Dossier zur Nutzenbewertung gemäß § 35a SGB V

Mavacamten (CAMZYOS®)

Bristol-Myers Squibb GmbH & Co. KGaA

Modul 4 A – Anhang 4-G

Behandlung der symptomatischen obstruktiven hypertrophen Kardiomyopathie (NYHA-Klasse II–III) bei Erwachsenen

Ergänzende Informationen zur Studie EXPLORER-HCM

Stand: 27.07.2023

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Abkürzungsverzeichnis

Abkürzung	Bedeutung
ANCOVA	*Analysis of Covariance*
AUC	Fläche unter der Zeit-Borg-Kurve *(Area Under the Curve)*
BMI	*Body Mass Index*
CI	Konfidenzintervall *(Confidence Interval)*
CPET	Kardiopulmonale Belastungsuntersuchung *(Cardiopulomonary Exercise Testing)*
CSS	*Clinical Summary Score*
E	*Peak velocity of early diastolic transmitral flow*
eCRF	*Electronic Case Report Form*
EQ-5D-5L	*European Quality of Life-5 Dimensions-5 Levels*
e'	*Peak velocity of early diastolic septal and lateral mitral annular motion*
HCM	Hypertrophe Kardiomyopathie
HCMSQ	*Hypertrophic Cardiomyopathy Symptom Questionnaire*
HOCM	Obstruktive hypertrophe Kardiomyopathie
HR	*Hazard Ratio*
hsTN I	Hochsensitives Troponin-I
ICD	Implantierter Kardioverter-Defibrilator
ITT	*Intention to Treat*
KCCQ	*Kansas City Cardiomyopathy Questionnaire*
KME	Kaplan-Meier-Schätzer *(Kaplan-Meier Estimate)*
LVEF	Linksventrikuläre Ejektionsfraktion
LVOT	Linksventrikulärer Ausflusstrakt
MedDRA	*Medical Dictionary for Regulatory Activities*
MMRM	*Mixed Model for Repeated Measurements*
N	Anzahl ausgewerteter Patient:innen
n	Anzahl der Patient:innen mit Ereignis
NT-proBNP	N-terminales pro B-Typ natriuretisches Peptid
NYHA	*New York Heart Association*
OSS	*Overall Summary Score*
PGI-C	*Patient Global Impression of Change*

Abkürzung	Bedeutung
PGI-S	*Patient Global Impression of Severity*
PT	Bevorzugter Begriff *(Preferred Term)*
SOC	System-Organ-Klasse *(System Organ Class)*
SUE	Schwerwiegendes UE
TEAE	*Treatment Emergent Adverse Event*
TSS	*Total Symptom Score*
UE	Unerwünschtes Ereignis
UESI	UE von besonderem Interesse
ULN	Obere Grenze des Referenzbereiches *(Upper Limit of Normal)*
VAS	Visuelle Analogskala

4 Ergänzende Informationen zur Studie EXPLORER-HCM

4.1 Hintergrund

Auf den nachfolgenden Seiten finden sich alle im Dossier angeführten ergänzenden Analysen und Zusatzanalysen sowie alle Subgruppenanalysen für die Hauptanalysen aller patienten-relevanten Endpunkte. Für die Verträglichkeit auf Ebene der SOC/PT wurden darüber hinaus Subgruppenanalysen für jegliche und schwere UE sowie SUE durchgeführt.

Alle Analysen werden, sofern als sinnvoll erachtet, als Ausgabe der Statistik-Software dargestellt.

4.2 Begleiterkrankungen zu Baseline

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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Subjects with Any Concomitant Disease	117 (95.1)	120 (93.8)	237 (94.4)
Blood and lymphatic system disorders	4 (3.3)	8 (6.3)	12 (4.8)
Anaemia	2 (1.6)	3 (2.3)	5 (2.0)
Iron deficiency anaemia	0	3 (2.3)	3 (1.2)
Deficiency anaemia	0	1 (0.8)	1 (0.4)
Leukopenia	0	1 (0.8)	1 (0.4)
Lymph node pain	1 (0.8)	0	1 (0.4)
Microcytosis	1 (0.8)	0	1 (0.4)
Cardiac disorders	53 (43.1)	63 (49.2)	116 (46.2)
Mitral valve incompetence	15 (12.2)	20 (15.6)	35 (13.9)
Palpitations	17 (13.8)	14 (10.9)	31 (12.4)
Angina pectoris	7 (5.7)	13 (10.2)	20 (8.0)
Atrial fibrillation	7 (5.7)	13 (10.2)	20 (8.0)
Ventricular tachycardia	10 (8.1)	9 (7.0)	19 (7.6)
Coronary artery disease	12 (9.8)	5 (3.9)	17 (6.8)
Cardiac failure	4 (3.3)	9 (7.0)	13 (5.2)
Left atrial enlargement	4 (3.3)	8 (6.3)	12 (4.8)
Tricuspid valve incompetence	3 (2.4)	6 (4.7)	9 (3.6)
Systolic anterior motion of mitral valve	3 (2.4)	4 (3.1)	7 (2.8)
Aortic valve incompetence	1 (0.8)	5 (3.9)	6 (2.4)
Bundle branch block left	1 (0.8)	5 (3.9)	6 (2.4)
Myocardial fibrosis	0	5 (3.9)	5 (2.0)
Cardiac failure congestive	2 (1.6)	2 (1.6)	4 (1.6)
Bundle branch block right	1 (0.8)	2 (1.6)	3 (1.2)
Left ventricular hypertrophy	1 (0.8)	2 (1.6)	3 (1.2)
Sinus bradycardia	1 (0.8)	2 (1.6)	3 (1.2)

Data Cutoff Date: 30JUN2020.
Note: At each level of subject summarization, a subject is counted once if the subject reported one or more events. Concomitant Disease includes all the medical records collected in the eCRF at the time of randomization, and is coded by MedDRA Version 21.0.
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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Ventricular extrasystoles	2 (1.6)	1 (0.8)	3 (1.2)
Arrhythmia supraventricular	0	2 (1.6)	2 (0.8)
Atrioventricular block first degree	0	2 (1.6)	2 (0.8)
Cardiac valve sclerosis	0	2 (1.6)	2 (0.8)
Left atrial dilatation	1 (0.8)	1 (0.8)	2 (0.8)
Left ventricular failure	0	2 (1.6)	2 (0.8)
Mitral valve disease	1 (0.8)	1 (0.8)	2 (0.8)
Supraventricular extrasystoles	1 (0.8)	1 (0.8)	2 (0.8)
Supraventricular tachycardia	1 (0.8)	1 (0.8)	2 (0.8)
Aortic valve stenosis	1 (0.8)	0	1 (0.4)
Arrhythmia	1 (0.8)	0	1 (0.4)
Arteriosclerosis coronary artery	1 (0.8)	0	1 (0.4)
Atrial flutter	0	1 (0.8)	1 (0.4)
Atrial tachycardia	1 (0.8)	0	1 (0.4)
Atrioventricular block	0	1 (0.8)	1 (0.4)
Cardiac failure chronic	0	1 (0.8)	1 (0.4)
Cardiovascular disorder	1 (0.8)	0	1 (0.4)
Degenerative mitral valve disease	0	1 (0.8)	1 (0.4)
Diastolic dysfunction	0	1 (0.8)	1 (0.4)
Left ventricular dysfunction	0	1 (0.8)	1 (0.4)
Mitral valve calcification	0	1 (0.8)	1 (0.4)
Mitral valve prolapse	1 (0.8)	0	1 (0.4)
Pericardial effusion	0	1 (0.8)	1 (0.4)
Tachycardia	0	1 (0.8)	1 (0.4)
Tricuspid valve disease	0	1 (0.8)	1 (0.4)
Ventricular hyperkinesia	0	1 (0.8)	1 (0.4)

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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Congenital, familial and genetic disorders	19 (15.4)	22 (17.2)	41 (16.3)
Hypertrophic cardiomyopathy	13 (10.6)	18 (14.1)	31 (12.4)
Type V hyperlipidaemia	1 (0.8)	1 (0.8)	2 (0.8)
Atrial septal defect	1 (0.8)	0	1 (0.4)
Congenital cystic kidney disease	1 (0.8)	0	1 (0.4)
Dolichocolon	1 (0.8)	0	1 (0.4)
Gilbert's syndrome	0	1 (0.8)	1 (0.4)
Hereditary spherocytosis	1 (0.8)	0	1 (0.4)
Left ventricle outflow tract obstruction	0	1 (0.8)	1 (0.4)
Microphthalmos	0	1 (0.8)	1 (0.4)
Thalassaemia	1 (0.8)	0	1 (0.4)
Thalassaemia beta	0	1 (0.8)	1 (0.4)
Type IIa hyperlipidaemia	1 (0.8)	0	1 (0.4)
Ventricular hypoplasia	0	1 (0.8)	1 (0.4)
Ear and labyrinth disorders	12 (9.8)	4 (3.1)	16 (6.4)
Deafness	2 (1.6)	1 (0.8)	3 (1.2)
Tinnitus	2 (1.6)	1 (0.8)	3 (1.2)
Vertigo	2 (1.6)	1 (0.8)	3 (1.2)
Deafness unilateral	2 (1.6)	0	2 (0.8)
Meniere's disease	2 (1.6)	0	2 (0.8)
Vertigo positional	2 (1.6)	0	2 (0.8)
Deafness neurosensory	0	1 (0.8)	1 (0.4)
Inner ear disorder	0	1 (0.8)	1 (0.4)
Neurosensory hypoacusis	1 (0.8)	0	1 (0.4)
Otosclerosis	1 (0.8)	0	1 (0.4)
Endocrine disorders	15 (12.2)	9 (7.0)	24 (9.6)
Hypothyroidism	13 (10.6)	3 (2.3)	16 (6.4)

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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Hyperthyroidism	1 (0.8)	1 (0.8)	2 (0.8)
Thyroid disorder	1 (0.8)	1 (0.8)	2 (0.8)
Autoimmune thyroiditis	0	1 (0.8)	1 (0.4)
Hyperparathyroidism	0	1 (0.8)	1 (0.4)
Hyperparathyroidism secondary	0	1 (0.8)	1 (0.4)
Hypogonadism	0	1 (0.8)	1 (0.4)
Eye disorders	14 (11.4)	7 (5.5)	21 (8.4)
Dry eye	5 (4.1)	1 (0.8)	6 (2.4)
Cataract	3 (2.4)	2 (1.6)	5 (2.0)
Glaucoma	2 (1.6)	1 (0.8)	3 (1.2)
Vision blurred	1 (0.8)	1 (0.8)	2 (0.8)
Amblyopia	0	1 (0.8)	1 (0.4)
Astigmatism	1 (0.8)	0	1 (0.4)
Blindness	1 (0.8)	0	1 (0.4)
Blindness transient	0	1 (0.8)	1 (0.4)
Corneal opacity	1 (0.8)	0	1 (0.4)
Exfoliation glaucoma	1 (0.8)	0	1 (0.4)
Myopia	1 (0.8)	0	1 (0.4)
Normal tension glaucoma	1 (0.8)	0	1 (0.4)
Ocular hypertension	1 (0.8)	0	1 (0.4)
Ocular rosacea	1 (0.8)	0	1 (0.4)
Open angle glaucoma	0	1 (0.8)	1 (0.4)
Presbyopia	1 (0.8)	0	1 (0.4)
Retinal artery embolism	1 (0.8)	0	1 (0.4)
Vitreous detachment	1 (0.8)	0	1 (0.4)

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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Gastrointestinal disorders	39 (31.7)	45 (35.2)	84 (33.5)
Gastrooesophageal reflux disease	20 (16.3)	24 (18.8)	44 (17.5)
Dyspepsia	4 (3.3)	6 (4.7)	10 (4.0)
Haemorrhoids	3 (2.4)	7 (5.5)	10 (4.0)
Irritable bowel syndrome	2 (1.6)	5 (3.9)	7 (2.8)
Constipation	5 (4.1)	1 (0.8)	6 (2.4)
Hiatus hernia	2 (1.6)	4 (3.1)	6 (2.4)
Large intestine polyp	0	4 (3.1)	4 (1.6)
Colitis ulcerative	0	3 (2.3)	3 (1.2)
Diverticulum	1 (0.8)	2 (1.6)	3 (1.2)
Abdominal pain	1 (0.8)	1 (0.8)	2 (0.8)
Chronic gastritis	1 (0.8)	1 (0.8)	2 (0.8)
Diarrhoea	2 (1.6)	0	2 (0.8)
Abdominal distension	1 (0.8)	0	1 (0.4)
Abdominal pain lower	1 (0.8)	0	1 (0.4)
Anal incontinence	0	1 (0.8)	1 (0.4)
Anal pruritus	1 (0.8)	0	1 (0.4)
Barrett's oesophagus	0	1 (0.8)	1 (0.4)
Breath odour	0	1 (0.8)	1 (0.4)
Coeliac disease	0	1 (0.8)	1 (0.4)
Colitis	1 (0.8)	0	1 (0.4)
Crohn's disease	0	1 (0.8)	1 (0.4)
Dental caries	1 (0.8)	0	1 (0.4)
Diaphragmatic hernia	0	1 (0.8)	1 (0.4)
Diverticulum intestinal	1 (0.8)	0	1 (0.4)
Dry mouth	1 (0.8)	0	1 (0.4)
Duodenal ulcer	1 (0.8)	0	1 (0.4)
Gastric ulcer	0	1 (0.8)	1 (0.4)
Gastroduodenal ulcer	1 (0.8)	0	1 (0.4)

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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Gastrointestinal melanosis	0	1 (0.8)	1 (0.4)
Inguinal hernia	1 (0.8)	0	1 (0.4)
Oesophageal pain	0	1 (0.8)	1 (0.4)
Oral disorder	0	1 (0.8)	1 (0.4)
Pancreatic cyst	1 (0.8)	0	1 (0.4)
Pancreatitis	0	1 (0.8)	1 (0.4)
Peptic ulcer	1 (0.8)	0	1 (0.4)
Rectal haemorrhage	0	1 (0.8)	1 (0.4)
Umbilical hernia	1 (0.8)	0	1 (0.4)
General disorders and administration site conditions	26 (21.1)	19 (14.8)	45 (17.9)
Fatigue	18 (14.6)	11 (8.6)	29 (11.6)
Oedema peripheral	4 (3.3)	4 (3.1)	8 (3.2)
Chest discomfort	3 (2.4)	3 (2.3)	6 (2.4)
Peripheral swelling	2 (1.6)	3 (2.3)	5 (2.0)
Chest pain	0	3 (2.3)	3 (1.2)
Asthenia	1 (0.8)	1 (0.8)	2 (0.8)
Pain	2 (1.6)	0	2 (0.8)
Device related thrombosis	1 (0.8)	0	1 (0.4)
Drug intolerance	0	1 (0.8)	1 (0.4)
Gait disturbance	0	1 (0.8)	1 (0.4)
Systemic inflammatory response syndrome	0	1 (0.8)	1 (0.4)
Hepatobiliary disorders	5 (4.1)	5 (3.9)	10 (4.0)
Hepatic steatosis	3 (2.4)	2 (1.6)	5 (2.0)
Cholelithiasis	1 (0.8)	2 (1.6)	3 (1.2)
Gallbladder polyp	0	1 (0.8)	1 (0.4)
Hepatic cyst	1 (0.8)	0	1 (0.4)

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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Hyperbilirubinaemia	1 (0.8)	0	1 (0.4)
Immune system disorders	33 (26.8)	33 (25.8)	66 (26.3)
Drug hypersensitivity	21 (17.1)	17 (13.3)	38 (15.1)
Seasonal allergy	16 (13.0)	17 (13.3)	33 (13.1)
Food allergy	3 (2.4)	4 (3.1)	7 (2.8)
Rubber sensitivity	3 (2.4)	2 (1.6)	5 (2.0)
Allergy to animal	2 (1.6)	1 (0.8)	3 (1.2)
Dust allergy	1 (0.8)	2 (1.6)	3 (1.2)
Iodine allergy	2 (1.6)	1 (0.8)	3 (1.2)
Milk allergy	1 (0.8)	1 (0.8)	2 (0.8)
Anaphylactic reaction	1 (0.8)	0	1 (0.4)
Immunosuppression	0	1 (0.8)	1 (0.4)
Mite allergy	1 (0.8)	0	1 (0.4)
Infections and infestations	19 (15.4)	10 (7.8)	29 (11.6)
Sinusitis	3 (2.4)	2 (1.6)	5 (2.0)
Chronic sinusitis	2 (1.6)	2 (1.6)	4 (1.6)
Bronchitis	0	2 (1.6)	2 (0.8)
Onychomycosis	1 (0.8)	1 (0.8)	2 (0.8)
Oral herpes	2 (1.6)	0	2 (0.8)
Anisakiasis	1 (0.8)	0	1 (0.4)
Appendicitis	1 (0.8)	0	1 (0.4)
Conjunctivitis	1 (0.8)	0	1 (0.4)
Diverticulitis	0	1 (0.8)	1 (0.4)
Folliculitis	0	1 (0.8)	1 (0.4)
Herpes simplex	1 (0.8)	0	1 (0.4)
Herpes zoster	1 (0.8)	0	1 (0.4)

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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Lyme disease	0	1 (0.8)	1 (0.4)
Ophthalmic herpes zoster	1 (0.8)	0	1 (0.4)
Pharyngitis	1 (0.8)	0	1 (0.4)
Pneumonia	1 (0.8)	0	1 (0.4)
Rhinitis	1 (0.8)	0	1 (0.4)
Tinea versicolour	0	1 (0.8)	1 (0.4)
Upper respiratory tract infection	1 (0.8)	0	1 (0.4)
Urinary tract infection	1 (0.8)	0	1 (0.4)
Vestibular neuronitis	0	1 (0.8)	1 (0.4)
Injury, poisoning and procedural complications	4 (3.3)	3 (2.3)	7 (2.8)
Contusion	1 (0.8)	0	1 (0.4)
Epicondylitis	1 (0.8)	0	1 (0.4)
Limb crushing injury	0	1 (0.8)	1 (0.4)
Median nerve injury	1 (0.8)	0	1 (0.4)
Meniscus injury	0	1 (0.8)	1 (0.4)
Procedural pain	0	1 (0.8)	1 (0.4)
Skin injury	1 (0.8)	0	1 (0.4)
Investigations	16 (13.0)	24 (18.8)	40 (15.9)
Cardiac murmur	9 (7.3)	10 (7.8)	19 (7.6)
N-terminal prohormone brain natriuretic peptide increased	1 (0.8)	6 (4.7)	7 (2.8)
Blood cholesterol increased	1 (0.8)	2 (1.6)	3 (1.2)
Blood testosterone decreased	0	2 (1.6)	2 (0.8)
Pulmonary arterial pressure increased	2 (1.6)	0	2 (0.8)
QRS axis abnormal	0	2 (1.6)	2 (0.8)
Alanine aminotransferase increased	0	1 (0.8)	1 (0.4)
Electrocardiogram Q waves	0	1 (0.8)	1 (0.4)

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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Electrocardiogram QT prolonged	0	1 (0.8)	1 (0.4)
Electrocardiogram ST segment elevation	0	1 (0.8)	1 (0.4)
Electrocardiogram T wave peaked	0	1 (0.8)	1 (0.4)
Hepatic enzyme increased	1 (0.8)	0	1 (0.4)
Human papilloma virus test positive	1 (0.8)	0	1 (0.4)
Low density lipoprotein increased	0	1 (0.8)	1 (0.4)
Prostatic specific antigen increased	0	1 (0.8)	1 (0.4)
Smear cervix abnormal	0	1 (0.8)	1 (0.4)
Troponin increased	1 (0.8)	0	1 (0.4)
Troponin T increased	0	1 (0.8)	1 (0.4)
Vitamin D decreased	0	1 (0.8)	1 (0.4)
Metabolism and nutrition disorders	74 (60.2)	76 (59.4)	150 (59.8)
Hyperlipidaemia	27 (22.0)	39 (30.5)	66 (26.3)
Dyslipidaemia	20 (16.3)	18 (14.1)	38 (15.1)
Obesity	15 (12.2)	14 (10.9)	29 (11.6)
Hypercholesterolaemia	14 (11.4)	6 (4.7)	20 (8.0)
Type 2 diabetes mellitus	6 (4.9)	7 (5.5)	13 (5.2)
Hyperuricaemia	4 (3.3)	4 (3.1)	8 (3.2)
Vitamin D deficiency	6 (4.9)	2 (1.6)	8 (3.2)
Glucose tolerance impaired	4 (3.3)	3 (2.3)	7 (2.8)
Gout	2 (1.6)	5 (3.9)	7 (2.8)
Lactose intolerance	3 (2.4)	3 (2.3)	6 (2.4)
Diabetes mellitus	3 (2.4)	2 (1.6)	5 (2.0)
Hypertriglyceridaemia	3 (2.4)	0	3 (1.2)
Fluid retention	1 (0.8)	0	1 (0.4)
Haemochromatosis	1 (0.8)	0	1 (0.4)
Hyperkalaemia	1 (0.8)	0	1 (0.4)

Data Cutoff Date: 30JUN2020.
Note: At each level of subject summarization, a subject is counted once if the subject reported one or more events. Concomitant Disease includes all the medical records collected in the eCRF at the time of randomization, and is coded by MedDRA Version 21.0.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-mh-comdist.sas 18NOV2022:07:09

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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Hypokalaemia	0	1 (0.8)	1 (0.4)
Hypomagnesaemia	0	1 (0.8)	1 (0.4)
Hyponatraemia	0	1 (0.8)	1 (0.4)
Impaired fasting glucose	1 (0.8)	0	1 (0.4)
Type 1 diabetes mellitus	0	1 (0.8)	1 (0.4)
Vitamin B12 deficiency	0	1 (0.8)	1 (0.4)
Musculoskeletal and connective tissue disorders	45 (36.6)	41 (32.0)	86 (34.3)
Osteoarthritis	11 (8.9)	10 (7.8)	21 (8.4)
Back pain	12 (9.8)	5 (3.9)	17 (6.8)
Arthralgia	5 (4.1)	4 (3.1)	9 (3.6)
Spinal osteoarthritis	6 (4.9)	3 (2.3)	9 (3.6)
Intervertebral disc protrusion	1 (0.8)	5 (3.9)	6 (2.4)
Musculoskeletal chest pain	3 (2.4)	2 (1.6)	5 (2.0)
Osteopenia	3 (2.4)	2 (1.6)	5 (2.0)
Arthritis	2 (1.6)	2 (1.6)	4 (1.6)
Osteoporosis	3 (2.4)	1 (0.8)	4 (1.6)
Musculoskeletal pain	0	3 (2.3)	3 (1.2)
Myalgia	1 (0.8)	2 (1.6)	3 (1.2)
Neck pain	2 (1.6)	1 (0.8)	3 (1.2)
Plantar fasciitis	1 (0.8)	2 (1.6)	3 (1.2)
Rheumatoid arthritis	2 (1.6)	1 (0.8)	3 (1.2)
Systemic lupus erythematosus	2 (1.6)	1 (0.8)	3 (1.2)
Diastasis recti abdominis	1 (0.8)	1 (0.8)	2 (0.8)
Fibromyalgia	2 (1.6)	0	2 (0.8)
Foot deformity	1 (0.8)	1 (0.8)	2 (0.8)
Intervertebral disc degeneration	1 (0.8)	1 (0.8)	2 (0.8)
Joint swelling	2 (1.6)	0	2 (0.8)

Data Cutoff Date: 30JUN2020.
Note: At each level of subject summarization, a subject is counted once if the subject reported one or more events. Concomitant Disease includes all the medical records collected in the eCRF at the time of randomization, and is coded by MedDRA Version 21.0.
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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Muscle spasms	1 (0.8)	1 (0.8)	2 (0.8)
Pain in extremity	2 (1.6)	0	2 (0.8)
Spondylitis	1 (0.8)	1 (0.8)	2 (0.8)
Spondylolisthesis	2 (1.6)	0	2 (0.8)
Bone metabolism disorder	1 (0.8)	0	1 (0.4)
Bone pain	1 (0.8)	0	1 (0.4)
Bursitis	1 (0.8)	0	1 (0.4)
Cervical spinal stenosis	1 (0.8)	0	1 (0.4)
Intervertebral disc disorder	0	1 (0.8)	1 (0.4)
Joint effusion	0	1 (0.8)	1 (0.4)
Limb discomfort	1 (0.8)	0	1 (0.4)
Lupus myositis	0	1 (0.8)	1 (0.4)
Muscular weakness	0	1 (0.8)	1 (0.4)
Osteoarthropathy	0	1 (0.8)	1 (0.4)
Patellofemoral pain syndrome	0	1 (0.8)	1 (0.4)
Periarthritis	0	1 (0.8)	1 (0.4)
Polyarthritis	1 (0.8)	0	1 (0.4)
Psoriatic arthropathy	1 (0.8)	0	1 (0.4)
Rotator cuff syndrome	0	1 (0.8)	1 (0.4)
Scoliosis	0	1 (0.8)	1 (0.4)
Sjogren's syndrome	1 (0.8)	0	1 (0.4)
Spinal pain	0	1 (0.8)	1 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (4.1)	10 (7.8)	15 (6.0)
Colon adenoma	1 (0.8)	4 (3.1)	5 (2.0)
Adenoma benign	1 (0.8)	1 (0.8)	2 (0.8)
Adrenal adenoma	1 (0.8)	0	1 (0.4)
Cholesteatoma	0	1 (0.8)	1 (0.4)

Data Cutoff Date: 30JUN2020.
Note: At each level of subject summarization, a subject is counted once if the subject reported one or more events. Concomitant Disease includes all the medical records collected in the eCRF at the time of randomization, and is coded by MedDRA Version 21.0.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-mh-comdist.sas 18NOV2022:07:09

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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Fibrous histiocytoma	0	1 (0.8)	1 (0.4)
Haemangioma	1 (0.8)	0	1 (0.4)
Haemangioma of liver	0	1 (0.8)	1 (0.4)
Lipoma	1 (0.8)	0	1 (0.4)
Malignant melanoma	0	1 (0.8)	1 (0.4)
Meningioma	1 (0.8)	0	1 (0.4)
Pancreatic neoplasm	1 (0.8)	0	1 (0.4)
Seborrhoeic keratosis	0	1 (0.8)	1 (0.4)
Nervous system disorders	38 (30.9)	38 (29.7)	76 (30.3)
Dizziness	14 (11.4)	9 (7.0)	23 (9.2)
Headache	11 (8.9)	7 (5.5)	18 (7.2)
Migraine	5 (4.1)	6 (4.7)	11 (4.4)
Sciatica	2 (1.6)	4 (3.1)	6 (2.4)
Dizziness postural	1 (0.8)	3 (2.3)	4 (1.6)
Paraesthesia	2 (1.6)	2 (1.6)	4 (1.6)
Amnesia	2 (1.6)	1 (0.8)	3 (1.2)
Hypoaesthesia	1 (0.8)	2 (1.6)	3 (1.2)
Restless legs syndrome	1 (0.8)	2 (1.6)	3 (1.2)
Carotid arteriosclerosis	2 (1.6)	0	2 (0.8)
Migraine with aura	2 (1.6)	0	2 (0.8)
Neuropathy peripheral	1 (0.8)	1 (0.8)	2 (0.8)
Parkinson's disease	1 (0.8)	1 (0.8)	2 (0.8)
Peroneal nerve palsy	2 (1.6)	0	2 (0.8)
Presyncope	0	2 (1.6)	2 (0.8)
Syncope	0	2 (1.6)	2 (0.8)
Arachnoid cyst	1 (0.8)	0	1 (0.4)
Autonomic neuropathy	0	1 (0.8)	1 (0.4)

Data Cutoff Date: 30JUN2020.
Note: At each level of subject summarization, a subject is counted once if the subject reported one or more events. Concomitant Disease includes all the medical records collected in the eCRF at the time of randomization, and is coded by MedDRA Version 21.0.
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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Carpal tunnel syndrome	0	1 (0.8)	1 (0.4)
Cerebral microhaemorrhage	1 (0.8)	0	1 (0.4)
Cubital tunnel syndrome	1 (0.8)	0	1 (0.4)
Diabetic neuropathy	0	1 (0.8)	1 (0.4)
Dizziness exertional	0	1 (0.8)	1 (0.4)
Epilepsy	0	1 (0.8)	1 (0.4)
Essential tremor	1 (0.8)	0	1 (0.4)
Head discomfort	1 (0.8)	0	1 (0.4)
Hyporeflexia	0	1 (0.8)	1 (0.4)
Meralgia paraesthetica	0	1 (0.8)	1 (0.4)
Neuralgia	0	1 (0.8)	1 (0.4)
Seizure	1 (0.8)	0	1 (0.4)
Sensory disturbance	0	1 (0.8)	1 (0.4)
Shift work disorder	1 (0.8)	0	1 (0.4)
Sinus headache	1 (0.8)	0	1 (0.4)
Psychiatric disorders	36 (29.3)	32 (25.0)	68 (27.1)
Depression	11 (8.9)	13 (10.2)	24 (9.6)
Anxiety	14 (11.4)	8 (6.3)	22 (8.8)
Insomnia	14 (11.4)	6 (4.7)	20 (8.0)
Attention deficit/hyperactivity disorder	1 (0.8)	2 (1.6)	3 (1.2)
Affective disorder	0	2 (1.6)	2 (0.8)
Anxiety disorder	0	2 (1.6)	2 (0.8)
Generalised anxiety disorder	2 (1.6)	0	2 (0.8)
Post-traumatic stress disorder	1 (0.8)	1 (0.8)	2 (0.8)
Adjustment disorder	1 (0.8)	0	1 (0.4)
Bipolar disorder	1 (0.8)	0	1 (0.4)
Nervousness	1 (0.8)	0	1 (0.4)

Data Cutoff Date: 30JUN2020.
Note: At each level of subject summarization, a subject is counted once if the subject reported one or more events. Concomitant Disease includes all the medical records collected in the eCRF at the time of randomization, and is coded by MedDRA Version 21.0.
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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Obsessive-compulsive disorder	0	1 (0.8)	1 (0.4)
Sleep disorder	1 (0.8)	0	1 (0.4)
Tobacco abuse	0	1 (0.8)	1 (0.4)
Renal and urinary disorders	12 (9.8)	9 (7.0)	21 (8.4)
Chronic kidney disease	3 (2.4)	3 (2.3)	6 (2.4)
Nephrolithiasis	2 (1.6)	3 (2.3)	5 (2.0)
Urinary incontinence	3 (2.4)	1 (0.8)	4 (1.6)
Bladder outlet obstruction	1 (0.8)	0	1 (0.4)
Haematuria	1 (0.8)	0	1 (0.4)
Hypertonic bladder	1 (0.8)	0	1 (0.4)
Lower urinary tract symptoms	1 (0.8)	0	1 (0.4)
Pollakiuria	1 (0.8)	0	1 (0.4)
Renal failure	1 (0.8)	0	1 (0.4)
Renal mass	1 (0.8)	0	1 (0.4)
Urge incontinence	1 (0.8)	0	1 (0.4)
Urinary hesitation	0	1 (0.8)	1 (0.4)
Urinary tract obstruction	0	1 (0.8)	1 (0.4)
Reproductive system and breast disorders	12 (9.8)	19 (14.8)	31 (12.4)
Benign prostatic hyperplasia	5 (4.1)	9 (7.0)	14 (5.6)
Erectile dysfunction	4 (3.3)	3 (2.3)	7 (2.8)
Endometriosis	0	3 (2.3)	3 (1.2)
Prostatomegaly	2 (1.6)	1 (0.8)	3 (1.2)
Atrophic vulvovaginitis	1 (0.8)	1 (0.8)	2 (0.8)
Breast cyst	1 (0.8)	0	1 (0.4)
Cervical dysplasia	0	1 (0.8)	1 (0.4)
Fibrocystic breast disease	0	1 (0.8)	1 (0.4)

Data Cutoff Date: 30JUN2020.
Note: At each level of subject summarization, a subject is counted once if the subject reported one or more events. Concomitant Disease includes all the medical records collected in the eCRF at the time of randomization, and is coded by MedDRA Version 21.0.
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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Hydrometra	0	1 (0.8)	1 (0.4)
Menopausal disorder	0	1 (0.8)	1 (0.4)
Ovarian cyst	0	1 (0.8)	1 (0.4)
Pelvic discomfort	0	1 (0.8)	1 (0.4)
Perineal pain	1 (0.8)	0	1 (0.4)
Postmenopausal haemorrhage	0	1 (0.8)	1 (0.4)
Prostatic disorder	1 (0.8)	0	1 (0.4)
Respiratory, thoracic and mediastinal disorders	47 (38.2)	52 (40.6)	99 (39.4)
Sleep apnoea syndrome	19 (15.4)	22 (17.2)	41 (16.3)
Dyspnoea	20 (16.3)	19 (14.8)	39 (15.5)
Asthma	15 (12.2)	11 (8.6)	26 (10.4)
Dyspnoea exertional	6 (4.9)	6 (4.7)	12 (4.8)
Cough	4 (3.3)	3 (2.3)	7 (2.8)
Chronic obstructive pulmonary disease	2 (1.6)	3 (2.3)	5 (2.0)
Rhinitis allergic	1 (0.8)	4 (3.1)	5 (2.0)
Pulmonary hypertension	1 (0.8)	2 (1.6)	3 (1.2)
Bronchiectasis	1 (0.8)	1 (0.8)	2 (0.8)
Pulmonary artery dilatation	0	2 (1.6)	2 (0.8)
Dyspnoea paroxysmal nocturnal	1 (0.8)	0	1 (0.4)
Hypoxia	1 (0.8)	0	1 (0.4)
Orthopnoea	1 (0.8)	0	1 (0.4)
Paranasal cyst	0	1 (0.8)	1 (0.4)
Paranasal sinus hypersecretion	1 (0.8)	0	1 (0.4)
Pulmonary mass	0	1 (0.8)	1 (0.4)
Sinus disorder	0	1 (0.8)	1 (0.4)
Snoring	0	1 (0.8)	1 (0.4)

Data Cutoff Date: 30JUN2020.
Note: At each level of subject summarization, a subject is counted once if the subject reported one or more events. Concomitant Disease includes all the medical records collected in the eCRF at the time of randomization, and is coded by MedDRA Version 21.0.
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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Skin and subcutaneous tissue disorders	14 (11.4)	14 (10.9)	28 (11.2)
Psoriasis	4 (3.3)	3 (2.3)	7 (2.8)
Alopecia	2 (1.6)	2 (1.6)	4 (1.6)
Dermatitis contact	3 (2.4)	1 (0.8)	4 (1.6)
Actinic keratosis	1 (0.8)	1 (0.8)	2 (0.8)
Angioedema	0	1 (0.8)	1 (0.4)
Dermatitis	1 (0.8)	0	1 (0.4)
Dermatitis atopic	0	1 (0.8)	1 (0.4)
Eczema	0	1 (0.8)	1 (0.4)
Hand dermatitis	0	1 (0.8)	1 (0.4)
Ingrowing nail	0	1 (0.8)	1 (0.4)
Lichen planus	0	1 (0.8)	1 (0.4)
Pruritus	1 (0.8)	0	1 (0.4)
Pruritus generalised	0	1 (0.8)	1 (0.4)
Rosacea	1 (0.8)	0	1 (0.4)
Skin wrinkling	1 (0.8)	0	1 (0.4)
Urticaria cholinergic	0	1 (0.8)	1 (0.4)
Social circumstances	42 (34.1)	32 (25.0)	74 (29.5)
Postmenopause	31 (25.2)	24 (18.8)	55 (21.9)
Tobacco user	8 (6.5)	2 (1.6)	10 (4.0)
Menopause	3 (2.4)	5 (3.9)	8 (3.2)
Corrective lens user	2 (1.6)	2 (1.6)	4 (1.6)
Surgical and medical procedures	3 (2.4)	4 (3.1)	7 (2.8)
Implantable defibrillator insertion	0	3 (2.3)	3 (1.2)
Finger amputation	1 (0.8)	0	1 (0.4)
Gastrooesophageal reflux prophylaxis	0	1 (0.8)	1 (0.4)

Data Cutoff Date: 30JUN2020.
Note: At each level of subject summarization, a subject is counted once if the subject reported one or more events. Concomitant Disease includes all the medical records collected in the eCRF at the time of randomization, and is coded by MedDRA Version 21.0.
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Concomitant Disease
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Implantable cardiac monitor insertion	1 (0.8)	0	1 (0.4)
Intraocular lens implant	1 (0.8)	0	1 (0.4)
Vascular disorders	61 (49.6)	63 (49.2)	124 (49.4)
Hypertension	56 (45.5)	53 (41.4)	109 (43.4)
Essential hypertension	3 (2.4)	6 (4.7)	9 (3.6)
Aortic dilatation	1 (0.8)	2 (1.6)	3 (1.2)
Peripheral venous disease	0	3 (2.3)	3 (1.2)
Aortic aneurysm	1 (0.8)	1 (0.8)	2 (0.8)
Varicose vein	0	2 (1.6)	2 (0.8)
Aortic arteriosclerosis	1 (0.8)	0	1 (0.4)
Aortic stenosis	1 (0.8)	0	1 (0.4)
Arteriosclerosis	1 (0.8)	0	1 (0.4)
Hot flush	0	1 (0.8)	1 (0.4)
Hypotension	0	1 (0.8)	1 (0.4)
Orthostatic hypotension	1 (0.8)	0	1 (0.4)
Peripheral vascular disorder	0	1 (0.8)	1 (0.4)
Raynaud's phenomenon	0	1 (0.8)	1 (0.4)

Data Cutoff Date: 30JUN2020.
Note: At each level of subject summarization, a subject is counted once if the subject reported one or more events. Concomitant Disease includes all the medical records collected in the eCRF at the time of randomization, and is coded by MedDRA Version 21.0.
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4.3 Begleittherapien im Studienverlauf

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Total Number of Concomitant Medications	1229	1148	2377
Number of Subjects With at Least One Concomitant Medication	123 (100.0)	126 (98.4)	249 (99.2)
Agents Acting On The Renin-Angiotensin System	30 (24.4)	29 (22.7)	59 (23.5)
Losartan	11 (8.9)	6 (4.7)	17 (6.8)
Ramipril	6 (4.9)	9 (7.0)	15 (6.0)
Lisinopril	4 (3.3)	2 (1.6)	6 (2.4)
Losartan Potassium	3 (2.4)	2 (1.6)	5 (2.0)
Olmesartan	2 (1.6)	1 (0.8)	3 (1.2)
Perindopril	1 (0.8)	2 (1.6)	3 (1.2)
Valsartan	0	3 (2.3)	3 (1.2)
Cilazapril;hydrochlorothiazide	1 (0.8)	1 (0.8)	2 (0.8)
Enalapril	2 (1.6)	0	2 (0.8)
Hydrochlorothiazide;telmisartan	0	2 (1.6)	2 (0.8)
Telmisartan	2 (1.6)	0	2 (0.8)
Amlodipine Besilate;hydrochlorothiazide;olmesartan Medoxomil	0	1 (0.8)	1 (0.4)
Amlodipine Besilate;olmesartan Medoxomil	0	1 (0.8)	1 (0.4)
Benazepril	1 (0.8)	0	1 (0.4)
Candesartan	0	1 (0.8)	1 (0.4)
Candesartan Cilexetil	1 (0.8)	0	1 (0.4)
Captopril	1 (0.8)	0	1 (0.4)
Irbesartan	1 (0.8)	0	1 (0.4)

Data Cutoff Date: 30JUN2020
Note: Subjects may have more than one medication per preferred term per ATC class.
At each level of subject summarization, a subject is counted only once if the subject reported the same medication multiple times.
Concomitant medications were coded with the WHO Drug dictionary version 2018.03.
The concomitant medication is defined as the medication having a stop date on or after the first dose or it is still ongoing at the time of data cut.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-cm-cmt.sas 25FEB2022:08:53

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
All Other Therapeutic Products	2 (1.6)	3 (2.3)	5 (2.0)
Chlorophyllin	0	1 (0.8)	1 (0.4)
Cholesterol	0	1 (0.8)	1 (0.4)
Honey	1 (0.8)	0	1 (0.4)
Propolis	0	1 (0.8)	1 (0.4)
Sodium Polystyrene Sulfonate	1 (0.8)	0	1 (0.4)
Analgesics	47 (38.2)	38 (29.7)	85 (33.9)
Paracetamol	32 (26.0)	26 (20.3)	58 (23.1)
Metamizole	3 (2.4)	2 (1.6)	5 (2.0)
Acetylsalicylic Acid	3 (2.4)	1 (0.8)	4 (1.6)
Tramadol	2 (1.6)	2 (1.6)	4 (1.6)
Codeine Phosphate	0	3 (2.3)	3 (1.2)
Gabapentin	3 (2.4)	0	3 (1.2)
Paracetamol;tramadol Hydrochloride	2 (1.6)	1 (0.8)	3 (1.2)
Pregabalin	2 (1.6)	1 (0.8)	3 (1.2)
Codeine Phosphate;paracetamol	0	2 (1.6)	2 (0.8)
Dextromethorphan Hydrobromide;doxylamine Succinate;ephedrine Sulfate;ethanol;paracetamol	0	2 (1.6)	2 (0.8)
Dextromethorphan Hydrobromide;guaifenesin;paracetamol;pseudoephedrine Hydrochloride	1 (0.8)	1 (0.8)	2 (0.8)
Dextromethorphan Hydrobromide;paracetamol;phenylephrine Hydrochloride	1 (0.8)	1 (0.8)	2 (0.8)
Diphenhydramine Hydrochloride;paracetamol	1 (0.8)	1 (0.8)	2 (0.8)
Hydrocodone Bitartrate;paracetamol	1 (0.8)	1 (0.8)	2 (0.8)
Metamizole Magnesium	0	2 (1.6)	2 (0.8)
Oxycodone	1 (0.8)	1 (0.8)	2 (0.8)
Acetylsalicylic Acid;caffeine;paracetamol	1 (0.8)	0	1 (0.4)

Data Cutoff Date: 30JUN2020
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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Acetylsalicylic Acid;citric Acid;sodium Bicarbonate	1 (0.8)	0	1 (0.4)
Amitriptyline	0	1 (0.8)	1 (0.4)
Ascorbic Acid;paracetamol;phenylephrine Hydrochloride	1 (0.8)	0	1 (0.4)
Chlorphenamine Maleate;dextromethorphan Hydrobromide;paracetamol	0	1 (0.8)	1 (0.4)
Dextromethorphan Hydrobromide;doxylamine Succinate;paracetamol	1 (0.8)	0	1 (0.4)
Dextromethorphan Hydrobromide;doxylamine Succinate;paracetamol;phenylephrine Hydrochloride	0	1 (0.8)	1 (0.4)
Dextromethorphan Hydrobromide;guaifenesin;paracetamol;phenylephrine Hydrochloride	1 (0.8)	0	1 (0.4)
Diphenhydramine;paracetamol	0	1 (0.8)	1 (0.4)
Duloxetine Hydrochloride	1 (0.8)	0	1 (0.4)
Fentanyl	1 (0.8)	0	1 (0.4)
Metamizole Sodium	1 (0.8)	0	1 (0.4)
Opium Alkaloids Total	1 (0.8)	0	1 (0.4)
Oxycodone;paracetamol	0	1 (0.8)	1 (0.4)
Papaver Somniferum;paracetamol	1 (0.8)	0	1 (0.4)
Paracetamol;phenylephrine	1 (0.8)	0	1 (0.4)
Paracetamol;tramadol	1 (0.8)	0	1 (0.4)
Pethidine	0	1 (0.8)	1 (0.4)
Rizatriptan	1 (0.8)	0	1 (0.4)
Rizatriptan Benzoate	0	1 (0.8)	1 (0.4)
Sumatriptan	1 (0.8)	0	1 (0.4)
Anesthetics	2 (1.6)	2 (1.6)	4 (1.6)
Lidocaine	1 (0.8)	1 (0.8)	2 (0.8)
Epinephrine;lidocaine Hydrochloride	1 (0.8)	0	1 (0.4)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Propofol	0	1 (0.8)	1 (0.4)
Anti-Parkinson Drugs	1 (0.8)	3 (2.3)	4 (1.6)
Carbidopa;levodopa	0	1 (0.8)	1 (0.4)
Pramipexole Dihydrochloride	0	1 (0.8)	1 (0.4)
Ropinirole	1 (0.8)	0	1 (0.4)
Ropinirole Hydrochloride	0	1 (0.8)	1 (0.4)
Antianemic Preparations	13 (10.6)	14 (10.9)	27 (10.8)
Folic Acid	5 (4.1)	2 (1.6)	7 (2.8)
Ferrous Sulfate	3 (2.4)	3 (2.3)	6 (2.4)
Cyanocobalamin	1 (0.8)	4 (3.1)	5 (2.0)
Iron	2 (1.6)	1 (0.8)	3 (1.2)
Vitamin B12 Nos	1 (0.8)	2 (1.6)	3 (1.2)
Ferric Carboxymaltose	0	1 (0.8)	1 (0.4)
Ferric Hydroxide Polymaltose Complex	0	1 (0.8)	1 (0.4)
Ferrous Fumarate	0	1 (0.8)	1 (0.4)
Ferrous Gluconate	1 (0.8)	0	1 (0.4)
Ferrous Glycine Sulfate	0	1 (0.8)	1 (0.4)
Antibacterials For Systemic Use	40 (32.5)	36 (28.1)	76 (30.3)
Amoxicillin	6 (4.9)	8 (6.3)	14 (5.6)
Azithromycin	9 (7.3)	5 (3.9)	14 (5.6)
Metronidazole	4 (3.3)	3 (2.3)	7 (2.8)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Nitrofurantoin	4 (3.3)	3 (2.3)	7 (2.8)
Amoxicillin;clavulanic Acid	5 (4.1)	1 (0.8)	6 (2.4)
Clindamycin	2 (1.6)	4 (3.1)	6 (2.4)
Doxycycline Hyclate	5 (4.1)	1 (0.8)	6 (2.4)
Ciprofloxacin	1 (0.8)	4 (3.1)	5 (2.0)
Doxycycline	2 (1.6)	3 (2.3)	5 (2.0)
Amoxicillin;clavulanate Potassium	1 (0.8)	3 (2.3)	4 (1.6)
Cefalexin	2 (1.6)	2 (1.6)	4 (1.6)
Cefuroxime	4 (3.3)	0	4 (1.6)
Fosfomycin	1 (0.8)	3 (2.3)	4 (1.6)
Levofloxacin	2 (1.6)	2 (1.6)	4 (1.6)
Cefdinir	1 (0.8)	1 (0.8)	2 (0.8)
Ciprofloxacin Hydrochloride	2 (1.6)	0	2 (0.8)
Piperacillin Sodium;tazobactam Sodium	1 (0.8)	1 (0.8)	2 (0.8)
Sulfamethoxazole;trimethoprim	2 (1.6)	0	2 (0.8)
Amoxicillin Trihydrate	0	1 (0.8)	1 (0.4)
Cefazolin	1 (0.8)	0	1 (0.4)
Cefotaxime	1 (0.8)	0	1 (0.4)
Cefpodoxime	1 (0.8)	0	1 (0.4)
Ceftriaxone	0	1 (0.8)	1 (0.4)
Clarithromycin	0	1 (0.8)	1 (0.4)
Doxycycline Hydrochloride	0	1 (0.8)	1 (0.4)
Doxycycline Monohydrate	1 (0.8)	0	1 (0.4)
Fosfomycin Trometamol	1 (0.8)	0	1 (0.4)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Penicillin Nos	1 (0.8)	0	1 (0.4)
Phenoxymethylpenicillin	0	1 (0.8)	1 (0.4)
Vancomycin	1 (0.8)	0	1 (0.4)
Antibiotics And Chemotherapeutics For Dermatological Use	3 (2.4)	2 (1.6)	5 (2.0)
Bacitracin Zinc;neomycin Sulfate;polymyxin B Sulfate	1 (0.8)	0	1 (0.4)
Gentamicin	0	1 (0.8)	1 (0.4)
Metronidazole	1 (0.8)	0	1 (0.4)
Mupirocin	0	1 (0.8)	1 (0.4)
Sulfadiazine Silver	1 (0.8)	0	1 (0.4)
Antidiarrheals, Intestinal Antiinflammatory/Antiinfective Agents	5 (4.1)	3 (2.3)	8 (3.2)
Lactobacillus Acidophilus	1 (0.8)	1 (0.8)	2 (0.8)
Loperamide	2 (1.6)	0	2 (0.8)
Mesalazine	0	2 (1.6)	2 (0.8)
Lactobacillus Nos	1 (0.8)	0	1 (0.4)
Lactobacillus Reuteri	0	1 (0.8)	1 (0.4)
Loperamide Hydrochloride	1 (0.8)	0	1 (0.4)
Antiemetics And Antinauseants	4 (3.3)	4 (3.1)	8 (3.2)
Ondansetron	3 (2.4)	3 (2.3)	6 (2.4)
Granisetron	1 (0.8)	0	1 (0.4)
Hyoscine	0	1 (0.8)	1 (0.4)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Antiepileptics	3 (2.4)	3 (2.3)	6 (2.4)
Lamotrigine	1 (0.8)	1 (0.8)	2 (0.8)
Levetiracetam	0	1 (0.8)	1 (0.4)
Phenobarbital	1 (0.8)	0	1 (0.4)
Valproate Semisodium	1 (0.8)	0	1 (0.4)
Valproic Acid	0	1 (0.8)	1 (0.4)
Antifungals For Dermatological Use	0	2 (1.6)	2 (0.8)
Isoconazole	0	1 (0.8)	1 (0.4)
Ketoconazole	0	1 (0.8)	1 (0.4)
Antigout Preparations	5 (4.1)	10 (7.8)	15 (6.0)
Allopurinol	3 (2.4)	10 (7.8)	13 (5.2)
Colchicine	2 (1.6)	1 (0.8)	3 (1.2)
Antihemorrhagics	1 (0.8)	2 (1.6)	3 (1.2)
Etamsilate	0	1 (0.8)	1 (0.4)
Factor Ii (Prothrombin);factor Ix;factor Vii (Proconvertin);factor X (Stuart Prower Factor);protein C (Coagulation Inhibitor);protein S	1 (0.8)	0	1 (0.4)
Phytomenadione	0	1 (0.8)	1 (0.4)
Tranexamic Acid	1 (0.8)	0	1 (0.4)
Antihistamines For Systemic Use	19 (15.4)	24 (18.8)	43 (17.1)
Loratadine	4 (3.3)	4 (3.1)	8 (3.2)
Cetirizine Hydrochloride	3 (2.4)	4 (3.1)	7 (2.8)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Diphenhydramine	5 (4.1)	2 (1.6)	7 (2.8)
Cetirizine	2 (1.6)	4 (3.1)	6 (2.4)
Fexofenadine	3 (2.4)	2 (1.6)	5 (2.0)
Ebastine	1 (0.8)	3 (2.3)	4 (1.6)
Diphenhydramine Hydrochloride	0	3 (2.3)	3 (1.2)
Promethazine	2 (1.6)	0	2 (0.8)
Chlorphenamine	1 (0.8)	0	1 (0.4)
Doxylamine Succinate	1 (0.8)	0	1 (0.4)
Fexofenadine Hydrochloride	0	1 (0.8)	1 (0.4)
Meclozine	1 (0.8)	0	1 (0.4)
Mepyramine	0	1 (0.8)	1 (0.4)
Promethazine Hydrochloride	0	1 (0.8)	1 (0.4)
Antihypertensives	5 (4.1)	3 (2.3)	8 (3.2)
Clonidine	3 (2.4)	1 (0.8)	4 (1.6)
Doxazosin	2 (1.6)	0	2 (0.8)
Clonidine Hydrochloride	0	1 (0.8)	1 (0.4)
Rilmenidine Phosphate	1 (0.8)	0	1 (0.4)
Urapidil	0	1 (0.8)	1 (0.4)
Antiinflammatory And Antirheumatic Products	38 (30.9)	31 (24.2)	69 (27.5)
Ibuprofen	24 (19.5)	20 (15.6)	44 (17.5)
Naproxen Sodium	3 (2.4)	2 (1.6)	5 (2.0)
Ketorolac	2 (1.6)	2 (1.6)	4 (1.6)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Celecoxib	2 (1.6)	1 (0.8)	3 (1.2)
Indometacin	2 (1.6)	1 (0.8)	3 (1.2)
Meloxicam	3 (2.4)	0	3 (1.2)
Dexketoprofen	1 (0.8)	1 (0.8)	2 (0.8)
Dexketoprofen Trometamol	1 (0.8)	1 (0.8)	2 (0.8)
Ketoprofen	2 (1.6)	0	2 (0.8)
Naproxen	0	2 (1.6)	2 (0.8)
Chondroitin;glucosamine	1 (0.8)	0	1 (0.4)
Collagen	0	1 (0.8)	1 (0.4)
Curcumin	1 (0.8)	0	1 (0.4)
Diclofenac	0	1 (0.8)	1 (0.4)
Etodolac	0	1 (0.8)	1 (0.4)
Etoricoxib	1 (0.8)	0	1 (0.4)
Hydroxychloroquine Sulfate	0	1 (0.8)	1 (0.4)
Ketorolac Tromethamine	1 (0.8)	0	1 (0.4)
Morniflumate	0	1 (0.8)	1 (0.4)
Nimesulide	0	1 (0.8)	1 (0.4)
Sulfasalazine	0	1 (0.8)	1 (0.4)
Antimycotics For Systemic Use	3 (2.4)	0	3 (1.2)
Fluconazole	2 (1.6)	0	2 (0.8)
Amphotericin B	1 (0.8)	0	1 (0.4)
Nystatin	1 (0.8)	0	1 (0.4)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Antineoplastic Agents	0	1 (0.8)	1 (0.4)
Fluorouracil	0	1 (0.8)	1 (0.4)
Antiprotozoals	1 (0.8)	0	1 (0.4)
Atovaquone;proguanil	1 (0.8)	0	1 (0.4)
Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	3 (2.4)	3 (2.3)	6 (2.4)
Diphenhydramine Hydrochloride	1 (0.8)	1 (0.8)	2 (0.8)
Lidocaine	1 (0.8)	1 (0.8)	2 (0.8)
Diphenhydramine;zinc Acetate	1 (0.8)	0	1 (0.4)
Lidocaine;prilocaine	0	1 (0.8)	1 (0.4)
Antipsoriatics	2 (1.6)	0	2 (0.8)
Betamethasone Dipropionate;calcipotriol	1 (0.8)	0	1 (0.4)
Calcitriol	1 (0.8)	0	1 (0.4)
Antithrombotic Agents	43 (35.0)	56 (43.8)	99 (39.4)
Acetylsalicylic Acid	25 (20.3)	32 (25.0)	57 (22.7)
Rivaroxaban	8 (6.5)	11 (8.6)	19 (7.6)
Apixaban	4 (3.3)	13 (10.2)	17 (6.8)
Clopidogrel	2 (1.6)	1 (0.8)	3 (1.2)
Dabigatran	1 (0.8)	2 (1.6)	3 (1.2)
Dabigatran Etexilate Mesilate	2 (1.6)	1 (0.8)	3 (1.2)
Edoxaban	1 (0.8)	2 (1.6)	3 (1.2)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Enoxaparin	2 (1.6)	1 (0.8)	3 (1.2)
Heparin	2 (1.6)	1 (0.8)	3 (1.2)
Carbasalate Calcium	1 (0.8)	1 (0.8)	2 (0.8)
Warfarin	1 (0.8)	1 (0.8)	2 (0.8)
Acenocoumarol	0	1 (0.8)	1 (0.4)
Acetylsalicylic Acid;glycine	0	1 (0.8)	1 (0.4)
Bivalirudin	0	1 (0.8)	1 (0.4)
Clopidogrel Bisulfate	1 (0.8)	0	1 (0.4)
Dalteparin Sodium	1 (0.8)	0	1 (0.4)
Enoxaparin Sodium	1 (0.8)	0	1 (0.4)
Ticagrelor	1 (0.8)	0	1 (0.4)
Antivirals For Systemic Use	4 (3.3)	3 (2.3)	7 (2.8)
Valaciclovir	2 (1.6)	2 (1.6)	4 (1.6)
Oseltamivir Phosphate	1 (0.8)	1 (0.8)	2 (0.8)
Aciclovir	1 (0.8)	0	1 (0.4)
Beta Blocking Agents	97 (78.9)	96 (75.0)	193 (76.9)
Bisoprolol	27 (22.0)	20 (15.6)	47 (18.7)
Metoprolol Succinate	23 (18.7)	23 (18.0)	46 (18.3)
Metoprolol	23 (18.7)	22 (17.2)	45 (17.9)
Bisoprolol Fumarate	5 (4.1)	11 (8.6)	16 (6.4)
Metoprolol Tartrate	6 (4.9)	7 (5.5)	13 (5.2)
Atenolol	6 (4.9)	6 (4.7)	12 (4.8)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Carvedilol	2 (1.6)	4 (3.1)	6 (2.4)
Nadolol	3 (2.4)	2 (1.6)	5 (2.0)
Propranolol	4 (3.3)	1 (0.8)	5 (2.0)
Sotalol	1 (0.8)	2 (1.6)	3 (1.2)
Nebivolol Hydrochloride	0	2 (1.6)	2 (0.8)
Propranolol Hydrochloride	2 (1.6)	0	2 (0.8)
Amlodipine;bisoprolol Fumarate	1 (0.8)	0	1 (0.4)
Betaxolol Hydrochloride	0	1 (0.8)	1 (0.4)
Esmolol	1 (0.8)	0	1 (0.4)
Labetalol	1 (0.8)	0	1 (0.4)
Bile And Liver Therapy	0	1 (0.8)	1 (0.4)
Coenzyme A	0	1 (0.8)	1 (0.4)
Blood Substitutes And Perfusion Solutions	2 (1.6)	1 (0.8)	3 (1.2)
Sodium Chloride	2 (1.6)	1 (0.8)	3 (1.2)
Glucose	1 (0.8)	0	1 (0.4)
Magnesium Sulfate	1 (0.8)	0	1 (0.4)
Potassium Chloride	1 (0.8)	0	1 (0.4)
Calcium Channel Blockers	35 (28.5)	31 (24.2)	66 (26.3)
Verapamil	18 (14.6)	11 (8.6)	29 (11.6)
Amlodipine	4 (3.3)	8 (6.3)	12 (4.8)
Diltiazem Hydrochloride	3 (2.4)	4 (3.1)	7 (2.8)

