 (1.8)	362	6 (1.7)	0.16 [-1.97; 2.25]	1.10 [0.36; 3.29]	1.09 [0.37; 3.22]	0.870	
IV diuretic for HF (without hospitalization) within 3 Months	327	7 (2.1)	315	4 (1.3)	0.87 [-1.34; 3.24]	1.70 [0.49; 5.87]	1.69 [0.50; 5.70]	0.401	

a: Database Cutoff Date: 18JUN2019

b: Number of participants: all-subjects-as-treated (ASaT) population with screening ejection fraction < 40%

c: Based on Unstratified Miettinen & Nurminen method.

d: Based on logistic regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Odds Ratio if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

e: Based on Log Binomial regression model with treatment as covariate using Wald confidence interval. Peto-Odds Ratio is calculated instead of Relative Risk if incidence is ≤ 1% or ≥ 99% in at least one cell of the stratum

f: Two-sided p-value using Wald test (Cochran Mantel Haenszel test in case of incidence ≤ 1% or ≥ 99% in at least one cell of the stratum)

g: Based on Logistic regression model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value for likelihood ratio test for interaction term). P-value for Wald test for interaction term based on a penalized likelihood estimate if participant has 0 event in at least one cell of the stratum.

CI: Confidence Interval; ECI: Events of Clinical Interest; n.a.: Not Applicable (when estimation not possible).