Data Cutoff Date: 30JUN2020
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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Verapamil Hydrochloride	3 (2.4)	3 (2.3)	6 (2.4)
Diltiazem	3 (2.4)	2 (1.6)	5 (2.0)
Amlodipine Besilate	3 (2.4)	1 (0.8)	4 (1.6)
Lercanidipine	2 (1.6)	0	2 (0.8)
Nifedipine	0	2 (1.6)	2 (0.8)
Amlodipine Maleate	0	1 (0.8)	1 (0.4)
Calcium Homeostasis	0	1 (0.8)	1 (0.4)
Paricalcitol	0	1 (0.8)	1 (0.4)
Cardiac Therapy	9 (7.3)	12 (9.4)	21 (8.4)
Amiodarone	2 (1.6)	6 (4.7)	8 (3.2)
Amiodarone Hydrochloride	4 (3.3)	2 (1.6)	6 (2.4)
Dofetilide	1 (0.8)	1 (0.8)	2 (0.8)
Glyceryl Trinitrate	1 (0.8)	1 (0.8)	2 (0.8)
Isosorbide Mononitrate	1 (0.8)	1 (0.8)	2 (0.8)
Norepinephrine	2 (1.6)	0	2 (0.8)
Digoxin	0	1 (0.8)	1 (0.4)
Disopyramide Phosphate	1 (0.8)	0	1 (0.4)
Dobutamine Hydrochloride	1 (0.8)	0	1 (0.4)
Epinephrine	0	1 (0.8)	1 (0.4)
Magnesium Aspartate;potassium Aspartate	0	1 (0.8)	1 (0.4)
Ranolazine	1 (0.8)	0	1 (0.4)
Trimetazidine Hydrochloride	0	1 (0.8)	1 (0.4)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Corticosteroids For Systemic Use	13 (10.6)	12 (9.4)	25 (10.0)
Prednisone	9 (7.3)	8 (6.3)	17 (6.8)
Methylprednisolone	2 (1.6)	1 (0.8)	3 (1.2)
Cortisone	1 (0.8)	1 (0.8)	2 (0.8)
Beclometasone	0	1 (0.8)	1 (0.4)
Beclometasone Dipropionate	0	1 (0.8)	1 (0.4)
Betamethasone	1 (0.8)	0	1 (0.4)
Cortisone Acetate	1 (0.8)	0	1 (0.4)
Dexamethasone	1 (0.8)	0	1 (0.4)
Hydrocortisone	1 (0.8)	0	1 (0.4)
Prednisolone	0	1 (0.8)	1 (0.4)
Triamcinolone Acetonide	0	1 (0.8)	1 (0.4)
Triamcinolone Diacetate	0	1 (0.8)	1 (0.4)
Corticosteroids, Dermatological Preparations	9 (7.3)	4 (3.1)	13 (5.2)
Hydrocortisone	2 (1.6)	3 (2.3)	5 (2.0)
Clobetasol Propionate	3 (2.4)	0	3 (1.2)
Betamethasone	1 (0.8)	1 (0.8)	2 (0.8)
Clobetasol	1 (0.8)	0	1 (0.4)
Diflucortolone	0	1 (0.8)	1 (0.4)
Fluocinolone Acetonide	1 (0.8)	0	1 (0.4)
Hydrocortisone Butyrate	1 (0.8)	0	1 (0.4)
Mometasone Furoate	1 (0.8)	0	1 (0.4)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Triamcinolone	0	1 (0.8)	1 (0.4)
Cough And Cold Preparations	18 (14.6)	12 (9.4)	30 (12.0)
Guaifenesin	6 (4.9)	4 (3.1)	10 (4.0)
Benzonatate	4 (3.3)	2 (1.6)	6 (2.4)
Acetylcysteine	1 (0.8)	3 (2.3)	4 (1.6)
Codeine	4 (3.3)	0	4 (1.6)
Dextromethorphan Hydrobromide;guaifenesin	3 (2.4)	0	3 (1.2)
Dextromethorphan	1 (0.8)	1 (0.8)	2 (0.8)
Bromhexine Hydrochloride	1 (0.8)	0	1 (0.4)
Carbocisteine Lysine	1 (0.8)	0	1 (0.4)
Chlorphenamine Maleate;dextromethorphan Hydrobromide	0	1 (0.8)	1 (0.4)
Codeine Phosphate;guaifenesin	1 (0.8)	0	1 (0.4)
Codeine Phosphate;promethazine Hydrochloride	0	1 (0.8)	1 (0.4)
Dextromethorphan Hydrobromide;guaifenesin;pseudoephedrine Hydrochloride	1 (0.8)	0	1 (0.4)
Eucalyptus Globulus Oil;menthol	1 (0.8)	0	1 (0.4)
Menthol	0	1 (0.8)	1 (0.4)
Digestives, Incl. Enzymes	1 (0.8)	2 (1.6)	3 (1.2)
Tilactase	1 (0.8)	1 (0.8)	2 (0.8)
Enzyme Preparations	0	1 (0.8)	1 (0.4)
Diuretics	33 (26.8)	33 (25.8)	66 (26.3)
Furosemide	13 (10.6)	15 (11.7)	28 (11.2)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Spironolactone	6 (4.9)	11 (8.6)	17 (6.8)
Hydrochlorothiazide	9 (7.3)	7 (5.5)	16 (6.4)
Torasemide	2 (1.6)	5 (3.9)	7 (2.8)
Chlortalidone	2 (1.6)	2 (1.6)	4 (1.6)
Hydrochlorothiazide;triamterene	3 (2.4)	1 (0.8)	4 (1.6)
Eplerenone	2 (1.6)	1 (0.8)	3 (1.2)
Indapamide	1 (0.8)	1 (0.8)	2 (0.8)
Amiloride	1 (0.8)	0	1 (0.4)
Amiloride Hydrochloride Dihydrate	1 (0.8)	0	1 (0.4)
Drugs For Acid Related Disorders	35 (28.5)	40 (31.3)	75 (29.9)
Pantoprazole	15 (12.2)	18 (14.1)	33 (13.1)
Famotidine	5 (4.1)	6 (4.7)	11 (4.4)
Lansoprazole	5 (4.1)	5 (3.9)	10 (4.0)
Ranitidine	3 (2.4)	6 (4.7)	9 (3.6)
Calcium Carbonate	3 (2.4)	2 (1.6)	5 (2.0)
Omeprazole	3 (2.4)	2 (1.6)	5 (2.0)
Esomeprazole	2 (1.6)	2 (1.6)	4 (1.6)
Pantoprazole Sodium Sesquihydrate	3 (2.4)	1 (0.8)	4 (1.6)
Aluminium Hydroxide;magnesium Hydroxide	1 (0.8)	2 (1.6)	3 (1.2)
Ranitidine Hydrochloride	1 (0.8)	2 (1.6)	3 (1.2)
Bismuth Subsalicylate	1 (0.8)	1 (0.8)	2 (0.8)
Aluminium Hydroxide;calcium Carbonate;sodium Alginate;sodium Bicarbonate	1 (0.8)	0	1 (0.4)
Aluminium Hydroxide;magnesium Carbonate	1 (0.8)	0	1 (0.4)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Aluminium Hydroxide;magnesium Hydroxide;simeticone	0	1 (0.8)	1 (0.4)
Aluminium Silicate	1 (0.8)	0	1 (0.4)
Calcium Carbonate;sodium Alginate;sodium Bicarbonate	0	1 (0.8)	1 (0.4)
Dexlansoprazole	0	1 (0.8)	1 (0.4)
Rabeprazole	0	1 (0.8)	1 (0.4)
Sodium Alginate;sodium Bicarbonate	1 (0.8)	0	1 (0.4)
Sucralfate	1 (0.8)	0	1 (0.4)
Drugs For Constipation	6 (4.9)	2 (1.6)	8 (3.2)
Bisacodyl	2 (1.6)	0	2 (0.8)
Docusate Sodium	1 (0.8)	1 (0.8)	2 (0.8)
Lactitol Monohydrate	1 (0.8)	0	1 (0.4)
Lactulose	1 (0.8)	0	1 (0.4)
Lubiprostone	1 (0.8)	0	1 (0.4)
Macrogol 3350	1 (0.8)	0	1 (0.4)
Psyllium Hydrophilic Mucilloid	0	1 (0.8)	1 (0.4)
Sodium Picosulfate	1 (0.8)	0	1 (0.4)
Drugs For Functional Gastrointestinal Disorders	1 (0.8)	5 (3.9)	6 (2.4)
Simeticone	0	2 (1.6)	2 (0.8)
Atropine Sulfate;codeine Phosphate;papaverine Hydrochloride;paracetamol	1 (0.8)	0	1 (0.4)
Butylscopolamine	0	1 (0.8)	1 (0.4)
Cinitapride	0	1 (0.8)	1 (0.4)
Hyoscyamine	0	1 (0.8)	1 (0.4)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Metoclopramide Hydrochloride	1 (0.8)	0	1 (0.4)
Drugs For Obstructive Airway Diseases	19 (15.4)	15 (11.7)	34 (13.5)
Salbutamol	8 (6.5)	6 (4.7)	14 (5.6)
Montelukast	6 (4.9)	1 (0.8)	7 (2.8)
Fluticasone	3 (2.4)	2 (1.6)	5 (2.0)
Budesonide;formoterol Fumarate	3 (2.4)	1 (0.8)	4 (1.6)
Budesonide	0	3 (2.3)	3 (1.2)
Fluticasone Furoate;vilanterol Trifenatate	2 (1.6)	1 (0.8)	3 (1.2)
Ipratropium	0	2 (1.6)	2 (0.8)
Levosalbutamol	2 (1.6)	0	2 (0.8)
Salbutamol Sulfate	0	2 (1.6)	2 (0.8)
Tiotropium Bromide	1 (0.8)	1 (0.8)	2 (0.8)
Umeclidinium Bromide	1 (0.8)	1 (0.8)	2 (0.8)
Beclometasone	0	1 (0.8)	1 (0.4)
Beclometasone Dipropionate	1 (0.8)	0	1 (0.4)
Budesonide;formoterol	1 (0.8)	0	1 (0.4)
Ciclesonide	1 (0.8)	0	1 (0.4)
Fenoterol	0	1 (0.8)	1 (0.4)
Fluticasone Propionate	0	1 (0.8)	1 (0.4)
Fluticasone Propionate;salmeterol Xinafoate	1 (0.8)	0	1 (0.4)
Formoterol	0	1 (0.8)	1 (0.4)
Formoterol Fumarate;mometasone Furoate	0	1 (0.8)	1 (0.4)
Salmeterol	1 (0.8)	0	1 (0.4)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Salmeterol Xinafoate	1 (0.8)	0	1 (0.4)
Terbutaline Sulfate	1 (0.8)	0	1 (0.4)
Tiotropium	0	1 (0.8)	1 (0.4)
Drugs For Treatment Of Bone Diseases	2 (1.6)	0	2 (0.8)
Denosumab	1 (0.8)	0	1 (0.4)
Ibandronate Sodium	1 (0.8)	0	1 (0.4)
Drugs Used In Diabetes	12 (9.8)	12 (9.4)	24 (9.6)
Metformin	5 (4.1)	9 (7.0)	14 (5.6)
Metformin Hydrochloride	3 (2.4)	1 (0.8)	4 (1.6)
Vildagliptin	1 (0.8)	1 (0.8)	2 (0.8)
Canagliflozin	1 (0.8)	0	1 (0.4)
Dapagliflozin Propanediol Monohydrate	0	1 (0.8)	1 (0.4)
Empagliflozin	1 (0.8)	0	1 (0.4)
Gliclazide	1 (0.8)	0	1 (0.4)
Glimepiride	0	1 (0.8)	1 (0.4)
Glipizide	1 (0.8)	0	1 (0.4)
Insulin Glargine	1 (0.8)	0	1 (0.4)
Insulin Human	1 (0.8)	0	1 (0.4)
Insulin Lispro	0	1 (0.8)	1 (0.4)
Liraglutide	1 (0.8)	0	1 (0.4)
Metformin Hydrochloride;vildagliptin	0	1 (0.8)	1 (0.4)
Semaglutide	1 (0.8)	0	1 (0.4)

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Concomitant Medication
Safety Analysis (SAF) population

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Sitagliptin	0	1 (0.8)	1 (0.4)
Sitagliptin Phosphate	1 (0.8)	0	1 (0.4)
Emollients And Protectives	1 (0.8)	1 (0.8)	2 (0.8)
Paraffin	0	1 (0.8)	1 (0.4)
Salicylic Acid;urea	1 (0.8)	0	1 (0.4)
General Nutrients	5 (4.1)	6 (4.7)	11 (4.4)
Fish Oil	3 (2.4)	6 (4.7)	9 (3.6)
Lysine	2 (1.6)	0	2 (0.8)
Gynecological Antiinfectives And Antiseptics	3 (2.4)	0	3 (1.2)
Clotrimazole	3 (2.4)	0	3 (1.2)
Homeopathic Preparation	0	1 (0.8)	1 (0.4)
Sambucus Nigra	0	1 (0.8)	1 (0.4)
Immune Sera And Immunoglobulins	0	1 (0.8)	1 (0.4)
Immunoglobulin Human Normal	0	1 (0.8)	1 (0.4)
Immunosuppressants	2 (1.6)	8 (6.3)	10 (4.0)
Mycophenolate Sodium	1 (0.8)	2 (1.6)	3 (1.2)
Tacrolimus	1 (0.8)	2 (1.6)	3 (1.2)
Adalimumab	0	2 (1.6)	2 (0.8)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Methotrexate	1 (0.8)	1 (0.8)	2 (0.8)
Apremilast	0	1 (0.8)	1 (0.4)
Hydroxychloroquine	0	1 (0.8)	1 (0.4)
Infliximab	1 (0.8)	0	1 (0.4)
Ixekizumab	0	1 (0.8)	1 (0.4)
Vedolizumab	0	1 (0.8)	1 (0.4)
Lipid Modifying Agents	57 (46.3)	61 (47.7)	118 (47.0)
Atorvastatin	25 (20.3)	23 (18.0)	48 (19.1)
Simvastatin	9 (7.3)	11 (8.6)	20 (8.0)
Atorvastatin Calcium	4 (3.3)	10 (7.8)	14 (5.6)
Rosuvastatin	8 (6.5)	6 (4.7)	14 (5.6)
Rosuvastatin Calcium	8 (6.5)	3 (2.3)	11 (4.4)
Ezetimibe	1 (0.8)	5 (3.9)	6 (2.4)
Fenofibrate	2 (1.6)	4 (3.1)	6 (2.4)
Fish Oil	4 (3.3)	0	4 (1.6)
Pravastatin	2 (1.6)	2 (1.6)	4 (1.6)
Omega-3 Fatty Acids	2 (1.6)	1 (0.8)	3 (1.2)
Lovastatin	0	2 (1.6)	2 (0.8)
Berberine	0	1 (0.8)	1 (0.4)
Bezafibrate	1 (0.8)	0	1 (0.4)
Docosahexaenoic Acid;eicosapentaenoic Acid	0	1 (0.8)	1 (0.4)
Eicosapentaenoic Acid Ethyl Ester	1 (0.8)	0	1 (0.4)
Fluvastatin	0	1 (0.8)	1 (0.4)

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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Omega-3-Acid Ethyl Ester	1 (0.8)	0	1 (0.4)
Other Lipid Modifying Agents	1 (0.8)	0	1 (0.4)
Pitavastatin	0	1 (0.8)	1 (0.4)
Mineral Supplements	26 (21.1)	29 (22.7)	55 (21.9)
Potassium Chloride	11 (8.9)	8 (6.3)	19 (7.6)
Magnesium	4 (3.3)	9 (7.0)	13 (5.2)
Potassium	0	6 (4.7)	6 (2.4)
Calcium	3 (2.4)	1 (0.8)	4 (1.6)
Calcium Carbonate	3 (2.4)	1 (0.8)	4 (1.6)
Magnesium Oxide	2 (1.6)	2 (1.6)	4 (1.6)
Calcium;vitamin D Nos	1 (0.8)	2 (1.6)	3 (1.2)
Calcium;colecalciferol	2 (1.6)	0	2 (0.8)
Calcium;magnesium;zinc	0	2 (1.6)	2 (0.8)
Magnesium Aspartate;potassium Aspartate	1 (0.8)	1 (0.8)	2 (0.8)
Magnesium Citrate	1 (0.8)	1 (0.8)	2 (0.8)
Potassium Citrate	1 (0.8)	1 (0.8)	2 (0.8)
Calcium Carbonate;colecalciferol	1 (0.8)	0	1 (0.4)
Calcium Citrate;colecalciferol	0	1 (0.8)	1 (0.4)
Calcium Citrate;vitamin D Nos	1 (0.8)	0	1 (0.4)
Chromium Picolinate	0	1 (0.8)	1 (0.4)
Magnesium Aspartate	0	1 (0.8)	1 (0.4)
Minerals Nos;vitamins Nos	1 (0.8)	0	1 (0.4)

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The concomitant medication is defined as the medication having a stop date on or after the first dose or it is still ongoing at the time of data cut.
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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Muscle Relaxants	2 (1.6)	2 (1.6)	4 (1.6)
Cyclobenzaprine	1 (0.8)	1 (0.8)	2 (0.8)
Baclofen	1 (0.8)	0	1 (0.4)
Cyclobenzaprine Hydrochloride	0	1 (0.8)	1 (0.4)
Metaxalone	0	1 (0.8)	1 (0.4)
Nasal Preparations	11 (8.9)	7 (5.5)	18 (7.2)
Fluticasone	5 (4.1)	2 (1.6)	7 (2.8)
Fluticasone Propionate	2 (1.6)	3 (2.3)	5 (2.0)
Azelastine	0	1 (0.8)	1 (0.4)
Azelastine Hydrochloride	1 (0.8)	0	1 (0.4)
Ipratropium Bromide	1 (0.8)	0	1 (0.4)
Mometasone	0	1 (0.8)	1 (0.4)
Olopatadine Hydrochloride	1 (0.8)	0	1 (0.4)
Phenylephrine	0	1 (0.8)	1 (0.4)
Pseudoephedrine Hydrochloride	1 (0.8)	0	1 (0.4)
Sodium Chloride	1 (0.8)	0	1 (0.4)
Triamcinolone Acetonide	1 (0.8)	0	1 (0.4)
Ophthalmologicals	12 (9.8)	8 (6.3)	20 (8.0)
Ciclosporin	2 (1.6)	1 (0.8)	3 (1.2)
Brimonidine Tartrate	1 (0.8)	1 (0.8)	2 (0.8)
Ofloxacin	1 (0.8)	1 (0.8)	2 (0.8)
Artificial Tears [umbrella Term]	1 (0.8)	0	1 (0.4)

Data Cutoff Date: 30JUN2020
Note: Subjects may have more than one medication per preferred term per ATC class.
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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Ascorbic Acid;colecalciferol;fish Oil;thioctic Acid;tocopherol;tocopherols Mixed;xantofyl;zeaxanthin	0	1 (0.8)	1 (0.4)
Ascorbic Acid;cupric Oxide;dl-Alpha Tocopheryl Acetate;xantofyl;zeaxanthin;zinc Oxide	0	1 (0.8)	1 (0.4)
Azelastine Hydrochloride	1 (0.8)	0	1 (0.4)
Bimatoprost	1 (0.8)	0	1 (0.4)
Ciprofloxacin Hydrochloride	1 (0.8)	0	1 (0.4)
Dexamethasone	1 (0.8)	0	1 (0.4)
Dexamethasone Sodium Phosphate	0	1 (0.8)	1 (0.4)
Dexamethasone Sodium Phosphate;framycetin Sulfate	1 (0.8)	0	1 (0.4)
Dexamethasone;tobramycin	1 (0.8)	0	1 (0.4)
Dorzolamide Hydrochloride;timolol Maleate	1 (0.8)	0	1 (0.4)
Fluorometholone	1 (0.8)	0	1 (0.4)
Glycerol;hypromellose;macrogol	0	1 (0.8)	1 (0.4)
Gramicidin;neomycin Sulfate;polymyxin B Sulfate	1 (0.8)	0	1 (0.4)
Ketorolac	0	1 (0.8)	1 (0.4)
Ketotifen Fumarate	1 (0.8)	0	1 (0.4)
Latanoprost	1 (0.8)	0	1 (0.4)
Moxifloxacin	0	1 (0.8)	1 (0.4)
Naphazoline;pheniramine	1 (0.8)	0	1 (0.4)
Prednisolone Acetate	0	1 (0.8)	1 (0.4)
Prednisolone Sodium Phosphate	1 (0.8)	0	1 (0.4)
Tafluprost	1 (0.8)	0	1 (0.4)
Timolol Hemihydrate	1 (0.8)	0	1 (0.4)
Timolol Maleate;travoprost	0	1 (0.8)	1 (0.4)
Travoprost	0	1 (0.8)	1 (0.4)

Data Cutoff Date: 30JUN2020
Note: Subjects may have more than one medication per preferred term per ATC class.
At each level of subject summarization, a subject is counted only once if the subject reported the same medication multiple times.
Concomitant medications were coded with the WHO Drug dictionary version 2018.03.
The concomitant medication is defined as the medication having a stop date on or after the first dose or it is still ongoing at the time of data cut.
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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Xantofyl	0	1 (0.8)	1 (0.4)
Other Alimentary Tract And Metabolism Products	5 (4.1)	7 (5.5)	12 (4.8)
Ubidecarenone	1 (0.8)	3 (2.3)	4 (1.6)
Probiotics Nos	2 (1.6)	1 (0.8)	3 (1.2)
Sodium Bicarbonate	1 (0.8)	1 (0.8)	2 (0.8)
Bromelains;superoxide Dismutase;vitamin D Nos	1 (0.8)	0	1 (0.4)
Levoglutamide	0	1 (0.8)	1 (0.4)
Ubiquinol	1 (0.8)	0	1 (0.4)
Zinc	0	1 (0.8)	1 (0.4)
Other Dermatological Preparations	1 (0.8)	0	1 (0.4)
Tretinoin	1 (0.8)	0	1 (0.4)
Other Drugs For Disorders Of The Musculo-Skeletal System	1 (0.8)	0	1 (0.4)
Hyaluronic Acid	1 (0.8)	0	1 (0.4)
Other Nervous System Drugs	3 (2.4)	1 (0.8)	4 (1.6)
Betahistine	2 (1.6)	1 (0.8)	3 (1.2)
Acetylleucine	1 (0.8)	0	1 (0.4)
Other Respiratory System Products	3 (2.4)	1 (0.8)	4 (1.6)
Oxygen	2 (1.6)	1 (0.8)	3 (1.2)
Caffeine	1 (0.8)	0	1 (0.4)

Data Cutoff Date: 30JUN2020
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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Otologicals	0	1 (0.8)	1 (0.4)
Ciprofloxacin	0	1 (0.8)	1 (0.4)
Pancreatic Hormones	0	1 (0.8)	1 (0.4)
Glucagon	0	1 (0.8)	1 (0.4)
Peripheral Vasodilators	1 (0.8)	1 (0.8)	2 (0.8)
Iloprost	1 (0.8)	0	1 (0.4)
Pentoxifylline	0	1 (0.8)	1 (0.4)
Psychoanaleptics	14 (11.4)	19 (14.8)	33 (13.1)
Citalopram	1 (0.8)	3 (2.3)	4 (1.6)
Escitalopram	1 (0.8)	3 (2.3)	4 (1.6)
Sertraline Hydrochloride	2 (1.6)	2 (1.6)	4 (1.6)
Escitalopram Oxalate	2 (1.6)	1 (0.8)	3 (1.2)
Paroxetine	3 (2.4)	0	3 (1.2)
Sertraline	1 (0.8)	2 (1.6)	3 (1.2)
Venlafaxine Hydrochloride	1 (0.8)	2 (1.6)	3 (1.2)
Mirtazapine	1 (0.8)	1 (0.8)	2 (0.8)
Trazodone	0	2 (1.6)	2 (0.8)
Venlafaxine	1 (0.8)	1 (0.8)	2 (0.8)
Amitriptyline	0	1 (0.8)	1 (0.4)
Bupropion	0	1 (0.8)	1 (0.4)

Data Cutoff Date: 30JUN2020
Note: Subjects may have more than one medication per preferred term per ATC class.
At each level of subject summarization, a subject is counted only once if the subject reported the same medication multiple times.
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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Desvenlafaxine	0	1 (0.8)	1 (0.4)
Duloxetine	0	1 (0.8)	1 (0.4)
Ginkgo Biloba;vinpocetine	1 (0.8)	0	1 (0.4)
Methylphenidate	1 (0.8)	0	1 (0.4)
Methylphenidate Hydrochloride	0	1 (0.8)	1 (0.4)
Piracetam	1 (0.8)	0	1 (0.4)
Trazodone Hydrochloride	1 (0.8)	0	1 (0.4)
Psycholeptics	34 (27.6)	23 (18.0)	57 (22.7)
Lorazepam	8 (6.5)	4 (3.1)	12 (4.8)
Melatonin	8 (6.5)	3 (2.3)	11 (4.4)
Alprazolam	3 (2.4)	6 (4.7)	9 (3.6)
Zolpidem	5 (4.1)	2 (1.6)	7 (2.8)
Bromazepam	2 (1.6)	4 (3.1)	6 (2.4)
Diazepam	2 (1.6)	3 (2.3)	5 (2.0)
Zolpidem Tartrate	2 (1.6)	3 (2.3)	5 (2.0)
Clonazepam	3 (2.4)	1 (0.8)	4 (1.6)
Zaleplon	2 (1.6)	0	2 (0.8)
Buspirone	1 (0.8)	0	1 (0.4)
Buspirone Hydrochloride	0	1 (0.8)	1 (0.4)
Diphenhydramine Hydrochloride	0	1 (0.8)	1 (0.4)
Ethyl Loflazepate	1 (0.8)	0	1 (0.4)
Flurazepam	1 (0.8)	0	1 (0.4)
Haloperidol	1 (0.8)	0	1 (0.4)

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Note: Subjects may have more than one medication per preferred term per ATC class.
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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Lormetazepam	0	1 (0.8)	1 (0.4)
Mexazolam	1 (0.8)	0	1 (0.4)
Midazolam	0	1 (0.8)	1 (0.4)
Oxazepam	0	1 (0.8)	1 (0.4)
Sex Hormones And Modulators Of The Genital System	5 (4.1)	7 (5.5)	12 (4.8)
Estradiol	0	3 (2.3)	3 (1.2)
Desogestrel	2 (1.6)	0	2 (0.8)
Testosterone	0	2 (1.6)	2 (0.8)
Drospirenone;ethinylestradiol	0	1 (0.8)	1 (0.4)
Estriol	0	1 (0.8)	1 (0.4)
Ethinylestradiol;gestodene	1 (0.8)	0	1 (0.4)
Progesterone	0	1 (0.8)	1 (0.4)
Promestriene	1 (0.8)	0	1 (0.4)
Raloxifene Hydrochloride	1 (0.8)	0	1 (0.4)
Stomatological Preparations	0	2 (1.6)	2 (0.8)
Chlorhexidine Gluconate	0	1 (0.8)	1 (0.4)
Phenol	0	1 (0.8)	1 (0.4)
Thyroid Therapy	15 (12.2)	6 (4.7)	21 (8.4)
Levothyroxine	7 (5.7)	2 (1.6)	9 (3.6)
Levothyroxine Sodium	7 (5.7)	1 (0.8)	8 (3.2)
Levothyroxine;liothyronine	0	2 (1.6)	2 (0.8)

Data Cutoff Date: 30JUN2020
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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Potassium Iodide	0	1 (0.8)	1 (0.4)
Thiamazole	1 (0.8)	0	1 (0.4)
Tonics	1 (0.8)	2 (1.6)	3 (1.2)
Dietary Supplement	1 (0.8)	1 (0.8)	2 (0.8)
N,n-Dimethylglycine	0	1 (0.8)	1 (0.4)
Topical Products For Joint And Muscular Pain	2 (1.6)	3 (2.3)	5 (2.0)
Diclofenac	2 (1.6)	2 (1.6)	4 (1.6)
Menthol;methyl Salicylate	0	1 (0.8)	1 (0.4)
Unspecified Herbal And Traditional Medicine	6 (4.9)	9 (7.0)	15 (6.0)
Unspecified Herbal And Traditional Medicine	1 (0.8)	4 (3.1)	5 (2.0)
Krill Oil	1 (0.8)	2 (1.6)	3 (1.2)
Linum Usitatissimum Seed Oil	1 (0.8)	2 (1.6)	3 (1.2)
Curcuma Longa Rhizome	0	2 (1.6)	2 (0.8)
Herbal Preparation	1 (0.8)	1 (0.8)	2 (0.8)
Aloe Vera	0	1 (0.8)	1 (0.4)
Cinnamomum Verum	0	1 (0.8)	1 (0.4)
Gentiana Lutea Root;primula Spp. Flower;rumex Spp. Herb;sambucus Nigra Flower;verbena Officinalis Herb	0	1 (0.8)	1 (0.4)
Plantago Afra	1 (0.8)	0	1 (0.4)
Plantago Ovata Husk	1 (0.8)	0	1 (0.4)
Sambucus Nigra	1 (0.8)	0	1 (0.4)
Sambucus Nigra;zinc	0	1 (0.8)	1 (0.4)

Data Cutoff Date: 30JUN2020
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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Serenoa Repens	0	1 (0.8)	1 (0.4)
Spirulina Spp.	1 (0.8)	0	1 (0.4)
Thymus Vulgaris	1 (0.8)	0	1 (0.4)
Urtica Dioica	1 (0.8)	0	1 (0.4)
Urologicals	13 (10.6)	10 (7.8)	23 (9.2)
Tamsulosin	3 (2.4)	2 (1.6)	5 (2.0)
Finasteride	2 (1.6)	1 (0.8)	3 (1.2)
Sildenafil Citrate	2 (1.6)	1 (0.8)	3 (1.2)
Mirabegron	1 (0.8)	1 (0.8)	2 (0.8)
Silodosin	0	2 (1.6)	2 (0.8)
Tadalafil	1 (0.8)	1 (0.8)	2 (0.8)
Tamsulosin Hydrochloride	1 (0.8)	1 (0.8)	2 (0.8)
Tolterodine L-Tartrate	2 (1.6)	0	2 (0.8)
Alfuzosin	1 (0.8)	0	1 (0.4)
Dutasteride	0	1 (0.8)	1 (0.4)
Sildenafil	1 (0.8)	0	1 (0.4)
Solifenacin Succinate;tamsulosin Hydrochloride	1 (0.8)	0	1 (0.4)
Tolterodine	0	1 (0.8)	1 (0.4)
Vardenafil	0	1 (0.8)	1 (0.4)
Vaccines	10 (8.1)	7 (5.5)	17 (6.8)
Influenza Vaccine	5 (4.1)	5 (3.9)	10 (4.0)
Influenza Vaccine Inact Split Virion 4v	1 (0.8)	1 (0.8)	2 (0.8)

Data Cutoff Date: 30JUN2020
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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Pneumococcal Vaccine Conj 13v (Crm197)	0	2 (1.6)	2 (0.8)
Varicella Zoster Vaccine	2 (1.6)	0	2 (0.8)
Varicella Zoster Vaccine Rge (Cho)	2 (1.6)	0	2 (0.8)
Diphtheria Vaccine;pertussis Vaccine;tetanus Vaccine	1 (0.8)	0	1 (0.4)
Influenza Vaccine Inact	1 (0.8)	0	1 (0.4)
Pneumococcal Vaccine	0	1 (0.8)	1 (0.4)
Tetanus Vaccine	1 (0.8)	0	1 (0.4)
Vasoprotectives	0	1 (0.8)	1 (0.4)
Glyceryl Trinitrate	0	1 (0.8)	1 (0.4)
Lidocaine Hydrochloride;pentosan Polysulfate Sodium;triamcinolone Acetonide	0	1 (0.8)	1 (0.4)
Vitamins	36 (29.3)	38 (29.7)	74 (29.5)
Colecalciferol	14 (11.4)	15 (11.7)	29 (11.6)
Vitamins Nos	11 (8.9)	15 (11.7)	26 (10.4)
Ascorbic Acid	3 (2.4)	9 (7.0)	12 (4.8)
Biotin	5 (4.1)	1 (0.8)	6 (2.4)
Minerals Nos;vitamins Nos	3 (2.4)	2 (1.6)	5 (2.0)
Multivitamins With Minerals [umbrella Term]	3 (2.4)	2 (1.6)	5 (2.0)
Vitamin D Nos	4 (3.3)	1 (0.8)	5 (2.0)
Vitamin E Nos	1 (0.8)	3 (2.3)	4 (1.6)
Calcifediol	2 (1.6)	1 (0.8)	3 (1.2)
Ascorbic Acid;betacarotene;cupric Oxide;tocopheryl Acetate;zinc Oxide	1 (0.8)	1 (0.8)	2 (0.8)
Calcitriol	0	2 (1.6)	2 (0.8)

Data Cutoff Date: 30JUN2020
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Concomitant Medication
Safety Analysis (SAF) population

ATC Class Level 2 Preferred Term	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Overall (N = 251) n (%)
Vitamin B Complex	1 (0.8)	1 (0.8)	2 (0.8)
Ascorbic Acid;betacarotene;biotin;calcium Pantothenate;calcium Phosphate Dibasic;chromium Picolinate;colecalciferol;cupric Oxide;cyanocobalamin;ferrous Fumarate;folic Acid;magnesium Oxide;manganese	0	1 (0.8)	1 (0.4)
Ascorbic Acid;biotin;folic Acid;mecobalamin;nicotinic Acid;pantothenic Acid;pyridoxine Hydrochloride;riboflavin;thiamine	0	1 (0.8)	1 (0.4)
Calcium Ascorbate	1 (0.8)	0	1 (0.4)
Cod-Liver Oil	0	1 (0.8)	1 (0.4)
Colecalciferol;menaquinone-7	1 (0.8)	0	1 (0.4)
Ergocalciferol	0	1 (0.8)	1 (0.4)
Multivitamins, Other Combinations	0	1 (0.8)	1 (0.4)
Pyridoxine Hydrochloride	0	1 (0.8)	1 (0.4)
Retinol;tocopheryl Acetate	1 (0.8)	0	1 (0.4)
Sodium Ascorbate	0	1 (0.8)	1 (0.4)
Tocopheryl Acetate	0	1 (0.8)	1 (0.4)
Vitamin B Nos	1 (0.8)	0	1 (0.4)
Vitamins With Minerals	1 (0.8)	0	1 (0.4)
Vitamins, Other Combinations	0	1 (0.8)	1 (0.4)

Data Cutoff Date: 30JUN2020
Note: Subjects may have more than one medication per preferred term per ATC class.
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4.4 Analysen für den Endpunkt klinisches Ansprechen

4.4.1 Subgruppenanalyse für den Anteil an Patient:innen mit klinischem Ansprechen zu Woche 30

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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
SUBJECTS WITH CLINICAL RESPONSE (A)								
OVERALL	123	45 (36.6)	128	22 (17.2)	2.13 (1.36, 3.32) 0.0009	2.78 (1.49, 5.26) 0.0006	19.40 (8.67, 30.13) 0.0004	
BETA-BLOCKER USE								0.0101*
YES	94	28 (29.8)	95	20 (21.1)	1.41 (0.86, 2.33) 0.1719	1.59 (0.78, 3.27) 0.1843	8.73 (-3.62, 21.09) 0.1659	
NO	29	17 (58.6)	33	2 (6.1)	9.67 (2.44, 38.36) 0.0012	21.96 (4.01, 211.73) <0.0001	52.56 (32.87, 72.25) <0.0001	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
TYPE OF EXERCISE TESTING								0.1513
EXERCISE BICYCLE	55	15 (27.3)	58	11 (19.0)	1.44 (0.72, 2.85) 0.2986	1.60 (0.61, 4.32) 0.3725	8.31 (-7.20, 23.81) 0.2936	
TREADMILL	68	30 (44.1)	70	11 (15.7)	2.81 (1.53, 5.14) 0.0008	4.23 (1.79, 10.43) 0.0003	28.40 (13.84, 42.96) 0.0001	
NYHA CLASS								0.6127
CLASS II	88	29 (33.0)	95	16 (16.8)	1.96 (1.14, 3.35) 0.0143	2.43 (1.15, 5.23) 0.0157	16.11 (3.74, 28.49) 0.0107	
CLASS III	35	16 (45.7)	33	6 (18.2)	2.51 (1.12, 5.65) 0.0255	3.79 (1.12, 13.85) 0.0202	27.53 (6.42, 48.64) 0.0106	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CONSENT FOR THE CMR SUBSTUDY								0.2911
YES	20	5 (25.0)	24	1 (4.2)	6.00 (0.76, 47.24) 0.0888	7.67 (0.72, 377.98) 0.0773	20.83 (0.24, 41.43) 0.0474	
NO	103	40 (38.8)	104	21 (20.2)	1.92 (1.22, 3.02) 0.0046	2.51 (1.29, 4.93) 0.0038	18.64 (6.47, 30.81) 0.0027	
SEX								0.4033
FEMALE	57	19 (33.3)	45	5 (11.1)	3.00 (1.21, 7.41) 0.0173	4.00 (1.26, 14.91) 0.0099	22.22 (6.92, 37.52) 0.0044	
MALE	66	26 (39.4)	83	17 (20.5)	1.92 (1.14, 3.23) 0.0135	2.52 (1.15, 5.59) 0.0174	18.91 (4.27, 33.55) 0.0113	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
AGE								0.4023
<= 49	27	10 (37.0)	25	6 (24.0)	1.54 (0.66, 3.62) 0.3191	1.86 (0.48, 7.59) 0.3758	13.04 (-11.70, 37.78) 0.3017	
50 - 64	51	21 (41.2)	63	13 (20.6)	2.00 (1.11, 3.58) 0.0206	2.69 (1.09, 6.74) 0.0234	20.54 (3.74, 37.34) 0.0166	
>= 65	45	14 (31.1)	40	3 (7.5)	4.15 (1.28, 13.39) 0.0173	5.57 (1.35, 32.35) 0.0073	23.61 (7.81, 39.41) 0.0034	
BMI								0.7542
<30	77	35 (45.5)	77	16 (20.8)	2.19 (1.33, 3.61) 0.0022	3.18 (1.48, 6.94) 0.0019	24.68 (10.33, 39.02) 0.0007	
>=30	46	10 (21.7)	51	6 (11.8)	1.85 (0.73, 4.68) 0.1958	2.08 (0.61, 7.62) 0.2734	9.97 (-4.87, 24.82) 0.1878	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
RACE								0.3722
NON-WHITE	8	3 (37.5)	14	1 (7.1)	5.25 (0.65, 42.44) 0.1199	7.80 (0.44, 440.03) 0.1167	30.36 (-5.80, 66.52) 0.0999	
WHITE	115	42 (36.5)	114	21 (18.4)	1.98 (1.26, 3.13) 0.0032	2.55 (1.34, 4.93) 0.0029	18.10 (6.78, 29.42) 0.0017	
REGION								0.5974
US	53	17 (32.1)	55	7 (12.7)	2.52 (1.14, 5.58) 0.0227	3.24 (1.12, 10.16) 0.0205	19.35 (4.00, 34.69) 0.0135	
EX-US	70	28 (40.0)	73	15 (20.5)	1.95 (1.14, 3.32) 0.0146	2.58 (1.16, 5.85) 0.0172	19.45 (4.70, 34.20) 0.0098	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CALCIUM CHANNEL BLOCKER USE								0.2251
YES	25	13 (52.0)	17	2 (11.8)	4.42 (1.14, 17.14) 0.0316	8.13 (1.35, 83.77) 0.0097	40.24 (15.37, 65.10) 0.0015	
NO	98	32 (32.7)	111	20 (18.0)	1.81 (1.11, 2.95) 0.0170	2.21 (1.11, 4.44) 0.0166	14.64 (2.92, 26.35) 0.0144	
PRESENCE OF HCM PATHOGENIC MUTATION								0.9513
PATHOGENIC OR LIKELY PATHOGENIC	28	16 (57.1)	22	6 (27.3)	2.10 (0.99, 4.45) 0.0545	3.56 (0.93, 14.34) 0.0470	29.87 (3.75, 55.99) 0.0250	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	32	13 (40.6)	43	8 (18.6)	2.18 (1.03, 4.63) 0.0419	2.99 (0.94, 9.82) 0.0420	22.02 (1.41, 42.63) 0.0363	
NEGATIVE	30	6 (20.0)	35	4 (11.4)	1.75 (0.54, 5.62) 0.3474	1.94 (0.40, 10.33) 0.4931	8.57 (-9.20, 26.35) 0.3446	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
TIME FROM DIAGNOSIS OF OHCM (Years)								0.1712
<=5	65	24 (36.9)	55	13 (23.6)	1.56 (0.88, 2.77) 0.1261	1.89 (0.79, 4.61) 0.1646	13.29 (-2.95, 29.53) 0.1088	
>5	58	21 (36.2)	73	9 (12.3)	2.94 (1.46, 5.92) 0.0026	4.04 (1.56, 11.00) 0.0016	23.88 (9.39, 38.36) 0.0012	
SEPTAL REDUCTION THERAPY(SRT) HISTORY								0.7520
YES	11	4 (36.4)	8	1 (12.5)	2.91 (0.40, 21.35) 0.2937	4.00 (0.27, 224.60) 0.3378	23.86 (-12.65, 60.38) 0.2002	
NO	112	41 (36.6)	120	21 (17.5)	2.09 (1.32, 3.31) 0.0016	2.72 (1.43, 5.27) 0.0011	19.11 (7.89, 30.32) 0.0008	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
IMPLANTABLE CARDIOVERTERDEFIBRILLATOR (ICD) IMPLANTED								0.0490*
YES	27	11 (40.7)	29	10 (34.5)	1.18 (0.60, 2.33) 0.6293	1.31 (0.39, 4.44) 0.7833	6.26 (-19.09, 31.61) 0.6285	
NO	96	34 (35.4)	99	12 (12.1)	2.92 (1.61, 5.30) 0.0004	3.98 (1.82, 9.07) 0.0002	23.30 (11.77, 34.82) <0.0001	
HISTORY OF HYPERTENSION								0.9078
YES	60	19 (31.7)	59	9 (15.3)	2.08 (1.02, 4.21) 0.0429	2.57 (0.98, 7.14) 0.0509	16.41 (1.49, 31.34) 0.0311	
NO	63	26 (41.3)	69	13 (18.8)	2.19 (1.24, 3.88) 0.0072	3.03 (1.30, 7.24) 0.0071	22.43 (7.17, 37.69) 0.0040	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
RESTING LVEF								0.7153
<75%	69	25 (36.2)	70	11 (15.7)	2.31 (1.23, 4.31) 0.0089	3.05 (1.27, 7.58) 0.0068	20.52 (6.33, 34.71) 0.0046	
>=75%	54	20 (37.0)	58	11 (19.0)	1.95 (1.03, 3.69) 0.0390	2.51 (0.99, 6.58) 0.0370	18.07 (1.71, 34.43) 0.0304	
LVOT RESTING PEAK GRADIENT (mmHg)								0.3337
<=50	60	18 (30.0)	67	12 (17.9)	1.68 (0.88, 3.18) 0.1153	1.96 (0.79, 4.98) 0.1433	12.09 (-2.70, 26.88) 0.1091	
>50	63	27 (42.9)	61	10 (16.4)	2.61 (1.39, 4.93) 0.0030	3.83 (1.54, 9.91) 0.0016	26.46 (11.11, 41.81) 0.0007	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
LVOT RESTING PEAK GRADIENT (mmHg)								0.8725
<=30	35	12 (34.3)	41	7 (17.1)	2.01 (0.89, 4.54) 0.0939	2.53 (0.77, 8.73) 0.1126	17.21 (-2.28, 36.70) 0.0835	
>30	88	33 (37.5)	87	15 (17.2)	2.18 (1.28, 3.71) 0.0043	2.88 (1.36, 6.27) 0.0038	20.26 (7.40, 33.12) 0.0020	
E/E' LATERAL								0.8358
<=14	56	22 (39.3)	67	11 (16.4)	2.39 (1.27, 4.50) 0.0067	3.29 (1.32, 8.45) 0.0074	22.87 (7.30, 38.43) 0.0040	
>14	62	22 (35.5)	55	9 (16.4)	2.17 (1.09, 4.30) 0.0268	2.81 (1.08, 7.71) 0.0221	19.12 (3.71, 34.53) 0.0150	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
E/E' SEPTAL								0.5496
<=14	17	10 (58.8)	28	6 (21.4)	2.75 (1.22, 6.19) 0.0149	5.24 (1.17, 24.21) 0.0229	37.39 (9.50, 65.29) 0.0086	
>14	106	35 (33.0)	99	16 (16.2)	2.04 (1.21, 3.45) 0.0076	2.56 (1.25, 5.36) 0.0060	16.86 (5.34, 28.38) 0.0041	
E/E' AVERAGE								0.6320
<=14	26	14 (53.8)	33	7 (21.2)	2.54 (1.20, 5.36) 0.0146	4.33 (1.22, 15.95) 0.0138	32.63 (8.93, 56.33) 0.0070	
>14	97	31 (32.0)	95	15 (15.8)	2.02 (1.17, 3.50) 0.0116	2.51 (1.19, 5.42) 0.0110	16.17 (4.34, 28.00) 0.0074	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
LEFT ATRIAL VOLUME INDEX								0.5807
<=MEDIAN	60	15 (25.0)	65	9 (13.8)	1.81 (0.85, 3.82) 0.1217	2.07 (0.76, 5.88) 0.1719	11.15 (-2.65, 24.96) 0.1133	
>MEDIAN	62	30 (48.4)	63	13 (20.6)	2.34 (1.36, 4.06) 0.0023	3.61 (1.54, 8.65) 0.0014	27.75 (11.80, 43.71) 0.0007	
NT-PROBNP								0.4824
<=MEDIAN	55	18 (32.7)	68	13 (19.1)	1.71 (0.92, 3.18) 0.0885	2.06 (0.83, 5.15) 0.0976	13.61 (-1.92, 29.14) 0.0858	
>MEDIAN	65	24 (36.9)	58	9 (15.5)	2.38 (1.21, 4.69) 0.0124	3.19 (1.25, 8.63) 0.0084	21.41 (6.42, 36.39) 0.0051	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
HS-CARDIAC TROPONIN-I								0.3716
<=ULN	88	33 (37.5)	96	14 (14.6)	2.57 (1.48, 4.48) 0.0008	3.51 (1.64, 7.75) 0.0006	22.92 (10.58, 35.25) 0.0003	
>ULN	32	11 (34.4)	23	5 (21.7)	1.58 (0.64, 3.93) 0.3244	1.89 (0.48, 8.20) 0.3766	12.64 (-10.92, 36.19) 0.2931	
E/E' LATERAL >14 OR HS-CARDIACTROPONIN >ULN VS OTHERS								0.8612
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	41	13 (31.7)	55	8 (14.5)	2.18 (1.00, 4.77) 0.0509	2.73 (0.91, 8.53) 0.0506	17.16 (0.14, 34.18) 0.0481	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	78	30 (38.5)	62	10 (16.1)	2.38 (1.27, 4.49) 0.0071	3.25 (1.36, 8.22) 0.0046	22.33 (8.18, 36.49) 0.0020	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
E/E' SEPTAL >14 OR HS-CARDIACTROPONIN >ULN VS OTHERS								0.9542
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	14	7 (50.0)	22	5 (22.7)	2.20 (0.87, 5.59) 0.0972	3.40 (0.64, 18.47) 0.1478	27.27 (-4.23, 58.78) 0.0898	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	109	38 (34.9)	104	17 (16.3)	2.13 (1.29, 3.53) 0.0033	2.74 (1.37, 5.61) 0.0028	18.52 (7.09, 29.94) 0.0015	
E/E' AVERAGE >14 OR HS-CARDIACTROPONIN >ULN VS OTHERS								0.9045
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	21	10 (47.6)	24	5 (20.8)	2.29 (0.93, 5.62) 0.0717	3.45 (0.79, 16.08) 0.1116	26.79 (-0.05, 53.62) 0.0504	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	102	35 (34.3)	100	16 (16.0)	2.14 (1.27, 3.62) 0.0043	2.74 (1.34, 5.76) 0.0034	18.31 (6.63, 30.00) 0.0021	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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Comparison Between Mavacamten and Placebo Groups in Clinical Response at Week 30 across Subgroups
Intention-to-treat (ITT) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CREATININE CLEARANCE (CRCL) (mL/min)								0.6616
<60	14	5 (35.7)	16	2 (12.5)	2.86 (0.65, 12.48) 0.1629	3.89 (0.48, 47.02) 0.2040	23.21 (-6.66, 53.09) 0.1278	
>=60	108	39 (36.1)	112	20 (17.9)	2.02 (1.26, 3.23) 0.0033	2.60 (1.34, 5.13) 0.0024	18.25 (6.75, 29.76) 0.0019	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) Clinical response is defined as either: Type 1: pVO2 improved >=1.5 mL/kg/min and NYHA improved by >=1 or Type 2: pVO2 improved by >=3 and no worsening in NYHA class. Missing NYHA class at Week30 is imputed using available NYHA class at week 26. After the imputation, the subjects whose response status at Week 30 is still missing will be classified as nonresponders. The subgroups by stratification factors were determined using the data in eCRF.
The subgroup by HCM gene mutation was determined using the current test results.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochrane's Q heterogeneity test.
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4.5 Analysen für den Endpunkt maximale Belastungszeit

4.5.1 Subgruppenanalyse für die Veränderung der maximalen Belastungszeit zu Woche 30 gegenüber Baseline mittels ANCOVA

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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Peak Exercise Time Change from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
PEAK EXERCISE TIME (MIN)									
BETA-BLOCKER USE									0.0138*
YES	91	9.81 (3.938)	0.50 (0.05, 0.95)	94	10.42 (4.168)	0.21 (-0.23, 0.65)	0.29 (-0.34, 0.92) 0.3576	0.13 (-0.15, 0.42)	
NO	29	10.81 (4.281)	1.88 (1.08, 2.67)	31	10.47 (3.797)	-0.02 (-0.79, 0.75)	1.90 (0.79, 3.00) 0.0008	0.86 (0.33, 1.39)	
TYPE OF EXERCISE TESTING									0.1940
EXERCISE BICYCLE	53	8.99 (3.255)	0.35 (-0.25, 0.95)	57	9.04 (2.969)	0.08 (-0.50, 0.66)	0.27 (-0.55, 1.09) 0.5199	0.12 (-0.25, 0.50)	
TREADMILL	67	10.89 (4.391)	1.22 (0.69, 1.74)	68	11.59 (4.494)	0.21 (-0.32, 0.74)	1.00 (0.26, 1.75) 0.0085	0.45 (0.11, 0.79)	

Data Cutoff Date: 30JUN2020. CPET=Cardiopulmonary Exercise Testing.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
Subjects with missing baseline or missing week 30 were excluded from this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Peak Exercise Time Change from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
NYHA CLASS									0.8685
CLASS II	85	10.87 (3.874)	0.93 (0.46, 1.41)	93	11.09 (3.646)	0.27 (-0.19, 0.72)	0.67 (0.02, 1.32) 0.0448	0.30 (0.00, 0.60)	
CLASS III	35	8.07 (3.742)	0.59 (-0.16, 1.34)	32	8.52 (4.645)	-0.19 (-0.96, 0.59)	0.77 (-0.29, 1.83) 0.1536	0.34 (-0.14, 0.83)	
CONSENT FOR THE CMR SUBSTUDY									0.1034
YES	20	11.02 (4.171)	-0.07 (-1.04, 0.89)	21	10.26 (3.693)	0.26 (-0.68, 1.20)	-0.34 (-1.68, 1.01) 0.6246	-0.15 (-0.76, 0.46)	
NO	100	9.86 (3.992)	1.02 (0.59, 1.45)	104	10.47 (4.151)	0.13 (-0.30, 0.55)	0.89 (0.29, 1.50) 0.0040	0.40 (0.13, 0.68)	

Data Cutoff Date: 30JUN2020. CPET=Cardiopulmonary Exercise Testing.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
Subjects with missing baseline or missing week 30 were excluded from this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
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Protocol: MYK-461-005

Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Peak Exercise Time Change from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
SEX									0.9898
MALE	65	11.92 (3.445)	0.93 (0.37, 1.48)	82	11.84 (3.705)	0.22 (-0.28, 0.72)	0.71 (-0.01, 1.43) 0.0549	0.32 (-0.01, 0.64)	
FEMALE	55	7.84 (3.537)	0.72 (0.11, 1.34)	43	7.75 (3.331)	0.02 (-0.67, 0.71)	0.70 (-0.19, 1.59) 0.1206	0.31 (-0.09, 0.71)	
AGE									0.4201
<= 49	26	11.54 (4.047)	1.85 (1.01, 2.70)	24	11.79 (4.157)	0.65 (-0.23, 1.53)	1.20 (-0.01, 2.41) 0.0510	0.54 (-0.02, 1.11)	
50 - 64	49	11.22 (3.533)	0.61 (-0.00, 1.23)	62	10.65 (3.961)	0.31 (-0.23, 0.86)	0.30 (-0.52, 1.12) 0.4720	0.14 (-0.24, 0.51)	
>=65	45	7.92 (3.669)	0.48 (-0.18, 1.13)	39	9.25 (3.949)	-0.41 (-1.09, 0.28)	0.88 (-0.06, 1.82) 0.0663	0.40 (-0.04, 0.83)	

Data Cutoff Date: 30JUN2020. CPET=Cardiopulmonary Exercise Testing.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
Subjects with missing baseline or missing week 30 were excluded from this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Peak Exercise Time Change from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
BMI									0.1726
<30	75	10.18 (4.220)	1.13 (0.64, 1.63)	76	10.13 (4.094)	0.15 (-0.34, 0.65)	0.98 (0.28, 1.68) 0.0064	0.44 (0.12, 0.77)	
>=30	45	9.83 (3.722)	0.33 (-0.31, 0.98)	49	10.89 (4.016)	0.14 (-0.48, 0.76)	0.19 (-0.70, 1.09) 0.6739	0.09 (-0.32, 0.49)	
RACE									0.7751
NON-WHITE	8	9.37 (3.755)	1.11 (-0.43, 2.65)	14	11.86 (4.103)	0.67 (-0.49, 1.84)	0.44 (-1.49, 2.37) 0.6554	0.19 (-0.68, 1.06)	
WHITE	112	10.10 (4.058)	0.82 (0.40, 1.23)	111	10.25 (4.042)	0.08 (-0.33, 0.50)	0.73 (0.15, 1.31) 0.0140	0.33 (0.06, 0.59)	

Data Cutoff Date: 30JUN2020. CPET=Cardiopulmonary Exercise Testing.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
Subjects with missing baseline or missing week 30 were excluded from this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
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Protocol: MYK-461-005

Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Peak Exercise Time Change from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
REGION									0.3108
US	50	10.70 (4.078)	0.58 (-0.03, 1.20)	53	11.26 (4.008)	0.23 (-0.37, 0.84)	0.35 (-0.51, 1.21) 0.4221	0.16 (-0.23, 0.54)	
EX-US	70	9.59 (3.956)	1.01 (0.49, 1.54)	72	9.82 (4.024)	0.09 (-0.43, 0.60)	0.93 (0.20, 1.66) 0.0127	0.42 (0.08, 0.75)	
CALCIUM CHANNEL BLOCKER USE									0.0128*
YES	25	10.60 (4.219)	1.98 (1.13, 2.84)	16	10.45 (4.154)	-0.25 (-1.31, 0.82)	2.23 (0.86, 3.59) 0.0015	1.00 (0.34, 1.67)	
NO	95	9.91 (3.987)	0.53 (0.09, 0.97)	109	10.43 (4.071)	0.21 (-0.20, 0.62)	0.32 (-0.28, 0.92) 0.2881	0.15 (-0.13, 0.42)	

Data Cutoff Date: 30JUN2020. CPET=Cardiopulmonary Exercise Testing.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
Subjects with missing baseline or missing week 30 were excluded from this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
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Protocol: MYK-461-005

Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Peak Exercise Time Change from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
PRESENCE OF HCM PATHOGENIC MUTATION									0.4358
PATHOGENIC OR LIKELY PATHOGENIC	27	9.14 (3.223)	1.51 (0.69, 2.33)	22	10.44 (5.283)	0.55 (-0.36, 1.45)	0.96 (-0.26, 2.18) 0.1224	0.44 (-0.13, 1.01)	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	32	10.88 (4.046)	1.06 (0.31, 1.81)	42	10.73 (3.882)	-0.04 (-0.69, 0.62)	1.09 (0.10, 2.08) 0.0316	0.50 (0.03, 0.97)	
NEGATIVE	29	8.85 (3.957)	0.30 (-0.49, 1.10)	34	10.40 (4.132)	0.12 (-0.60, 0.85)	0.18 (-0.90, 1.26) 0.7416	0.08 (-0.41, 0.58)	
TIME FROM DIAGNOSIS OF OHCM									0.0504
<=5	65	10.64 (4.365)	0.69 (0.15, 1.22)	54	10.14 (3.908)	0.60 (0.01, 1.18)	0.09 (-0.70, 0.89) 0.8204	0.04 (-0.32, 0.40)	
>5	55	9.36 (3.503)	1.01 (0.43, 1.60)	71	10.65 (4.194)	-0.19 (-0.70, 0.32)	1.21 (0.43, 1.99) 0.0026	0.54 (0.18, 0.90)	

Data Cutoff Date: 30JUN2020. CPET=Cardiopulmonary Exercise Testing.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
Subjects with missing baseline or missing week 30 were excluded from this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-ocpetrsub.sas 06APR2023:04:26

Protocol: MYK-461-005

Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Peak Exercise Time Change from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
SEPTAL REDUCTION THERAPY (SRT) HISTORY									0.6868
YES	11	9.05 (3.739)	0.89 (-0.43, 2.20)	8	9.39 (4.385)	0.61 (-0.93, 2.15)	0.28 (-1.74, 2.30) 0.7839	0.12 (-0.79, 1.03)	
NO	109	10.15 (4.058)	0.83 (0.41, 1.25)	117	10.50 (4.052)	0.12 (-0.28, 0.52)	0.71 (0.13, 1.29) 0.0162	0.32 (0.06, 0.58)	
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED									0.1555
YES	27	9.15 (3.702)	1.78 (0.95, 2.61)	29	11.22 (4.290)	0.35 (-0.45, 1.15)	1.43 (0.27, 2.58) 0.0158	0.64 (0.10, 1.18)	
NO	93	10.31 (4.100)	0.56 (0.12, 1.01)	96	10.19 (3.986)	0.09 (-0.35, 0.53)	0.48 (-0.15, 1.10) 0.1345	0.22 (-0.07, 0.50)	

Data Cutoff Date: 30JUN2020. CPET=Cardiopulmonary Exercise Testing.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
Subjects with missing baseline or missing week 30 were excluded from this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-ocpetrsub.sas 06APR2023:04:26

Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Peak Exercise Time Change from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
HISTORY OF HYPERTENSION									0.1011
YES	60	9.36 (3.743)	0.43 (-0.13, 0.99)	58	9.43 (3.905)	0.21 (-0.36, 0.78)	0.22 (-0.58, 1.01) 0.5893	0.10 (-0.26, 0.46)	
NO	60	10.74 (4.213)	1.24 (0.68, 1.80)	67	11.30 (4.029)	0.10 (-0.43, 0.63)	1.14 (0.37, 1.91) 0.0038	0.51 (0.16, 0.87)	
RESTING LVEF									0.9819
<75%	68	11.03 (4.106)	0.86 (0.33, 1.39)	67	11.07 (4.195)	0.18 (-0.35, 0.72)	0.68 (-0.07, 1.43) 0.0761	0.30 (-0.04, 0.64)	
>=75%	52	8.77 (3.574)	0.80 (0.19, 1.41)	58	9.69 (3.810)	0.11 (-0.46, 0.68)	0.69 (-0.14, 1.52) 0.1041	0.31 (-0.07, 0.68)	

Data Cutoff Date: 30JUN2020. CPET=Cardiopulmonary Exercise Testing.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
Subjects with missing baseline or missing week 30 were excluded from this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Peak Exercise Time Change from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
LVOT RESTING PEAK GRADIENT									0.7091
<=50	59	10.53 (4.409)	0.60 (0.04, 1.17)	65	11.12 (4.006)	0.03 (-0.51, 0.57)	0.57 (-0.21, 1.36) 0.1487	0.26 (-0.10, 0.61)	
>50	61	9.59 (3.599)	1.06 (0.50, 1.62)	60	9.69 (4.028)	0.28 (-0.29, 0.84)	0.78 (-0.00, 1.57) 0.0511	0.35 (-0.01, 0.71)	
LVOT RESTING PEAK GRADIENT									0.6811
<=30	34	10.40 (4.637)	0.56 (-0.18, 1.31)	39	11.85 (4.199)	-0.29 (-0.99, 0.41)	0.85 (-0.17, 1.87) 0.1006	0.38 (-0.08, 0.84)	
>30	86	9.91 (3.782)	0.95 (0.48, 1.41)	86	9.79 (3.857)	0.35 (-0.12, 0.81)	0.60 (-0.06, 1.26) 0.0747	0.27 (-0.03, 0.57)	

Data Cutoff Date: 30JUN2020. CPET=Cardiopulmonary Exercise Testing.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
Subjects with missing baseline or missing week 30 were excluded from this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Peak Exercise Time Change from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
E/E' LATERAL									0.3361
<=14	54	11.22 (3.728)	1.07 (0.49, 1.66)	65	11.05 (3.942)	0.11 (-0.42, 0.64)	0.97 (0.18, 1.75) 0.0163	0.44 (0.08, 0.81)	
>14	61	9.09 (3.957)	0.54 (-0.01, 1.09)	55	9.58 (4.209)	0.12 (-0.46, 0.70)	0.42 (-0.38, 1.21) 0.3005	0.19 (-0.17, 0.56)	
E/E' SEPTAL									0.2251
<=14	16	11.54 (4.272)	1.85 (0.77, 2.93)	27	12.15 (3.896)	0.37 (-0.46, 1.21)	1.48 (0.12, 2.84) 0.0336	0.66 (0.02, 1.29)	
>14	104	9.82 (3.961)	0.68 (0.25, 1.10)	97	10.00 (4.001)	0.12 (-0.32, 0.56)	0.56 (-0.05, 1.16) 0.0729	0.25 (-0.03, 0.53)	

Data Cutoff Date: 30JUN2020. CPET=Cardiopulmonary Exercise Testing.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
Subjects with missing baseline or missing week 30 were excluded from this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Peak Exercise Time Change from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
E/E' AVERAGE									0.2330
<=14	25	11.41 (3.838)	1.46 (0.59, 2.33)	32	12.00 (3.621)	0.14 (-0.63, 0.92)	1.32 (0.16, 2.47) 0.0259	0.59 (0.05, 1.12)	
>14	95	9.69 (4.020)	0.67 (0.22, 1.12)	93	9.89 (4.086)	0.15 (-0.30, 0.60)	0.52 (-0.12, 1.15) 0.1087	0.23 (-0.05, 0.52)	
LEFT ATRIAL VOLUME INDEX									0.6266
<=MEDIAN	59	9.93 (4.501)	0.54 (-0.03, 1.10)	62	10.69 (4.181)	-0.03 (-0.58, 0.53)	0.56 (-0.23, 1.35) 0.1633	0.25 (-0.11, 0.61)	
>MEDIAN	60	10.11 (3.547)	1.15 (0.60, 1.71)	63	10.17 (3.963)	0.32 (-0.23, 0.87)	0.83 (0.05, 1.62) 0.0363	0.38 (0.02, 0.73)	

Data Cutoff Date: 30JUN2020. CPET=Cardiopulmonary Exercise Testing.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
Subjects with missing baseline or missing week 30 were excluded from this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Peak Exercise Time Change from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
NT-PROBNP									0.3066
<=MEDIAN	54	11.10 (4.133)	0.69 (0.09, 1.28)	66	11.08 (3.974)	0.33 (-0.21, 0.87)	0.36 (-0.44, 1.16) 0.3800	0.16 (-0.20, 0.52)	
>MEDIAN	63	9.21 (3.810)	0.97 (0.41, 1.52)	57	9.70 (4.088)	0.02 (-0.56, 0.60)	0.95 (0.15, 1.74) 0.0205	0.42 (0.06, 0.78)	
HS-CARDIAC TROPONIN-I									0.4835
<=ULN	85	10.13 (4.084)	0.97 (0.51, 1.43)	94	10.84 (4.202)	0.02 (-0.41, 0.46)	0.95 (0.32, 1.58) 0.0035	0.44 (0.14, 0.73)	
>ULN	32	9.87 (4.048)	0.68 (-0.07, 1.42)	23	8.84 (3.172)	0.20 (-0.69, 1.08)	0.48 (-0.68, 1.63) 0.4151	0.22 (-0.32, 0.76)	

Data Cutoff Date: 30JUN2020. CPET=Cardiopulmonary Exercise Testing.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
Subjects with missing baseline or missing week 30 were excluded from this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-ocpetrsub.sas 06APR2023:04:26

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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Peak Exercise Time Change from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.3312
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	39	11.43 (3.698)	1.10 (0.42, 1.78)	54	11.22 (4.040)	0.05 (-0.53, 0.63)	1.05 (0.16, 1.94) 0.0211	0.48 (0.06, 0.90)	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	77	9.46 (3.946)	0.65 (0.17, 1.14)	62	9.51 (4.083)	0.17 (-0.37, 0.71)	0.48 (-0.24, 1.20) 0.1894	0.22 (-0.11, 0.56)	
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.2249
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	13	12.07 (4.535)	1.74 (0.53, 2.95)	22	12.42 (3.888)	0.14 (-0.80, 1.07)	1.60 (0.09, 3.12) 0.0378	0.71 (0.00, 1.42)	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	107	9.81 (3.915)	0.72 (0.30, 1.14)	102	9.94 (3.947)	0.12 (-0.30, 0.55)	0.60 (0.00, 1.20) 0.0498	0.27 (-0.00, 0.54)	

Data Cutoff Date: 30JUN2020. CPET=Cardiopulmonary Exercise Testing.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
Subjects with missing baseline or missing week 30 were excluded from this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-ocpetrsub.sas 06APR2023:04:26

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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Peak Exercise Time Change from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.1906
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	20	11.74 (3.894)	1.56 (0.59, 2.52)	24	12.22 (3.783)	0.09 (-0.80, 0.97)	1.47 (0.17, 2.77) 0.0266	0.66 (0.05, 1.27)	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	100	9.71 (3.988)	0.69 (0.26, 1.12)	98	9.90 (4.019)	0.17 (-0.26, 0.61)	0.52 (-0.09, 1.12) 0.0972	0.23 (-0.04, 0.51)	
CREATININE CLEARANCE (CRCL)									0.0691
<60	14	8.18 (3.228)	1.55 (0.38, 2.71)	16	9.77 (4.372)	-0.51 (-1.60, 0.57)	2.06 (0.47, 3.65) 0.0113	0.90 (0.15, 1.66)	
>=60	105	10.29 (4.089)	0.74 (0.31, 1.16)	109	10.53 (4.030)	0.25 (-0.17, 0.66)	0.49 (-0.10, 1.08) 0.1049	0.22 (-0.05, 0.49)	

Data Cutoff Date: 30JUN2020. CPET=Cardiopulmonary Exercise Testing.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
Subjects with missing baseline or missing week 30 were excluded from this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
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4.5.2 Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Baseline

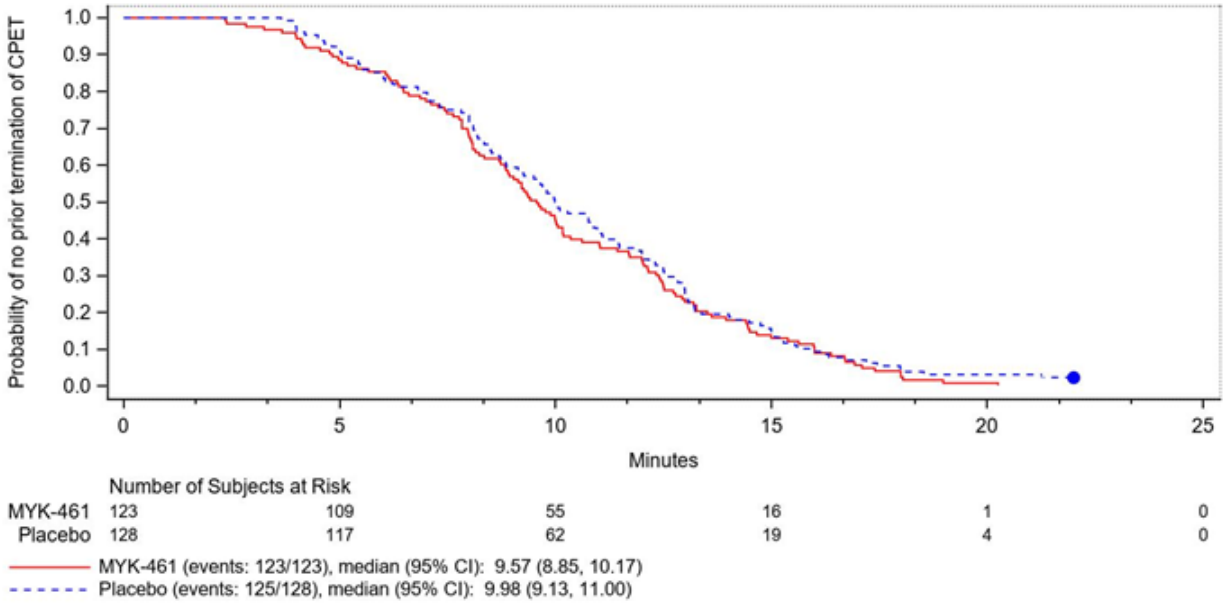

Abbildung 4-1: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Baseline

4.5.3 Subgruppenanalyse für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 mittels Ereigniszeitanalyse

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Main Analysis: Time to Termination of CPET at Week 30, Subgroup Analyses
Intention-to-treat (ITT) Population

Subgroup	Mavacamten (N = 123) N	Mavacamten (N = 123) Subjects with Event n (%) (A)	Mavacamten (N = 123) KME (95% CI)	Placebo (N = 128) N	Placebo (N = 128) Subjects with Event n (%) (A)	Placebo (N = 128) KME (95% CI)	Mavacamten vs Placebo HR (95% CI) p-value (B)	Test for Interaction p-value (C)
BETA-BLOCKER USE								0.0004*
YES	91	90 (98.9)	9.98 (9.35, 10.47)	94	92 (97.9)	9.43 (8.77, 10.00)	0.82 (0.61, 1.11) 0.1948	
NO	29	27 (93.1)	12.75 (11.65, 13.98)	31	31 (100.0)	9.43 (8.62, 10.23)	0.27 (0.16, 0.47) <0.0001	
TYPE OF EXERCISE TESTING								0.2441
EXERCISE BICYCLE	53	53 (100.0)	8.75 (8.15, 9.85)	57	57 (100.0)	8.15 (7.83, 8.77)	0.74 (0.51, 1.08) 0.1187	
TREADMILL	67	64 (95.5)	12.43 (11.65, 13.55)	68	66 (97.1)	10.77 (10.02, 11.72)	0.54 (0.38, 0.78) 0.0010	

Data Cutoff Date: 30JUN2020. HR = hazard ratio; KME = Kaplan-Meier estimate; CPET=Cardiopulmonary Exercise Testing.
(A) Event: patients with prior termination of CPET. If a patient completed CPET it will be right-censored at 22 minutes.
(B) HR, 95% CI and p value use unstratified Cox proportional hazards model with treatment, subgroup and treatment*subgroup interaction and baseline peak exercise time as covariates.
(C) p-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Denominator is based on patients with non-missing peak exercise time at baseline and week 30.
Program Source: BMS_GMA\MyK_MMA2\IAB50008\Biostatistics\Production\Tables\EBR567_AddendumII\rt-ef-tttsubrmain.sas 02MAR2023:00:11

Protocol: MYK-461-005

Main Analysis: Time to Termination of CPET at Week 30, Subgroup Analyses
Intention-to-treat (ITT) Population

Subgroup	Mavacamten (N = 123) N	Subjects with Event n (%) (A)	KME (95% CI)	Placebo (N = 128) N	Subjects with Event n (%) (A)	KME (95% CI)	Mavacamten vs Placebo HR (95% CI) p-value (B)	Test for Interaction p-value (C)
NYHA CLASS								0.0593
CLASS II	85	82 (96.5)	11.17 (10.40, 11.98)	93	92 (98.9)	10.15 (9.92, 11.00)	0.71 (0.52, 0.96) 0.0273	
CLASS III	35	35 (100.0)	8.75 (8.13, 9.93)	32	31 (96.9)	7.28 (6.63, 8.00)	0.41 (0.24, 0.68) 0.0005	
CONSENT FOR THE CMR SUBSTUDY								0.0040*
YES	20	20 (100.0)	9.43 (8.48, 10.48)	21	21 (100.0)	10.15 (9.35, 11.72)	1.47 (0.79, 2.74) 0.2244	
NO	100	97 (97.0)	10.65 (10.02, 11.63)	104	102 (98.1)	9.30 (8.67, 9.93)	0.52 (0.39, 0.71) <0.0001	

Data Cutoff Date: 30JUN2020. HR = hazard ratio; KME = Kaplan-Meier estimate; CPET=Cardiopulmonary Exercise Testing.
(A) Event: patients with prior termination of CPET. If a patient completed CPET it will be right-censored at 22 minutes.
(B) HR, 95% CI and p value use unstratified Cox proportional hazards model with treatment, subgroup and treatment*subgroup interaction and baseline peak exercise time as covariates.
(C) p-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Denominator is based on patients with non-missing peak exercise time at baseline and week 30.
Program Source: BMS_GMA\MyK_MMA2\IAB50008\Biostatistics\Production\Tables\EBR567_AddendumII\rt-ef-tttsubrmain.sas 02MAR2023:00:11

Protocol: MYK-461-005

Main Analysis: Time to Termination of CPET at Week 30, Subgroup Analyses
Intention-to-treat (ITT) Population

Subgroup	Mavacamten (N = 123) N	Subjects with Event n (%) (A)	KME (95% CI)	Placebo (N = 128) N	Subjects with Event n (%) (A)	KME (95% CI)	Mavacamten vs Placebo HR (95% CI) p-value (B)	Test for Interaction p-value (C)
SEX								0.5097
MALE	65	62 (95.4)	12.13 (11.55, 13.00)	82	80 (97.6)	11.05 (10.33, 11.87)	0.66 (0.47, 0.93) 0.0173	
FEMALE	55	55 (100.0)	8.47 (8.00, 9.22)	43	43 (100.0)	7.55 (7.00, 8.13)	0.55 (0.37, 0.84) 0.0051	
AGE								0.1689
<= 49	26	24 (92.3)	13.00 (12.05, 14.38)	24	23 (95.8)	11.58 (10.33, 12.57)	0.51 (0.28, 0.91) 0.0237	
50 - 64	49	49 (100.0)	10.33 (9.88, 11.35)	62	61 (98.4)	10.00 (9.35, 10.53)	0.84 (0.57, 1.23) 0.3617	
>= 65	45	44 (97.8)	9.20 (8.47, 10.00)	39	39 (100.0)	7.87 (7.23, 8.48)	0.50 (0.32, 0.79) 0.0031	

Data Cutoff Date: 30JUN2020. HR = hazard ratio; KME = Kaplan-Meier estimate; CPET=Cardiopulmonary Exercise Testing.
(A) Event: patients with prior termination of CPET. If a patient completed CPET it will be right-censored at 22 minutes.
(B) HR, 95% CI and p value use unstratified Cox proportional hazards model with treatment, subgroup and treatment*subgroup interaction and baseline peak exercise time as covariates.
(C) p-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Denominator is based on patients with non-missing peak exercise time at baseline and week 30.
Program Source: BMS_GMA\MyK_MMA2\IAB50008\Biostatistics\Production\Tables\EBR567_AddendumII\rt-ef-tttsubrmain.sas 02MAR2023:00:11

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Main Analysis: Time to Termination of CPET at Week 30, Subgroup Analyses
Intention-to-treat (ITT) Population

Subgroup	Mavacamten (N = 123) N	Subjects with Event n (%) (A)	KME (95% CI)	Placebo (N = 128) N	Subjects with Event n (%) (A)	KME (95% CI)	Mavacamten vs Placebo HR (95% CI) p-value (B)	Test for Interaction p-value (C)
BMI								0.0023*
<30	75	73 (97.3)	11.00 (10.12, 11.83)	76	75 (98.7)	9.00 (8.48, 9.92)	0.45 (0.32, 0.64) <0.0001	
>=30	45	44 (97.8)	9.93 (9.18, 10.53)	49	48 (98.0)	10.00 (9.30, 10.77)	1.06 (0.70, 1.60) 0.7959	
RACE								0.1974
NON-WHITE	8	7 (87.5)	10.77 (9.22, 13.55)	14	13 (92.9)	11.08 (9.93, 12.82)	1.11 (0.43, 2.86) 0.8344	
WHITE	112	110 (98.2)	10.33 (9.98, 11.17)	111	110 (99.1)	9.20 (8.63, 9.92)	0.58 (0.44, 0.76) 0.0001	

Data Cutoff Date: 30JUN2020. HR = hazard ratio; KME = Kaplan-Meier estimate; CPET=Cardiopulmonary Exercise Testing.
(A) Event: patients with prior termination of CPET. If a patient completed CPET it will be right-censored at 22 minutes.
(B) HR, 95% CI and p value use unstratified Cox proportional hazards model with treatment, subgroup and treatment*subgroup interaction and baseline peak exercise time as covariates.
(C) p-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Denominator is based on patients with non-missing peak exercise time at baseline and week 30.
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Main Analysis: Time to Termination of CPET at Week 30, Subgroup Analyses
Intention-to-treat (ITT) Population

Subgroup	Mavacamten (N = 123) N	Subjects with Event n (%) (A)	KME (95% CI)	Placebo (N = 128) N	Subjects with Event n (%) (A)	KME (95% CI)	Mavacamten vs Placebo HR (95% CI) p-value (B)	Test for Interaction p-value (C)
REGION								0.0800
US	50	49 (98.0)	11.05 (10.12, 11.98)	53	51 (96.2)	10.33 (9.92, 11.55)	0.81 (0.54, 1.22) 0.3207	
EX-US	70	68 (97.1)	10.08 (9.85, 11.05)	72	72 (100.0)	8.63 (8.13, 9.35)	0.51 (0.36, 0.72) 0.0001	
CALCIUM CHANNEL BLOCKER USE								0.0002*
YES	25	23 (92.0)	12.87 (11.83, 14.27)	16	16 (100.0)	9.00 (8.13, 10.23)	0.21 (0.11, 0.41) <0.0001	
NO	95	94 (98.9)	10.00 (9.40, 10.48)	109	107 (98.2)	9.72 (8.80, 10.00)	0.81 (0.61, 1.07) 0.1401	

Data Cutoff Date: 30JUN2020. HR = hazard ratio; KME = Kaplan-Meier estimate; CPET=Cardiopulmonary Exercise Testing.
(A) Event: patients with prior termination of CPET. If a patient completed CPET it will be right-censored at 22 minutes.
(B) HR, 95% CI and p value use unstratified Cox proportional hazards model with treatment, subgroup and treatment*subgroup interaction and baseline peak exercise time as covariates.
(C) p-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Denominator is based on patients with non-missing peak exercise time at baseline and week 30.
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Main Analysis: Time to Termination of CPET at Week 30, Subgroup Analyses
Intention-to-treat (ITT) Population

Subgroup	Mavacamten (N = 123) N	Subjects with Event n (%) (A)	KME (95% CI)	Placebo (N = 128) N	Subjects with Event n (%) (A)	KME (95% CI)	Mavacamten vs Placebo HR (95% CI) p-value (B)	Test for Interaction p-value (C)
PRESENCE OF HCM PATHOGENIC MUTATION								0.1292
PATHOGENIC OR LIKELY PATHOGENIC	27	26 (96.3)	10.52 (10.00, 11.98)	22	21 (95.5)	8.93 (8.15, 9.98)	0.38 (0.21, 0.70) 0.0018	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	32	31 (96.9)	10.65 (10.00, 12.05)	42	42 (100.0)	9.98 (9.30, 10.47)	0.61 (0.37, 0.98) 0.0420	
NEGATIVE	29	28 (96.6)	9.18 (8.37, 10.00)	34	33 (97.1)	8.72 (8.13, 9.90)	0.86 (0.51, 1.44) 0.5661	
TIME FROM DIAGNOSIS OF OHCM (Years)								0.0121*
<=5	65	63 (96.9)	10.33 (9.90, 11.35)	54	53 (98.1)	10.00 (9.35, 10.93)	0.86 (0.60, 1.25) 0.4424	
>5	55	54 (98.2)	10.53 (10.00, 11.75)	71	70 (98.6)	8.72 (8.15, 9.72)	0.44 (0.30, 0.65) <0.0001	

Data Cutoff Date: 30JUN2020. HR = hazard ratio; KME = Kaplan-Meier estimate; CPET=Cardiopulmonary Exercise Testing.
(A) Event: patients with prior termination of CPET. If a patient completed CPET it will be right-censored at 22 minutes.
(B) HR, 95% CI and p value use unstratified Cox proportional hazards model with treatment, subgroup and treatment*subgroup interaction and baseline peak exercise time as covariates.
(C) p-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Denominator is based on patients with non-missing peak exercise time at baseline and week 30.
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Main Analysis: Time to Termination of CPET at Week 30, Subgroup Analyses
Intention-to-treat (ITT) Population

Subgroup	Mavacamten (N = 123) N	Subjects with Event n (%) (A)	KME (95% CI)	Placebo (N = 128) N	Subjects with Event n (%) (A)	KME (95% CI)	Mavacamten vs Placebo HR (95% CI) p-value (B)	Test for Interaction p-value (C)
SEPTAL REDUCTION THERAPY (SRT) HISTORY								0.5414
YES	11	11 (100.0)	10.00 (8.72, 12.00)	8	8 (100.0)	8.37 (7.28, 10.23)	0.47 (0.19, 1.21) 0.1180	
NO	109	106 (97.2)	10.40 (9.98, 11.35)	117	115 (98.3)	9.43 (8.80, 10.00)	0.64 (0.49, 0.85) 0.0017	
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED								0.0339*
YES	27	26 (96.3)	11.98 (10.93, 13.03)	29	28 (96.6)	9.72 (8.62, 10.47)	0.38 (0.21, 0.66) 0.0007	
NO	93	91 (97.8)	10.02 (9.72, 10.77)	96	95 (99.0)	9.43 (8.75, 10.00)	0.74 (0.55, 0.99) 0.0450	

Data Cutoff Date: 30JUN2020. HR = hazard ratio; KME = Kaplan-Meier estimate; CPET=Cardiopulmonary Exercise Testing.
(A) Event: patients with prior termination of CPET. If a patient completed CPET it will be right-censored at 22 minutes.
(B) HR, 95% CI and p value use unstratified Cox proportional hazards model with treatment, subgroup and treatment*subgroup interaction and baseline peak exercise time as covariates.
(C) p-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Denominator is based on patients with non-missing peak exercise time at baseline and week 30.
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Main Analysis: Time to Termination of CPET at Week 30, Subgroup Analyses
Intention-to-treat (ITT) Population

Subgroup	Mavacamten (N = 123) N	Subjects with Event n (%) (A)	KME (95% CI)	Placebo (N = 128) N	Subjects with Event n (%) (A)	KME (95% CI)	Mavacamten vs Placebo HR (95% CI) p-value (B)	Test for Interaction p-value (C)
HISTORY OF HYPERTENSION								0.0008*
YES	60	59 (98.3)	8.75 (8.18, 9.73)	58	57 (98.3)	8.77 (8.18, 9.85)	1.02 (0.70, 1.47) 0.9222	
NO	60	58 (96.7)	12.17 (11.63, 13.00)	67	66 (98.5)	10.02 (9.72, 10.77)	0.41 (0.28, 0.60) <0.0001	
RESTING LVEF								0.7231
<75%	68	65 (95.6)	11.52 (10.47, 12.17)	67	66 (98.5)	10.12 (9.85, 11.08)	0.65 (0.46, 0.93) 0.0178	
>=75%	52	52 (100.0)	9.90 (8.93, 10.40)	58	57 (98.3)	8.48 (8.00, 9.22)	0.59 (0.40, 0.88) 0.0092	

Data Cutoff Date: 30JUN2020. HR = hazard ratio; KME = Kaplan-Meier estimate; CPET=Cardiopulmonary Exercise Testing.
(A) Event: patients with prior termination of CPET. If a patient completed CPET it will be right-censored at 22 minutes.
(B) HR, 95% CI and p value use unstratified Cox proportional hazards model with treatment, subgroup and treatment*subgroup interaction and baseline peak exercise time as covariates.
(C) p-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Denominator is based on patients with non-missing peak exercise time at baseline and week 30.
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Main Analysis: Time to Termination of CPET at Week 30, Subgroup Analyses
Intention-to-treat (ITT) Population

Subgroup	Mavacamten (N = 123) N	Subjects with Event n (%) (A)	KME (95% CI)	Placebo (N = 128) N	Subjects with Event n (%) (A)	KME (95% CI)	Mavacamten vs Placebo HR (95% CI) p-value (B)	Test for Interaction p-value (C)
LVOT RESTING PEAK GRADIENT (mmHg)								0.1235
<=50	59	57 (96.6)	10.33 (9.90, 11.35)	65	64 (98.5)	9.92 (9.18, 10.40)	0.77 (0.54, 1.11) 0.1621	
>50	61	60 (98.4)	10.48 (9.98, 11.63)	60	59 (98.3)	9.00 (8.37, 9.93)	0.51 (0.35, 0.75) 0.0006	
LVOT RESTING PEAK GRADIENT (mmHg)								0.4819
<=30	34	32 (94.1)	10.33 (9.73, 11.58)	39	38 (97.4)	9.88 (8.72, 10.33)	0.72 (0.44, 1.16) 0.1739	
>30	86	85 (98.8)	10.48 (10.00, 11.55)	86	85 (98.8)	9.35 (8.70, 10.00)	0.59 (0.43, 0.80) 0.0009	

Data Cutoff Date: 30JUN2020. HR = hazard ratio; KME = Kaplan-Meier estimate; CPET=Cardiopulmonary Exercise Testing.
(A) Event: patients with prior termination of CPET. If a patient completed CPET it will be right-censored at 22 minutes.
(B) HR, 95% CI and p value use unstratified Cox proportional hazards model with treatment, subgroup and treatment*subgroup interaction and baseline peak exercise time as covariates.
(C) p-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Denominator is based on patients with non-missing peak exercise time at baseline and week 30.
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Main Analysis: Time to Termination of CPET at Week 30, Subgroup Analyses
Intention-to-treat (ITT) Population

Subgroup	Mavacamten (N = 123) N	Subjects with Event n (%) (A)	KME (95% CI)	Placebo (N = 128) N	Subjects with Event n (%) (A)	KME (95% CI)	Mavacamten vs Placebo HR (95% CI) p-value (B)	Test for Interaction p-value (C)
E/E' LATERAL								0.0047*
<=14	54	51 (94.4)	11.83 (11.05, 12.75)	65	64 (98.5)	9.98 (9.35, 10.48)	0.44 (0.30, 0.65) <0.0001	
>14	61	61 (100.0)	8.75 (8.18, 9.85)	55	54 (98.2)	8.70 (8.15, 9.72)	0.96 (0.66, 1.40) 0.8339	
E/E' SEPTAL								0.1566
<=14	16	15 (93.8)	13.17 (11.98, 15.03)	27	27 (100.0)	10.93 (9.98, 12.00)	0.41 (0.22, 0.79) 0.0073	
>14	104	102 (98.1)	10.00 (9.43, 10.53)	97	95 (97.9)	9.18 (8.58, 9.92)	0.68 (0.51, 0.92) 0.0109	

Data Cutoff Date: 30JUN2020. HR = hazard ratio; KME = Kaplan-Meier estimate; CPET=Cardiopulmonary Exercise Testing.
(A) Event: patients with prior termination of CPET. If a patient completed CPET it will be right-censored at 22 minutes.
(B) HR, 95% CI and p value use unstratified Cox proportional hazards model with treatment, subgroup and treatment*subgroup interaction and baseline peak exercise time as covariates.
(C) p-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Denominator is based on patients with non-missing peak exercise time at baseline and week 30.
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Main Analysis: Time to Termination of CPET at Week 30, Subgroup Analyses
Intention-to-treat (ITT) Population

Subgroup	Mavacamten (N = 123) N	Subjects with Event n (%) (A)	KME (95% CI)	Placebo (N = 128) N	Subjects with Event n (%) (A)	KME (95% CI)	Mavacamten vs Placebo HR (95% CI) p-value (B)	Test for Interaction p-value (C)
E/E' AVERAGE								0.2521
<=14	25	24 (96.0)	12.57 (11.63, 13.98)	32	32 (100.0)	10.47 (9.90, 11.75)	0.48 (0.28, 0.82) 0.0073	
>14	95	93 (97.9)	9.98 (9.30, 10.48)	93	91 (97.8)	9.00 (8.47, 9.88)	0.68 (0.50, 0.92) 0.0126	
LEFT ATRIAL VOLUME INDEX								0.2742
<=MEDIAN	59	57 (96.6)	9.92 (9.00, 10.33)	62	60 (96.8)	8.93 (8.25, 9.88)	0.71 (0.49, 1.03) 0.0688	
>MEDIAN	60	59 (98.3)	11.55 (10.48, 12.17)	63	63 (100.0)	9.93 (9.22, 10.48)	0.53 (0.37, 0.77) 0.0010	

Data Cutoff Date: 30JUN2020. HR = hazard ratio; KME = Kaplan-Meier estimate; CPET=Cardiopulmonary Exercise Testing.
(A) Event: patients with prior termination of CPET. If a patient completed CPET it will be right-censored at 22 minutes.
(B) HR, 95% CI and p value use unstratified Cox proportional hazards model with treatment, subgroup and treatment*subgroup interaction and baseline peak exercise time as covariates.
(C) p-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Denominator is based on patients with non-missing peak exercise time at baseline and week 30.
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Main Analysis: Time to Termination of CPET at Week 30, Subgroup Analyses
Intention-to-treat (ITT) Population

Subgroup	Mavacamten (N = 123) N	Subjects with Event n (%) (A)	KME (95% CI)	Placebo (N = 128) N	Subjects with Event n (%) (A)	KME (95% CI)	Mavacamten vs Placebo HR (95% CI) p-value (B)	Test for Interaction p-value (C)
NT-PROBNP								0.0140*
<=MEDIAN	54	51 (94.4)	10.77 (10.00, 11.83)	66	66 (100.0)	10.33 (9.93, 11.47)	0.87 (0.60, 1.27) 0.4741	
>MEDIAN	63	63 (100.0)	10.12 (9.73, 11.13)	57	55 (96.5)	8.37 (7.87, 9.18)	0.44 (0.30, 0.65) <0.0001	
HS-CARDIAC TROPONIN-I								0.2621
<=ULN	85	83 (97.6)	11.35 (10.47, 12.00)	94	92 (97.9)	9.73 (8.80, 10.03)	0.50 (0.36, 0.69) <0.0001	
>ULN	32	31 (96.9)	9.40 (8.58, 10.33)	23	23 (100.0)	8.62 (7.93, 9.90)	0.71 (0.41, 1.23) 0.2282	

Data Cutoff Date: 30JUN2020. HR = hazard ratio; KME = Kaplan-Meier estimate; CPET=Cardiopulmonary Exercise Testing.
(A) Event: patients with prior termination of CPET. If a patient completed CPET it will be right-censored at 22 minutes.
(B) HR, 95% CI and p value use unstratified Cox proportional hazards model with treatment, subgroup and treatment*subgroup interaction and baseline peak exercise time as covariates.
(C) p-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Denominator is based on patients with non-missing peak exercise time at baseline and week 30.
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Main Analysis: Time to Termination of CPET at Week 30, Subgroup Analyses
Intention-to-treat (ITT) Population

Subgroup	Mavacamten (N = 123) N	Subjects with Event n (%) (A)	KME (95% CI)	Placebo (N = 128) N	Subjects with Event n (%) (A)	KME (95% CI)	Mavacamten vs Placebo HR (95% CI) p-value (B)	Test for Interaction p-value (C)
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.0279*
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	39	37 (94.9)	11.98 (11.08, 12.88)	54	53 (98.1)	10.00 (9.40, 10.77)	0.44 (0.28, 0.68) 0.0002	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	77	76 (98.7)	9.35 (8.67, 10.00)	62	61 (98.4)	8.77 (8.23, 9.85)	0.82 (0.58, 1.16) 0.2549	
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.2390
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	13	12 (92.3)	13.63 (12.05, 16.12)	22	22 (100.0)	11.17 (10.00, 12.57)	0.42 (0.20, 0.86) 0.0174	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	107	105 (98.1)	10.00 (9.43, 10.65)	102	100 (98.0)	9.00 (8.48, 9.90)	0.66 (0.50, 0.88) 0.0048	

Data Cutoff Date: 30JUN2020. HR = hazard ratio; KME = Kaplan-Meier estimate; CPET=Cardiopulmonary Exercise Testing.
(A) Event: patients with prior termination of CPET. If a patient completed CPET it will be right-censored at 22 minutes.
(B) HR, 95% CI and p value use unstratified Cox proportional hazards model with treatment, subgroup and treatment*subgroup interaction and baseline peak exercise time as covariates.
(C) p-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Denominator is based on patients with non-missing peak exercise time at baseline and week 30.
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Main Analysis: Time to Termination of CPET at Week 30, Subgroup Analyses
Intention-to-treat (ITT) Population

Subgroup	Mavacamten (N = 123) N	Subjects with Event n (%) (A)	KME (95% CI)	Placebo (N = 128) N	Subjects with Event n (%) (A)	KME (95% CI)	Mavacamten vs Placebo HR (95% CI) p-value (B)	Test for Interaction p-value (C)
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.2832
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	20	19 (95.0)	12.82 (11.72, 14.28)	24	24 (100.0)	10.53 (9.92, 11.98)	0.46 (0.25, 0.85) 0.0137	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	100	98 (98.0)	10.00 (9.40, 10.52)	98	96 (98.0)	9.00 (8.48, 9.88)	0.67 (0.50, 0.90) 0.0074	
CREATININE CLEARANCE (CRCL) (mL/min)								0.1029
<60	14	14 (100.0)	10.15 (9.18, 11.98)	16	16 (100.0)	8.02 (7.28, 9.20)	0.36 (0.17, 0.74) 0.0059	
>=60	105	102 (97.1)	10.40 (9.98, 11.35)	109	107 (98.2)	9.85 (9.00, 10.08)	0.68 (0.51, 0.91) 0.0083	

Data Cutoff Date: 30JUN2020. HR = hazard ratio; KME = Kaplan-Meier estimate; CPET=Cardiopulmonary Exercise Testing.
(A) Event: patients with prior termination of CPET. If a patient completed CPET it will be right-censored at 22 minutes.
(B) HR, 95% CI and p value use unstratified Cox proportional hazards model with treatment, subgroup and treatment*subgroup interaction and baseline peak exercise time as covariates.
(C) p-values <0.05 are indicated by 1 asterisk (indicates potential effect modification).
Denominator is based on patients with non-missing peak exercise time at baseline and week 30.
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4.5.4 Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 für signifikante Subgruppen

4.5.4.1 HOCM-Begleittherapie mit Betablockern

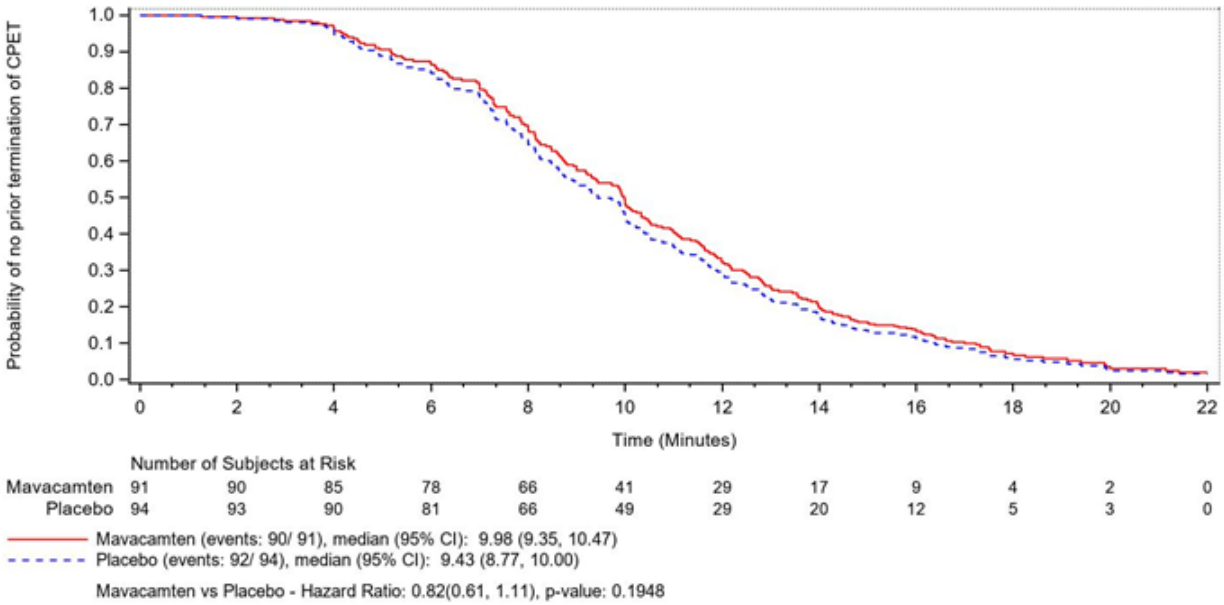

Abbildung 4-2: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal HOCM-Begleittherapie mit Betablockern (ja)

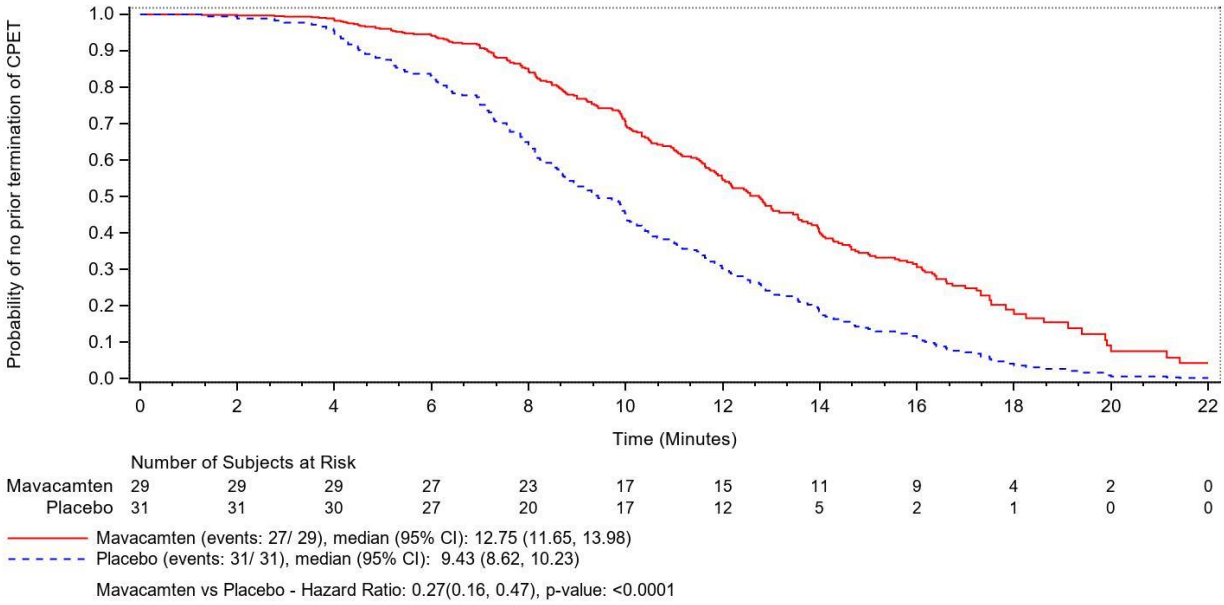

Abbildung 4-3: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal HOCM-Begleittherapie mit Betablockern (nein)

4.5.4.2 BMI

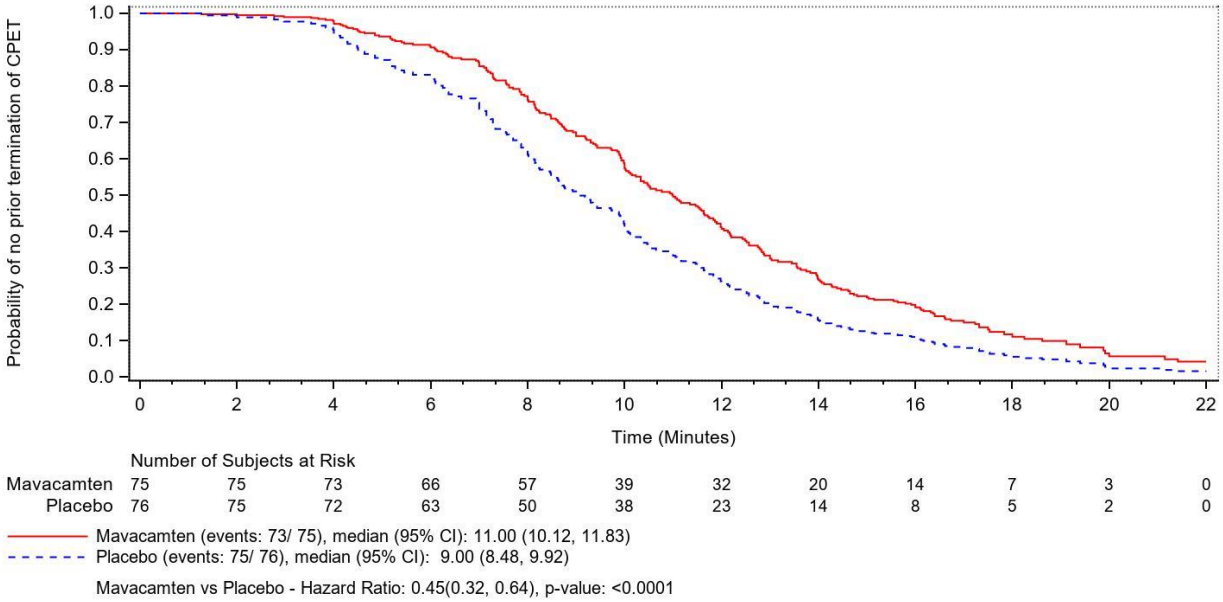

Abbildung 4-4: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse – für das Merkmal BMI (< 30)

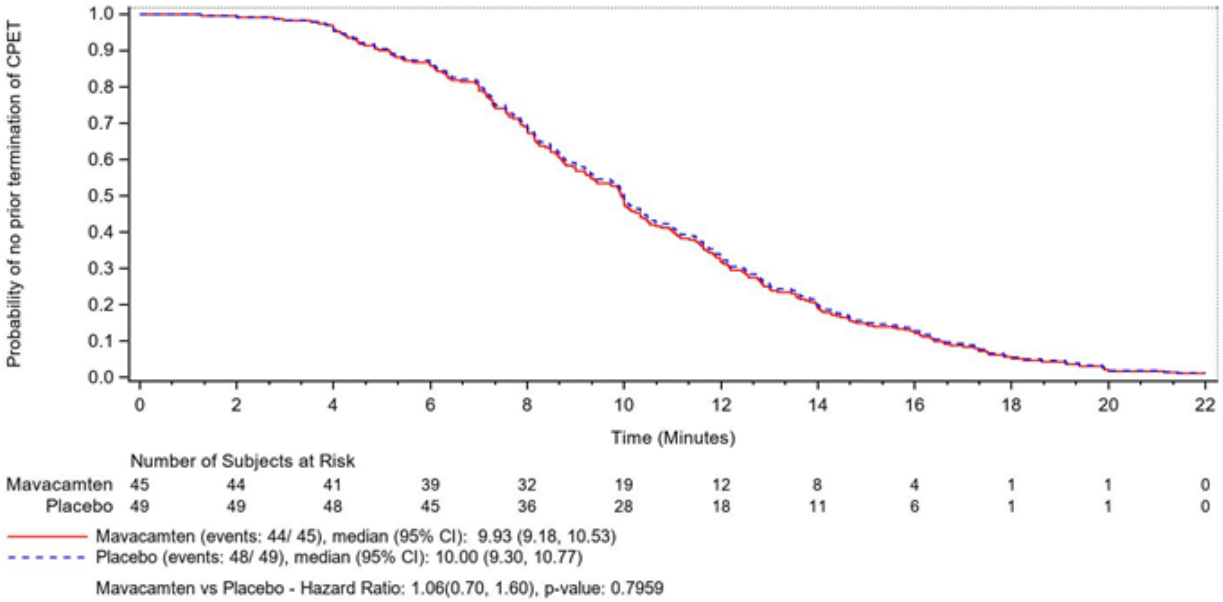

Abbildung 4-5: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal BMI (≥ 30)

4.5.4.3 Krankheitsdauer der HOCM

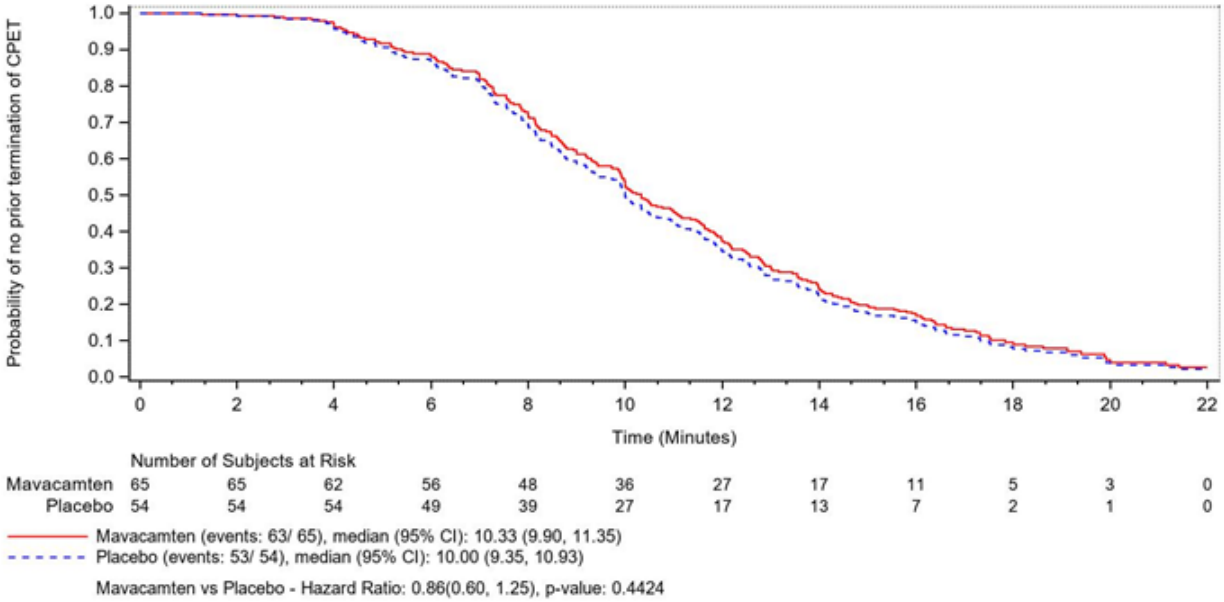

Abbildung 4-6: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal Krankheitsdauer der HOCM (≤ 5 Jahre)

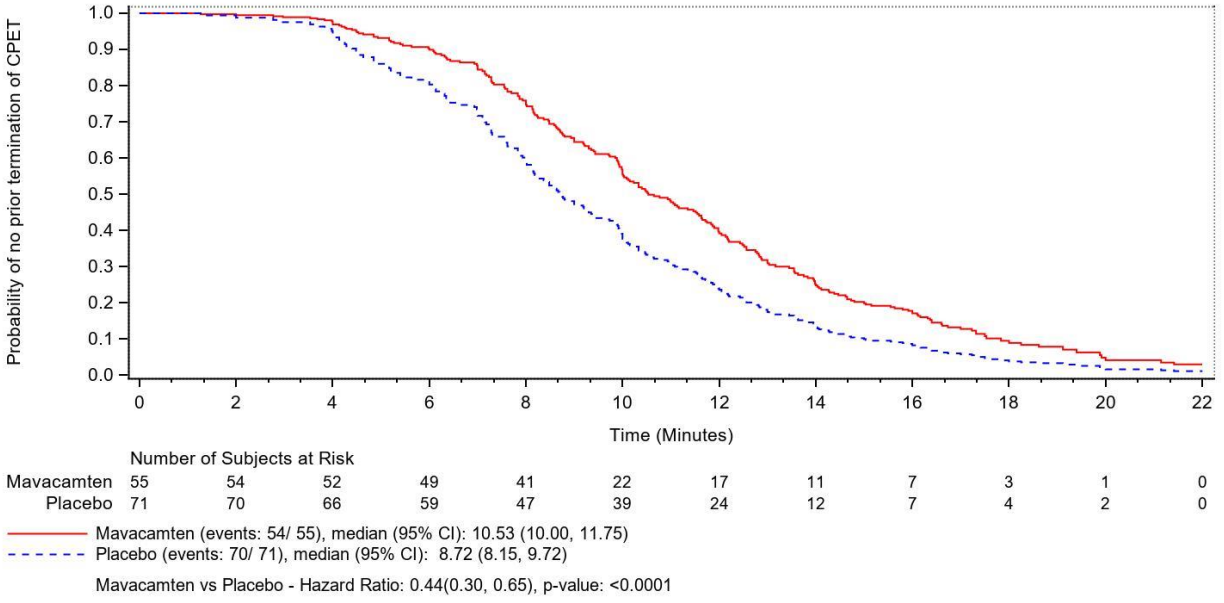

Abbildung 4-7: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal Krankheitsdauer der HOCM (> 5 Jahre)

4.5.4.4 HOCM-Begleittherapie mit Calciumantagonisten

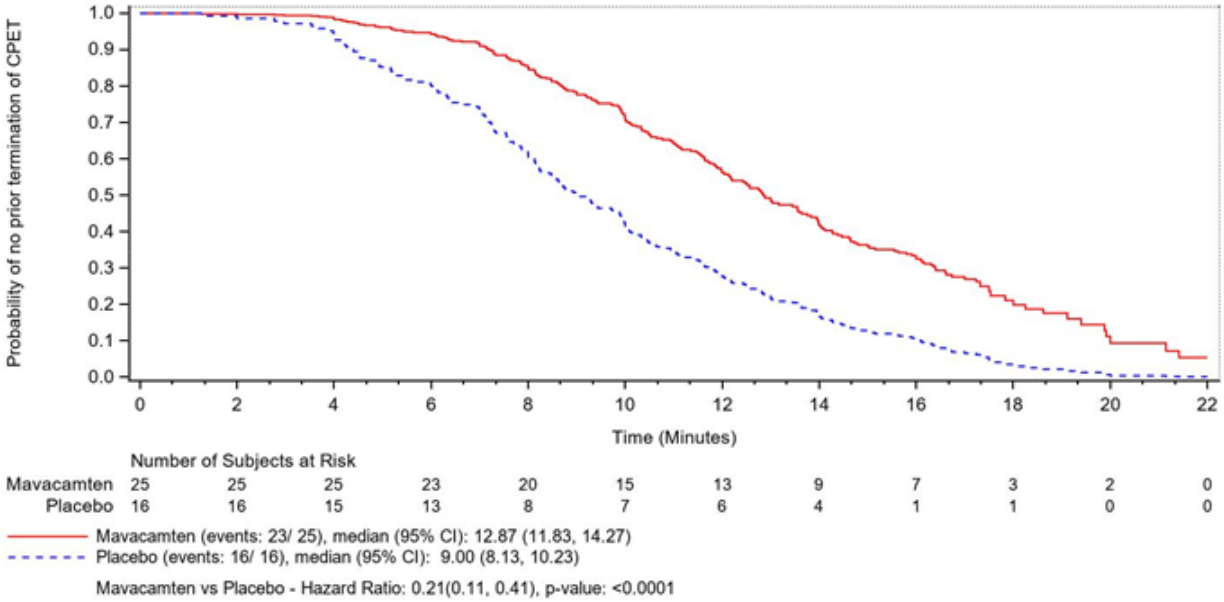

Abbildung 4-8: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal HOCM-Begleittherapie mit Calciumantagonisten (ja)

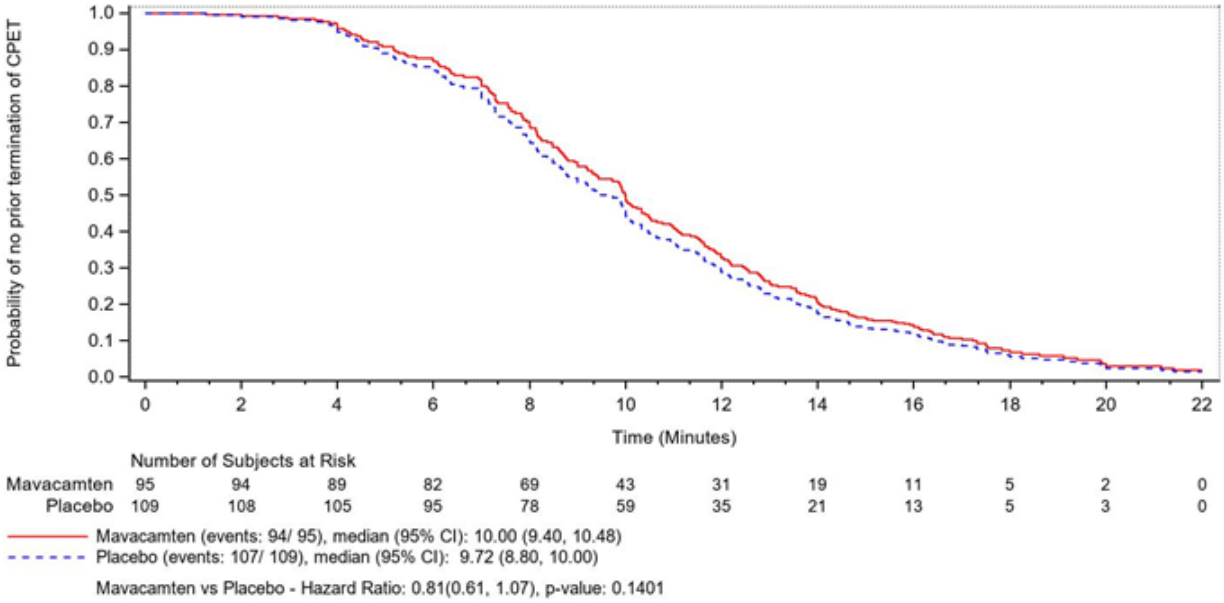

Abbildung 4-9: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal HOCM-Begleittherapie mit Calciumantagonisten (nein)

4.5.4.5 ICD

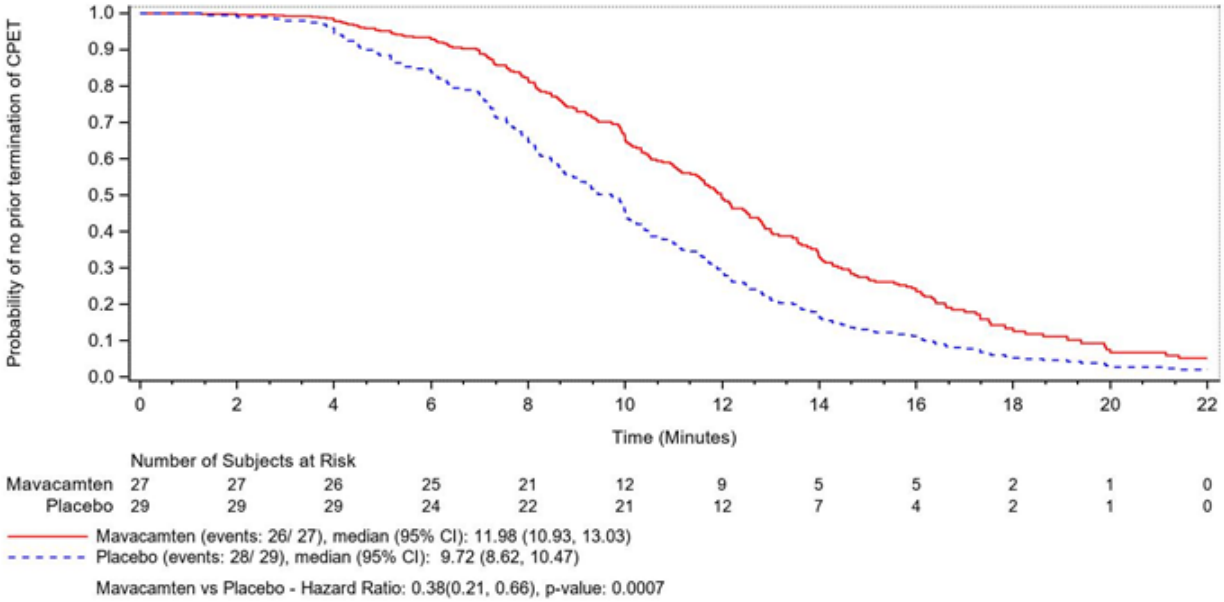

Abbildung 4-10: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal ICD (ja)

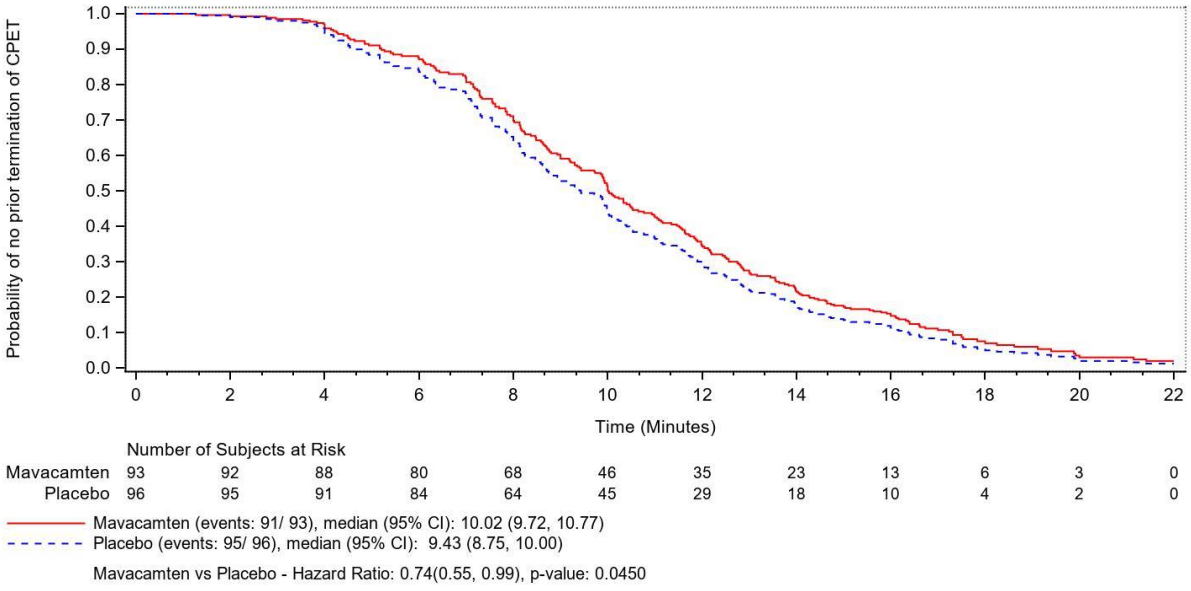

Abbildung 4-11: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal ICD (nein)

4.5.4.6 Hypertonie in der Anamnese

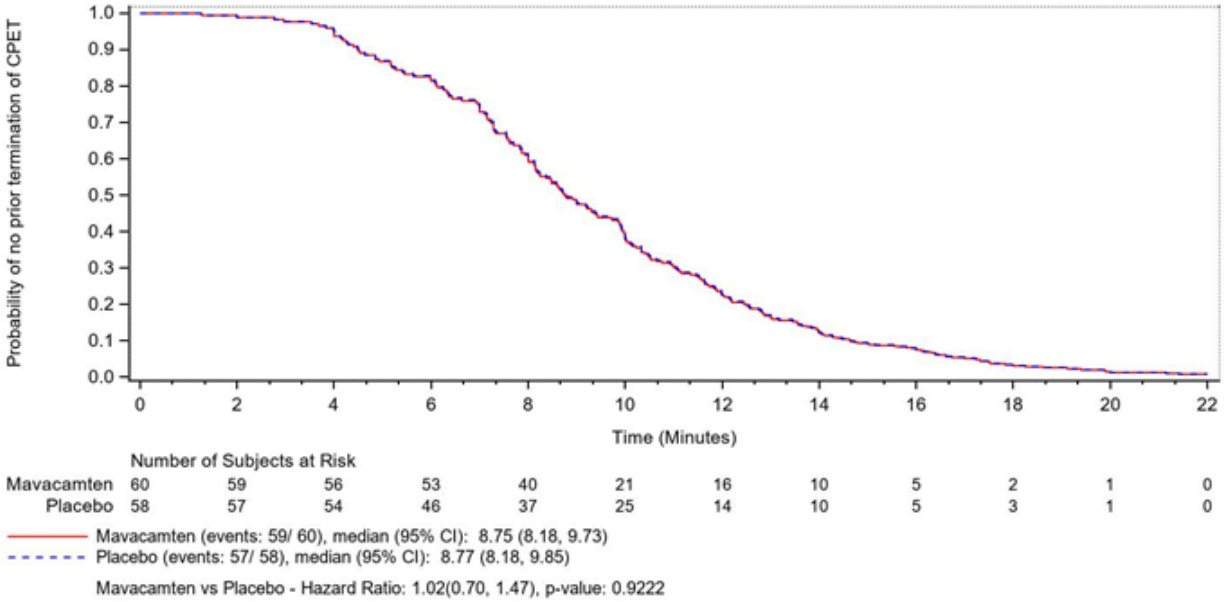

Abbildung 4-12: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal Hypertonie in der Anamnese (ja)

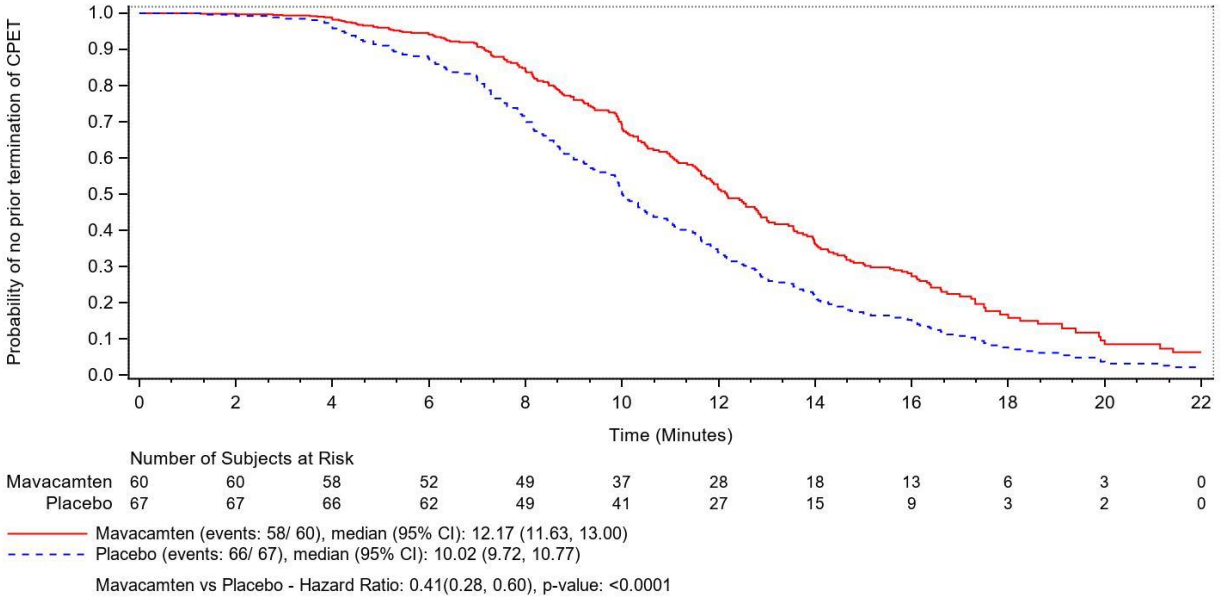

Abbildung 4-13: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal Hypertonie in der Anamnese (nein)

4.5.4.7 NT-proBNP

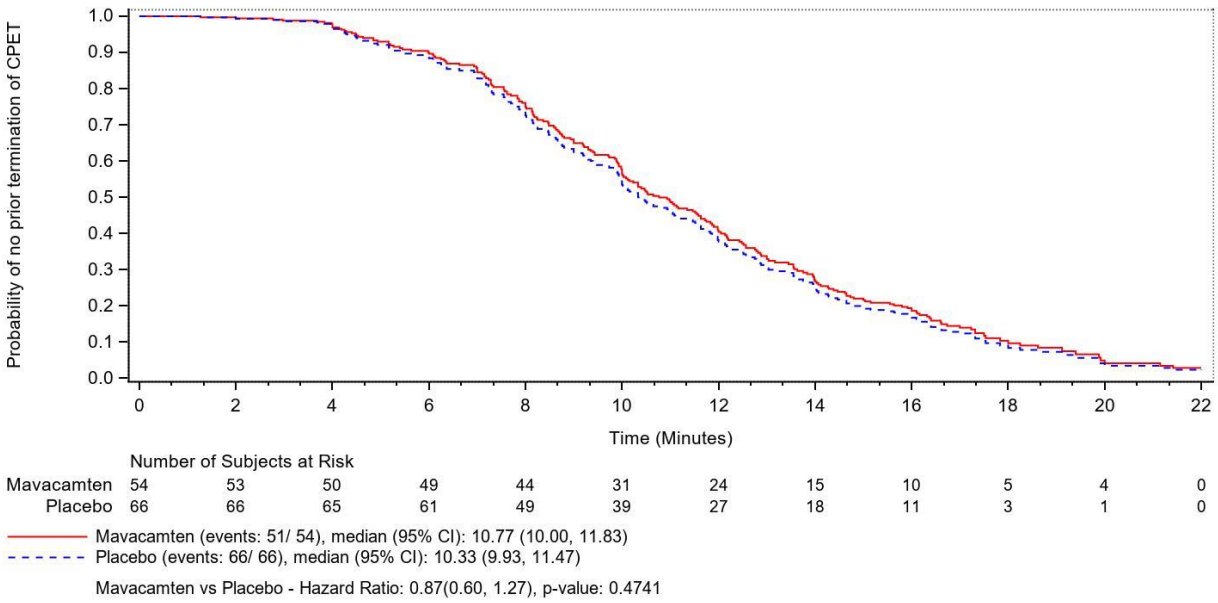

Abbildung 4-14: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal NT-proBNP (≤ Median)

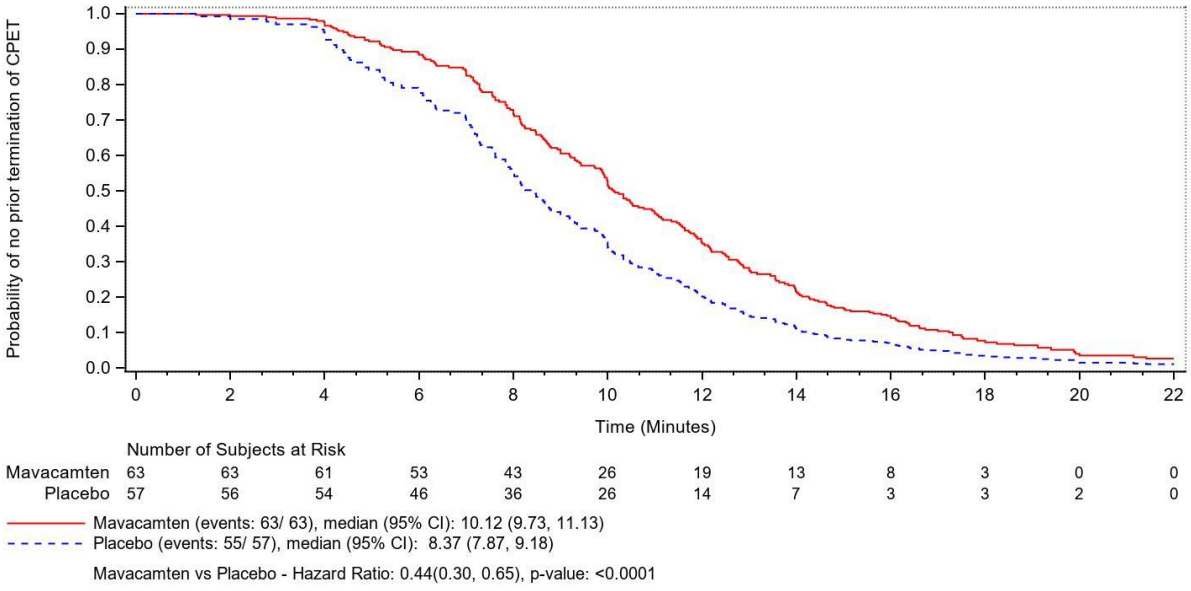

Abbildung 4-15: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal NT-proBNP (> Median)

4.5.4.8 Einwilligung zur CMR-Substudie

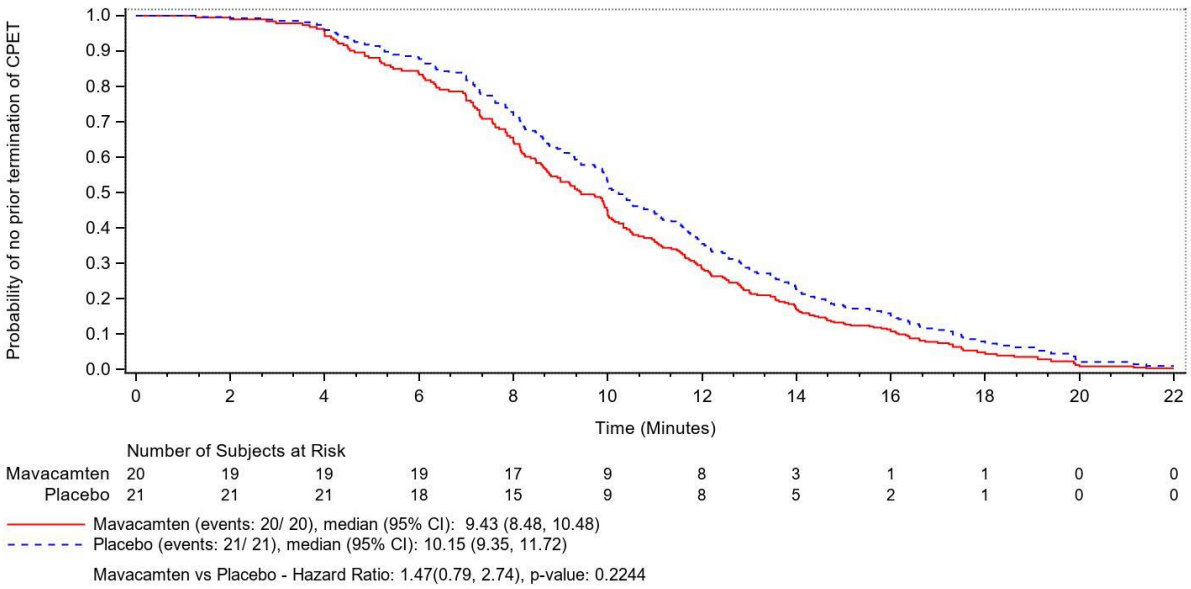

Abbildung 4-16: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal Einwilligung zur CMR-Substudie (ja)

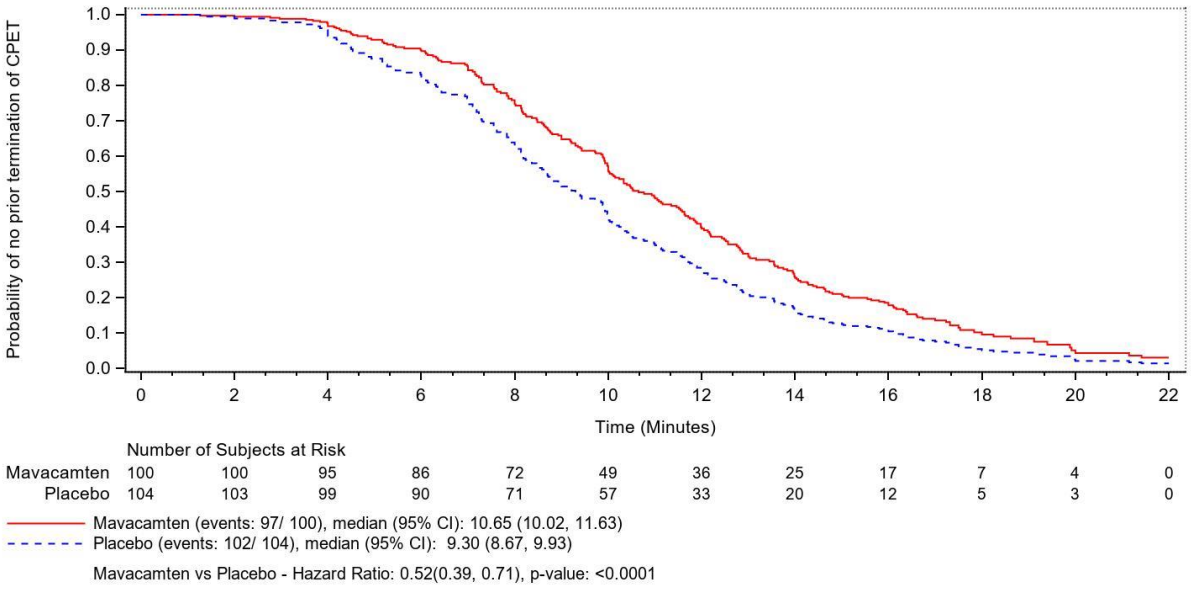

Abbildung 4-17: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal Einwilligung zur CMR-Substudie (nein)

4.5.4.9 E/e' lateral

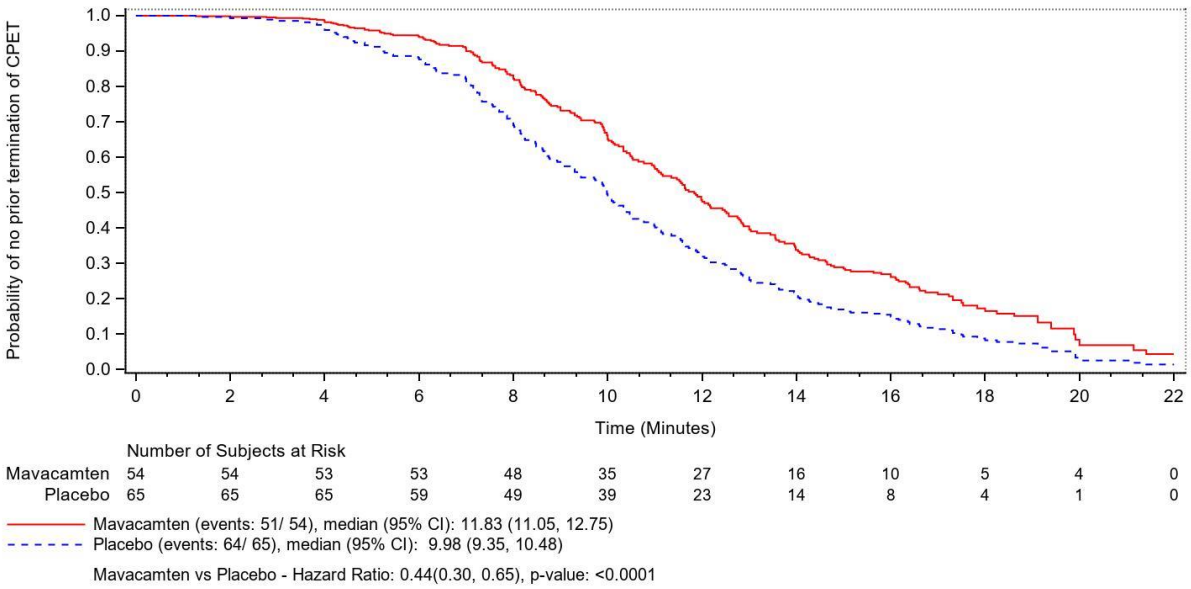

Abbildung 4-18: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal E/e' lateral (≤ 14)

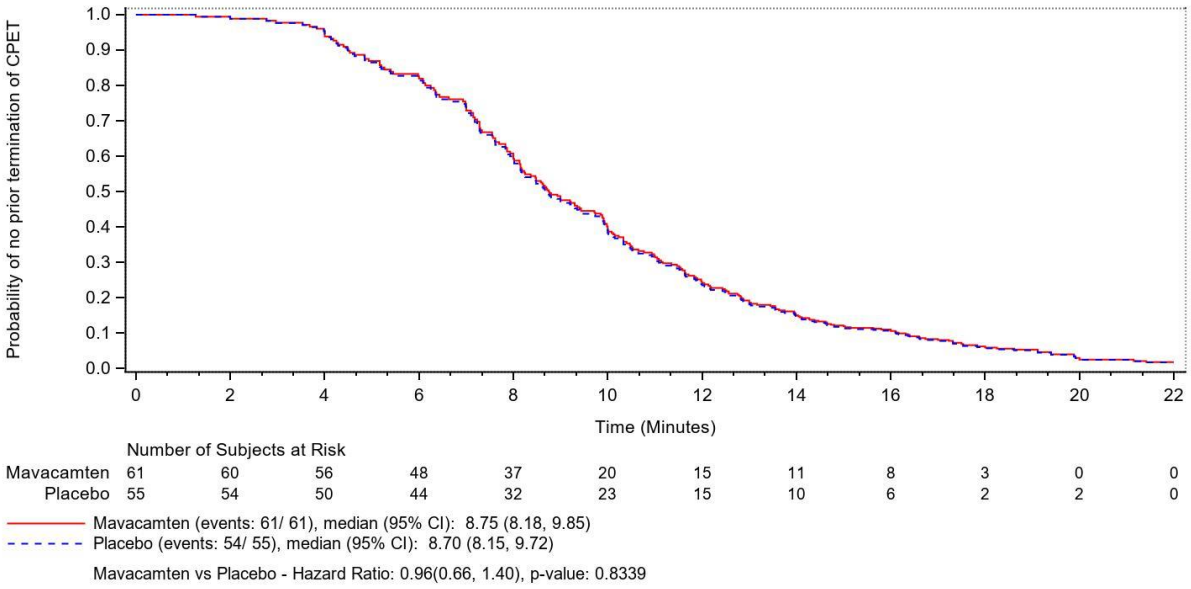

Abbildung 4-19: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal E/e' lateral (> 14)

4.5.4.10 E/e' lateral > 14 oder hsTN- I > ULN vs. andere

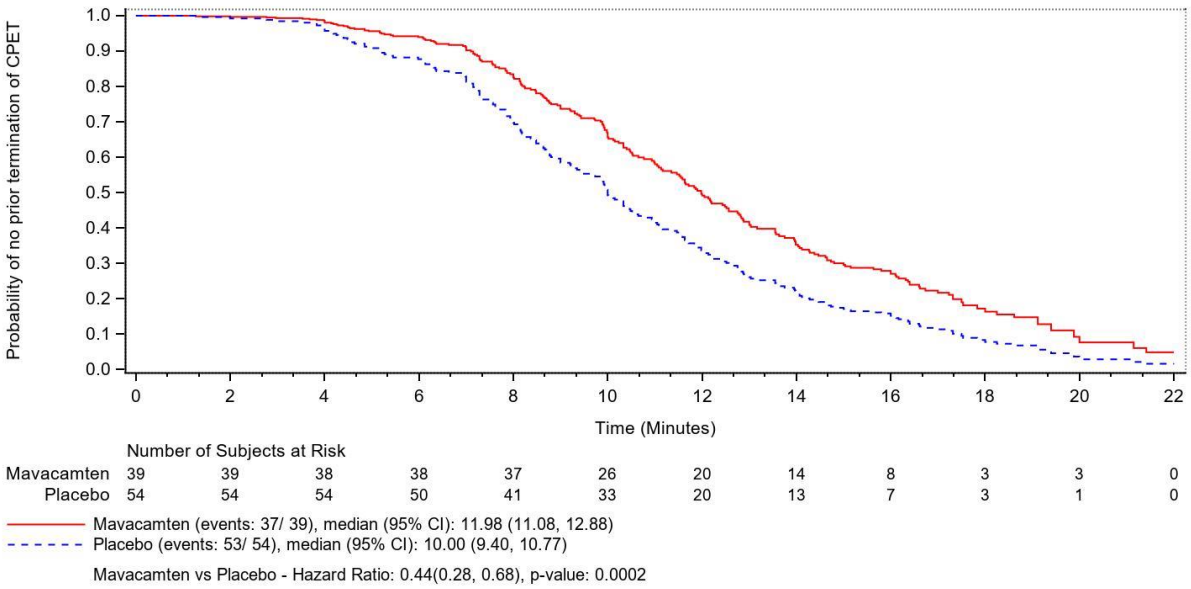

Abbildung 4-20: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal E/e' lateral > 14 oder hsTN- I > ULN vs. andere (E/e' lateral in Ruhe ≤ 14 und hsTN-I ≤ ULN)

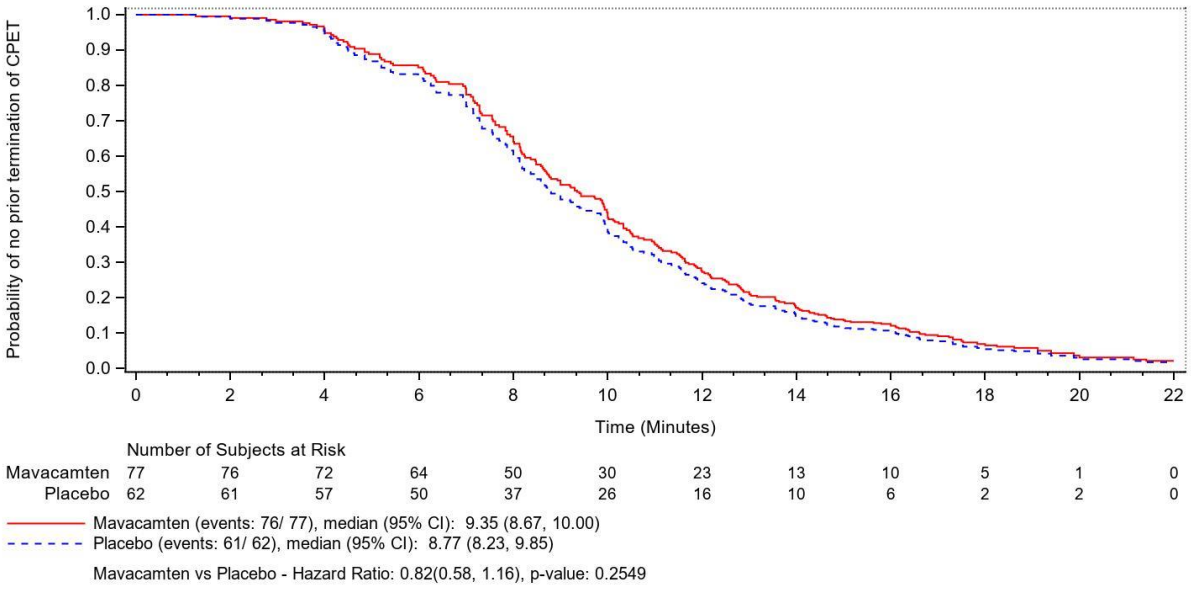

Abbildung 4-21: Kaplan-Meier-Kurven für die Zeit bis zum Abbruch der Belastungsuntersuchung zu Woche 30 – Subgruppenanalyse für das Merkmal E/e' lateral > 14 oder hsTN- I > ULN vs. andere (E/e' lateral in Ruhe > 14 und hsTN-I ≤ ULN)

4.6 Analysen für den Endpunkt Belastungsempfinden gemäß RPE-Skala nach Borg

4.6.1 Deskriptive Darstellung der Borg-Scores gemäß RPE-Skala im Verlauf der kardiopulmonalen Belastungsuntersuchung (pro Erhebungszeitpunkt) zu Baseline und zu Woche 30

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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
Baseline			
Pre-exercise (after 5min supine)			
Borg Score			
n	94	96	190
MEAN(SD)	6.0 (0.25)	6.0 (0.81)	6.0 (0.60)
MEDIAN	6.0	6.0	6.0
MIN, MAX	6, 8	0, 11	0, 11
Q1, Q3	6, 6	6, 6	6, 6
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	94/123 (76.4)	96/128 (75.0)	190/251 (75.7)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	94/123 (76.4)	96/128 (75.0)	190/251 (75.7)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	94/123 (76.4)	96/128 (75.0)	190/251 (75.7)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Protocol: MYK-461-005

Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
Pre-exercise (after 2 min standing)			
Borg Score			
n	97	96	193
MEAN(SD)	6.1 (0.59)	6.1 (0.85)	6.1 (0.73)
MEDIAN	6.0	6.0	6.0
MIN, MAX	6, 11	0, 11	0, 11
Q1, Q3	6, 6	6, 6	6, 6
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	97/123 (78.9)	96/128 (75.0)	193/251 (76.9)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	97/123 (78.9)	96/128 (75.0)	193/251 (76.9)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	97/123 (78.9)	96/128 (75.0)	193/251 (76.9)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Protocol: MYK-461-005

Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 1 min			
Borg Score			
n	102	103	205
MEAN(SD)	7.6 (1.94)	7.2 (1.83)	7.4 (1.89)
MEDIAN	7.0	7.0	7.0
MIN, MAX	6, 15	1, 13	1, 15
Q1, Q3	6, 9	6, 8	6, 8
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	102/123 (82.9)	103/128 (80.5)	205/251 (81.7)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	102/123 (82.9)	103/128 (80.5)	205/251 (81.7)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	102/123 (82.9)	103/128 (80.5)	205/251 (81.7)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 2 min			
Borg Score			
n	114	114	228
MEAN(SD)	8.8 (2.48)	8.1 (2.48)	8.5 (2.50)
MEDIAN	8.0	7.0	7.0
MIN, MAX	6, 15	1, 17	1, 17
Q1, Q3	7, 11	6, 10	7, 10
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	114/123 (92.7)	114/128 (89.1)	228/251 (90.8)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	114/123 (92.7)	114/128 (89.1)	228/251 (90.8)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	114/123 (92.7)	114/128 (89.1)	228/251 (90.8)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 3 min			
Borg Score			
n	100	102	202
MEAN(SD)	9.9 (2.67)	9.5 (3.05)	9.7 (2.87)
MEDIAN	9.0	9.0	9.0
MIN, MAX	6, 19	1, 18	1, 19
Q1, Q3	8, 12	7, 11	8, 11
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	100/123 (81.3)	102/128 (79.7)	202/251 (80.5)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	100/120 (83.3)	102/128 (79.7)	202/248 (81.5)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	100/120 (83.3)	102/128 (79.7)	202/248 (81.5)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 4 min			
Borg Score			
n	109	114	223
MEAN(SD)	11.0 (3.08)	10.5 (3.41)	10.7 (3.25)
MEDIAN	11.0	10.0	10.0
MIN, MAX	6, 20	3, 20	3, 20
Q1, Q3	9, 13	8, 13	8, 13
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	109/123 (88.6)	114/128 (89.1)	223/251 (88.8)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	107/116 (92.2)	110/123 (89.4)	217/239 (90.8)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	107/116 (92.2)	110/123 (89.4)	217/239 (90.8)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 5 min			
Borg Score			
n	95	95	190
MEAN(SD)	12.0 (2.90)	11.5 (3.39)	11.8 (3.16)
MEDIAN	12.0	11.0	11.5
MIN, MAX	7, 19	4, 20	4, 20
Q1, Q3	10, 13	9, 14	9, 13
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	95/123 (77.2)	95/128 (74.2)	190/251 (75.7)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	90/109 (82.6)	92/117 (78.6)	182/226 (80.5)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	90/109 (82.6)	92/117 (78.6)	182/226 (80.5)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 6 min			
Borg Score			
n	101	101	202
MEAN(SD)	12.8 (3.05)	12.2 (3.27)	12.5 (3.16)
MEDIAN	13.0	12.0	12.0
MIN, MAX	7, 20	5, 20	5, 20
Q1, Q3	11, 14	10, 14	11, 14
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	101/123 (82.1)	101/128 (78.9)	202/251 (80.5)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	98/105 (93.3)	98/108 (90.7)	196/213 (92.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	98/105 (93.3)	98/108 (90.7)	196/213 (92.0)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 7 min			
Borg Score			
n	83	85	168
MEAN(SD)	13.7 (3.03)	13.1 (3.08)	13.4 (3.06)
MEDIAN	13.0	13.0	13.0
MIN, MAX	7, 20	6, 20	6, 20
Q1, Q3	12, 16	11, 15	12, 15
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	83/123 (67.5)	85/128 (66.4)	168/251 (66.9)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	79/95 (83.2)	81/102 (79.4)	160/197 (81.2)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	79/95 (83.2)	81/102 (79.4)	160/197 (81.2)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 8 min			
Borg Score			
n	86	90	176
MEAN(SD)	14.4 (3.01)	13.9 (3.10)	14.1 (3.06)
MEDIAN	14.0	14.0	14.0
MIN, MAX	7, 20	7, 20	7, 20
Q1, Q3	12, 17	12, 16	12, 16
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	86/123 (69.9)	90/128 (70.3)	176/251 (70.1)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	79/83 (95.2)	82/92 (89.1)	161/175 (92.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	79/83 (95.2)	82/92 (89.1)	161/175 (92.0)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-borgcompr.sas 22JUN2022:06:02

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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 9 min			
Borg Score			
n	68	70	138
MEAN(SD)	15.1 (2.96)	14.6 (3.09)	14.9 (3.03)
MEDIAN	15.0	15.0	15.0
MIN, MAX	8, 20	7, 20	7, 20
Q1, Q3	13, 18	13, 17	13, 17
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	68/123 (55.3)	70/128 (54.7)	138/251 (55.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	61/70 (87.1)	62/76 (81.6)	123/146 (84.2)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	61/70 (87.1)	62/76 (81.6)	123/146 (84.2)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 10 min			
Borg Score			
n	63	69	132
MEAN(SD)	15.1 (2.82)	15.0 (2.96)	15.0 (2.88)
MEDIAN	15.0	15.0	15.0
MIN, MAX	8, 20	7, 20	7, 20
Q1, Q3	13, 17	13, 17	13, 17
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	63/123 (51.2)	69/128 (53.9)	132/251 (52.6)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	53/55 (96.4)	57/62 (91.9)	110/117 (94.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	53/55 (96.4)	57/62 (91.9)	110/117 (94.0)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 11 min			
Borg Score			
n	45	49	94
MEAN(SD)	15.5 (2.70)	15.5 (3.29)	15.5 (3.01)
MEDIAN	15.0	16.0	16.0
MIN, MAX	9, 20	7, 20	7, 20
Q1, Q3	14, 18	14, 18	14, 18
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	45/123 (36.6)	49/128 (38.3)	94/251 (37.5)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	42/48 (87.5)	42/53 (79.2)	84/101 (83.2)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	42/48 (87.5)	42/53 (79.2)	84/101 (83.2)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 12 min			
Borg Score			
n	44	50	94
MEAN(SD)	15.8 (2.74)	15.9 (3.18)	15.9 (2.97)
MEDIAN	15.5	16.5	16.0
MIN, MAX	9, 20	7, 20	7, 20
Q1, Q3	14, 18	14, 19	14, 18
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	44/123 (35.8)	50/128 (39.1)	94/251 (37.5)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	40/42 (95.2)	42/45 (93.3)	82/87 (94.3)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	40/42 (95.2)	42/45 (93.3)	82/87 (94.3)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 13 min			
Borg Score			
n	30	35	65
MEAN(SD)	16.4 (2.22)	16.5 (3.15)	16.4 (2.74)
MEDIAN	17.0	17.0	17.0
MIN, MAX	12, 20	7, 20	7, 20
Q1, Q3	15, 18	15, 19	15, 19
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	30/123 (24.4)	35/128 (27.3)	65/251 (25.9)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	23/28 (82.1)	25/30 (83.3)	48/58 (82.8)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	23/28 (82.1)	25/30 (83.3)	48/58 (82.8)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 14 min			
Borg Score			
n	25	26	51
MEAN(SD)	16.0 (2.04)	15.9 (2.80)	15.9 (2.44)
MEDIAN	16.0	16.0	16.0
MIN, MAX	12, 19	8, 20	8, 20
Q1, Q3	15, 18	15, 18	15, 18
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	25/123 (20.3)	26/128 (20.3)	51/251 (20.3)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	21/22 (95.5)	22/25 (88.0)	43/47 (91.5)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	21/22 (95.5)	22/25 (88.0)	43/47 (91.5)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 15 min			
Borg Score			
n	15	17	32
MEAN(SD)	16.8 (2.11)	16.2 (2.92)	16.5 (2.55)
MEDIAN	17.0	17.0	17.0
MIN, MAX	13, 19	10, 20	10, 20
Q1, Q3	15, 19	15, 18	15, 19
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	15/123 (12.2)	17/128 (13.3)	32/251 (12.7)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	14/16 (87.5)	15/19 (78.9)	29/35 (82.9)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	14/16 (87.5)	15/19 (78.9)	29/35 (82.9)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 16 min			
Borg Score			
n	15	19	34
MEAN(SD)	17.1 (1.98)	17.1 (2.59)	17.1 (2.31)
MEDIAN	17.0	17.0	17.0
MIN, MAX	14, 20	11, 20	11, 20
Q1, Q3	15, 19	15, 19	15, 19
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	15/123 (12.2)	19/128 (14.8)	34/251 (13.5)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	11/11 (100.0)	11/12 (91.7)	22/23 (95.7)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	11/11 (100.0)	11/12 (91.7)	22/23 (95.7)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 17 min			
Borg Score			
n	11	8	19
MEAN(SD)	17.6 (1.80)	17.4 (2.33)	17.5 (1.98)
MEDIAN	18.0	18.0	18.0
MIN, MAX	15, 20	13, 20	13, 20
Q1, Q3	16, 19	16, 19	16, 19
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	11/123 (8.9)	8/128 (6.3)	19/251 (7.6)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	7/7 (100.0)	8/9 (88.9)	15/16 (93.8)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	7/7 (100.0)	8/9 (88.9)	15/16 (93.8)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 18 min			
Borg Score			
n	7	8	15
MEAN(SD)	17.3 (1.60)	16.1 (3.56)	16.7 (2.79)
MEDIAN	17.0	16.5	17.0
MIN, MAX	15, 20	9, 20	9, 20
Q1, Q3	16, 18	15, 19	15, 19
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	7/123 (5.7)	8/128 (6.3)	15/251 (6.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	3/3 (100.0)	5/5 (100.0)	8/8 (100.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	3/3 (100.0)	5/5 (100.0)	8/8 (100.0)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 19 min			
Borg Score			
n	2	4	6
MEAN(SD)	17.5 (2.12)	16.0 (1.41)	16.5 (1.64)
MEDIAN	17.5	16.5	16.5
MIN, MAX	16, 19	14, 17	14, 19
Q1, Q3	16, 19	15, 17	16, 17
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	2/123 (1.6)	4/128 (3.1)	6/251 (2.4)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	1/1 (100.0)	3/4 (75.0)	4/5 (80.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	1/1 (100.0)	3/4 (75.0)	4/5 (80.0)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 20 min			
Borg Score			
n	1	4	5
MEAN(SD)	17.0 (0)	16.5 (1.00)	16.6 (0.89)
MEDIAN	17.0	17.0	17.0
MIN, MAX	17, 17	15, 17	15, 17
Q1, Q3	17, 17	16, 17	17, 17
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	1/123 (0.8)	4/128 (3.1)	5/251 (2.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	1/1 (100.0)	4/4 (100.0)	5/5 (100.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	1/1 (100.0)	4/4 (100.0)	5/5 (100.0)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 21 min			
Borg Score			
n	0	3	3
MEAN(SD)		16.3 (1.15)	16.3 (1.15)
MEDIAN		17.0	17.0
MIN, MAX		15, 17	15, 17
Q1, Q3		15, 17	15, 17
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	0	3/128 (2.3)	3/251 (1.2)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	0	3/4 (75.0)	3/4 (75.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	0	3/4 (75.0)	3/4 (75.0)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 22 min			
Borg Score			
n	0	3	3
MEAN(SD)		16.3 (1.15)	16.3 (1.15)
MEDIAN		17.0	17.0
MIN, MAX		15, 17	15, 17
Q1, Q3		15, 17	15, 17
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	0	3/128 (2.3)	3/251 (1.2)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	0	1/1 (100.0)	1/1 (100.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	0	1/1 (100.0)	1/1 (100.0)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
Week 30			
Pre-exercise (after 5min supine)			
Borg Score			
n	93	92	185
MEAN(SD)	6.0 (0.18)	6.1 (0.54)	6.1 (0.40)
MEDIAN	6.0	6.0	6.0
MIN, MAX	6, 7	6, 10	6, 10
Q1, Q3	6, 6	6, 6	6, 6
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	93/123 (75.6)	92/128 (71.9)	185/251 (73.7)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	93/120 (77.5)	92/125 (73.6)	185/245 (75.5)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	93/123 (75.6)	92/128 (71.9)	185/251 (73.7)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
Pre-exercise (after 2 min standing)			
Borg Score			
n	96	95	191
MEAN(SD)	6.1 (0.22)	6.2 (0.62)	6.1 (0.47)
MEDIAN	6.0	6.0	6.0
MIN, MAX	6, 7	6, 10	6, 10
Q1, Q3	6, 6	6, 6	6, 6
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	96/123 (78.0)	95/128 (74.2)	191/251 (76.1)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	96/120 (80.0)	95/125 (76.0)	191/245 (78.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	96/123 (78.0)	95/128 (74.2)	191/251 (76.1)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 1 min			
Borg Score			
n	93	101	194
MEAN(SD)	7.3 (1.46)	7.3 (1.57)	7.3 (1.52)
MEDIAN	7.0	7.0	7.0
MIN, MAX	6, 13	6, 13	6, 13
Q1, Q3	6, 8	6, 8	6, 8
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	93/123 (75.6)	101/128 (78.9)	194/251 (77.3)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	93/120 (77.5)	101/125 (80.8)	194/245 (79.2)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	93/123 (75.6)	101/128 (78.9)	194/251 (77.3)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 2 min			
Borg Score			
n	109	115	224
MEAN(SD)	8.3 (2.31)	8.3 (2.32)	8.3 (2.31)
MEDIAN	8.0	7.0	7.5
MIN, MAX	1, 16	6, 16	1, 16
Q1, Q3	7, 9	7, 10	7, 9
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	109/123 (88.6)	115/128 (89.8)	224/251 (89.2)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	108/119 (90.8)	115/124 (92.7)	223/243 (91.8)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	108/122 (88.5)	115/127 (90.6)	223/249 (89.6)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-borgcompr.sas 22JUN2022:06:02

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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 3 min			
Borg Score			
n	93	101	194
MEAN(SD)	9.2 (2.53)	9.6 (2.84)	9.4 (2.70)
MEDIAN	9.0	9.0	9.0
MIN, MAX	5, 17	6, 19	5, 19
Q1, Q3	7, 11	7, 11	7, 11
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	93/123 (75.6)	101/128 (78.9)	194/251 (77.3)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	93/118 (78.8)	100/123 (81.3)	193/241 (80.1)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	93/121 (76.9)	100/126 (79.4)	193/247 (78.1)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 4 min			
Borg Score			
n	111	114	225
MEAN(SD)	10.4 (3.29)	10.6 (3.32)	10.5 (3.30)
MEDIAN	9.0	10.0	10.0
MIN, MAX	1, 20	6, 20	1, 20
Q1, Q3	8, 13	8, 13	8, 13
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	111/123 (90.2)	114/128 (89.1)	225/251 (89.6)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	107/114 (93.9)	111/120 (92.5)	218/234 (93.2)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	107/117 (91.5)	111/123 (90.2)	218/240 (90.8)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 5 min			
Borg Score			
n	90	94	184
MEAN(SD)	11.3 (3.21)	11.4 (3.36)	11.4 (3.28)
MEDIAN	11.0	11.0	11.0
MIN, MAX	6, 20	6, 20	6, 20
Q1, Q3	9, 13	9, 13	9, 13
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	90/123 (73.2)	94/128 (73.4)	184/251 (73.3)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	87/109 (79.8)	92/113 (81.4)	179/222 (80.6)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	87/112 (77.7)	92/116 (79.3)	179/228 (78.5)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 6 min			
Borg Score			
n	102	102	204
MEAN(SD)	12.1 (3.41)	12.4 (3.14)	12.3 (3.27)
MEDIAN	12.0	12.0	12.0
MIN, MAX	6, 19	6, 20	6, 20
Q1, Q3	9, 15	10, 14	10, 15
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	102/123 (82.9)	102/128 (79.7)	204/251 (81.3)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	98/105 (93.3)	100/108 (92.6)	198/213 (93.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	98/108 (90.7)	100/111 (90.1)	198/219 (90.4)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 7 min			
Borg Score			
n	81	85	166
MEAN(SD)	13.0 (3.30)	13.1 (2.90)	13.1 (3.09)
MEDIAN	13.0	13.0	13.0
MIN, MAX	6, 20	6, 20	6, 20
Q1, Q3	11, 15	11, 15	11, 15
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	81/123 (65.9)	85/128 (66.4)	166/251 (66.1)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	78/99 (78.8)	83/100 (83.0)	161/199 (80.9)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	78/102 (76.5)	83/103 (80.6)	161/205 (78.5)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 8 min			
Borg Score			
n	90	91	181
MEAN(SD)	13.6 (3.26)	14.0 (2.95)	13.8 (3.10)
MEDIAN	13.0	14.0	14.0
MIN, MAX	6, 20	7, 20	6, 20
Q1, Q3	12, 16	12, 16	12, 16
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	90/123 (73.2)	91/128 (71.1)	181/251 (72.1)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	84/89 (94.4)	82/86 (95.3)	166/175 (94.9)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	84/92 (91.3)	82/89 (92.1)	166/181 (91.7)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 9 min			
Borg Score			
n	66	70	136
MEAN(SD)	14.2 (3.12)	14.6 (3.09)	14.4 (3.10)
MEDIAN	14.0	15.0	14.0
MIN, MAX	6, 20	6, 20	6, 20
Q1, Q3	13, 16	12, 17	13, 17
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	66/123 (53.7)	70/128 (54.7)	136/251 (54.2)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	59/73 (80.8)	65/76 (85.5)	124/149 (83.2)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	59/76 (77.6)	65/79 (82.3)	124/155 (80.0)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 10 min			
Borg Score			
n	69	74	143
MEAN(SD)	14.6 (3.30)	15.4 (3.05)	15.0 (3.19)
MEDIAN	15.0	15.0	15.0
MIN, MAX	6, 20	6, 20	6, 20
Q1, Q3	13, 17	13, 17	13, 17
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	69/123 (56.1)	74/128 (57.8)	143/251 (57.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	56/58 (96.6)	64/66 (97.0)	120/124 (96.8)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	56/61 (91.8)	64/69 (92.8)	120/130 (92.3)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 11 min			
Borg Score			
n	48	51	99
MEAN(SD)	14.9 (3.14)	15.9 (3.36)	15.4 (3.28)
MEDIAN	15.0	16.0	16.0
MIN, MAX	6, 20	6, 20	6, 20
Q1, Q3	14, 17	14, 19	14, 18
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	48/123 (39.0)	51/128 (39.8)	99/251 (39.4)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	42/51 (82.4)	44/54 (81.5)	86/105 (81.9)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	42/54 (77.8)	44/57 (77.2)	86/111 (77.5)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 12 min			
Borg Score			
n	50	47	97
MEAN(SD)	15.0 (3.26)	16.1 (2.71)	15.5 (3.04)
MEDIAN	15.0	16.0	16.0
MIN, MAX	6, 20	9, 20	6, 20
Q1, Q3	14, 17	14, 18	14, 17
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	50/123 (40.7)	47/128 (36.7)	97/251 (38.6)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	42/44 (95.5)	39/41 (95.1)	81/85 (95.3)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	42/47 (89.4)	39/44 (88.6)	81/91 (89.0)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 13 min			
Borg Score			
n	31	29	60
MEAN(SD)	15.1 (3.35)	16.3 (3.07)	15.7 (3.25)
MEDIAN	15.0	17.0	16.0
MIN, MAX	7, 20	6, 20	6, 20
Q1, Q3	14, 18	15, 18	15, 18
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	31/123 (25.2)	29/128 (22.7)	60/251 (23.9)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	25/33 (75.8)	26/34 (76.5)	51/67 (76.1)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	25/36 (69.4)	26/37 (70.3)	51/73 (69.9)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 14 min			
Borg Score			
n	34	31	65
MEAN(SD)	15.3 (3.04)	16.8 (2.05)	16.0 (2.71)
MEDIAN	15.0	17.0	17.0
MIN, MAX	8, 20	12, 20	8, 20
Q1, Q3	14, 17	15, 18	15, 18
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	34/123 (27.6)	31/128 (24.2)	65/251 (25.9)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	25/28 (89.3)	23/25 (92.0)	48/53 (90.6)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	25/31 (80.6)	23/28 (82.1)	48/59 (81.4)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 15 min			
Borg Score			
n	21	18	39
MEAN(SD)	16.8 (2.94)	17.7 (2.05)	17.2 (2.58)
MEDIAN	17.0	18.5	18.0
MIN, MAX	8, 20	14, 20	8, 20
Q1, Q3	15, 19	16, 19	15, 19
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	21/123 (17.1)	18/128 (14.1)	39/251 (15.5)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	17/21 (81.0)	13/19 (68.4)	30/40 (75.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	17/24 (70.8)	13/22 (59.1)	30/46 (65.2)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 16 min			
Borg Score			
n	21	17	38
MEAN(SD)	16.9 (3.09)	18.0 (2.03)	17.4 (2.70)
MEDIAN	17.0	18.0	18.0
MIN, MAX	9, 20	13, 20	9, 20
Q1, Q3	15, 19	17, 20	16, 20
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	21/123 (17.1)	17/128 (13.3)	38/251 (15.1)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	16/18 (88.9)	13/14 (92.9)	29/32 (90.6)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	16/21 (76.2)	13/17 (76.5)	29/38 (76.3)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 17 min			
Borg Score			
n	12	8	20
MEAN(SD)	16.9 (2.94)	17.1 (2.80)	17.0 (2.81)
MEDIAN	17.5	17.5	17.5
MIN, MAX	9, 20	11, 20	9, 20
Q1, Q3	16, 19	17, 19	16, 19
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	12/123 (9.8)	8/128 (6.3)	20/251 (8.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	10/13 (76.9)	6/8 (75.0)	16/21 (76.2)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	10/16 (62.5)	6/11 (54.5)	16/27 (59.3)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 18 min			
Borg Score			
n	11	8	19
MEAN(SD)	16.7 (3.07)	17.9 (2.10)	17.2 (2.70)
MEDIAN	18.0	18.5	18.0
MIN, MAX	10, 20	14, 20	10, 20
Q1, Q3	16, 19	17, 20	16, 19
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	11/123 (8.9)	8/128 (6.3)	19/251 (7.6)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	7/8 (87.5)	6/6 (100.0)	13/14 (92.9)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	7/11 (63.6)	6/9 (66.7)	13/20 (65.0)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-borgcompr.sas 22JUN2022:06:02

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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 19 min			
Borg Score			
n	6	4	10
MEAN(SD)	16.7 (3.39)	18.3 (1.71)	17.3 (2.83)
MEDIAN	17.5	18.5	18.0
MIN, MAX	10, 19	16, 20	10, 20
Q1, Q3	17, 19	17, 20	17, 19
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	6/123 (4.9)	4/128 (3.1)	10/251 (4.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	5/7 (71.4)	4/5 (80.0)	9/12 (75.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	5/10 (50.0)	4/8 (50.0)	9/18 (50.0)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-borgcompr.sas 22JUN2022:06:02

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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 20 min			
Borg Score			
n	7	4	11
MEAN(SD)	16.7 (3.09)	17.5 (1.91)	17.0 (2.65)
MEDIAN	18.0	18.0	18.0
MIN, MAX	11, 19	15, 19	11, 19
Q1, Q3	14, 19	16, 19	15, 19
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	7/123 (5.7)	4/128 (3.1)	11/251 (4.4)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	4/4 (100.0)	3/3 (100.0)	7/7 (100.0)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	4/7 (57.1)	3/6 (50.0)	7/13 (53.8)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-borgcompr.sas 22JUN2022:06:02

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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 21 min			
Borg Score			
n	5	3	8
MEAN(SD)	18.0 (1.58)	19.0 (1.73)	18.4 (1.60)
MEDIAN	18.0	20.0	18.5
MIN, MAX	16, 20	17, 20	16, 20
Q1, Q3	17, 19	17, 20	17, 20
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	5/123 (4.1)	3/128 (2.3)	8/251 (3.2)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	4/4 (100.0)	2/3 (66.7)	6/7 (85.7)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	4/7 (57.1)	2/6 (33.3)	6/13 (46.2)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-borgcompr.sas 22JUN2022:06:02

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Compliance Rates and Descriptive Statistics for Borg Score in Baseline and Week 30
Intention-to-treat (ITT) population

	Mavacamten N = 123	Placebo N = 128	Overall N = 251
At 22 min			
Borg Score			
n	4	2	6
MEAN(SD)	18.5 (1.29)	19.0 (1.41)	18.7 (1.21)
MEDIAN	18.5	19.0	18.5
MIN, MAX	17, 20	18, 20	17, 20
Q1, Q3	18, 20	18, 20	18, 20
Number of Subjects Who Complete the Borg Score /Number of all randomized subjects n/N (%)	4/123 (3.3)	2/128 (1.6)	6/251 (2.4)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 1 n/N (%)	1/1 (100.0)	1/2 (50.0)	2/3 (66.7)
Number of Subjects Who Completed the Borg Score /Number of subpopulation 2 n/N (%)	1/4 (25.0)	1/5 (20.0)	2/9 (22.2)

Data Cutoff: 30JUN2020. Baseline is defined as the corresponding value derived from CPET exercise at screening.
Subpopulation 1: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are excluded from (de)nominators.
Subpopulation 2: number of randomized subjects minus subjects who cannot report a Borg score due to premature termination of CPET. Subjects with missing peak exercise time are expected to have reported Borg score until min 22.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-borgcompr.sas 22JUN2022:06:02

4.6.2 Subgruppenanalyse für die Veränderung des Belastungsempfindens gemäß RPE-Skala nach Borg (AUC) zu Woche 30 gegenüber Baseline mittels ANCOVA

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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Change of AUC from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
AREA UNDER THE BORG SCORE CURVE									
BETA-BLOCKER USE									0.0931
YES	83	359.47 (37.977)	-8.30 (-14.06, -2.53)	84	352.07 (36.703)	-0.36 (-6.07, 5.35)	-7.94 (-16.06, 0.19) 0.0555	-0.30 (-0.60, 0.01)	
NO	27	347.48 (37.855)	-19.82 (-29.90, -9.74)	28	346.92 (41.392)	2.05 (-7.86, 11.95)	-21.87 (-35.97, -7.76) 0.0025	-0.81 (-1.36, -0.26)	
TYPE OF EXERCISE TESTING									0.1536
EXERCISE BICYCLE	46	363.63 (30.737)	-4.20 (-11.94, 3.55)	48	357.51 (34.332)	1.13 (-6.40, 8.66)	-5.33 (-16.10, 5.44) 0.3306	-0.20 (-0.60, 0.21)	
TREADMILL	64	351.43 (42.155)	-16.08 (-22.60, -9.56)	64	345.74 (39.728)	-0.46 (-7.01, 6.10)	-15.62 (-24.85, -6.39) 0.0010	-0.58 (-0.94, -0.23)	

Data Cutoff Date: 30JUN2020.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
AUC=area under the Borg score curve. Computed Borg score is used in this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-aucrsub.sas 06APR2023:04:36

Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Change of AUC from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NYHA CLASS									0.8498
CLASS II	78	349.35 (36.737)	-13.45 (-19.40, -7.50)	82	342.61 (34.643)	-1.61 (-7.50, 4.28)	-11.84 (-20.16, -3.53) 0.0054	-0.44 (-0.75, -0.13)	
CLASS III	32	374.01 (36.249)	-5.26 (-14.73, 4.22)	30	373.13 (37.580)	5.08 (-4.68, 14.83)	-10.33 (-23.65, 2.98) 0.1276	-0.38 (-0.88, 0.12)	
CONSENT FOR THE CMR SUBSTUDY									0.9896
YES	20	354.03 (34.801)	-12.93 (-24.73, -1.14)	20	355.31 (38.446)	-1.42 (-13.22, 10.37)	-11.51 (-28.19, 5.17) 0.1754	-0.42 (-1.05, 0.21)	
NO	90	357.08 (38.989)	-10.75 (-16.32, -5.18)	92	349.80 (37.803)	0.63 (-4.88, 6.14)	-11.39 (-19.24, -3.53) 0.0047	-0.42 (-0.71, -0.13)	

Data Cutoff Date: 30JUN2020.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
AUC=area under the Borg score curve. Computed Borg score is used in this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-aucrsub.sas 06APR2023:04:36

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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Change of AUC from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
SEX									0.6583
MALE	61	340.85 (33.619)	-12.75 (-19.61, -5.89)	74	339.15 (33.347)	-2.22 (-8.51, 4.08)	-10.53 (-19.62, -1.44) 0.0234	-0.39 (-0.73, -0.05)	
FEMALE	49	376.05 (34.448)	-8.96 (-16.83, -1.10)	38	373.45 (35.985)	4.84 (-3.94, 13.61)	-13.80 (-25.16, -2.44) 0.0175	-0.51 (-0.94, -0.08)	
AGE									0.6719
<= 49	21	341.60 (42.318)	-22.45 (-33.90, -11.01)	20	337.56 (32.023)	-5.04 (-16.81, 6.74)	-17.42 (-33.72, -1.11) 0.0364	-0.64 (-1.27, -0.01)	
50 - 64	46	343.60 (33.382)	-11.89 (-19.64, -4.13)	58	347.14 (36.334)	-0.17 (-7.05, 6.71)	-11.72 (-22.03, -1.42) 0.0260	-0.44 (-0.83, -0.05)	
>=65	43	377.65 (31.219)	-4.53 (-12.84, 3.77)	34	364.77 (40.066)	3.73 (-5.29, 12.74)	-8.26 (-20.30, 3.78) 0.1779	-0.31 (-0.76, 0.15)	

Data Cutoff Date: 30JUN2020.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
AUC=area under the Borg score curve. Computed Borg score is used in this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-aucrsub.sas 06APR2023:04:36

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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Change of AUC from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
BMI									0.4468
<30	72	356.73 (40.255)	-12.28 (-18.50, -6.06)	68	354.87 (37.844)	1.20 (-5.19, 7.59)	-13.48 (-22.40, -4.57) 0.0032	-0.50 (-0.84, -0.16)	
>=30	38	356.15 (34.246)	-8.99 (-17.54, -0.43)	44	344.47 (37.288)	-1.19 (-9.19, 6.80)	-7.79 (-19.51, 3.93) 0.1917	-0.29 (-0.72, 0.15)	
RACE									0.9070
NON-WHITE	7	357.28 (34.259)	-17.54 (-37.45, 2.37)	13	342.70 (35.763)	-4.42 (-19.07, 10.22)	-13.12 (-37.85, 11.62) 0.2971	-0.47 (-1.40, 0.46)	
WHITE	103	356.48 (38.528)	-10.71 (-15.91, -5.51)	99	351.84 (38.108)	0.87 (-4.42, 6.17)	-11.58 (-19.01, -4.16) 0.0024	-0.43 (-0.71, -0.15)	

Data Cutoff Date: 30JUN2020.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
AUC=area under the Borg score curve. Computed Borg score is used in this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-aucrsub.sas 06APR2023:04:36

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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Change of AUC from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
REGION									0.6470
US	49	350.02 (39.320)	-11.74 (-19.28, -4.21)	49	341.81 (33.540)	-2.25 (-9.86, 5.36)	-9.50 (-20.17, 1.17) 0.0808	-0.35 (-0.75, 0.05)	
EX-US	61	361.76 (36.628)	-10.63 (-17.42, -3.84)	63	357.76 (39.681)	2.18 (-4.47, 8.83)	-12.81 (-22.28, -3.34) 0.0082	-0.47 (-0.83, -0.12)	
CALCIUM CHANNEL BLOCKER USE									0.1553
YES	23	350.11 (35.433)	-16.20 (-27.16, -5.25)	16	350.95 (46.698)	6.43 (-6.71, 19.56)	-22.63 (-39.73, -5.53) 0.0097	-0.83 (-1.49, -0.16)	
NO	87	358.22 (38.825)	-9.80 (-15.45, -4.15)	96	350.76 (36.407)	-0.77 (-6.14, 4.59)	-9.03 (-16.84, -1.22) 0.0236	-0.33 (-0.63, -0.04)	

Data Cutoff Date: 30JUN2020.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
AUC=area under the Borg score curve. Computed Borg score is used in this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-aucrsub.sas 06APR2023:04:36

Protocol: MYK-461-005

Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Change of AUC from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
PRESENCE OF HCM PATHOGENIC MUTATION									0.9177
PATHOGENIC OR LIKELY PATHOGENIC	24	366.86 (30.924)	-14.53 (-25.96, -3.10)	20	349.27 (38.785)	-2.26 (-14.67, 10.15)	-12.27 (-29.18, 4.65) 0.1542	-0.42 (-1.02, 0.18)	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	29	345.81 (41.122)	-8.11 (-18.45, 2.23)	37	349.32 (40.982)	1.77 (-7.36, 10.90)	-9.88 (-23.64, 3.87) 0.1579	-0.35 (-0.83, 0.14)	
NEGATIVE	26	368.11 (35.374)	-9.72 (-20.73, 1.29)	29	354.53 (31.512)	4.43 (-5.87, 14.73)	-14.15 (-29.22, 0.91) 0.0653	-0.49 (-1.03, 0.05)	
TIME FROM DIAGNOSIS OF OHCM									0.2710
<=5	58	351.09 (38.874)	-11.55 (-18.43, -4.66)	49	356.48 (32.678)	-4.66 (-12.16, 2.83)	-6.88 (-17.07, 3.30) 0.1842	-0.26 (-0.64, 0.13)	
>5	52	362.59 (36.701)	-10.75 (-18.07, -3.43)	63	346.35 (41.063)	4.13 (-2.51, 10.77)	-14.88 (-24.82, -4.94) 0.0035	-0.55 (-0.92, -0.17)	

Data Cutoff Date: 30JUN2020.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
AUC=area under the Borg score curve. Computed Borg score is used in this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-aucrsub.sas 06APR2023:04:36

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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Change of AUC from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
SEPTAL REDUCTION THERAPY (SRT) HISTORY									0.4093
YES	10	374.33 (29.216)	-18.41 (-35.18, -1.64)	7	360.82 (37.091)	3.41 (-16.51, 23.33)	-21.82 (-47.81, 4.16) 0.0993	-0.77 (-1.77, 0.23)	
NO	100	354.75 (38.571)	-10.44 (-15.70, -5.17)	105	350.11 (37.930)	0.07 (-5.09, 5.22)	-10.50 (-17.87, -3.13) 0.0055	-0.39 (-0.67, -0.11)	
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED									0.7126
YES	26	365.31 (37.073)	-15.43 (-25.81, -5.05)	25	350.59 (31.619)	-1.62 (-12.15, 8.92)	-13.81 (-28.63, 1.00) 0.0675	-0.50 (-1.06, 0.05)	
NO	84	353.81 (38.255)	-9.84 (-15.59, -4.09)	87	350.84 (39.566)	0.82 (-4.83, 6.47)	-10.66 (-18.72, -2.60) 0.0098	-0.39 (-0.70, -0.09)	

Data Cutoff Date: 30JUN2020.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
AUC=area under the Borg score curve. Computed Borg score is used in this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-aucrsub.sas 06APR2023:04:36

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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Change of AUC from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
HISTORY OF HYPERTENSION									0.1804
YES	56	362.20 (35.910)	-6.86 (-13.91, 0.20)	53	355.49 (35.555)	-0.24 (-7.44, 6.97)	-6.62 (-16.69, 3.45) 0.1963	-0.25 (-0.62, 0.13)	
NO	54	350.64 (39.778)	-15.56 (-22.70, -8.42)	59	346.55 (39.536)	0.67 (-6.19, 7.53)	-16.23 (-26.11, -6.35) 0.0014	-0.60 (-0.98, -0.22)	
RESTING LVEF									0.6938
<75%	63	348.75 (39.201)	-12.27 (-18.91, -5.63)	62	349.41 (40.688)	-2.22 (-8.91, 4.48)	-10.05 (-19.46, -0.64) 0.0364	-0.37 (-0.73, -0.02)	
>=75%	47	366.95 (34.344)	-9.61 (-17.39, -1.83)	50	352.48 (34.221)	3.30 (-4.14, 10.74)	-12.92 (-23.69, -2.14) 0.0190	-0.47 (-0.88, -0.07)	

Data Cutoff Date: 30JUN2020.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
AUC=area under the Borg score curve. Computed Borg score is used in this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Change of AUC from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
LVOT RESTING PEAK GRADIENT									0.4797
<=50	56	352.17 (37.356)	-9.89 (-16.94, -2.85)	60	344.92 (39.822)	-0.92 (-7.77, 5.94)	-8.98 (-18.80, 0.84) 0.0730	-0.33 (-0.70, 0.04)	
>50	54	361.05 (38.738)	-12.45 (-19.65, -5.24)	52	357.55 (34.476)	1.62 (-5.70, 8.94)	-14.07 (-24.32, -3.82) 0.0074	-0.52 (-0.91, -0.13)	
LVOT RESTING PEAK GRADIENT									0.6877
<=30	32	356.95 (37.274)	-8.23 (-17.55, 1.10)	37	338.33 (39.865)	0.92 (-7.86, 9.71)	-9.15 (-22.00, 3.70) 0.1619	-0.33 (-0.81, 0.14)	
>30	78	356.35 (38.709)	-12.35 (-18.33, -6.38)	75	356.93 (35.422)	-0.06 (-6.15, 6.04)	-12.30 (-20.82, -3.77) 0.0049	-0.46 (-0.78, -0.13)	

Data Cutoff Date: 30JUN2020.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
AUC=area under the Borg score curve. Computed Borg score is used in this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-aucrsub.sas 06APR2023:04:36

Protocol: MYK-461-005

Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Change of AUC from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
E/E' LATERAL									0.9027
<=14	49	345.91 (34.640)	-14.06 (-21.57, -6.56)	56	347.83 (32.259)	-1.67 (-8.67, 5.34)	-12.40 (-22.62, -2.17) 0.0177	-0.46 (-0.85, -0.07)	
>14	56	365.59 (38.914)	-9.23 (-16.32, -2.15)	51	357.07 (40.969)	4.06 (-3.27, 11.38)	-13.29 (-23.44, -3.14) 0.0105	-0.49 (-0.88, -0.11)	
E/E' SEPTAL									0.1538
<=14	14	347.74 (32.484)	-23.60 (-37.61, -9.60)	24	341.66 (30.360)	-0.01 (-10.75, 10.74)	-23.59 (-41.21, -5.98) 0.0089	-0.86 (-1.55, -0.18)	
>14	96	357.81 (38.865)	-9.31 (-14.67, -3.96)	88	353.27 (39.376)	0.32 (-5.26, 5.90)	-9.63 (-17.37, -1.89) 0.0149	-0.36 (-0.65, -0.07)	

Data Cutoff Date: 30JUN2020.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
AUC=area under the Borg score curve. Computed Borg score is used in this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-aucrsub.sas 06APR2023:04:36

Protocol: MYK-461-005

Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Change of AUC from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE									0.1008
<=14	23	348.37 (33.983)	-20.45 (-31.37, -9.53)	29	343.21 (29.843)	1.85 (-7.92, 11.62)	-22.30 (-36.92, -7.68) 0.0030	-0.82 (-1.39, -0.25)	
>14	87	358.69 (39.045)	-8.67 (-14.30, -3.04)	83	353.43 (40.038)	-0.31 (-6.06, 5.43)	-8.36 (-16.40, -0.31) 0.0418	-0.31 (-0.61, -0.01)	
LEFT ATRIAL VOLUME INDEX									0.1939
<=MEDIAN	55	356.83 (38.561)	-7.95 (-15.06, -0.85)	55	348.38 (35.051)	-1.43 (-8.54, 5.68)	-6.53 (-16.59, 3.54) 0.2024	-0.24 (-0.62, 0.13)	
>MEDIAN	54	356.56 (38.321)	-14.02 (-21.18, -6.85)	57	353.10 (40.458)	1.88 (-5.09, 8.85)	-15.90 (-25.89, -5.90) 0.0020	-0.59 (-0.97, -0.21)	

Data Cutoff Date: 30JUN2020.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
AUC=area under the Borg score curve. Computed Borg score is used in this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-aucrsub.sas 06APR2023:04:36

Protocol: MYK-461-005

Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Change of AUC from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NT-PROBNP									0.3619
<=MEDIAN	51	346.89 (36.177)	-11.68 (-19.00, -4.36)	60	347.51 (38.662)	-3.77 (-10.52, 2.97)	-7.91 (-17.82, 2.01) 0.1175	-0.30 (-0.67, 0.08)	
>MEDIAN	57	364.36 (38.570)	-9.86 (-16.83, -2.89)	51	354.33 (37.128)	4.60 (-2.69, 11.89)	-14.46 (-24.54, -4.38) 0.0051	-0.54 (-0.92, -0.15)	
HS-CARDIAC TROPONIN-I									0.5986
<=ULN	78	355.56 (38.705)	-13.11 (-19.07, -7.14)	85	346.55 (39.054)	0.56 (-5.19, 6.31)	-13.67 (-21.97, -5.37) 0.0014	-0.50 (-0.82, -0.19)	
>ULN	29	358.69 (38.338)	-8.06 (-17.85, 1.73)	19	366.01 (26.503)	0.88 (-11.26, 13.02)	-8.95 (-24.50, 6.61) 0.2582	-0.33 (-0.91, 0.25)	

Data Cutoff Date: 30JUN2020.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
AUC=area under the Borg score curve. Computed Borg score is used in this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-aucrsub.sas 06APR2023:04:36

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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Change of AUC from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.8644
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	35	345.79 (34.303)	-16.59 (-25.46, -7.72)	46	345.62 (31.798)	-2.69 (-10.44, 5.05)	-13.90 (-25.62, -2.17) 0.0204	-0.52 (-0.96, -0.07)	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	71	360.81 (38.653)	-8.99 (-15.23, -2.75)	57	358.78 (39.625)	3.61 (-3.33, 10.55)	-12.60 (-21.90, -3.30) 0.0081	-0.47 (-0.82, -0.12)	
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.4410
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	11	344.66 (36.188)	-19.02 (-34.95, -3.09)	20	339.31 (28.545)	-0.06 (-11.94, 11.81)	-18.96 (-38.77, 0.86) 0.0607	-0.69 (-1.44, 0.07)	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	99	357.85 (38.284)	-10.26 (-15.58, -4.94)	91	353.86 (39.026)	0.38 (-5.15, 5.91)	-10.64 (-18.31, -2.97) 0.0068	-0.39 (-0.68, -0.11)	

Data Cutoff Date: 30JUN2020.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
AUC=area under the Borg score curve. Computed Borg score is used in this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-aucrsub.sas 06APR2023:04:36

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Subgroup Analysis: Comparison between Mavacamten and Placebo Group in Change of AUC from Baseline to Week 30
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.1795
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	18	347.75 (35.164)	-20.90 (-33.31, -8.49)	22	340.55 (27.876)	0.65 (-10.63, 11.94)	-21.55 (-38.29, -4.82) 0.0118	-0.79 (-1.43, -0.14)	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	92	358.24 (38.627)	-9.22 (-14.72, -3.72)	87	354.14 (39.426)	-0.30 (-5.94, 5.34)	-8.92 (-16.80, -1.05) 0.0266	-0.33 (-0.63, -0.04)	
CREATININE CLEARANCE (CRCL)									0.2723
<60	13	366.47 (30.332)	-11.15 (-25.65, 3.36)	14	355.29 (35.096)	10.24 (-3.70, 24.17)	-21.38 (-41.49, -1.28) 0.0372	-0.78 (-1.56, 0.00)	
>=60	96	355.24 (39.194)	-10.58 (-15.91, -5.26)	98	350.14 (38.300)	-1.17 (-6.45, 4.11)	-9.41 (-16.91, -1.91) 0.0142	-0.35 (-0.64, -0.07)	

Data Cutoff Date: 30JUN2020.
Note: The mean difference estimate, its 95% CI and p-values are from ANCOVA model with treatment group, baseline value, subgroup, and treatment*subgroup interaction as covariates.
AUC=area under the Borg score curve. Computed Borg score is used in this analysis.
Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ef-aucrsub.sas 06APR2023:04:36

4.6.3 Ergebnisse der weiteren prä-spezifizierte Analysen zum Endpunkt Belastungsempfinden nach Borg gemäß RPE

Die entsprechende Methodik ist im *SAP for Market Access* zu finden.

4.6.3.1 Zeit bis zum Erreichen intensiver Belastung (Hauptanalyse)

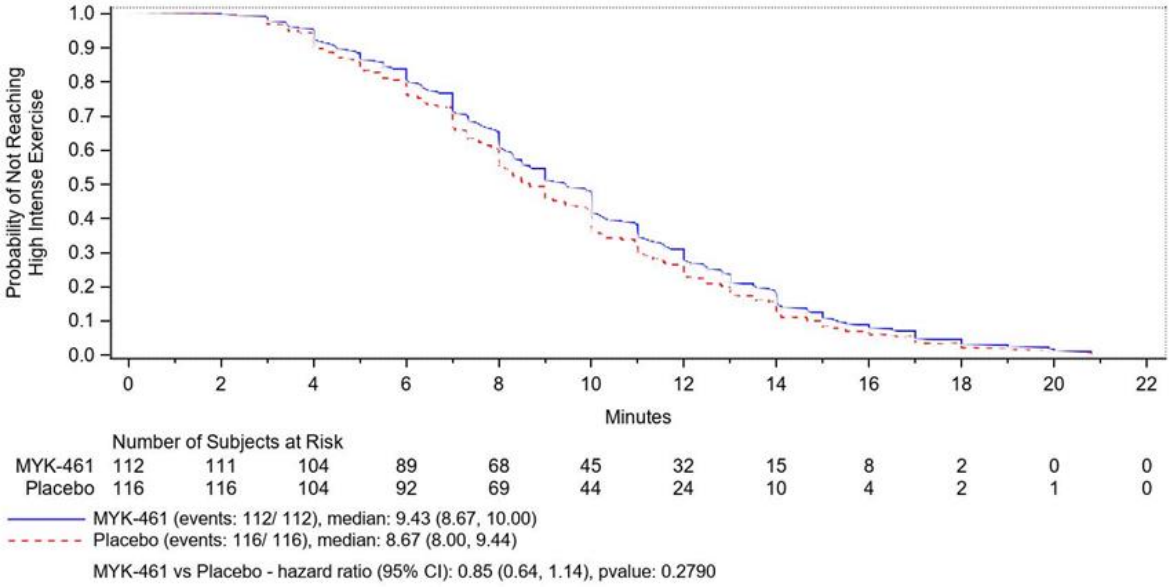

Abbildung 4-22: Kaplan-Meier-Kurven für die Zeit bis zum Erreichen intensiver Belastung zu Woche 30 – Hauptanalyse mit Borg-Score 17 im kombinierten Endpunkt

4.6.3.2 Zeit bis zum Erreichen intensiver Belastung (Sensitivitätsanalyse)

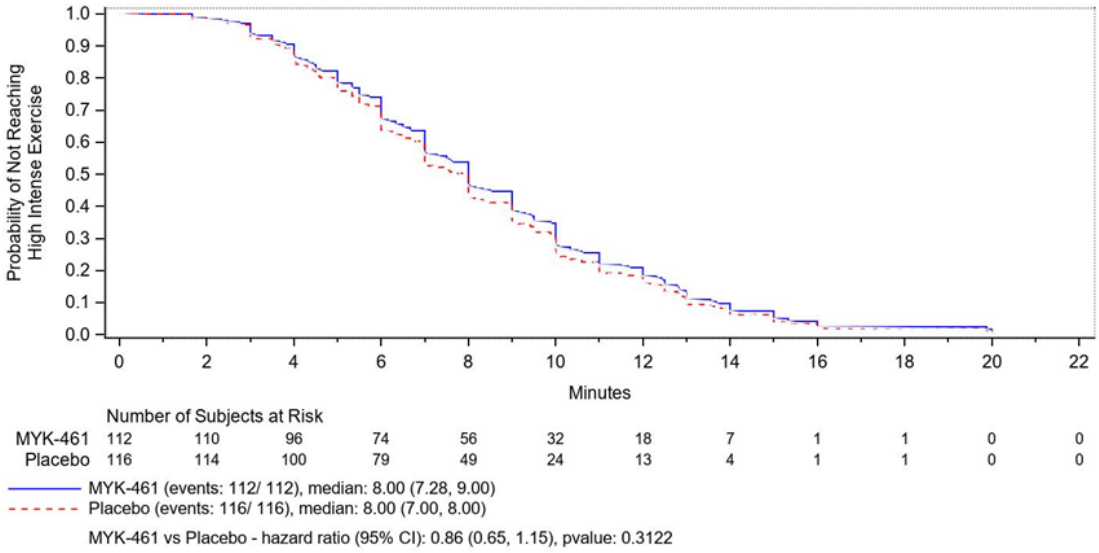

Abbildung 4-23: Kaplan-Meier-Kurven für die Zeit bis zum Erreichen intensiver Belastung zu Woche 30 – Hauptanalyse mit Borg-Score 15 im kombinierten Endpunkt

4.6.3.3 Zeit bis zum Erreichen intensiver Belastung (Sensitivitätsanalyse)

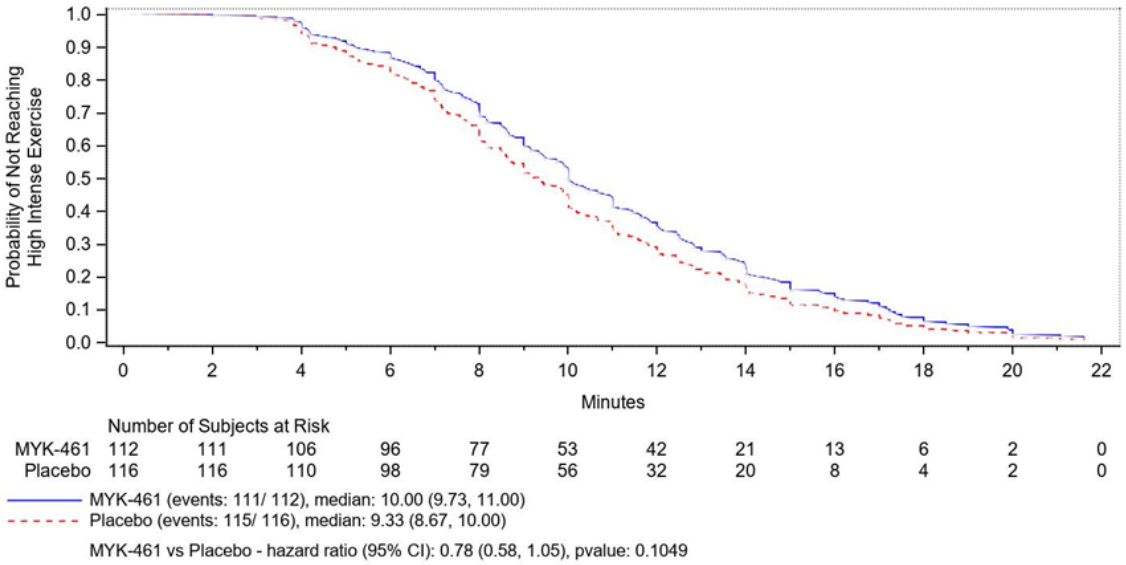

Abbildung 4-24: Kaplan-Meier-Kurven für die Zeit bis zum Erreichen intensiver Belastung zu Woche 30 – Hauptanalyse mit Borg-Score 19 im kombinierten Endpunkt

4.7 Analysen für den Endpunkt HOCM-spezifische Symptomatik gemäß HCMSQ

4.7.1 Veränderung aller Domänen und des Gesamtscores des HCMSQ im Studienverlauf als mittlere Veränderung des Scores gegenüber Baseline (pro Erhebungszeitpunkt) als Verlaufskurve

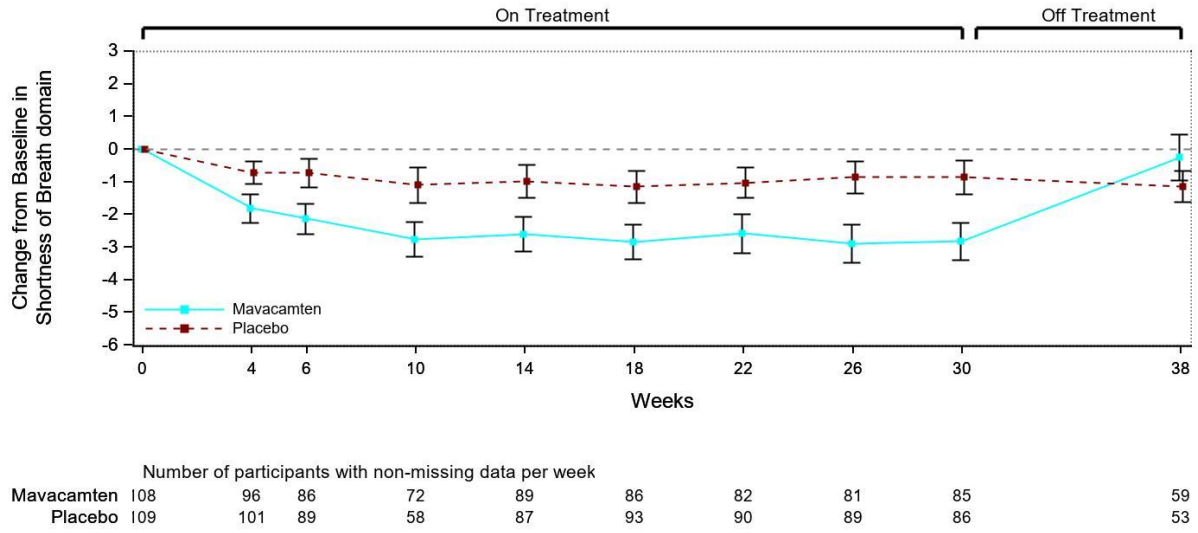

Abbildung 4-25: Mittlere Veränderung der Domäne *Kurzatmigkeit des HCMSQ* gegenüber Baseline im Studienverlauf

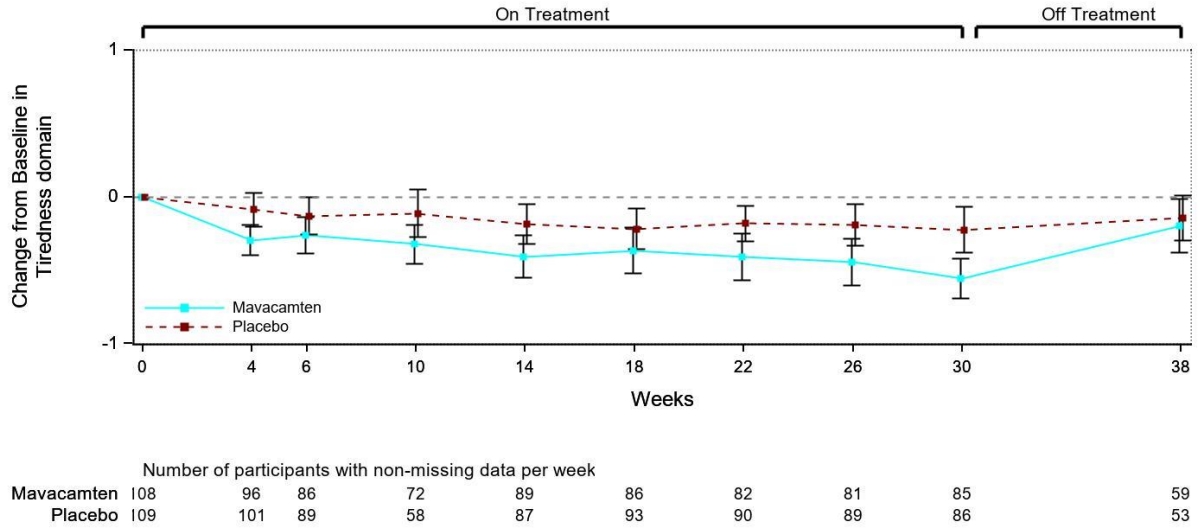

Abbildung 4-26: Mittlere Veränderung der Domäne *Fatigue des HCMSQ* gegenüber Baseline im Studienverlauf

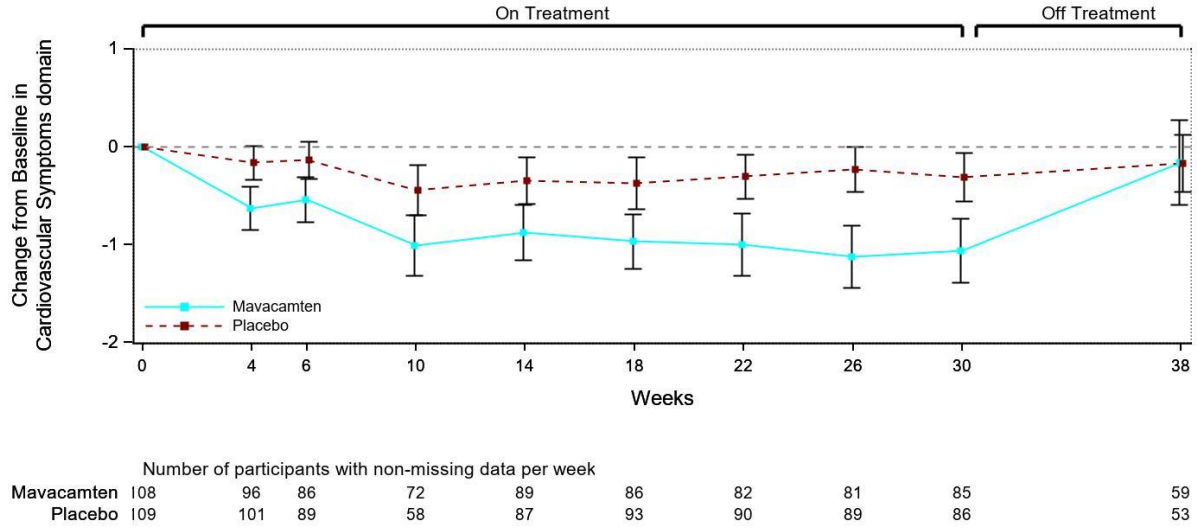

Abbildung 4-27: Mittlere Veränderung der Domäne *kardiovaskuläre Symptome des HCMSQ* gegenüber Baseline im Studienverlauf

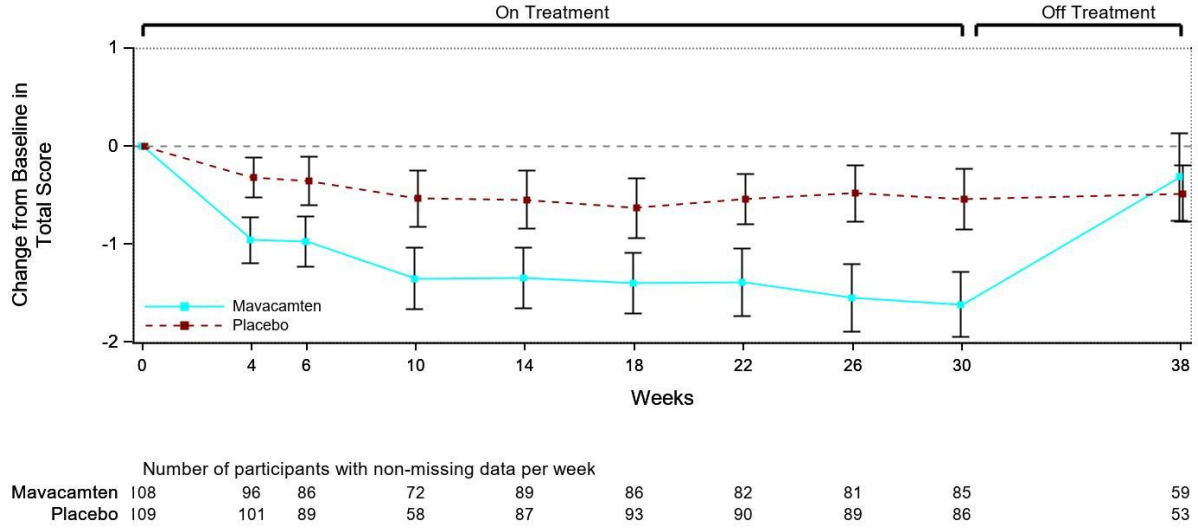

Abbildung 4-28: Mittlere Veränderung des *Gesamtscores des HCMSQ* gegenüber Baseline im Studienverlauf

4.7.2 Subgruppenanalyse für die Veränderung des HCMSQ zu Woche 30 gegenüber Baseline mittels MMRM

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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
WEEKLY AVERAGE HCMSQ SHORTNESS OF BREATH SCORE									
BETA-BLOCKER USE									0.8236
YES	80	4.84 (2.625)	-2.68 (-3.15, -2.21)	77	4.21 (2.917)	-0.83 (-1.31, -0.36)	-1.84 (-2.51, -1.17) <0.0001	-0.86 (-1.18, -0.53)	
NO	26	4.85 (2.091)	-2.48 (-3.23, -1.73)	27	5.20 (3.729)	-0.77 (-1.50, -0.04)	-1.72 (-2.76, -0.67) 0.0014	-0.87 (-1.43, -0.31)	
TYPE OF EXERCISE TESTING									0.1325
EXERCISE BICYCLE	49	4.79 (2.776)	-2.62 (-3.18, -2.06)	48	5.12 (3.195)	-0.41 (-0.97, 0.16)	-2.21 (-3.01, -1.42) <0.0001	-1.10 (-1.52, -0.67)	
TREADMILL	57	4.89 (2.249)	-2.64 (-3.17, -2.11)	56	3.90 (3.044)	-1.18 (-1.72, -0.64)	-1.46 (-2.22, -0.70) 0.0002	-0.70 (-1.08, -0.32)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-hcmsqmmrmrsubhq.sas 28OCT2022:03:39

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NYHA CLASS									0.7686
CLASS II	78	4.39 (2.373)	-2.73 (-3.21, -2.26)	76	3.80 (3.046)	-0.88 (-1.37, -0.40)	-1.85 (-2.52, -1.18) <0.0001	-0.86 (-1.19, -0.53)	
CLASS III	28	6.10 (2.432)	-2.33 (-3.07, -1.60)	28	6.29 (2.757)	-0.65 (-1.38, 0.08)	-1.68 (-2.70, -0.66) 0.0013	-0.85 (-1.40, -0.30)	
CONSENT FOR THE CMR SUBSTUDY									0.2382
YES	18	5.00 (2.336)	-2.11 (-2.98, -1.24)	18	3.99 (2.955)	-0.94 (-1.82, -0.06)	-1.17 (-2.40, 0.07) 0.0640	-0.60 (-1.27, 0.06)	
NO	88	4.81 (2.538)	-2.74 (-3.20, -2.29)	86	4.56 (3.207)	-0.79 (-1.25, -0.34)	-1.95 (-2.59, -1.31) <0.0001	-0.90 (-1.21, -0.59)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-hcmsqmmrmrsubhq.sas 28OCT2022:03:39

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
SEX									0.4361
MALE	55	4.42 (2.502)	-2.55 (-3.09, -2.01)	67	3.92 (2.981)	-0.90 (-1.40, -0.39)	-1.65 (-2.39, -0.91) <0.0001	-0.79 (-1.16, -0.42)	
FEMALE	51	5.30 (2.428)	-2.72 (-3.28, -2.16)	37	5.44 (3.276)	-0.67 (-1.31, -0.03)	-2.05 (-2.90, -1.20) <0.0001	-1.01 (-1.46, -0.57)	
AGE									0.2943
<= 49	23	4.73 (2.650)	-2.63 (-3.41, -1.85)	19	4.31 (3.080)	-0.95 (-1.81, -0.08)	-1.69 (-2.85, -0.52) 0.0047	-0.86 (-1.50, -0.23)	
50 - 64	47	4.67 (2.334)	-2.81 (-3.39, -2.23)	52	4.74 (3.426)	-0.60 (-1.16, -0.05)	-2.21 (-3.01, -1.41) <0.0001	-1.08 (-1.50, -0.65)	
>=65	36	5.15 (2.637)	-2.40 (-3.05, -1.76)	33	4.13 (2.798)	-1.08 (-1.75, -0.42)	-1.32 (-2.25, -0.39) 0.0055	-0.66 (-1.15, -0.18)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-hcmsqmmrmrsubhq.sas 28OCT2022:03:39

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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
BMI									0.9306
<30	68	4.85 (2.551)	-2.70 (-3.21, -2.20)	62	4.79 (3.440)	-0.88 (-1.39, -0.36)	-1.83 (-2.55, -1.11) <0.0001	-0.87 (-1.23, -0.51)	
>=30	38	4.83 (2.425)	-2.51 (-3.14, -1.88)	42	3.99 (2.659)	-0.73 (-1.34, -0.12)	-1.78 (-2.66, -0.91) <0.0001	-0.88 (-1.34, -0.42)	
RACE									0.1378
NON-WHITE	4	3.22 (1.579)	-1.58 (-3.45, 0.28)	10	3.99 (2.868)	-1.36 (-2.54, -0.18)	-0.22 (-2.42, 1.98) 0.8438	-0.11 (-1.27, 1.05)	
WHITE	102	4.91 (2.508)	-2.67 (-3.10, -2.24)	94	4.52 (3.198)	-0.76 (-1.20, -0.32)	-1.91 (-2.52, -1.29) <0.0001	-0.86 (-1.16, -0.57)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-hcmsqmmrmrsubhq.sas 28OCT2022:03:39

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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
REGION									0.0596
US	44	4.69 (2.318)	-2.43 (-3.02, -1.84)	42	3.63 (2.653)	-1.20 (-1.81, -0.59)	-1.23 (-2.08, -0.38) 0.0046	-0.61 (-1.04, -0.18)	
EX-US	62	4.95 (2.627)	-2.77 (-3.28, -2.26)	62	5.03 (3.363)	-0.57 (-1.08, -0.06)	-2.20 (-2.92, -1.47) <0.0001	-1.06 (-1.44, -0.69)	
CALCIUM CHANNEL BLOCKER USE									0.9093
YES	22	5.00 (2.129)	-2.32 (-3.13, -1.51)	15	4.88 (4.172)	-0.55 (-1.49, 0.40)	-1.77 (-3.02, -0.53) 0.0054	-0.91 (-1.60, -0.23)	
NO	84	4.80 (2.592)	-2.71 (-3.17, -2.25)	89	4.40 (2.979)	-0.86 (-1.32, -0.41)	-1.85 (-2.49, -1.20) <0.0001	-0.85 (-1.16, -0.54)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-hcmsqmmrmrsubhq.sas 28OCT2022:03:39

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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
PRESENCE OF HCM PATHOGENIC MUTATION									0.7241
PATHOGENIC OR LIKELY PATHOGENIC	25	4.85 (2.287)	-2.53 (-3.32, -1.74)	18	4.56 (3.426)	-1.06 (-1.97, -0.16)	-1.46 (-2.66, -0.26) 0.0170	-0.73 (-1.35, -0.10)	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	29	4.60 (2.646)	-2.47 (-3.20, -1.74)	35	4.88 (3.115)	-0.84 (-1.50, -0.17)	-1.63 (-2.62, -0.65) 0.0013	-0.80 (-1.32, -0.29)	
NEGATIVE	26	5.23 (2.715)	-2.60 (-3.36, -1.83)	30	3.87 (2.666)	-0.56 (-1.28, 0.17)	-2.04 (-3.10, -0.98) 0.0002	-1.00 (-1.56, -0.44)	
TIME FROM DIAGNOSIS OF OHCM									0.7137
<=5	56	4.95 (1.774)	-2.75 (-3.29, -2.21)	43	5.60 (3.209)	-0.85 (-1.46, -0.25)	-1.90 (-2.71, -1.09) <0.0001	-0.92 (-1.34, -0.51)	
>5	50	4.72 (3.127)	-2.50 (-3.06, -1.94)	61	3.66 (2.888)	-0.79 (-1.32, -0.27)	-1.71 (-2.48, -0.94) <0.0001	-0.83 (-1.22, -0.44)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
SEPTAL REDUCTION THERAPY (SRT) HISTORY									0.3174
YES	10	5.04 (2.402)	-1.45 (-2.60, -0.29)	8	4.41 (2.652)	-0.44 (-1.70, 0.82)	-1.01 (-2.72, 0.70) 0.2451	-0.52 (-1.47, 0.42)	
NO	96	4.82 (2.516)	-2.75 (-3.19, -2.32)	96	4.47 (3.209)	-0.85 (-1.29, -0.41)	-1.90 (-2.52, -1.28) <0.0001	-0.87 (-1.16, -0.57)	
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED									0.0889
YES	23	4.87 (3.294)	-3.28 (-4.06, -2.50)	21	4.55 (3.445)	-0.64 (-1.45, 0.16)	-2.63 (-3.76, -1.51) <0.0001	-1.36 (-2.02, -0.71)	
NO	83	4.84 (2.249)	-2.46 (-2.92, -1.99)	83	4.44 (3.104)	-0.86 (-1.32, -0.40)	-1.59 (-2.24, -0.94) <0.0001	-0.74 (-1.05, -0.43)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
HISTORY OF HYPERTENSION									0.7518
YES	51	4.79 (2.438)	-2.55 (-3.11, -2.00)	50	4.72 (3.288)	-0.82 (-1.38, -0.26)	-1.73 (-2.53, -0.94) <0.0001	-0.85 (-1.25, -0.44)	
NO	55	4.90 (2.567)	-2.71 (-3.25, -2.16)	54	4.23 (3.046)	-0.81 (-1.36, -0.27)	-1.89 (-2.66, -1.12) <0.0001	-0.91 (-1.31, -0.52)	
RESTING LVEF									0.9964
<75%	64	4.58 (2.353)	-2.85 (-3.35, -2.34)	61	4.48 (3.010)	-1.04 (-1.56, -0.52)	-1.80 (-2.53, -1.08) <0.0001	-0.87 (-1.23, -0.50)	
>=75%	42	5.25 (2.675)	-2.31 (-2.91, -1.71)	43	4.45 (3.395)	-0.51 (-1.10, 0.08)	-1.80 (-2.65, -0.96) <0.0001	-0.90 (-1.35, -0.45)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
LVOT RESTING PEAK GRADIENT									0.6056
<=50	52	4.86 (2.506)	-2.48 (-3.03, -1.92)	54	4.82 (2.900)	-0.55 (-1.09, -0.01)	-1.93 (-2.70, -1.15) <0.0001	-0.94 (-1.34, -0.54)	
>50	54	4.83 (2.508)	-2.78 (-3.32, -2.23)	50	4.09 (3.405)	-1.11 (-1.67, -0.55)	-1.67 (-2.45, -0.89) <0.0001	-0.82 (-1.22, -0.42)	
LVOT RESTING PEAK GRADIENT									0.2250
<=30	30	5.49 (2.393)	-2.73 (-3.44, -2.03)	31	5.94 (2.969)	-0.45 (-1.14, 0.25)	-2.29 (-3.27, -1.31) <0.0001	-1.16 (-1.70, -0.61)	
>30	76	4.59 (2.503)	-2.59 (-3.07, -2.11)	73	3.84 (3.043)	-0.98 (-1.46, -0.49)	-1.61 (-2.30, -0.93) <0.0001	-0.76 (-1.09, -0.42)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL									0.2035
<=14	46	4.69 (2.449)	-2.96 (-3.54, -2.39)	56	4.52 (2.998)	-0.80 (-1.34, -0.27)	-2.16 (-2.95, -1.37) <0.0001	-1.06 (-1.48, -0.64)	
>14	56	4.95 (2.619)	-2.42 (-2.95, -1.88)	42	4.27 (3.383)	-0.91 (-1.51, -0.31)	-1.51 (-2.31, -0.70) 0.0003	-0.74 (-1.16, -0.33)	
E/E' SEPTAL									0.2061
<=14	14	4.37 (2.150)	-3.42 (-4.40, -2.44)	21	5.41 (3.088)	-0.86 (-1.69, -0.04)	-2.56 (-3.84, -1.27) 0.0001	-1.32 (-2.06, -0.57)	
>14	92	4.91 (2.546)	-2.51 (-2.96, -2.07)	82	4.18 (3.137)	-0.83 (-1.29, -0.36)	-1.69 (-2.33, -1.04) <0.0001	-0.78 (-1.08, -0.47)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE									0.0356*
<=14	21	4.90 (2.538)	-3.66 (-4.47, -2.85)	26	4.74 (3.246)	-0.82 (-1.57, -0.08)	-2.83 (-3.93, -1.73) <0.0001	-1.46 (-2.10, -0.81)	
>14	85	4.83 (2.499)	-2.39 (-2.84, -1.93)	78	4.38 (3.145)	-0.82 (-1.28, -0.35)	-1.57 (-2.22, -0.92) <0.0001	-0.74 (-1.06, -0.42)	
LEFT ATRIAL VOLUME INDEX									0.0905
<=MEDIAN	53	5.17 (2.338)	-2.66 (-3.22, -2.11)	55	4.83 (3.133)	-0.46 (-1.00, 0.08)	-2.20 (-2.97, -1.43) <0.0001	-1.07 (-1.48, -0.67)	
>MEDIAN	52	4.50 (2.648)	-2.58 (-3.13, -2.03)	49	4.05 (3.168)	-1.23 (-1.79, -0.66)	-1.35 (-2.14, -0.57) 0.0008	-0.67 (-1.07, -0.26)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NT-PROBNP									0.3676
<=MEDIAN	47	5.03 (2.343)	-2.67 (-3.25, -2.08)	54	4.53 (2.711)	-0.67 (-1.22, -0.12)	-2.00 (-2.80, -1.20) <0.0001	-0.97 (-1.38, -0.55)	
>MEDIAN	57	4.67 (2.662)	-2.54 (-3.08, -2.01)	49	4.32 (3.602)	-1.01 (-1.57, -0.44)	-1.54 (-2.32, -0.76) 0.0001	-0.75 (-1.14, -0.35)	
HS-CARDIAC TROPONIN-I									0.0828
<=ULN	75	4.75 (2.501)	-2.72 (-3.20, -2.23)	78	4.68 (3.057)	-0.69 (-1.17, -0.20)	-2.03 (-2.72, -1.35) <0.0001	-0.94 (-1.27, -0.60)	
>ULN	28	5.25 (2.448)	-2.25 (-2.99, -1.52)	19	4.50 (3.671)	-1.30 (-2.16, -0.44)	-0.95 (-2.08, 0.18) 0.0992	-0.48 (-1.07, 0.11)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0691
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	34	4.54 (2.509)	-3.15 (-3.81, -2.49)	45	4.71 (2.849)	-0.70 (-1.30, -0.11)	-2.45 (-3.33, -1.56) <0.0001	-1.22 (-1.70, -0.73)	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	68	4.96 (2.556)	-2.36 (-2.87, -1.86)	48	4.36 (3.457)	-0.90 (-1.47, -0.32)	-1.47 (-2.23, -0.71) 0.0002	-0.71 (-1.09, -0.33)	
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.1475
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	12	4.44 (2.266)	-3.35 (-4.40, -2.29)	16	5.33 (2.819)	-0.57 (-1.51, 0.36)	-2.78 (-4.19, -1.36) 0.0001	-1.43 (-2.26, -0.59)	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	94	4.90 (2.529)	-2.54 (-2.98, -2.09)	86	4.34 (3.228)	-0.85 (-1.30, -0.39)	-1.69 (-2.33, -1.05) <0.0001	-0.77 (-1.07, -0.47)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-hcmsqmmrmrsubhq.sas 28OCT2022:03:39

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0206*
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	18	5.05 (2.690)	-3.64 (-4.51, -2.76)	18	5.23 (2.683)	-0.49 (-1.38, 0.40)	-3.15 (-4.40, -1.90) <0.0001	-1.61 (-2.36, -0.86)	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	88	4.80 (2.467)	-2.43 (-2.88, -1.98)	82	4.43 (3.242)	-0.84 (-1.30, -0.38)	-1.59 (-2.24, -0.94) <0.0001	-0.74 (-1.05, -0.42)	
CREATININE CLEARANCE (CRCL)									0.9067
<60	13	5.48 (2.113)	-3.05 (-4.07, -2.03)	11	3.69 (2.865)	-1.16 (-2.26, -0.06)	-1.89 (-3.39, -0.39) 0.0137	-0.98 (-1.83, -0.13)	
>=60	93	4.76 (2.541)	-2.57 (-3.02, -2.13)	93	4.56 (3.194)	-0.78 (-1.22, -0.33)	-1.80 (-2.43, -1.17) <0.0001	-0.82 (-1.12, -0.52)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-hcmsqmmrmrsubhq.sas 28OCT2022:03:39

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
WEEKLY AVERAGE FATIGUE SCORE									
BETA-BLOCKER USE									0.8083
YES	80	1.30 (0.681)	-0.52 (-0.65, -0.39)	77	1.25 (0.756)	-0.24 (-0.37, -0.11)	-0.27 (-0.46, -0.09) 0.0038	-0.46 (-0.78, -0.14)	
NO	26	1.44 (0.636)	-0.41 (-0.62, -0.20)	27	1.32 (0.913)	-0.10 (-0.30, 0.10)	-0.31 (-0.60, -0.02) 0.0349	-0.57 (-1.12, -0.02)	
TYPE OF EXERCISE TESTING									0.6985
EXERCISE BICYCLE	49	1.35 (0.755)	-0.43 (-0.58, -0.27)	48	1.43 (0.783)	-0.11 (-0.27, 0.04)	-0.31 (-0.53, -0.09) 0.0057	-0.56 (-0.96, -0.15)	
TREADMILL	57	1.32 (0.594)	-0.54 (-0.69, -0.40)	56	1.13 (0.788)	-0.29 (-0.43, -0.14)	-0.26 (-0.47, -0.05) 0.0156	-0.45 (-0.83, -0.08)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-hcmsqmmrmrsubhq.sas 28OCT2022:03:39

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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
NYHA CLASS									0.6360
CLASS II	78	1.25 (0.670)	-0.49 (-0.62, -0.35)	76	1.08 (0.759)	-0.18 (-0.31, -0.05)	-0.31 (-0.49, -0.12) 0.0014	-0.52 (-0.84, -0.19)	
CLASS III	28	1.58 (0.620)	-0.51 (-0.71, -0.30)	28	1.77 (0.673)	-0.27 (-0.48, -0.07)	-0.23 (-0.52, 0.05) 0.1112	-0.42 (-0.95, 0.11)	
CONSENT FOR THE CMR SUBSTUDY									0.0021*
YES	18	1.26 (0.667)	-0.23 (-0.46, 0.01)	18	1.20 (0.980)	-0.41 (-0.64, -0.17)	0.18 (-0.16, 0.51) 0.2976	0.34 (-0.32, 1.00)	
NO	88	1.35 (0.674)	-0.55 (-0.67, -0.42)	86	1.28 (0.758)	-0.16 (-0.29, -0.04)	-0.38 (-0.56, -0.21) <0.0001	-0.64 (-0.95, -0.34)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
SEX									0.2735
MALE	55	1.11 (0.648)	-0.44 (-0.59, -0.29)	67	1.08 (0.736)	-0.22 (-0.36, -0.08)	-0.22 (-0.42, -0.01) 0.0380	-0.38 (-0.74, -0.02)	
FEMALE	51	1.59 (0.606)	-0.55 (-0.71, -0.39)	37	1.60 (0.801)	-0.18 (-0.36, 0.00)	-0.37 (-0.61, -0.14) 0.0020	-0.67 (-1.10, -0.23)	
AGE									0.8249
<= 49	23	1.42 (0.724)	-0.48 (-0.69, -0.26)	19	1.37 (0.707)	-0.20 (-0.44, 0.04)	-0.28 (-0.60, 0.04) 0.0892	-0.52 (-1.13, 0.10)	
50 - 64	47	1.24 (0.584)	-0.44 (-0.60, -0.28)	52	1.21 (0.812)	-0.12 (-0.27, 0.03)	-0.32 (-0.54, -0.10) 0.0046	-0.57 (-0.97, -0.17)	
>=65	36	1.41 (0.740)	-0.56 (-0.74, -0.38)	33	1.30 (0.833)	-0.34 (-0.52, -0.15)	-0.22 (-0.48, 0.03) 0.0869	-0.41 (-0.88, 0.07)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
BMI									0.0364*
<30	68	1.28 (0.715)	-0.56 (-0.70, -0.42)	62	1.39 (0.828)	-0.16 (-0.30, -0.02)	-0.40 (-0.60, -0.20) <0.0001	-0.69 (-1.04, -0.34)	
>=30	38	1.45 (0.576)	-0.37 (-0.54, -0.20)	42	1.09 (0.718)	-0.27 (-0.44, -0.11)	-0.10 (-0.34, 0.15) 0.4411	-0.17 (-0.61, 0.27)	
RACE									0.6425
NON-WHITE	4	0.96 (0.750)	-0.42 (-0.94, 0.10)	10	1.50 (0.686)	-0.27 (-0.60, 0.05)	-0.15 (-0.76, 0.47) 0.6388	-0.26 (-1.42, 0.90)	
WHITE	102	1.35 (0.667)	-0.49 (-0.61, -0.37)	94	1.24 (0.806)	-0.20 (-0.32, -0.08)	-0.29 (-0.47, -0.12) 0.0008	-0.48 (-0.77, -0.20)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
REGION									0.0308*
US	44	1.21 (0.552)	-0.47 (-0.63, -0.31)	42	1.07 (0.709)	-0.37 (-0.54, -0.20)	-0.10 (-0.33, 0.13) 0.3972	-0.18 (-0.60, 0.24)	
EX-US	62	1.43 (0.734)	-0.50 (-0.64, -0.36)	62	1.40 (0.829)	-0.10 (-0.24, 0.04)	-0.40 (-0.60, -0.21) <0.0001	-0.71 (-1.07, -0.35)	
CALCIUM CHANNEL BLOCKER USE									0.6681
YES	22	1.50 (0.679)	-0.39 (-0.61, -0.16)	15	1.39 (0.960)	-0.16 (-0.43, 0.10)	-0.22 (-0.57, 0.12) 0.2024	-0.42 (-1.08, 0.25)	
NO	84	1.30 (0.666)	-0.52 (-0.64, -0.39)	89	1.25 (0.769)	-0.21 (-0.34, -0.09)	-0.30 (-0.48, -0.13) 0.0009	-0.51 (-0.81, -0.20)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
PRESENCE OF HCM PATHOGENIC MUTATION									0.8894
PATHOGENIC OR LIKELY PATHOGENIC	25	1.30 (0.571)	-0.53 (-0.74, -0.31)	18	1.34 (0.727)	-0.30 (-0.55, -0.05)	-0.22 (-0.55, 0.11) 0.1809	-0.40 (-1.02, 0.21)	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	29	1.30 (0.697)	-0.43 (-0.63, -0.23)	35	1.37 (0.852)	-0.16 (-0.34, 0.02)	-0.27 (-0.55, -0.00) 0.0479	-0.49 (-0.99, 0.01)	
NEGATIVE	26	1.42 (0.719)	-0.55 (-0.77, -0.34)	30	1.13 (0.822)	-0.23 (-0.43, -0.03)	-0.32 (-0.61, -0.03) 0.0282	-0.58 (-1.12, -0.04)	
TIME FROM DIAGNOSIS OF OHCM									0.1248
<=5	56	1.29 (0.538)	-0.57 (-0.72, -0.42)	43	1.47 (0.750)	-0.18 (-0.34, -0.01)	-0.39 (-0.62, -0.17) 0.0006	-0.70 (-1.10, -0.29)	
>5	50	1.39 (0.795)	-0.40 (-0.56, -0.25)	61	1.12 (0.800)	-0.23 (-0.37, -0.08)	-0.18 (-0.39, 0.04) 0.1036	-0.31 (-0.68, 0.07)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
SEPTAL REDUCTION THERAPY (SRT) HISTORY									0.6912
YES	10	1.47 (0.488)	-0.35 (-0.68, -0.03)	8	1.38 (0.807)	-0.16 (-0.51, 0.20)	-0.20 (-0.68, 0.28) 0.4232	-0.36 (-1.30, 0.58)	
NO	96	1.32 (0.687)	-0.50 (-0.63, -0.38)	96	1.26 (0.799)	-0.21 (-0.33, -0.09)	-0.29 (-0.47, -0.12) 0.0008	-0.48 (-0.77, -0.20)	
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED									0.2877
YES	23	1.45 (0.774)	-0.62 (-0.84, -0.40)	21	1.46 (0.729)	-0.19 (-0.42, 0.03)	-0.43 (-0.74, -0.11) 0.0076	-0.79 (-1.41, -0.18)	
NO	83	1.31 (0.640)	-0.46 (-0.58, -0.33)	83	1.22 (0.809)	-0.21 (-0.34, -0.08)	-0.25 (-0.43, -0.07) 0.0078	-0.41 (-0.72, -0.10)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
HISTORY OF HYPERTENSION									0.8792
YES	51	1.34 (0.705)	-0.54 (-0.70, -0.39)	50	1.34 (0.787)	-0.27 (-0.42, -0.11)	-0.27 (-0.49, -0.05) 0.0145	-0.48 (-0.88, -0.09)	
NO	55	1.34 (0.644)	-0.44 (-0.59, -0.29)	54	1.20 (0.806)	-0.15 (-0.30, 0.00)	-0.29 (-0.51, -0.08) 0.0067	-0.52 (-0.90, -0.14)	
RESTING LVEF									0.4427
<75%	64	1.24 (0.611)	-0.48 (-0.63, -0.34)	61	1.35 (0.829)	-0.25 (-0.39, -0.10)	-0.24 (-0.44, -0.04) 0.0203	-0.41 (-0.77, -0.06)	
>=75%	42	1.48 (0.736)	-0.50 (-0.67, -0.33)	43	1.15 (0.739)	-0.15 (-0.32, 0.02)	-0.35 (-0.59, -0.11) 0.0039	-0.62 (-1.06, -0.19)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
LVOT RESTING PEAK GRADIENT									0.7627
<=50	52	1.35 (0.690)	-0.44 (-0.59, -0.28)	54	1.31 (0.816)	-0.18 (-0.33, -0.03)	-0.26 (-0.48, -0.05) 0.0177	-0.46 (-0.84, -0.07)	
>50	54	1.32 (0.657)	-0.54 (-0.69, -0.39)	50	1.22 (0.778)	-0.24 (-0.39, -0.08)	-0.30 (-0.52, -0.09) 0.0062	-0.53 (-0.93, -0.14)	
LVOT RESTING PEAK GRADIENT									0.1122
<=30	30	1.46 (0.649)	-0.52 (-0.71, -0.32)	31	1.43 (0.795)	-0.06 (-0.25, 0.13)	-0.46 (-0.73, -0.19) 0.0010	-0.83 (-1.36, -0.31)	
>30	76	1.29 (0.677)	-0.48 (-0.61, -0.35)	73	1.20 (0.791)	-0.27 (-0.40, -0.13)	-0.21 (-0.40, -0.03) 0.0262	-0.36 (-0.69, -0.04)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL									0.0522
<=14	46	1.26 (0.708)	-0.58 (-0.74, -0.42)	56	1.21 (0.716)	-0.17 (-0.32, -0.02)	-0.41 (-0.63, -0.19) 0.0003	-0.72 (-1.12, -0.32)	
>14	56	1.39 (0.657)	-0.40 (-0.55, -0.25)	42	1.32 (0.909)	-0.27 (-0.44, -0.11)	-0.13 (-0.35, 0.09) 0.2469	-0.23 (-0.64, 0.17)	
E/E' SEPTAL									0.1600
<=14	14	1.11 (0.718)	-0.62 (-0.89, -0.34)	21	1.20 (0.763)	-0.11 (-0.34, 0.12)	-0.51 (-0.86, -0.15) 0.0056	-0.94 (-1.65, -0.23)	
>14	92	1.37 (0.660)	-0.47 (-0.59, -0.35)	82	1.27 (0.804)	-0.23 (-0.36, -0.11)	-0.24 (-0.42, -0.06) 0.0089	-0.40 (-0.70, -0.10)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-hcmsqmmrmrsubhq.sas 28OCT2022:03:39

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE									0.0405*
<=14	21	1.25 (0.746)	-0.66 (-0.89, -0.44)	26	1.13 (0.733)	-0.11 (-0.32, 0.10)	-0.56 (-0.87, -0.25) 0.0004	-1.02 (-1.64, -0.41)	
>14	85	1.36 (0.653)	-0.45 (-0.57, -0.32)	78	1.31 (0.815)	-0.24 (-0.37, -0.11)	-0.21 (-0.39, -0.03) 0.0217	-0.36 (-0.67, -0.05)	
LEFT ATRIAL VOLUME INDEX									0.0383*
<=MEDIAN	53	1.46 (0.707)	-0.50 (-0.65, -0.35)	55	1.16 (0.740)	-0.08 (-0.23, 0.07)	-0.42 (-0.63, -0.20) 0.0001	-0.73 (-1.12, -0.34)	
>MEDIAN	52	1.21 (0.618)	-0.47 (-0.62, -0.32)	49	1.38 (0.847)	-0.35 (-0.50, -0.19)	-0.13 (-0.34, 0.09) 0.2561	-0.22 (-0.62, 0.17)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NT-PROBNP									0.5034
<=MEDIAN	47	1.35 (0.609)	-0.52 (-0.68, -0.36)	54	1.31 (0.765)	-0.18 (-0.33, -0.03)	-0.34 (-0.56, -0.12) 0.0025	-0.60 (-1.00, -0.20)	
>MEDIAN	57	1.32 (0.732)	-0.49 (-0.64, -0.34)	49	1.19 (0.825)	-0.24 (-0.40, -0.09)	-0.25 (-0.46, -0.03) 0.0248	-0.43 (-0.82, -0.05)	
HS-CARDIAC TROPONIN-I									0.0773
<=ULN	75	1.32 (0.655)	-0.53 (-0.66, -0.40)	78	1.31 (0.766)	-0.19 (-0.32, -0.05)	-0.34 (-0.53, -0.16) 0.0004	-0.58 (-0.90, -0.25)	
>ULN	28	1.44 (0.705)	-0.39 (-0.59, -0.19)	19	1.30 (0.961)	-0.35 (-0.59, -0.11)	-0.04 (-0.35, 0.27) 0.8080	-0.07 (-0.65, 0.51)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0807
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	34	1.17 (0.718)	-0.62 (-0.80, -0.44)	45	1.26 (0.700)	-0.19 (-0.36, -0.03)	-0.43 (-0.67, -0.18) 0.0007	-0.77 (-1.23, -0.30)	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	68	1.41 (0.651)	-0.41 (-0.55, -0.27)	48	1.31 (0.899)	-0.24 (-0.40, -0.09)	-0.17 (-0.38, 0.04) 0.1212	-0.29 (-0.66, 0.08)	
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.1383
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	12	1.15 (0.770)	-0.57 (-0.86, -0.28)	16	1.22 (0.674)	-0.02 (-0.28, 0.24)	-0.55 (-0.94, -0.16) 0.0062	-1.02 (-1.81, -0.22)	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	94	1.36 (0.658)	-0.48 (-0.60, -0.36)	86	1.30 (0.810)	-0.24 (-0.37, -0.11)	-0.24 (-0.42, -0.06) 0.0074	-0.40 (-0.69, -0.10)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0208*
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	18	1.30 (0.795)	-0.66 (-0.91, -0.42)	18	1.21 (0.650)	-0.02 (-0.27, 0.22)	-0.64 (-0.99, -0.29) 0.0004	-1.18 (-1.88, -0.47)	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	88	1.35 (0.647)	-0.46 (-0.58, -0.33)	82	1.31 (0.825)	-0.25 (-0.38, -0.12)	-0.21 (-0.39, -0.03) 0.0238	-0.35 (-0.65, -0.04)	
CREATININE CLEARANCE (CRCL)									0.5987
<60	13	1.43 (0.698)	-0.52 (-0.80, -0.23)	11	0.96 (0.589)	-0.33 (-0.64, -0.03)	-0.18 (-0.60, 0.24) 0.3928	-0.34 (-1.15, 0.47)	
>=60	93	1.32 (0.669)	-0.49 (-0.61, -0.36)	93	1.30 (0.812)	-0.19 (-0.31, -0.07)	-0.30 (-0.47, -0.12) 0.0009	-0.49 (-0.78, -0.20)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
WEEKLY AVERAGE HEART SYMPTOM SCORE									
BETA-BLOCKER USE									0.2821
YES	80	1.72 (1.636)	-1.01 (-1.23, -0.78)	77	1.75 (1.815)	-0.32 (-0.54, -0.09)	-0.69 (-1.01, -0.37) <0.0001	-0.68 (-1.00, -0.36)	
NO	26	1.90 (1.429)	-0.79 (-1.15, -0.44)	27	1.83 (1.676)	-0.40 (-0.74, -0.05)	-0.40 (-0.89, 0.10) 0.1158	-0.43 (-0.97, 0.12)	
TYPE OF EXERCISE TESTING									0.2485
EXERCISE BICYCLE	49	2.07 (1.799)	-0.95 (-1.22, -0.68)	48	1.92 (1.760)	-0.18 (-0.45, 0.09)	-0.77 (-1.15, -0.39) <0.0001	-0.79 (-1.21, -0.38)	
TREADMILL	57	1.51 (1.334)	-0.96 (-1.22, -0.71)	56	1.64 (1.788)	-0.47 (-0.73, -0.22)	-0.49 (-0.85, -0.13) 0.0075	-0.50 (-0.88, -0.13)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NYHA CLASS									0.0732
CLASS II	78	1.63 (1.622)	-1.00 (-1.23, -0.78)	76	1.68 (1.688)	-0.25 (-0.48, -0.03)	-0.75 (-1.07, -0.43) <0.0001	-0.74 (-1.06, -0.41)	
CLASS III	28	2.14 (1.434)	-0.83 (-1.18, -0.49)	28	2.03 (1.993)	-0.57 (-0.91, -0.23)	-0.27 (-0.75, 0.22) 0.2807	-0.28 (-0.81, 0.24)	
CONSENT FOR THE CMR SUBSTUDY									0.0761
YES	18	1.35 (1.056)	-0.68 (-1.10, -0.27)	18	1.15 (1.301)	-0.52 (-0.94, -0.11)	-0.16 (-0.74, 0.42) 0.5887	-0.18 (-0.83, 0.48)	
NO	88	1.85 (1.663)	-1.01 (-1.23, -0.80)	86	1.90 (1.836)	-0.30 (-0.52, -0.08)	-0.72 (-1.02, -0.41) <0.0001	-0.69 (-1.00, -0.39)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
SEX									0.9143
MALE	55	1.55 (1.640)	-0.93 (-1.19, -0.67)	67	1.75 (1.728)	-0.33 (-0.56, -0.09)	-0.60 (-0.95, -0.25) 0.0008	-0.61 (-0.97, -0.24)	
FEMALE	51	2.00 (1.501)	-0.99 (-1.25, -0.72)	37	1.82 (1.873)	-0.36 (-0.66, -0.05)	-0.63 (-1.03, -0.22) 0.0024	-0.65 (-1.09, -0.22)	
AGE									0.2653
<= 49	23	2.20 (2.019)	-0.80 (-1.17, -0.43)	19	2.42 (1.627)	-0.20 (-0.61, 0.21)	-0.60 (-1.15, -0.05) 0.0337	-0.65 (-1.27, -0.02)	
50 - 64	47	1.75 (1.370)	-1.08 (-1.35, -0.80)	52	1.92 (2.026)	-0.26 (-0.52, 0.00)	-0.82 (-1.20, -0.43) <0.0001	-0.84 (-1.25, -0.43)	
>=65	36	1.51 (1.516)	-0.91 (-1.21, -0.60)	33	1.16 (1.190)	-0.53 (-0.85, -0.21)	-0.38 (-0.82, 0.06) 0.0929	-0.40 (-0.88, 0.08)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
BMI									0.6253
<30	68	1.82 (1.740)	-0.97 (-1.20, -0.73)	62	2.02 (1.949)	-0.30 (-0.54, -0.05)	-0.67 (-1.01, -0.32) 0.0002	-0.67 (-1.02, -0.31)	
>=30	38	1.68 (1.273)	-0.94 (-1.24, -0.64)	42	1.40 (1.415)	-0.40 (-0.69, -0.10)	-0.55 (-0.96, -0.13) 0.0102	-0.57 (-1.02, -0.12)	
RACE									0.0239*
NON-WHITE	4	0.91 (0.643)	-0.11 (-0.99, 0.77)	10	2.51 (1.792)	-0.65 (-1.21, -0.09)	0.54 (-0.50, 1.59) 0.3089	0.56 (-0.62, 1.74)	
WHITE	102	1.80 (1.601)	-0.99 (-1.19, -0.78)	94	1.69 (1.762)	-0.31 (-0.51, -0.10)	-0.68 (-0.98, -0.39) <0.0001	-0.65 (-0.94, -0.36)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
REGION									0.0084*
US	44	1.48 (1.174)	-0.85 (-1.13, -0.57)	42	1.43 (1.391)	-0.61 (-0.90, -0.32)	-0.24 (-0.64, 0.16) 0.2369	-0.25 (-0.68, 0.17)	
EX-US	62	1.97 (1.800)	-1.03 (-1.28, -0.79)	62	2.00 (1.967)	-0.16 (-0.40, 0.08)	-0.87 (-1.21, -0.53) <0.0001	-0.89 (-1.26, -0.52)	
CALCIUM CHANNEL BLOCKER USE									0.5167
YES	22	1.93 (1.491)	-0.80 (-1.19, -0.42)	15	1.47 (1.492)	-0.35 (-0.80, 0.10)	-0.46 (-1.05, 0.14) 0.1312	-0.49 (-1.16, 0.17)	
NO	84	1.72 (1.612)	-1.00 (-1.22, -0.78)	89	1.82 (1.818)	-0.34 (-0.55, -0.12)	-0.66 (-0.97, -0.35) <0.0001	-0.64 (-0.94, -0.33)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

Subgroup	Mavacamten N	Mavacamten Baseline Mean(SD)	Mavacamten Change from Baseline: LS Mean (95% CI)	Placebo N	Placebo Baseline Mean(SD)	Placebo Change from Baseline: LS Mean (95% CI)	Mavacamten vs Placebo Difference in LS Mean Change (95% CI) p-value	Mavacamten vs Placebo SMD as Hedge's g (95% CI)	Inter-action p-value
PRESENCE OF HCM PATHOGENIC MUTATION									0.2268
PATHOGENIC OR LIKELY PATHOGENIC	25	1.71 (1.343)	-0.70 (-1.07, -0.33)	18	1.97 (1.639)	-0.63 (-1.05, -0.21)	-0.07 (-0.64, 0.49) 0.7962	-0.08 (-0.68, 0.53)	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	29	1.73 (2.054)	-0.91 (-1.25, -0.57)	35	1.93 (2.211)	-0.32 (-0.64, -0.01)	-0.59 (-1.05, -0.12) 0.0132	-0.62 (-1.12, -0.11)	
NEGATIVE	26	1.87 (1.655)	-0.83 (-1.19, -0.47)	30	1.63 (1.499)	-0.20 (-0.54, 0.13)	-0.63 (-1.12, -0.13) 0.0128	-0.66 (-1.20, -0.12)	
TIME FROM DIAGNOSIS OF OHCM									0.6215
<=5	56	1.66 (1.330)	-0.97 (-1.23, -0.71)	43	2.46 (1.883)	-0.28 (-0.57, 0.01)	-0.69 (-1.08, -0.30) 0.0006	-0.70 (-1.11, -0.29)	
>5	50	1.88 (1.833)	-0.94 (-1.21, -0.67)	61	1.29 (1.529)	-0.37 (-0.62, -0.13)	-0.57 (-0.93, -0.20) 0.0025	-0.57 (-0.96, -0.19)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-hcmsqmmrmrsubhq.sas 28OCT2022:03:39

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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
SEPTAL REDUCTION THERAPY (SRT) HISTORY									0.3417
YES	10	1.94 (1.668)	-0.74 (-1.29, -0.19)	8	1.35 (1.250)	-0.49 (-1.10, 0.11)	-0.25 (-1.07, 0.57) 0.5499	-0.27 (-1.20, 0.66)	
NO	96	1.75 (1.582)	-0.98 (-1.19, -0.77)	96	1.81 (1.810)	-0.32 (-0.53, -0.11)	-0.66 (-0.95, -0.36) <0.0001	-0.62 (-0.91, -0.33)	
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED									0.1386
YES	23	1.78 (2.111)	-1.11 (-1.48, -0.74)	21	2.16 (1.927)	-0.15 (-0.53, 0.24)	-0.96 (-1.50, -0.43) 0.0005	-1.04 (-1.67, -0.41)	
NO	83	1.76 (1.419)	-0.91 (-1.14, -0.69)	83	1.67 (1.730)	-0.39 (-0.61, -0.17)	-0.53 (-0.84, -0.22) 0.0009	-0.51 (-0.82, -0.20)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
HISTORY OF HYPERTENSION									0.5821
YES	51	1.60 (1.391)	-0.92 (-1.19, -0.66)	50	1.73 (1.936)	-0.37 (-0.64, -0.10)	-0.55 (-0.93, -0.17) 0.0043	-0.57 (-0.96, -0.17)	
NO	55	1.92 (1.741)	-0.99 (-1.25, -0.73)	54	1.81 (1.623)	-0.31 (-0.57, -0.05)	-0.68 (-1.05, -0.32) 0.0003	-0.69 (-1.08, -0.31)	
RESTING LVEF									0.4834
<75%	64	1.69 (1.460)	-0.95 (-1.19, -0.71)	61	1.69 (1.721)	-0.40 (-0.65, -0.15)	-0.55 (-0.90, -0.20) 0.0021	-0.55 (-0.91, -0.19)	
>=75%	42	1.88 (1.768)	-0.97 (-1.26, -0.68)	43	1.89 (1.857)	-0.25 (-0.53, 0.03)	-0.72 (-1.12, -0.32) 0.0005	-0.75 (-1.19, -0.31)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
LVOT RESTING PEAK GRADIENT									0.6645
<=50	52	1.75 (1.304)	-0.92 (-1.19, -0.65)	54	1.96 (1.852)	-0.25 (-0.51, 0.01)	-0.67 (-1.04, -0.30) 0.0005	-0.68 (-1.07, -0.29)	
>50	54	1.78 (1.825)	-0.99 (-1.25, -0.73)	50	1.57 (1.678)	-0.43 (-0.70, -0.16)	-0.56 (-0.94, -0.19) 0.0031	-0.58 (-0.97, -0.19)	
LVOT RESTING PEAK GRADIENT									0.3381
<=30	30	1.91 (1.440)	-0.96 (-1.30, -0.63)	31	2.45 (2.173)	-0.17 (-0.50, 0.16)	-0.80 (-1.27, -0.33) 0.0009	-0.84 (-1.37, -0.32)	
>30	76	1.71 (1.642)	-0.95 (-1.18, -0.73)	73	1.48 (1.498)	-0.41 (-0.64, -0.18)	-0.55 (-0.87, -0.22) 0.0010	-0.54 (-0.86, -0.21)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL									0.1779
<=14	46	1.91 (1.727)	-1.16 (-1.43, -0.89)	56	1.83 (1.809)	-0.40 (-0.65, -0.15)	-0.76 (-1.13, -0.39) <0.0001	-0.80 (-1.20, -0.39)	
>14	56	1.63 (1.490)	-0.76 (-1.01, -0.51)	42	1.48 (1.637)	-0.32 (-0.60, -0.04)	-0.44 (-0.81, -0.06) 0.0220	-0.46 (-0.87, -0.06)	
E/E' SEPTAL									0.3443
<=14	14	1.97 (1.468)	-1.24 (-1.71, -0.77)	21	2.43 (1.900)	-0.35 (-0.75, 0.04)	-0.89 (-1.50, -0.28) 0.0046	-0.96 (-1.67, -0.25)	
>14	92	1.74 (1.606)	-0.91 (-1.13, -0.70)	82	1.60 (1.721)	-0.34 (-0.56, -0.11)	-0.58 (-0.89, -0.27) 0.0002	-0.56 (-0.86, -0.25)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE									0.0523
<=14	21	2.21 (2.049)	-1.42 (-1.81, -1.04)	26	2.20 (1.810)	-0.36 (-0.71, -0.00)	-1.07 (-1.59, -0.54) <0.0001	-1.15 (-1.77, -0.53)	
>14	85	1.66 (1.439)	-0.84 (-1.06, -0.63)	78	1.63 (1.748)	-0.33 (-0.55, -0.11)	-0.51 (-0.82, -0.20) 0.0012	-0.51 (-0.82, -0.20)	
LEFT ATRIAL VOLUME INDEX									0.0176*
<=MEDIAN	53	1.95 (1.668)	-1.03 (-1.29, -0.77)	55	1.93 (2.004)	-0.16 (-0.41, 0.09)	-0.87 (-1.24, -0.51) <0.0001	-0.90 (-1.29, -0.50)	
>MEDIAN	52	1.51 (1.427)	-0.85 (-1.11, -0.59)	49	1.60 (1.471)	-0.54 (-0.81, -0.27)	-0.31 (-0.68, 0.06) 0.1026	-0.32 (-0.71, 0.07)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NT-PROBNP									0.1989
<=MEDIAN	47	1.76 (1.310)	-1.09 (-1.37, -0.82)	54	1.87 (1.804)	-0.31 (-0.57, -0.05)	-0.78 (-1.16, -0.40) <0.0001	-0.80 (-1.20, -0.39)	
>MEDIAN	57	1.75 (1.800)	-0.84 (-1.10, -0.59)	49	1.65 (1.766)	-0.37 (-0.64, -0.10)	-0.47 (-0.84, -0.10) 0.0127	-0.48 (-0.87, -0.10)	
HS-CARDIAC TROPONIN-I									0.0274*
<=ULN	75	1.75 (1.566)	-1.11 (-1.34, -0.88)	78	1.92 (1.898)	-0.32 (-0.55, -0.09)	-0.79 (-1.12, -0.47) <0.0001	-0.77 (-1.10, -0.44)	
>ULN	28	1.88 (1.645)	-0.51 (-0.86, -0.17)	19	1.42 (1.352)	-0.37 (-0.77, 0.04)	-0.15 (-0.68, 0.38) 0.5818	-0.16 (-0.74, 0.42)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0868
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	34	1.86 (1.828)	-1.27 (-1.58, -0.97)	45	1.98 (1.904)	-0.41 (-0.69, -0.13)	-0.86 (-1.28, -0.45) <0.0001	-0.92 (-1.39, -0.46)	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	68	1.67 (1.471)	-0.75 (-0.99, -0.52)	48	1.44 (1.609)	-0.31 (-0.58, -0.04)	-0.44 (-0.80, -0.09) 0.0151	-0.46 (-0.83, -0.08)	
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.1488
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	12	2.11 (1.537)	-1.34 (-1.84, -0.84)	16	2.60 (2.011)	-0.26 (-0.71, 0.18)	-1.07 (-1.74, -0.40) 0.0018	-1.17 (-1.97, -0.36)	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	94	1.72 (1.592)	-0.91 (-1.12, -0.70)	86	1.61 (1.709)	-0.34 (-0.56, -0.13)	-0.56 (-0.87, -0.26) 0.0003	-0.54 (-0.84, -0.24)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0127*
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	18	2.42 (2.142)	-1.54 (-1.96, -1.13)	18	2.56 (1.892)	-0.26 (-0.69, 0.16)	-1.28 (-1.87, -0.69) <0.0001	-1.39 (-2.12, -0.66)	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	88	1.63 (1.422)	-0.84 (-1.05, -0.62)	82	1.61 (1.743)	-0.35 (-0.57, -0.13)	-0.49 (-0.80, -0.18) 0.0018	-0.48 (-0.78, -0.17)	
CREATININE CLEARANCE (CRCL)									0.9871
<60	13	1.75 (1.328)	-0.99 (-1.48, -0.51)	11	1.47 (1.003)	-0.38 (-0.90, 0.14)	-0.61 (-1.32, 0.10) 0.0898	-0.67 (-1.50, 0.15)	
>=60	93	1.77 (1.622)	-0.95 (-1.16, -0.74)	93	1.81 (1.843)	-0.33 (-0.54, -0.12)	-0.62 (-0.92, -0.32) <0.0001	-0.59 (-0.88, -0.30)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
WEEKLY AVERAGE HCMSQ TOTAL SCORE									
BETA-BLOCKER USE									0.7910
YES	80	3.09 (1.644)	-1.52 (-1.79, -1.25)	77	2.89 (1.818)	-0.55 (-0.83, -0.28)	-0.97 (-1.36, -0.58) <0.0001	-0.78 (-1.10, -0.46)	
NO	26	3.29 (1.344)	-1.30 (-1.74, -0.87)	27	3.23 (2.039)	-0.43 (-0.85, 0.00)	-0.88 (-1.49, -0.27) 0.0051	-0.76 (-1.32, -0.20)	
TYPE OF EXERCISE TESTING									0.2845
EXERCISE BICYCLE	49	3.24 (1.831)	-1.40 (-1.73, -1.08)	48	3.35 (1.806)	-0.29 (-0.62, 0.04)	-1.12 (-1.58, -0.65) <0.0001	-0.95 (-1.37, -0.53)	
TREADMILL	57	3.05 (1.320)	-1.52 (-1.83, -1.21)	56	2.65 (1.886)	-0.72 (-1.03, -0.41)	-0.80 (-1.24, -0.36) 0.0004	-0.67 (-1.05, -0.29)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
NYHA CLASS									0.3710
CLASS II	78	2.89 (1.587)	-1.49 (-1.77, -1.22)	76	2.59 (1.792)	-0.46 (-0.74, -0.18)	-1.03 (-1.42, -0.64) <0.0001	-0.83 (-1.16, -0.50)	
CLASS III	28	3.82 (1.334)	-1.40 (-1.83, -0.97)	28	4.02 (1.706)	-0.67 (-1.10, -0.24)	-0.73 (-1.33, -0.13) 0.0172	-0.63 (-1.17, -0.09)	
CONSENT FOR THE CMR SUBSTUDY									0.0165*
YES	18	2.96 (1.360)	-0.97 (-1.48, -0.47)	18	2.59 (1.782)	-0.80 (-1.31, -0.29)	-0.18 (-0.90, 0.54) 0.6260	-0.16 (-0.81, 0.50)	
NO	88	3.17 (1.617)	-1.57 (-1.83, -1.31)	86	3.05 (1.892)	-0.46 (-0.72, -0.20)	-1.11 (-1.48, -0.74) <0.0001	-0.89 (-1.20, -0.58)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
SEX									0.3909
MALE	55	2.73 (1.615)	-1.37 (-1.68, -1.05)	67	2.65 (1.828)	-0.54 (-0.83, -0.24)	-0.83 (-1.26, -0.40) 0.0002	-0.69 (-1.06, -0.32)	
FEMALE	51	3.58 (1.410)	-1.58 (-1.91, -1.25)	37	3.57 (1.832)	-0.49 (-0.86, -0.11)	-1.09 (-1.59, -0.60) <0.0001	-0.93 (-1.37, -0.48)	
AGE									0.4141
<= 49	23	3.34 (1.848)	-1.41 (-1.87, -0.95)	19	3.25 (1.745)	-0.51 (-1.02, -0.00)	-0.90 (-1.58, -0.22) 0.0098	-0.79 (-1.42, -0.16)	
50 - 64	47	2.99 (1.377)	-1.50 (-1.84, -1.16)	52	3.03 (2.064)	-0.36 (-0.68, -0.04)	-1.14 (-1.61, -0.67) <0.0001	-0.96 (-1.37, -0.54)	
>=65	36	3.20 (1.649)	-1.47 (-1.84, -1.09)	33	2.72 (1.636)	-0.77 (-1.16, -0.38)	-0.69 (-1.24, -0.15) 0.0124	-0.60 (-1.08, -0.11)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-hcmsqmmrmrsubhq.sas 28OCT2022:03:39

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
BMI									0.3065
<30	68	3.09 (1.720)	-1.56 (-1.85, -1.26)	62	3.26 (2.009)	-0.49 (-0.79, -0.19)	-1.07 (-1.48, -0.65) <0.0001	-0.88 (-1.24, -0.52)	
>=30	38	3.21 (1.284)	-1.32 (-1.68, -0.95)	42	2.55 (1.581)	-0.56 (-0.92, -0.21)	-0.75 (-1.26, -0.24) 0.0042	-0.64 (-1.09, -0.19)	
RACE									0.1184
NON-WHITE	4	2.07 (1.144)	-0.81 (-1.90, 0.29)	10	3.34 (1.840)	-0.85 (-1.54, -0.16)	0.04 (-1.26, 1.34) 0.9506	0.03 (-1.13, 1.19)	
WHITE	102	3.18 (1.576)	-1.49 (-1.74, -1.24)	94	2.93 (1.882)	-0.48 (-0.74, -0.23)	-1.01 (-1.36, -0.65) <0.0001	-0.79 (-1.08, -0.50)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
REGION									0.0132*
US	44	2.88 (1.251)	-1.35 (-1.70, -1.01)	42	2.45 (1.564)	-0.85 (-1.20, -0.50)	-0.50 (-0.99, -0.01) 0.0449	-0.43 (-0.86, -0.00)	
EX-US	62	3.32 (1.752)	-1.55 (-1.85, -1.25)	62	3.33 (1.992)	-0.30 (-0.60, -0.01)	-1.24 (-1.66, -0.83) <0.0001	-1.04 (-1.42, -0.67)	
CALCIUM CHANNEL BLOCKER USE									0.6881
YES	22	3.39 (1.407)	-1.25 (-1.72, -0.77)	15	3.10 (2.265)	-0.42 (-0.97, 0.14)	-0.83 (-1.56, -0.10) 0.0262	-0.73 (-1.41, -0.05)	
NO	84	3.07 (1.614)	-1.52 (-1.79, -1.26)	89	2.95 (1.813)	-0.54 (-0.80, -0.28)	-0.99 (-1.36, -0.62) <0.0001	-0.79 (-1.10, -0.48)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-hcmsqmmrmrsubhq.sas 28OCT2022:03:39

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
PRESENCE OF HCM PATHOGENIC MUTATION									0.5696
PATHOGENIC OR LIKELY PATHOGENIC	25	3.08 (1.363)	-1.39 (-1.85, -0.93)	18	3.14 (1.544)	-0.78 (-1.31, -0.25)	-0.61 (-1.31, 0.09) 0.0882	-0.52 (-1.13, 0.10)	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	29	3.03 (1.828)	-1.35 (-1.78, -0.93)	35	3.23 (2.112)	-0.49 (-0.87, -0.10)	-0.87 (-1.44, -0.29) 0.0033	-0.73 (-1.24, -0.22)	
NEGATIVE	26	3.35 (1.662)	-1.49 (-1.94, -1.05)	30	2.64 (1.749)	-0.41 (-0.83, 0.01)	-1.08 (-1.69, -0.47) 0.0006	-0.91 (-1.46, -0.36)	
TIME FROM DIAGNOSIS OF OHCM									0.4042
<=5	56	3.08 (1.182)	-1.58 (-1.89, -1.26)	43	3.69 (1.826)	-0.51 (-0.86, -0.15)	-1.07 (-1.55, -0.60) <0.0001	-0.89 (-1.31, -0.48)	
>5	50	3.20 (1.929)	-1.35 (-1.67, -1.02)	61	2.47 (1.748)	-0.53 (-0.83, -0.22)	-0.82 (-1.27, -0.37) 0.0004	-0.68 (-1.06, -0.29)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
SEPTAL REDUCTION THERAPY (SRT) HISTORY									0.3986
YES	10	3.37 (1.390)	-0.97 (-1.66, -0.29)	8	2.93 (1.528)	-0.43 (-1.18, 0.32)	-0.55 (-1.56, 0.47) 0.2906	-0.48 (-1.42, 0.47)	
NO	96	3.11 (1.595)	-1.52 (-1.77, -1.27)	96	2.98 (1.906)	-0.53 (-0.78, -0.27)	-0.99 (-1.35, -0.63) <0.0001	-0.78 (-1.07, -0.49)	
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED									0.1156
YES	23	3.26 (2.065)	-1.81 (-2.27, -1.35)	21	3.32 (1.977)	-0.41 (-0.89, 0.06)	-1.40 (-2.06, -0.74) <0.0001	-1.23 (-1.88, -0.59)	
NO	83	3.10 (1.420)	-1.37 (-1.64, -1.11)	83	2.89 (1.848)	-0.54 (-0.81, -0.28)	-0.83 (-1.21, -0.45) <0.0001	-0.66 (-0.98, -0.35)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
HISTORY OF HYPERTENSION									0.6918
YES	51	3.06 (1.529)	-1.48 (-1.81, -1.16)	50	3.09 (1.968)	-0.60 (-0.92, -0.27)	-0.89 (-1.35, -0.43) 0.0002	-0.74 (-1.15, -0.34)	
NO	55	3.20 (1.623)	-1.45 (-1.77, -1.14)	54	2.86 (1.793)	-0.45 (-0.76, -0.13)	-1.01 (-1.45, -0.56) <0.0001	-0.84 (-1.23, -0.45)	
RESTING LVEF									0.5313
<75%	64	2.95 (1.462)	-1.51 (-1.80, -1.21)	61	3.03 (1.862)	-0.64 (-0.94, -0.34)	-0.87 (-1.29, -0.45) <0.0001	-0.72 (-1.08, -0.35)	
>=75%	42	3.42 (1.706)	-1.41 (-1.76, -1.06)	43	2.89 (1.908)	-0.35 (-0.70, -0.01)	-1.06 (-1.55, -0.56) <0.0001	-0.90 (-1.35, -0.45)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
LVOT RESTING PEAK GRADIENT									0.8745
<=50	52	3.15 (1.493)	-1.37 (-1.69, -1.04)	54	3.17 (1.798)	-0.40 (-0.72, -0.09)	-0.97 (-1.42, -0.51) <0.0001	-0.81 (-1.20, -0.41)	
>50	54	3.12 (1.659)	-1.56 (-1.88, -1.25)	50	2.76 (1.947)	-0.64 (-0.97, -0.32)	-0.92 (-1.37, -0.46) <0.0001	-0.77 (-1.17, -0.37)	
LVOT RESTING PEAK GRADIENT									0.1467
<=30	30	3.47 (1.412)	-1.53 (-1.94, -1.12)	31	3.74 (1.877)	-0.25 (-0.65, 0.16)	-1.28 (-1.86, -0.71) <0.0001	-1.11 (-1.65, -0.57)	
>30	76	3.01 (1.621)	-1.44 (-1.72, -1.17)	73	2.65 (1.788)	-0.63 (-0.92, -0.35)	-0.81 (-1.20, -0.41) <0.0001	-0.66 (-0.99, -0.33)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL									0.0696
<=14	46	3.07 (1.654)	-1.71 (-2.04, -1.37)	56	2.95 (1.752)	-0.50 (-0.81, -0.19)	-1.21 (-1.66, -0.75) <0.0001	-1.03 (-1.44, -0.61)	
>14	56	3.17 (1.552)	-1.26 (-1.57, -0.95)	42	2.88 (2.013)	-0.60 (-0.95, -0.25)	-0.66 (-1.13, -0.20) 0.0053	-0.57 (-0.97, -0.16)	
E/E' SEPTAL									0.1606
<=14	14	2.86 (1.509)	-1.88 (-2.46, -1.30)	21	3.37 (1.727)	-0.44 (-0.93, 0.04)	-1.43 (-2.19, -0.68) 0.0002	-1.25 (-1.99, -0.52)	
>14	92	3.18 (1.585)	-1.41 (-1.66, -1.15)	82	2.85 (1.902)	-0.55 (-0.81, -0.28)	-0.86 (-1.23, -0.49) <0.0001	-0.68 (-0.99, -0.38)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE									0.0161*
<=14	21	3.21 (1.877)	-2.06 (-2.53, -1.58)	26	3.05 (1.762)	-0.42 (-0.86, 0.01)	-1.63 (-2.28, -0.99) <0.0001	-1.43 (-2.08, -0.79)	
>14	85	3.12 (1.500)	-1.33 (-1.59, -1.06)	78	2.95 (1.919)	-0.55 (-0.82, -0.28)	-0.78 (-1.15, -0.40) <0.0001	-0.63 (-0.95, -0.32)	
LEFT ATRIAL VOLUME INDEX									0.0162*
<=MEDIAN	53	3.40 (1.598)	-1.52 (-1.84, -1.20)	55	3.01 (1.938)	-0.25 (-0.56, 0.06)	-1.27 (-1.72, -0.83) <0.0001	-1.07 (-1.48, -0.67)	
>MEDIAN	52	2.84 (1.511)	-1.39 (-1.71, -1.07)	49	2.93 (1.817)	-0.83 (-1.15, -0.50)	-0.56 (-1.02, -0.11) 0.0155	-0.48 (-0.87, -0.08)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NT-PROBNP									0.3054
<=MEDIAN	47	3.19 (1.359)	-1.55 (-1.89, -1.21)	54	3.07 (1.679)	-0.45 (-0.77, -0.13)	-1.11 (-1.57, -0.64) <0.0001	-0.92 (-1.33, -0.51)	
>MEDIAN	57	3.07 (1.761)	-1.40 (-1.72, -1.09)	49	2.82 (2.073)	-0.61 (-0.94, -0.28)	-0.80 (-1.25, -0.34) 0.0007	-0.66 (-1.06, -0.27)	
HS-CARDIAC TROPONIN-I									0.0358*
<=ULN	75	3.09 (1.558)	-1.58 (-1.86, -1.30)	78	3.12 (1.842)	-0.47 (-0.74, -0.19)	-1.12 (-1.51, -0.72) <0.0001	-0.89 (-1.22, -0.56)	
>ULN	28	3.37 (1.586)	-1.14 (-1.57, -0.70)	19	2.90 (2.138)	-0.79 (-1.30, -0.29)	-0.34 (-1.01, 0.32) 0.3117	-0.29 (-0.88, 0.29)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0442*
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	34	2.92 (1.736)	-1.83 (-2.21, -1.44)	45	3.10 (1.711)	-0.50 (-0.85, -0.16)	-1.32 (-1.84, -0.81) <0.0001	-1.14 (-1.62, -0.66)	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	68	3.21 (1.519)	-1.26 (-1.55, -0.97)	48	2.89 (2.036)	-0.57 (-0.90, -0.24)	-0.69 (-1.13, -0.25) 0.0022	-0.58 (-0.95, -0.20)	
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0956
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	12	2.96 (1.595)	-1.85 (-2.47, -1.23)	16	3.42 (1.548)	-0.26 (-0.81, 0.29)	-1.59 (-2.42, -0.76) 0.0002	-1.39 (-2.23, -0.56)	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	94	3.16 (1.577)	-1.42 (-1.68, -1.16)	86	2.92 (1.931)	-0.56 (-0.83, -0.30)	-0.86 (-1.22, -0.49) <0.0001	-0.68 (-0.98, -0.38)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-hcmsqmmrmrsubhq.sas 28OCT2022:03:39

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in HCMSQ Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0058*
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	18	3.37 (1.982)	-2.10 (-2.61, -1.58)	18	3.37 (1.478)	-0.24 (-0.76, 0.28)	-1.86 (-2.59, -1.13) <0.0001	-1.63 (-2.38, -0.87)	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	88	3.09 (1.484)	-1.34 (-1.60, -1.08)	82	2.96 (1.960)	-0.57 (-0.84, -0.31)	-0.77 (-1.14, -0.40) <0.0001	-0.62 (-0.93, -0.31)	
CREATININE CLEARANCE (CRCL)									0.9062
<60	13	3.38 (1.298)	-1.62 (-2.22, -1.02)	11	2.37 (1.384)	-0.72 (-1.37, -0.08)	-0.90 (-1.78, -0.01) 0.0465	-0.79 (-1.62, 0.05)	
>=60	93	3.10 (1.610)	-1.45 (-1.70, -1.19)	93	3.04 (1.916)	-0.49 (-0.75, -0.24)	-0.95 (-1.32, -0.59) <0.0001	-0.75 (-1.05, -0.45)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
HCMSQ is hypertrophic cardiopathy symptom questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-hcmsqmmrmrsubhq.sas 28OCT2022:03:39

4.8 Analysen für die Endpunkte zur allgemeinen Symptomatik

4.8.1 PGI-C

4.8.1.1 Deskriptive Darstellung des PGI-C im Studienverlauf (pro Erhebungszeitpunkt)

Protocol: MYK-461-005 Page 1 of 3

Summary of PGI-C Scores by Visit and Treatment Group
Intention-to-treat (ITT) population

Time Point	Response	Mavacamten (N = 123)	Placebo (N = 128)
Week 6	n	106	103
	Very Much Improved	12 (11.3%)	2 (1.9%)
	Much Improved	38 (35.8%)	10 (9.7%)
	Minimally Improved	31 (29.2%)	38 (36.9%)
	No Change	20 (18.9%)	47 (45.6%)
	Minimally Worse	3 (2.8%)	6 (5.8%)
	Much Worse	2 (1.9%)	0
	Very Much Worse	0	0
Week 10	n	95	89
	Very Much Improved	22 (23.2%)	1 (1.1%)
	Much Improved	35 (36.8%)	15 (16.9%)
	Minimally Improved	21 (22.1%)	25 (28.1%)
	No Change	16 (16.8%)	39 (43.8%)
	Minimally Worse	0	9 (10.1%)
	Much Worse	1 (1.1%)	0
	Very Much Worse	0	0
Week 14	n	110	104
	Very Much Improved	23 (20.9%)	4 (3.8%)
	Much Improved	52 (47.3%)	23 (22.1%)
	Minimally Improved	19 (17.3%)	35 (33.7%)
	No Change	13 (11.8%)	36 (34.6%)
	Minimally Worse	3 (2.7%)	6 (5.8%)
	Much Worse	0	0
	Very Much Worse	0	0

Data Cutoff Date: 30JUN2020
Note: n is the number of subjects who answered the questionnaire at each visit.
PGI-C is patient global impression of change questionnaire.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-sy-pgicsumr.sas 09MAR2022:00:59

Protocol: MYK-461-005

Summary of PGI-C Scores by Visit and Treatment Group
Intention-to-treat (ITT) population

Time Point	Response	Mavacamten (N = 123)	Placebo (N = 128)
Week 18	n	112	120
	Very Much Improved	28 (25.0%)	6 (5.0%)
	Much Improved	48 (42.9%)	28 (23.3%)
	Minimally Improved	21 (18.8%)	35 (29.2%)
	No Change	12 (10.7%)	38 (31.7%)
	Minimally Worse	2 (1.8%)	12 (10.0%)
	Much Worse	1 (0.9%)	1 (0.8%)
	Very Much Worse	0	0
Week 22	n	108	115
	Very Much Improved	31 (28.7%)	6 (5.2%)
	Much Improved	40 (37.0%)	28 (24.3%)
	Minimally Improved	21 (19.4%)	32 (27.8%)
	No Change	14 (13.0%)	43 (37.4%)
	Minimally Worse	2 (1.9%)	6 (5.2%)
	Much Worse	0	0
	Very Much Worse	0	0
Week 26	n	112	114
	Very Much Improved	35 (31.3%)	4 (3.5%)
	Much Improved	40 (35.7%)	27 (23.7%)
	Minimally Improved	19 (17.0%)	29 (25.4%)
	No Change	13 (11.6%)	40 (35.1%)
	Minimally Worse	4 (3.6%)	10 (8.8%)
	Much Worse	1 (0.9%)	4 (3.5%)
	Very Much Worse	0	0

Data Cutoff Date: 30JUN2020
Note: n is the number of subjects who answered the questionnaire at each visit.
PGI-C is patient global impression of change questionnaire.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-sy-pgicsumr.sas 09MAR2022:00:59

Protocol: MYK-461-005

Summary of PGI-C Scores by Visit and Treatment Group
Intention-to-treat (ITT) population

Time Point	Response	Mavacamten (N = 123)	Placebo (N = 128)
Week 30	n	114	115
	Very Much Improved	40 (35.1%)	6 (5.2%)
	Much Improved	46 (40.4%)	33 (28.7%)
	Minimally Improved	13 (11.4%)	17 (14.8%)
	No Change	9 (7.9%)	42 (36.5%)
	Minimally Worse	5 (4.4%)	12 (10.4%)
	Much Worse	1 (0.9%)	4 (3.5%)
	Very Much Worse	0	1 (0.9%)
Week 38	n	78	81
	Very Much Improved	16 (20.5%)	3 (3.7%)
	Much Improved	26 (33.3%)	22 (27.2%)
	Minimally Improved	9 (11.5%)	13 (16.0%)
	No Change	10 (12.8%)	33 (40.7%)
	Minimally Worse	12 (15.4%)	10 (12.3%)
	Much Worse	5 (6.4%)	0
	Very Much Worse	0	0

Data Cutoff Date: 30JUN2020
Note: n is the number of subjects who answered the questionnaire at each visit.
PGI-C is patient global impression of change questionnaire.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-sy-pgicsumr.sas 09MAR2022:00:59

4.8.1.2 Subgruppenanalyse für den Anteil an Patient:innen mit jeglicher Verbesserung zu Woche 30 gegenüber Baseline

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Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
PGI-C RESPONDER AT WEEK 30 PATIENTS WITH IMPROVEMENT								
OVERALL	114	99 (86.8)	115	56 (48.7)	1.78 (1.46, 2.18) <0.0001	6.95 (3.48, 14.35) <0.0001	38.15 (27.10, 49.19) <0.0001	
BETA-BLOCKER USE								0.4914
YES	87	76 (87.4)	84	43 (51.2)	1.71 (1.36, 2.13) <0.0001	6.59 (2.92, 15.57) <0.0001	36.17 (23.40, 48.93) <0.0001	
NO	27	23 (85.2)	31	13 (41.9)	2.03 (1.30, 3.16) 0.0017	7.96 (1.96, 37.95) 0.0010	43.25 (21.31, 65.19) 0.0001	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
TYPE OF EXERCISE TESTING								0.0766
EXERCISE BICYCLE	52	45 (86.5)	54	21 (38.9)	2.23 (1.57, 3.16) <0.0001	10.10 (3.56, 30.91) <0.0001	47.65 (31.68, 63.62) <0.0001	
TREADMILL	62	54 (87.1)	61	35 (57.4)	1.52 (1.20, 1.92) 0.0005	5.01 (1.91, 14.15) 0.0003	29.72 (14.77, 44.67) <0.0001	
NYHA CLASS								0.6626
CLASS II	79	71 (89.9)	86	42 (48.8)	1.84 (1.46, 2.31) <0.0001	9.30 (3.81, 24.77) <0.0001	41.04 (28.55, 53.52) <0.0001	
CLASS III	35	28 (80.0)	29	14 (48.3)	1.66 (1.10, 2.50) 0.0161	4.29 (1.26, 15.21) 0.0096	31.72 (9.22, 54.23) 0.0057	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane's Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
CONSENT FOR THE CMR SUBSTUDY								0.6499
YES	20	17 (85.0)	21	11 (52.4)	1.62 (1.04, 2.54) 0.0340	5.15 (0.98, 34.29) 0.0431	32.62 (6.14, 59.10) 0.0158	
NO	94	82 (87.2)	94	45 (47.9)	1.82 (1.46, 2.28) <0.0001	7.44 (3.43, 16.83) <0.0001	39.36 (27.22, 51.51) <0.0001	
SEX								0.9795
FEMALE	52	46 (88.5)	38	19 (50.0)	1.77 (1.27, 2.47) 0.0008	7.67 (2.41, 26.61) <0.0001	38.46 (20.35, 56.58) <0.0001	
MALE	62	53 (85.5)	77	37 (48.1)	1.78 (1.38, 2.29) <0.0001	6.37 (2.61, 16.56) <0.0001	37.43 (23.24, 51.62) <0.0001	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
AGE								0.3688
<= 49	26	22 (84.6)	20	12 (60.0)	1.41 (0.95, 2.09) 0.0869	3.67 (0.76, 19.72) 0.0914	24.62 (-0.94, 50.18) 0.0591	
50 - 64	45	40 (88.9)	59	26 (44.1)	2.02 (1.49, 2.74) <0.0001	10.15 (3.28, 36.82) <0.0001	44.82 (29.18, 60.47) <0.0001	
>= 65	43	37 (86.0)	36	18 (50.0)	1.72 (1.21, 2.44) 0.0022	6.17 (1.89, 21.87) 0.0006	36.05 (16.71, 55.39) 0.0003	
BMI								0.7336
<30	73	64 (87.7)	69	33 (47.8)	1.83 (1.41, 2.38) <0.0001	7.76 (3.15, 20.29) <0.0001	39.85 (25.85, 53.84) <0.0001	
>=30	41	35 (85.4)	46	23 (50.0)	1.71 (1.25, 2.34) 0.0009	5.83 (1.89, 19.89) 0.0006	35.37 (17.32, 53.42) 0.0001	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane's Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
RACE								0.3744
NON-WHITE	7	7 (100.0)	12	8 (66.7)	1.50 (1.01, 2.24) 0.0470	NE (0.57, NE) 0.2451	33.33 (6.66, 60.01) 0.0143	
WHITE	107	92 (86.0)	103	48 (46.6)	1.85 (1.48, 2.30) <0.0001	7.03 (3.45, 14.72) <0.0001	39.38 (27.71, 51.04) <0.0001	
REGION								0.8739
US	48	42 (87.5)	48	24 (50.0)	1.75 (1.29, 2.37) 0.0003	7.00 (2.32, 23.48) 0.0001	37.50 (20.54, 54.46) <0.0001	
EX-US	66	57 (86.4)	67	32 (47.8)	1.81 (1.38, 2.36) <0.0001	6.93 (2.78, 18.28) <0.0001	38.60 (24.06, 53.15) <0.0001	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane's Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
CALCIUM CHANNEL BLOCKER USE								0.3824
YES	23	19 (82.6)	16	9 (56.3)	1.47 (0.92, 2.35) 0.1098	3.69 (0.69, 21.31) 0.1461	26.36 (-2.46, 55.18) 0.0731	
NO	91	80 (87.9)	99	47 (47.5)	1.85 (1.48, 2.31) <0.0001	8.05 (3.66, 18.63) <0.0001	40.44 (28.54, 52.34) <0.0001	
PRESENCE OF HCM PATHOGENIC MUTATION								0.2833
PATHOGENIC OR LIKELY PATHOGENIC	28	27 (96.4)	19	12 (63.2)	1.53 (1.08, 2.17) 0.0180	15.75 (1.63, 735.23) 0.0047	33.27 (10.52, 56.02) 0.0042	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	31	26 (83.9)	39	15 (38.5)	2.18 (1.42, 3.34) 0.0003	8.32 (2.36, 32.88) 0.0002	45.41 (25.39, 65.43) <0.0001	
NEGATIVE	27	20 (74.1)	34	18 (52.9)	1.40 (0.95, 2.06) 0.0894	2.54 (0.76, 8.96) 0.1149	21.13 (-2.42, 44.69) 0.0786	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane's Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
TIME FROM DIAGNOSIS OF OHCM (Years)								0.1825
<=5	59	53 (89.8)	47	20 (42.6)	2.11 (1.50, 2.98) <0.0001	11.93 (3.95, 39.69) <0.0001	47.28 (31.18, 63.38) <0.0001	
>5	55	46 (83.6)	68	36 (52.9)	1.58 (1.23, 2.03) 0.0004	4.54 (1.81, 12.11) 0.0005	30.70 (15.32, 46.07) <0.0001	
SEPTAL REDUCTION THERAPY (SRT) HISTORY								0.1939
YES	11	10 (90.9)	7	5 (71.4)	1.27 (0.77, 2.11) 0.3487	4.00 (0.16, 259.06) 0.5282	19.48 (-18.05, 57.01) 0.3090	
NO	103	89 (86.4)	108	51 (47.2)	1.83 (1.48, 2.27) <0.0001	7.11 (3.46, 15.09) <0.0001	39.19 (27.68, 50.69) <0.0001	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED								0.1137
YES	23	19 (82.6)	24	7 (29.2)	2.83 (1.48, 5.43) 0.0017	11.54 (2.44, 60.81) 0.0004	53.44 (29.55, 77.33) <0.0001	
NO	91	80 (87.9)	91	49 (53.8)	1.63 (1.33, 2.00) <0.0001	6.23 (2.80, 14.59) <0.0001	34.07 (21.83, 46.30) <0.0001	
HISTORY OF HYPERTENSION								0.3669
YES	54	48 (88.9)	55	30 (54.5)	1.63 (1.26, 2.11) 0.0002	6.67 (2.28, 21.86) <0.0001	34.34 (18.74, 49.95) <0.0001	
NO	60	51 (85.0)	60	26 (43.3)	1.96 (1.44, 2.67) <0.0001	7.41 (2.89, 19.99) <0.0001	41.67 (26.21, 57.12) <0.0001	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane's Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
RESTING LVEF								0.2369
<75%	66	58 (87.9)	64	35 (54.7)	1.61 (1.26, 2.04) 0.0001	6.01 (2.32, 16.74) <0.0001	33.19 (18.67, 47.71) <0.0001	
>=75%	48	41 (85.4)	51	21 (41.2)	2.07 (1.46, 2.94) <0.0001	8.37 (2.91, 25.90) <0.0001	44.24 (27.44, 61.04) <0.0001	
LVOT RESTING PEAK GRADIENT (mmHg)								0.0781
<=50	53	45 (84.9)	59	23 (39.0)	2.18 (1.55, 3.06) <0.0001	8.80 (3.28, 25.14) <0.0001	45.92 (30.18, 61.66) <0.0001	
>50	61	54 (88.5)	56	33 (58.9)	1.50 (1.19, 1.90) 0.0007	5.38 (1.93, 16.30) 0.0003	29.60 (14.43, 44.76) 0.0001	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
LVOT RESTING PEAK GRADIENT (mmHg)								0.1899
<=30	30	27 (90.0)	35	14 (40.0)	2.25 (1.47, 3.43) 0.0002	13.50 (3.10, 79.19) <0.0001	50.00 (30.54, 69.46) <0.0001	
>30	84	72 (85.7)	80	42 (52.5)	1.63 (1.30, 2.05) <0.0001	5.43 (2.43, 12.60) <0.0001	33.21 (19.96, 46.47) <0.0001	
E/E' LATERAL								0.6917
<=14	52	47 (90.4)	58	28 (48.3)	1.87 (1.41, 2.48) <0.0001	10.07 (3.28, 36.34) <0.0001	42.11 (26.96, 57.26) <0.0001	
>14	58	48 (82.8)	52	25 (48.1)	1.72 (1.27, 2.34) 0.0005	5.18 (2.01, 13.84) 0.0002	34.68 (17.98, 51.38) <0.0001	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
E/E' SEPTAL								0.3067
<=14	17	17 (100.0)	24	11 (45.8)	2.18 (1.41, 3.37) 0.0004	NE (4.68, NE) 0.0002	54.17 (34.23, 74.10) <0.0001	
>14	97	82 (84.5)	90	45 (50.0)	1.69 (1.35, 2.11) <0.0001	5.47 (2.62, 11.68) <0.0001	34.54 (21.95, 47.12) <0.0001	
E/E' AVERAGE								0.0784
<=14	25	25 (100.0)	28	11 (39.3)	2.55 (1.61, 4.03) <0.0001	NE (9.40, NE) <0.0001	60.71 (42.62, 78.80) <0.0001	
>14	89	74 (83.1)	87	45 (51.7)	1.61 (1.29, 2.01) <0.0001	4.60 (2.19, 9.93) <0.0001	31.42 (18.36, 44.49) <0.0001	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane's Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
LEFT ATRIAL VOLUME INDEX								0.1359
<=MEDIAN	55	47 (85.5)	59	24 (40.7)	2.10 (1.52, 2.91) <0.0001	8.57 (3.21, 24.37) <0.0001	44.78 (29.16, 60.39) <0.0001	
>MEDIAN	58	51 (87.9)	56	32 (57.1)	1.54 (1.20, 1.97) 0.0006	5.46 (1.97, 16.57) 0.0003	30.79 (15.35, 46.22) <0.0001	
NT-PROBNP								0.8530
<=MEDIAN	49	43 (87.8)	60	29 (48.3)	1.82 (1.37, 2.41) <0.0001	7.66 (2.65, 24.89) <0.0001	39.42 (23.80, 55.05) <0.0001	
>MEDIAN	63	54 (85.7)	53	26 (49.1)	1.75 (1.30, 2.34) 0.0002	6.23 (2.38, 17.07) <0.0001	36.66 (20.66, 52.65) <0.0001	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
HS-CARDIAC TROPONIN-I								0.7605
<=ULN	81	75 (92.6)	87	43 (49.4)	1.87 (1.50, 2.34) <0.0001	12.79 (4.82, 39.17) <0.0001	43.17 (31.21, 55.12) <0.0001	
>ULN	30	22 (73.3)	21	9 (42.9)	1.71 (1.00, 2.93) 0.0508	3.67 (0.97, 14.16) 0.0421	30.48 (4.05, 56.90) 0.0238	
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.8073
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	37	35 (94.6)	48	24 (50.0)	1.89 (1.41, 2.54) <0.0001	17.50 (3.65, 161.42) <0.0001	44.59 (28.68, 60.51) <0.0001	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	73	60 (82.2)	59	27 (45.8)	1.80 (1.33, 2.42) 0.0001	5.47 (2.33, 13.11) <0.0001	36.43 (20.98, 51.88) <0.0001	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.2664
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	14	14 (100.0)	19	8 (42.1)	2.38 (1.40, 4.02) 0.0013	NE (4.11, NE) 0.0005	57.89 (35.69, 80.10) <0.0001	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	100	85 (85.0)	95	47 (49.5)	1.72 (1.38, 2.14) <0.0001	5.79 (2.80, 12.27) <0.0001	35.53 (23.28, 47.78) <0.0001	
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.1189
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	20	20 (100.0)	21	8 (38.1)	2.63 (1.52, 4.53) 0.0005	NE (7.24, NE) <0.0001	61.90 (41.13, 82.67) <0.0001	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	94	79 (84.0)	92	47 (51.1)	1.65 (1.32, 2.05) <0.0001	5.04 (2.42, 10.77) <0.0001	32.96 (20.34, 45.57) <0.0001	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane's Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-C Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
CREATININE CLEARANCE (CRCL) (mL/min)								0.5084
<60	14	13 (92.9)	15	9 (60.0)	1.55 (1.00, 2.40) 0.0507	8.67 (0.77, 428.55) 0.0801	32.86 (4.63, 61.08) 0.0225	
>=60	99	85 (85.9)	100	47 (47.0)	1.83 (1.46, 2.28) <0.0001	6.85 (3.30, 14.69) <0.0001	38.86 (26.91, 50.81) <0.0001	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane's Q heterogeneity test.
PGI-C is patient global impression of change questionnaire.
Patients with missing week 30 are excluded from analysis.
Improvement is defined as 'minimally improved', 'much improved', or 'very much improved' at that visit.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgicreprsubcc1.sas 21OCT2022:05:02

4.8.2 PGI-S

4.8.2.1 Deskriptive Darstellung des PGI-S im Studienverlauf (pro Erhebungszeitpunkt)

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Summary of PGI-S Scores by Visit and Treatment Group
Intention-to-treat (ITT) population

Time Point	Response	Mavacamten (N = 123)	Placebo (N = 128)
Baseline	n	118	124
	No Symptoms	7 (5.9%)	14 (11.3%)
	Mild	50 (42.4%)	46 (37.1%)
	Moderate	56 (47.5%)	49 (39.5%)
	Severe	5 (4.2%)	14 (11.3%)
	Very Severe	0	1 (0.8%)
Week 6	n	110	105
	No Symptoms	24 (21.8%)	10 (9.5%)
	Mild	65 (59.1%)	51 (48.6%)
	Moderate	17 (15.5%)	38 (36.2%)
	Severe	4 (3.6%)	6 (5.7%)
	Very Severe	0	0
Week 10	n	95	93
	No Symptoms	24 (25.3%)	12 (12.9%)
	Mild	55 (57.9%)	42 (45.2%)
	Moderate	14 (14.7%)	36 (38.7%)
	Severe	1 (1.1%)	2 (2.2%)
	Very Severe	1 (1.1%)	1 (1.1%)
Week 14	n	110	105
	No Symptoms	32 (29.1%)	14 (13.3%)
	Mild	59 (53.6%)	47 (44.8%)
	Moderate	14 (12.7%)	41 (39.0%)
	Severe	5 (4.5%)	3 (2.9%)
	Very Severe	0	0

Data Cutoff Date: 30JUN2020
Note: n is the number of subjects who answered the questionnaire at each visit.
PGI-S is patient global impression of severity questionnaire.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-sy-pgissumr.sas 09MAR2022:00:58

Protocol: MYK-461-005

Summary of PGI-S Scores by Visit and Treatment Group
Intention-to-treat (ITT) population

Time Point	Response	Mavacamten (N = 123)	Placebo (N = 128)
Week 18	n	112	121
	No Symptoms	32 (28.6%)	20 (16.5%)
	Mild	57 (50.9%)	60 (49.6%)
	Moderate	18 (16.1%)	35 (28.9%)
	Severe	5 (4.5%)	6 (5.0%)
	Very Severe	0	0
Week 22	n	109	116
	No Symptoms	27 (24.8%)	16 (13.8%)
	Mild	65 (59.6%)	56 (48.3%)
	Moderate	14 (12.8%)	43 (37.1%)
	Severe	3 (2.8%)	1 (0.9%)
	Very Severe	0	0
Week 26	n	113	115
	No Symptoms	37 (32.7%)	14 (12.2%)
	Mild	57 (50.4%)	60 (52.2%)
	Moderate	17 (15.0%)	32 (27.8%)
	Severe	2 (1.8%)	9 (7.8%)
	Very Severe	0	0
Week 30	n	114	115
	No Symptoms	35 (30.7%)	19 (16.5%)
	Mild	58 (50.9%)	57 (49.6%)
	Moderate	18 (15.8%)	30 (26.1%)
	Severe	3 (2.6%)	9 (7.8%)
	Very Severe	0	0

Data Cutoff Date: 30JUN2020
Note: n is the number of subjects who answered the questionnaire at each visit.
PGI-S is patient global impression of severity questionnaire.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-sy-pgissumr.sas 09MAR2022:00:58

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Summary of PGI-S Scores by Visit and Treatment Group
Intention-to-treat (ITT) population

Time Point	Response	Mavacamten (N = 123)	Placebo (N = 128)
Week 38	n	78	81
	No Symptoms	6 (7.7%)	13 (16.0%)
	Mild	25 (32.1%)	33 (40.7%)
	Moderate	35 (44.9%)	30 (37.0%)
	Severe	12 (15.4%)	5 (6.2%)
	Very Severe	0	0

Data Cutoff Date: 30JUN2020
Note: n is the number of subjects who answered the questionnaire at each visit.
PGI-S is patient global impression of severity questionnaire.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-sy-pgissumr.sas 09MAR2022:00:58

4.8.2.2 Subgruppenanalyse für den Anteil an Patient:innen mit jeglicher Verbesserung zu Woche 30 gegenüber Baseline

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Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
PGI-S RESPONDER AT WEEK 30 PATIENTS WITH IMPROVEMENT								
OVERALL	110	60 (54.5)	112	38 (33.9)	1.61 (1.18, 2.19) 0.0027	2.34 (1.31, 4.17) 0.0029	20.62 (7.83, 33.40) 0.0016	
BETA-BLOCKER USE								0.8084
YES	83	46 (55.4)	83	28 (33.7)	1.64 (1.15, 2.35) 0.0066	2.44 (1.24, 4.81) 0.0077	21.69 (6.93, 36.45) 0.0040	
NO	27	14 (51.9)	29	10 (34.5)	1.50 (0.81, 2.79) 0.1968	2.05 (0.62, 6.89) 0.2801	17.37 (-8.21, 42.95) 0.1833	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-S is patient global impression of severity questionnaire.
Patients with missing baseline and/or week 30 are excluded from analysis.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgisreprsubcc.sas 21OCT2022:05:06

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
TYPE OF EXERCISE TESTING								0.6097
EXERCISE BICYCLE	50	27 (54.0)	52	19 (36.5)	1.48 (0.95, 2.30) 0.0820	2.04 (0.86, 4.86) 0.1110	17.46 (-1.57, 36.49) 0.0721	
TREADMILL	60	33 (55.0)	60	19 (31.7)	1.74 (1.12, 2.69) 0.0132	2.64 (1.18, 5.95) 0.0162	23.33 (6.10, 40.57) 0.0080	
NYHA CLASS								0.1264
CLASS II	77	41 (53.2)	84	24 (28.6)	1.86 (1.25, 2.77) 0.0022	2.85 (1.41, 5.76) 0.0021	24.68 (9.93, 39.42) 0.0010	
CLASS III	33	19 (57.6)	28	14 (50.0)	1.15 (0.72, 1.85) 0.5582	1.36 (0.44, 4.21) 0.6123	7.58 (-17.47, 32.62) 0.5533	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-S is patient global impression of severity questionnaire.
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Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
CONSENT FOR THE CMR SUBSTUDY								0.6480
YES	20	5 (25.0)	20	4 (20.0)	1.25 (0.39, 3.99) 0.7060	1.33 (0.23, 8.04) 1.0000	5.00 (-20.84, 30.84) 0.7044	
NO	90	55 (61.1)	92	34 (37.0)	1.65 (1.21, 2.26) 0.0017	2.68 (1.41, 5.10) 0.0018	24.15 (10.06, 38.25) 0.0008	
SEX								0.9706
FEMALE	50	29 (58.0)	38	14 (36.8)	1.57 (0.98, 2.54) 0.0630	2.37 (0.92, 6.18) 0.0562	21.16 (0.61, 41.71) 0.0436	
MALE	60	31 (51.7)	74	24 (32.4)	1.59 (1.06, 2.40) 0.0260	2.23 (1.04, 4.77) 0.0338	19.23 (2.69, 35.78) 0.0227	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-S is patient global impression of severity questionnaire.
Patients with missing baseline and/or week 30 are excluded from analysis.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgisreprsubcc.sas 21OCT2022:05:06

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
AGE								0.5244
<= 49	25	14 (56.0)	20	9 (45.0)	1.24 (0.69, 2.26) 0.4722	1.56 (0.41, 5.97) 0.5544	11.00 (-18.22, 40.22) 0.4607	
50 - 64	43	25 (58.1)	56	17 (30.4)	1.92 (1.20, 3.07) 0.0068	3.19 (1.28, 7.96) 0.0076	27.78 (8.74, 46.82) 0.0042	
>= 65	42	21 (50.0)	36	12 (33.3)	1.50 (0.86, 2.61) 0.1501	2.00 (0.73, 5.58) 0.1707	16.67 (-4.92, 38.25) 0.1301	
BMI								0.4330
<30	70	44 (62.9)	66	24 (36.4)	1.73 (1.20, 2.49) 0.0034	2.96 (1.39, 6.32) 0.0034	26.49 (10.28, 42.70) 0.0014	
>=30	40	16 (40.0)	46	14 (30.4)	1.31 (0.74, 2.34) 0.3547	1.52 (0.57, 4.09) 0.3741	9.57 (-10.62, 29.75) 0.3529	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-S is patient global impression of severity questionnaire.
Patients with missing baseline and/or week 30 are excluded from analysis.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgisreprsubcc.sas 21OCT2022:05:06

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
RACE								0.1980
NON-WHITE	7	2 (28.6)	12	5 (41.7)	0.69 (0.18, 2.64) 0.5836	0.56 (0.04, 5.68) 0.6562	-13.10 (-56.66, 30.47) 0.5558	
WHITE	103	58 (56.3)	100	33 (33.0)	1.71 (1.23, 2.37) 0.0014	2.62 (1.42, 4.82) 0.0011	23.31 (10.02, 36.60) 0.0006	
REGION								0.8045
US	47	21 (44.7)	46	12 (26.1)	1.71 (0.96, 3.06) 0.0696	2.29 (0.88, 6.06) 0.0831	18.59 (-0.46, 37.65) 0.0558	
EX-US	63	39 (61.9)	66	26 (39.4)	1.57 (1.10, 2.24) 0.0129	2.50 (1.16, 5.40) 0.0137	22.51 (5.70, 39.33) 0.0087	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-S is patient global impression of severity questionnaire.
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Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
CALCIUM CHANNEL BLOCKER USE								0.7546
YES	23	11 (47.8)	15	5 (33.3)	1.43 (0.62, 3.30) 0.3958	1.83 (0.40, 9.03) 0.5061	14.49 (-16.91, 45.89) 0.3656	
NO	87	49 (56.3)	97	33 (34.0)	1.66 (1.19, 2.31) 0.0030	2.50 (1.32, 4.75) 0.0030	22.30 (8.25, 36.36) 0.0019	
PRESENCE OF HCM PATHOGENIC MUTATION								0.7838
PATHOGENIC OR LIKELY PATHOGENIC	27	20 (74.1)	18	7 (38.9)	1.90 (1.02, 3.54) 0.0419	4.49 (1.06, 19.63) 0.0296	35.19 (7.25, 63.12) 0.0136	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	31	15 (48.4)	38	13 (34.2)	1.41 (0.80, 2.50) 0.2344	1.80 (0.61, 5.33) 0.3247	14.18 (-9.00, 37.35) 0.2305	
NEGATIVE	25	14 (56.0)	33	11 (33.3)	1.68 (0.93, 3.04) 0.0872	2.55 (0.77, 8.51) 0.1112	22.67 (-2.58, 47.91) 0.0784	

Data Cutoff Date: 30JUN2020.
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(C) Interaction p value is calculated from Cochrane's Q heterogeneity test.
PGI-S is patient global impression of severity questionnaire.
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Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-pgisreprsubcc.sas 21OCT2022:05:06

Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
TIME FROM DIAGNOSIS OF OHCM (Years)								0.5678
<=5	57	36 (63.2)	46	17 (37.0)	1.71 (1.12, 2.62) 0.0138	2.92 (1.22, 7.09) 0.0102	26.20 (7.46, 44.95) 0.0062	
>5	53	24 (45.3)	66	21 (31.8)	1.42 (0.90, 2.26) 0.1333	1.77 (0.78, 4.01) 0.1829	13.46 (-4.02, 30.95) 0.1313	
SEPTAL REDUCTION THERAPY (SRT) HISTORY								0.7245
YES	11	4 (36.4)	7	2 (28.6)	1.27 (0.31, 5.20) 0.7371	1.43 (0.13, 21.41) 1.0000	7.79 (-36.12, 51.70) 0.7280	
NO	99	56 (56.6)	105	36 (34.3)	1.65 (1.20, 2.26) 0.0019	2.50 (1.36, 4.58) 0.0019	22.28 (8.95, 35.61) 0.0011	

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(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-S is patient global impression of severity questionnaire.
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Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED								0.2283
YES	23	14 (60.9)	24	6 (25.0)	2.43 (1.13, 5.24) 0.0229	4.67 (1.15, 19.77) 0.0189	35.87 (9.45, 62.29) 0.0078	
NO	87	46 (52.9)	88	32 (36.4)	1.45 (1.03, 2.04) 0.0310	1.96 (1.03, 3.76) 0.0336	16.51 (1.98, 31.04) 0.0259	
HISTORY OF HYPERTENSION								0.7968
YES	54	27 (50.0)	54	16 (29.6)	1.69 (1.03, 2.75) 0.0363	2.38 (1.00, 5.67) 0.0487	20.37 (2.31, 38.43) 0.0271	
NO	56	33 (58.9)	58	22 (37.9)	1.55 (1.05, 2.31) 0.0289	2.35 (1.04, 5.33) 0.0387	21.00 (3.05, 38.94) 0.0218	

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(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-S is patient global impression of severity questionnaire.
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Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
RESTING LVEF								0.3057
<75%	64	37 (57.8)	64	20 (31.3)	1.85 (1.22, 2.81) 0.0040	3.01 (1.38, 6.65) 0.0042	26.56 (9.97, 43.16) 0.0017	
>=75%	46	23 (50.0)	48	18 (37.5)	1.33 (0.84, 2.12) 0.2260	1.67 (0.68, 4.11) 0.2984	12.50 (-7.41, 32.41) 0.2185	
LVOT RESTING PEAK GRADIENT (mmHg)								0.6117
<=50	52	27 (51.9)	57	20 (35.1)	1.48 (0.95, 2.30) 0.0804	2.00 (0.86, 4.64) 0.0850	16.84 (-1.55, 35.22) 0.0727	
>50	58	33 (56.9)	55	18 (32.7)	1.74 (1.12, 2.70) 0.0138	2.71 (1.18, 6.28) 0.0138	24.17 (6.39, 41.95) 0.0077	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-S is patient global impression of severity questionnaire.
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Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
LVOT RESTING PEAK GRADIENT (mmHg)								0.9914
<=30	29	15 (51.7)	34	11 (32.4)	1.60 (0.88, 2.91) 0.1253	2.24 (0.72, 7.06) 0.1336	19.37 (-4.67, 43.41) 0.1143	
>30	81	45 (55.6)	78	27 (34.6)	1.60 (1.12, 2.30) 0.0104	2.36 (1.19, 4.71) 0.0107	20.94 (5.82, 36.06) 0.0066	
E/E' LATERAL								0.8765
<=14	50	31 (62.0)	57	22 (38.6)	1.61 (1.08, 2.38) 0.0180	2.60 (1.11, 6.11) 0.0203	23.40 (4.94, 41.86) 0.0130	
>14	57	27 (47.4)	50	14 (28.0)	1.69 (1.00, 2.85) 0.0484	2.31 (0.96, 5.66) 0.0477	19.37 (1.40, 37.34) 0.0346	

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(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-S is patient global impression of severity questionnaire.
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Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
E/E' SEPTAL								0.0873
<=14	15	12 (80.0)	24	7 (29.2)	2.74 (1.40, 5.38) 0.0033	9.71 (1.74, 66.03) 0.0031	50.83 (23.62, 78.04) 0.0003	
>14	95	48 (50.5)	87	31 (35.6)	1.42 (1.00, 2.00) 0.0476	1.84 (0.98, 3.50) 0.0519	14.89 (0.67, 29.12) 0.0402	
E/E' AVERAGE								0.0547
<=14	23	18 (78.3)	28	8 (28.6)	2.74 (1.47, 5.11) 0.0016	9.00 (2.15, 40.60) 0.0006	49.69 (25.94, 73.44) <0.0001	
>14	87	42 (48.3)	84	30 (35.7)	1.35 (0.94, 1.94) 0.1009	1.68 (0.87, 3.25) 0.1214	12.56 (-2.11, 27.23) 0.0933	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-S is patient global impression of severity questionnaire.
Patients with missing baseline and/or week 30 are excluded from analysis.
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Protocol: MYK-461-005

Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
LEFT ATRIAL VOLUME INDEX								0.7690
<=MEDIAN	54	28 (51.9)	58	18 (31.0)	1.67 (1.05, 2.65) 0.0294	2.39 (1.03, 5.57) 0.0344	20.82 (2.95, 38.69) 0.0224	
>MEDIAN	55	31 (56.4)	54	20 (37.0)	1.52 (1.00, 2.31) 0.0491	2.20 (0.95, 5.09) 0.0554	19.33 (0.95, 37.70) 0.0393	
NT-PROBNP								0.7681
<=MEDIAN	47	23 (48.9)	59	19 (32.2)	1.52 (0.95, 2.44) 0.0820	2.02 (0.85, 4.80) 0.1097	16.73 (-1.88, 35.34) 0.0781	
>MEDIAN	61	36 (59.0)	51	18 (35.3)	1.67 (1.09, 2.56) 0.0181	2.64 (1.15, 6.13) 0.0144	23.72 (5.71, 41.73) 0.0098	

Data Cutoff Date: 30JUN2020.
(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
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Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
HS-CARDIAC TROPONIN-I								0.0695
<=ULN	78	40 (51.3)	84	33 (39.3)	1.31 (0.93, 1.84) 0.1275	1.63 (0.83, 3.18) 0.1552	12.00 (-3.24, 27.23) 0.1228	
>ULN	29	18 (62.1)	21	4 (19.0)	3.26 (1.29, 8.23) 0.0125	6.95 (1.61, 34.58) 0.0037	43.02 (18.65, 67.39) 0.0005	
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.4222
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	35	21 (60.0)	47	20 (42.6)	1.41 (0.92, 2.16) 0.1159	2.03 (0.76, 5.43) 0.1800	17.45 (-4.08, 38.97) 0.1121	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	72	37 (51.4)	57	16 (28.1)	1.83 (1.14, 2.94) 0.0121	2.71 (1.22, 6.11) 0.0113	23.32 (6.91, 39.73) 0.0054	

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(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-S is patient global impression of severity questionnaire.
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Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.1349
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	12	9 (75.0)	19	5 (26.3)	2.85 (1.25, 6.47) 0.0123	8.40 (1.28, 63.88) 0.0119	48.68 (17.18, 80.18) 0.0025	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	98	51 (52.0)	92	33 (35.9)	1.45 (1.04, 2.02) 0.0284	1.94 (1.04, 3.62) 0.0288	16.17 (2.25, 30.10) 0.0228	
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.0990
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	18	14 (77.8)	21	6 (28.6)	2.72 (1.33, 5.59) 0.0064	8.75 (1.69, 49.73) 0.0036	49.21 (21.96, 76.45) 0.0004	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	92	46 (50.0)	89	32 (36.0)	1.39 (0.99, 1.96) 0.0606	1.78 (0.94, 3.38) 0.0716	14.04 (-0.23, 28.32) 0.0538	

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(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-S is patient global impression of severity questionnaire.
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Responder Analysis (Improvement) for PGI-S Scores by Subgroups at Week 30, Complete Case Analysis
Intention-to-treat (ITT) population

	Mavacamten		Placebo		Mavacamten vs Placebo			
	N	Responders n (%)	N	Responders n (%)	Risk Ratio (95% CI) p-value (A)	Odds Ratio (95% CI) p-value (B)	Response Difference (95% CI) p-value (A)	Interaction p-value for Risk Ratio (C)
CREATININE CLEARANCE (CRCL) (mL/min)								0.4000
<60	14	8 (57.1)	13	3 (23.1)	2.48 (0.83, 7.37) 0.1034	4.44 (0.66, 34.73) 0.1201	34.07 (-0.52, 68.66) 0.0536	
>=60	95	51 (53.7)	99	35 (35.4)	1.52 (1.10, 2.10) 0.0119	2.12 (1.14, 3.93) 0.0138	18.33 (4.57, 32.09) 0.0090	

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(A) 95% CI and p-value is based on normal approximation. (B) 95% CIs and p-value are based on exact method.
(C) Interaction p value is calculated from Cochrane’s Q heterogeneity test.
PGI-S is patient global impression of severity questionnaire.
Patients with missing baseline and/or week 30 are excluded from analysis.
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4.9 Analysen für den Endpunkt allgemeiner Gesundheitszustand gemäß EQ-5D-5L VAS

4.9.1 Veränderung der EQ-5D-5L VAS im Studienverlauf als mittlere Veränderung des Scores gegenüber Baseline (pro Erhebungszeitpunkt) als Verlaufskurve

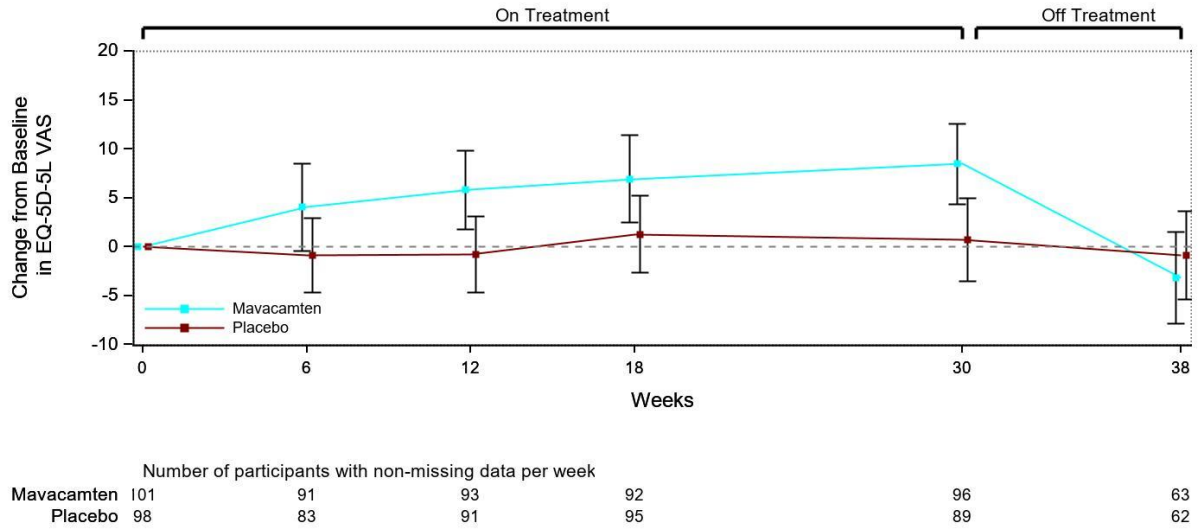

Abbildung 4-29: Mittlere Veränderung der *EQ-5D-5L VAS* gegenüber Baseline im Studienverlauf

4.9.2 Subgruppenanalyse für die Veränderung der EQ-5D-5L VAS zu Woche 30 gegenüber Baseline mittels MMRM

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Comparison between Mavacamten and Placebo in EQ-5D-5L Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
EQ-5D-5L VAS									
BETA-BLOCKER USE									0.2971
YES	80	70.19 (20.732)	9.17 (5.73, 12.61)	70	69.93 (19.642)	-0.65 (-4.32, 3.01)	9.82 (4.79, 14.85) 0.0001	0.62 (0.29, 0.95)	
NO	20	71.15 (14.317)	7.63 (1.55, 13.71)	27	66.89 (21.371)	2.44 (-2.89, 7.78)	5.19 (-2.91, 13.28) 0.2081	0.36 (-0.22, 0.95)	
TYPE OF EXERCISE TESTING									0.0297*
EXERCISE BICYCLE	45	68.36 (21.440)	10.90 (6.66, 15.14)	47	68.21 (20.259)	-2.06 (-6.28, 2.16)	12.96 (6.98, 18.94) <0.0001	0.88 (0.45, 1.31)	
TREADMILL	55	72.04 (17.901)	7.17 (3.24, 11.11)	50	69.90 (20.064)	2.36 (-1.76, 6.49)	4.81 (-0.89, 10.51) 0.0979	0.32 (-0.06, 0.71)	

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EQ-5D-5L is EuroQoL Group's 5 Dimensions 5 Levels questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-eq5dmmrmrsubhq.sas 28OCT2022:03:38

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in EQ-5D-5L Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NYHA CLASS									0.4324
CLASS II	71	75.45 (16.038)	10.41 (6.79, 14.04)	72	71.15 (19.588)	0.70 (-2.92, 4.31)	9.72 (4.61, 14.82) 0.0002	0.62 (0.29, 0.96)	
CLASS III	29	57.97 (22.011)	5.16 (-0.09, 10.42)	25	63.12 (20.651)	-1.24 (-6.78, 4.29)	6.41 (-1.12, 13.94) 0.0949	0.45 (-0.09, 0.99)	
CONSENT FOR THE CMR SUBSTUDY									0.3928
YES	19	72.95 (19.415)	2.92 (-3.22, 9.07)	19	67.42 (21.056)	-2.43 (-8.65, 3.78)	5.36 (-3.39, 14.11) 0.2289	0.38 (-0.26, 1.02)	
NO	81	69.78 (19.662)	10.24 (6.85, 13.63)	78	69.49 (19.945)	0.86 (-2.63, 4.36)	9.38 (4.51, 14.25) 0.0002	0.60 (0.28, 0.91)	

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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in EQ-5D-5L Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
SEX									0.9470
MALE	56	73.38 (18.210)	10.13 (6.20, 14.06)	63	71.90 (18.889)	1.11 (-2.68, 4.89)	9.02 (3.58, 14.47) 0.0012	0.59 (0.23, 0.96)	
FEMALE	44	66.57 (20.734)	7.25 (2.93, 11.58)	34	63.85 (21.407)	-1.52 (-6.43, 3.39)	8.77 (2.25, 15.28) 0.0085	0.60 (0.14, 1.05)	
AGE									0.3465
<= 49	25	68.96 (21.753)	12.17 (6.72, 17.63)	18	69.11 (19.888)	2.29 (-4.17, 8.75)	9.88 (1.42, 18.34) 0.0222	0.69 (0.07, 1.32)	
50 - 64	38	76.03 (14.210)	9.79 (5.18, 14.40)	49	70.31 (19.218)	-0.96 (-5.11, 3.19)	10.75 (4.55, 16.95) 0.0007	0.73 (0.29, 1.16)	
>=65	37	65.54 (21.673)	5.65 (1.00, 10.30)	30	67.07 (21.994)	0.94 (-4.17, 6.04)	4.71 (-2.18, 11.60) 0.1791	0.33 (-0.16, 0.81)	

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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in EQ-5D-5L Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
BMI									0.5299
<30	64	69.02 (19.766)	9.70 (5.97, 13.44)	57	67.16 (20.710)	0.18 (-3.78, 4.15)	9.52 (4.07, 14.97) 0.0007	0.62 (0.25, 0.99)	
>=30	36	72.81 (19.214)	7.36 (2.66, 12.07)	40	71.83 (19.044)	0.27 (-4.27, 4.81)	7.09 (0.56, 13.62) 0.0334	0.48 (0.03, 0.94)	
RACE									0.0389*
NON-WHITE	6	65.83 (24.153)	1.67 (-9.08, 12.43)	9	74.89 (20.497)	6.91 (-1.98, 15.79)	-5.24 (-19.20, 8.73) 0.4606	-0.36 (-1.41, 0.68)	
WHITE	94	70.67 (19.349)	9.33 (6.09, 12.56)	88	68.49 (20.052)	-0.47 (-3.84, 2.90)	9.80 (5.13, 14.47) <0.0001	0.61 (0.31, 0.90)	

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Comparison between Mavacamten and Placebo in EQ-5D-5L Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
REGION									0.0053*
US	45	73.71 (18.135)	5.78 (1.54, 10.02)	39	73.77 (17.530)	3.18 (-1.37, 7.72)	2.60 (-3.59, 8.80) 0.4086	0.18 (-0.25, 0.61)	
EX-US	55	67.65 (20.406)	11.35 (7.45, 15.25)	58	65.93 (21.178)	-1.77 (-5.66, 2.12)	13.12 (7.63, 18.61) <0.0001	0.88 (0.49, 1.26)	
CALCIUM CHANNEL BLOCKER USE									0.2135
YES	17	67.94 (12.882)	6.92 (0.39, 13.44)	15	67.00 (20.840)	3.57 (-3.37, 10.50)	3.35 (-6.17, 12.86) 0.4888	0.24 (-0.46, 0.93)	
NO	83	70.88 (20.686)	9.26 (5.87, 12.66)	82	69.46 (20.037)	-0.40 (-3.86, 3.06)	9.66 (4.81, 14.51) 0.0001	0.61 (0.29, 0.92)	

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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in EQ-5D-5L Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
PRESENCE OF HCM PATHOGENIC MUTATION									0.3559
PATHOGENIC OR LIKELY PATHOGENIC	22	63.95 (21.845)	8.88 (2.63, 15.13)	17	65.24 (21.571)	4.45 (-2.55, 11.46)	4.43 (-4.92, 13.77) 0.3509	0.29 (-0.34, 0.93)	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	27	73.70 (18.941)	5.25 (-0.45, 10.95)	33	71.52 (20.022)	0.99 (-4.26, 6.24)	4.26 (-3.48, 12.00) 0.2792	0.28 (-0.23, 0.79)	
NEGATIVE	24	68.75 (21.501)	10.54 (4.57, 16.52)	26	63.35 (18.075)	-0.71 (-6.54, 5.11)	11.26 (2.92, 19.59) 0.0084	0.74 (0.16, 1.31)	
TIME FROM DIAGNOSIS OF OHCM									0.1928
<=5	51	70.88 (19.877)	10.50 (6.43, 14.57)	39	66.51 (19.992)	-0.75 (-5.34, 3.84)	11.25 (5.11, 17.39) 0.0004	0.76 (0.33, 1.19)	
>5	49	69.86 (19.410)	7.17 (3.05, 11.29)	58	70.81 (20.112)	0.87 (-3.06, 4.79)	6.30 (0.61, 11.99) 0.0301	0.42 (0.03, 0.80)	

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Comparison between Mavacamten and Placebo in EQ-5D-5L Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
SEPTAL REDUCTION THERAPY (SRT) HISTORY									0.2438
YES	8	62.25 (24.973)	-0.41 (-9.71, 8.89)	8	64.75 (20.638)	-1.75 (-11.05, 7.55)	1.34 (-11.79, 14.47) 0.8405	0.09 (-0.89, 1.08)	
NO	92	71.09 (19.021)	9.68 (6.42, 12.94)	89	69.47 (20.094)	0.38 (-2.97, 3.73)	9.29 (4.62, 13.97) 0.0001	0.58 (0.28, 0.87)	
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED									0.2132
YES	23	67.43 (20.318)	10.27 (4.54, 15.99)	21	67.43 (22.049)	-2.75 (-8.71, 3.21)	13.01 (4.75, 21.27) 0.0021	0.92 (0.29, 1.54)	
NO	77	71.26 (19.373)	8.45 (4.97, 11.92)	76	69.54 (19.623)	1.03 (-2.52, 4.59)	7.41 (2.44, 12.38) 0.0036	0.47 (0.15, 0.79)	

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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in EQ-5D-5L Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
HISTORY OF HYPERTENSION									0.5739
YES	52	69.83 (20.516)	8.66 (4.63, 12.70)	43	66.95 (19.528)	-1.18 (-5.58, 3.22)	9.85 (3.87, 15.82) 0.0013	0.66 (0.25, 1.08)	
NO	48	70.98 (18.661)	9.07 (4.90, 13.25)	54	70.78 (20.517)	1.35 (-2.70, 5.40)	7.73 (1.91, 13.54) 0.0093	0.51 (0.12, 0.91)	
RESTING LVEF									0.2611
<75%	57	75.96 (15.046)	9.74 (5.80, 13.68)	52	71.29 (17.498)	-0.82 (-4.92, 3.27)	10.56 (4.89, 16.23) 0.0003	0.70 (0.31, 1.08)	
>=75%	43	62.98 (22.389)	7.70 (3.28, 12.11)	45	66.53 (22.621)	1.41 (-2.93, 5.75)	6.29 (0.14, 12.44) 0.0452	0.42 (0.00, 0.85)	

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Comparison between Mavacamten and Placebo in EQ-5D-5L Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
LVOT RESTING PEAK GRADIENT									0.8188
<=50	47	69.74 (18.632)	8.12 (3.89, 12.34)	49	70.51 (19.716)	-0.89 (-5.06, 3.29)	9.00 (3.06, 14.94) 0.0031	0.60 (0.19, 1.01)	
>50	53	70.94 (20.504)	9.50 (5.51, 13.50)	48	67.63 (20.533)	1.36 (-2.88, 5.60)	8.14 (2.31, 13.97) 0.0064	0.54 (0.14, 0.94)	
LVOT RESTING PEAK GRADIENT									0.2116
<=30	25	66.00 (19.039)	9.20 (3.70, 14.69)	29	68.79 (21.555)	-3.14 (-8.30, 2.02)	12.34 (4.80, 19.87) 0.0014	0.86 (0.30, 1.42)	
>30	75	71.84 (19.634)	8.75 (5.24, 12.25)	68	69.21 (19.571)	1.66 (-2.03, 5.35)	7.09 (2.00, 12.18) 0.0065	0.45 (0.12, 0.79)	

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Comparison between Mavacamten and Placebo in EQ-5D-5L Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL									0.0100*
<=14	44	71.84 (17.568)	12.87 (8.66, 17.08)	55	66.85 (21.776)	-0.09 (-4.03, 3.84)	12.96 (7.19, 18.74) <0.0001	0.88 (0.47, 1.30)	
>14	52	69.98 (21.195)	6.09 (2.16, 10.02)	36	72.06 (18.000)	2.97 (-1.63, 7.57)	3.12 (-2.93, 9.17) 0.3110	0.22 (-0.21, 0.64)	
E/E' SEPTAL									0.0176*
<=14	14	75.36 (10.300)	14.73 (7.67, 21.79)	20	60.85 (22.458)	-3.87 (-9.96, 2.22)	18.60 (9.23, 27.97) 0.0001	1.32 (0.57, 2.08)	
>14	86	69.57 (20.604)	7.90 (4.58, 11.23)	77	71.22 (18.982)	1.27 (-2.24, 4.79)	6.63 (1.79, 11.47) 0.0074	0.42 (0.11, 0.73)	

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Comparison between Mavacamten and Placebo in EQ-5D-5L Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE									0.0061*
<=14	21	75.00 (13.315)	14.28 (8.40, 20.16)	22	63.45 (23.027)	-4.15 (-9.95, 1.65)	18.43 (10.14, 26.72) <0.0001	1.30 (0.65, 1.96)	
>14	79	69.15 (20.802)	7.45 (4.05, 10.86)	75	70.73 (18.973)	1.48 (-2.05, 5.01)	5.97 (1.07, 10.88) 0.0172	0.38 (0.06, 0.70)	
LEFT ATRIAL VOLUME INDEX									0.4660
<=MEDIAN	46	69.22 (17.734)	8.93 (4.66, 13.20)	48	68.35 (20.827)	-1.08 (-5.32, 3.16)	10.01 (3.99, 16.02) 0.0012	0.67 (0.25, 1.08)	
>MEDIAN	53	71.23 (21.276)	8.73 (4.71, 12.75)	49	69.80 (19.492)	1.48 (-2.72, 5.67)	7.25 (1.44, 13.06) 0.0146	0.48 (0.09, 0.88)	

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Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-eq5dmmrmrsubhq.sas 28OCT2022:03:38

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Comparison between Mavacamten and Placebo in EQ-5D-5L Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NT-PROBNP									0.9313
<=MEDIAN	43	71.42 (20.074)	8.10 (3.70, 12.50)	53	69.64 (18.395)	-0.88 (-4.96, 3.19)	8.98 (2.98, 14.98) 0.0035	0.60 (0.19, 1.01)	
>MEDIAN	55	69.35 (19.568)	9.33 (5.36, 13.30)	43	69.35 (21.476)	0.68 (-3.77, 5.12)	8.65 (2.69, 14.61) 0.0046	0.57 (0.17, 0.98)	
HS-CARDIAC TROPONIN-I									0.0259*
<=ULN	75	69.77 (20.340)	9.72 (6.23, 13.20)	75	68.84 (20.246)	-0.46 (-4.04, 3.11)	10.18 (5.19, 15.17) <0.0001	0.65 (0.32, 0.98)	
>ULN	23	70.96 (17.413)	5.72 (0.08, 11.36)	16	68.88 (22.917)	6.07 (-0.59, 12.72)	-0.35 (-9.07, 8.38) 0.9375	-0.02 (-0.66, 0.61)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
EQ-5D-5L is EuroQoL Group's 5 Dimensions 5 Levels questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-eq5dmmrmrsubhq.sas 28OCT2022:03:38

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in EQ-5D-5L Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0047*
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	33	70.97 (19.199)	13.32 (8.62, 18.03)	45	67.13 (21.569)	-0.92 (-5.16, 3.33)	14.24 (7.90, 20.58) <0.0001	1.00 (0.52, 1.47)	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	63	70.65 (19.816)	6.59 (2.95, 10.24)	43	70.16 (19.810)	3.29 (-0.98, 7.56)	3.30 (-2.31, 8.92) 0.2479	0.23 (-0.16, 0.62)	
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0053*
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	12	75.00 (10.686)	14.47 (6.94, 22.01)	15	65.60 (22.370)	-7.37 (-14.22, -0.51)	21.84 (11.63, 32.04) <0.0001	1.57 (0.71, 2.44)	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	88	69.75 (20.432)	8.09 (4.81, 11.38)	81	69.74 (19.828)	1.42 (-2.03, 4.86)	6.67 (1.91, 11.43) 0.0061	0.42 (0.12, 0.73)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
EQ-5D-5L is EuroQoL Group's 5 Dimensions 5 Levels questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-eq5dmmrmrsubhq.sas 28OCT2022:03:38

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in EQ-5D-5L Scores Change from Baseline to Week 30, Subgroup Analysis
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0019*
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	18	74.83 (14.176)	14.10 (7.87, 20.33)	15	65.60 (22.370)	-7.41 (-14.21, -0.61)	21.51 (12.27, 30.75) <0.0001	1.56 (0.77, 2.34)	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	82	69.40 (20.492)	7.72 (4.37, 11.06)	80	69.56 (19.888)	1.66 (-1.78, 5.10)	6.05 (1.26, 10.85) 0.0134	0.39 (0.08, 0.70)	
CREATININE CLEARANCE (CRCL)									0.5073
<60	12	65.00 (19.155)	11.74 (4.00, 19.47)	12	67.75 (21.797)	-0.10 (-7.85, 7.65)	11.84 (0.90, 22.77) 0.0341	0.84 (0.00, 1.67)	
>=60	87	70.95 (19.660)	8.28 (4.93, 11.63)	85	69.27 (19.948)	0.26 (-3.17, 3.70)	8.01 (3.21, 12.82) 0.0011	0.50 (0.19, 0.80)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
EQ-5D-5L is EuroQoL Group's 5 Dimensions 5 Levels questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-eq5dmmrmrsubhq.sas 28OCT2022:03:38

4.10 Analysen für den Endpunkt gesundheitsbezogene Lebensqualität gemäß KCCQ

4.10.1 Veränderung der einzelnen Domänen und der Summenscores des KCCQ im Studienverlauf als mittlere Veränderung des Scores gegenüber Baseline (pro Erhebungszeitpunkt) als Verlaufskurve

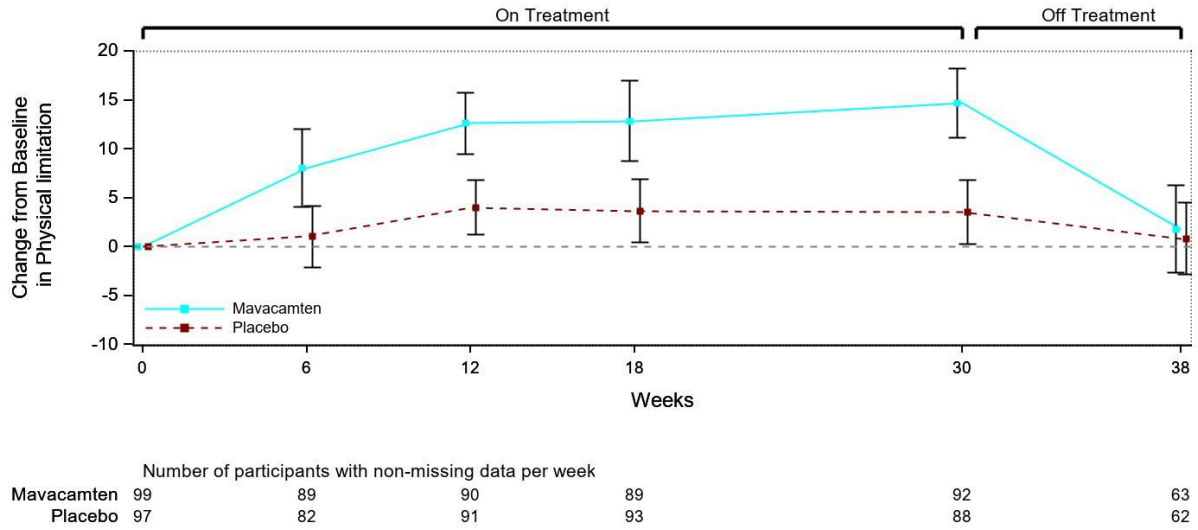

Abbildung 4-30: Mittlere Veränderung der Domäne *körperliche Einschränkung des KCCQ* gegenüber Baseline im Studienverlauf

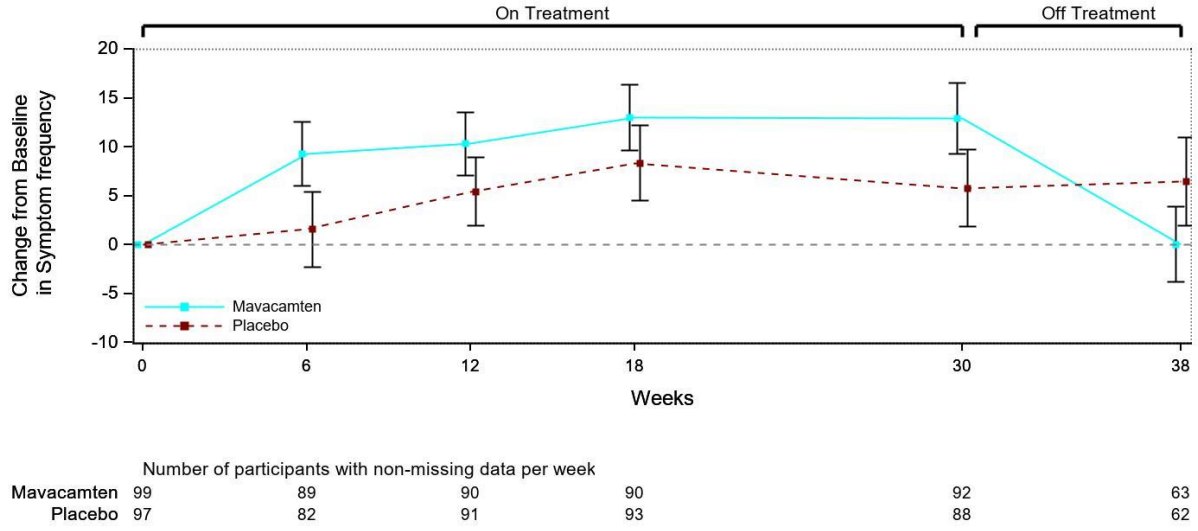

Abbildung 4-31: Mittlere Veränderung der Domäne *Symptomhäufigkeit des KCCQ* gegenüber Baseline im Studienverlauf

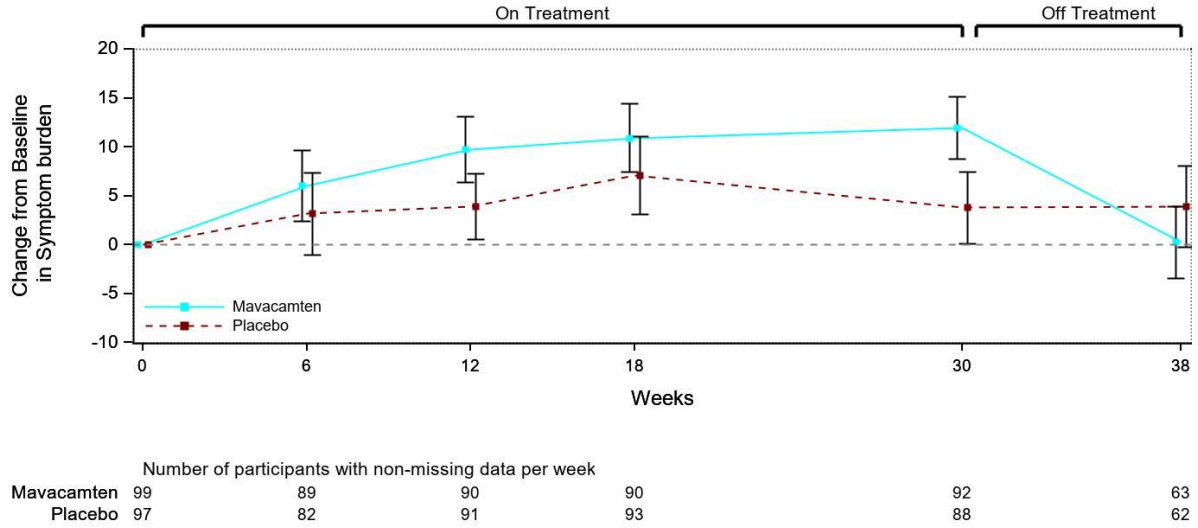

Abbildung 4-32: Mittlere Veränderung der Domäne *Symptomlast des KCCQ* gegenüber Baseline im Studienverlauf

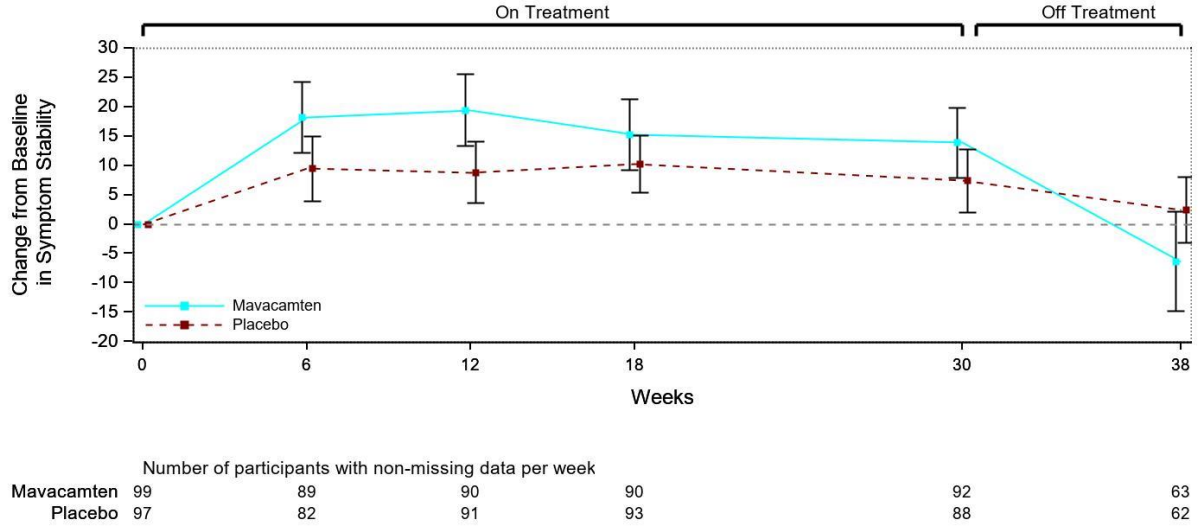

Abbildung 4-33: Mittlere Veränderung der Domäne *Symptomstabilität des KCCQ* gegenüber Baseline im Studienverlauf

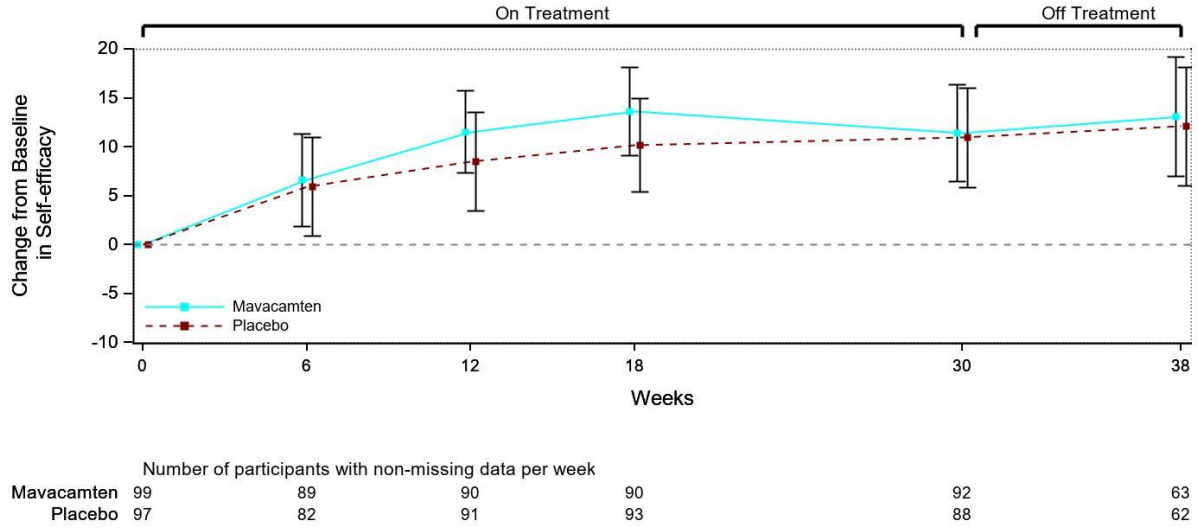

Abbildung 4-34: Mittlere Veränderung der Domäne *Selbstwirksamkeit des KCCQ* gegenüber Baseline im Studienverlauf

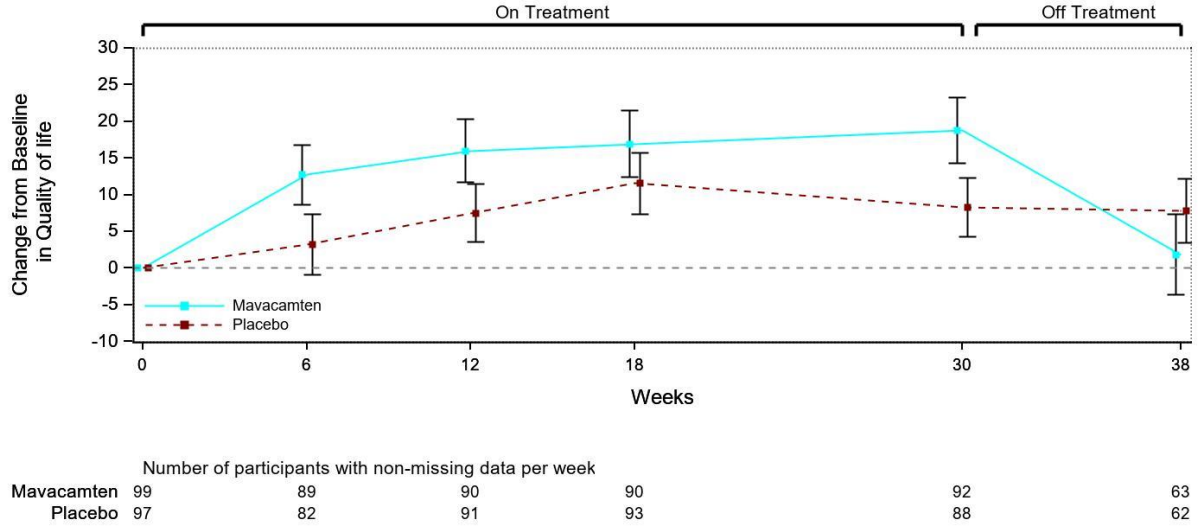

Abbildung 4-35: Mittlere Veränderung der Domäne *Lebensqualität des KCCQ* gegenüber Baseline im Studienverlauf

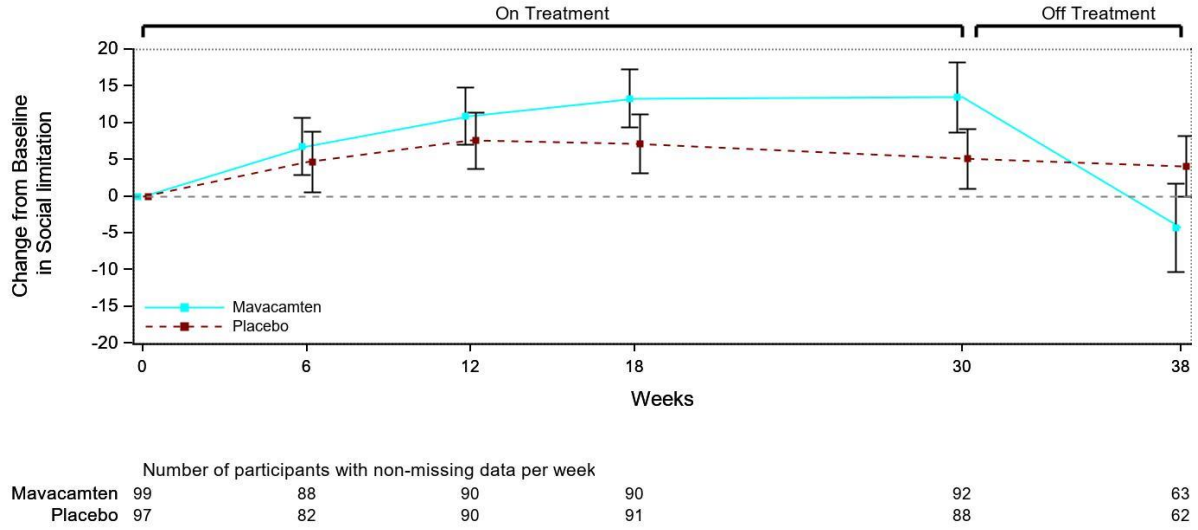

Abbildung 4-36: Mittlere Veränderung der Domäne *soziale Einschränkung des KCCQ* gegenüber Baseline im Studienverlauf

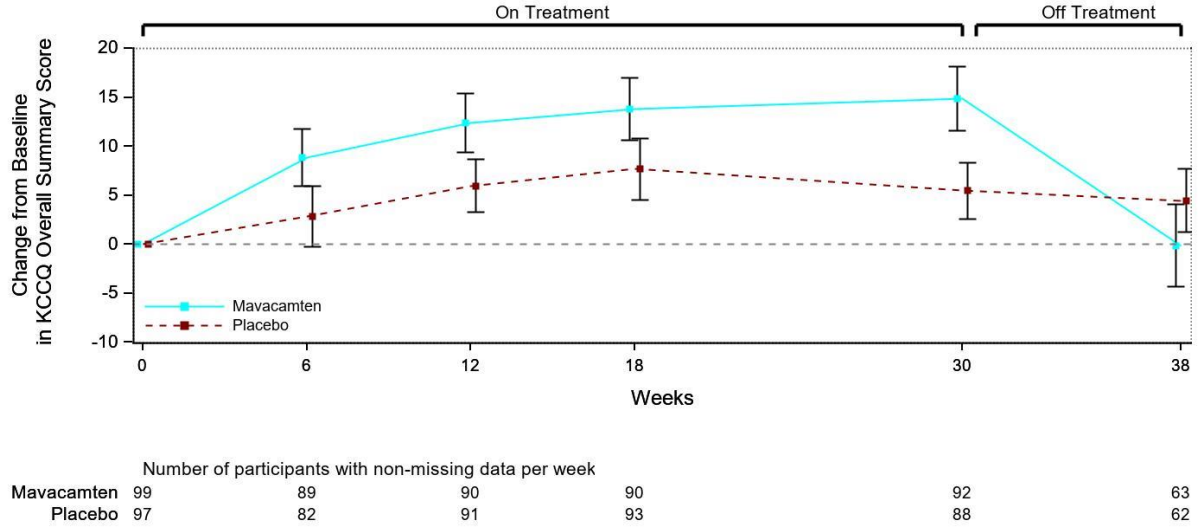

Abbildung 4-37: Mittlere Veränderung des *OSS des KCCQ* gegenüber Baseline im Studienverlauf

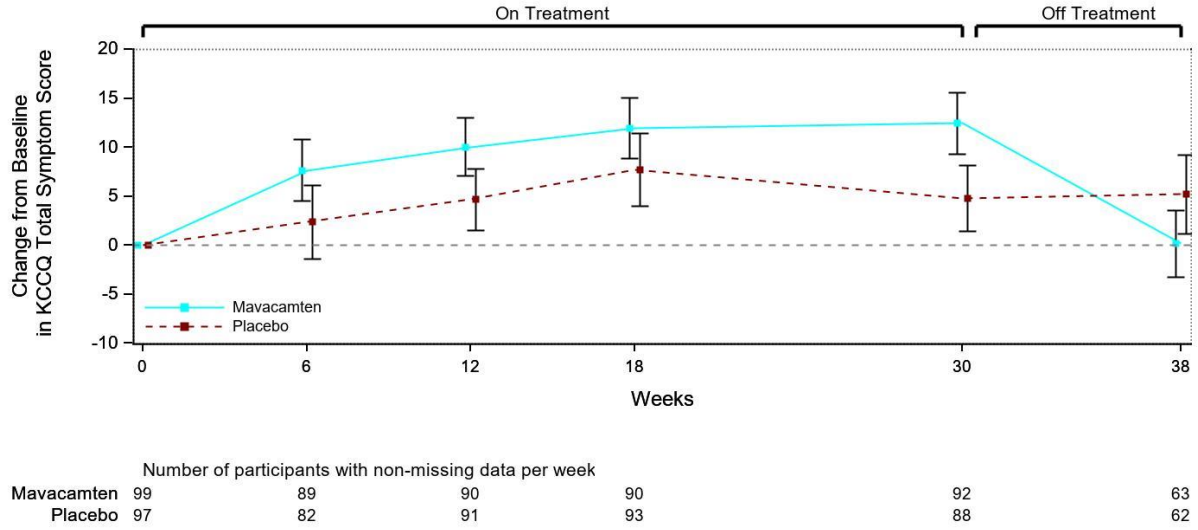

Abbildung 4-38: Mittlere Veränderung des *TSS des KCCQ* gegenüber Baseline im Studienverlauf

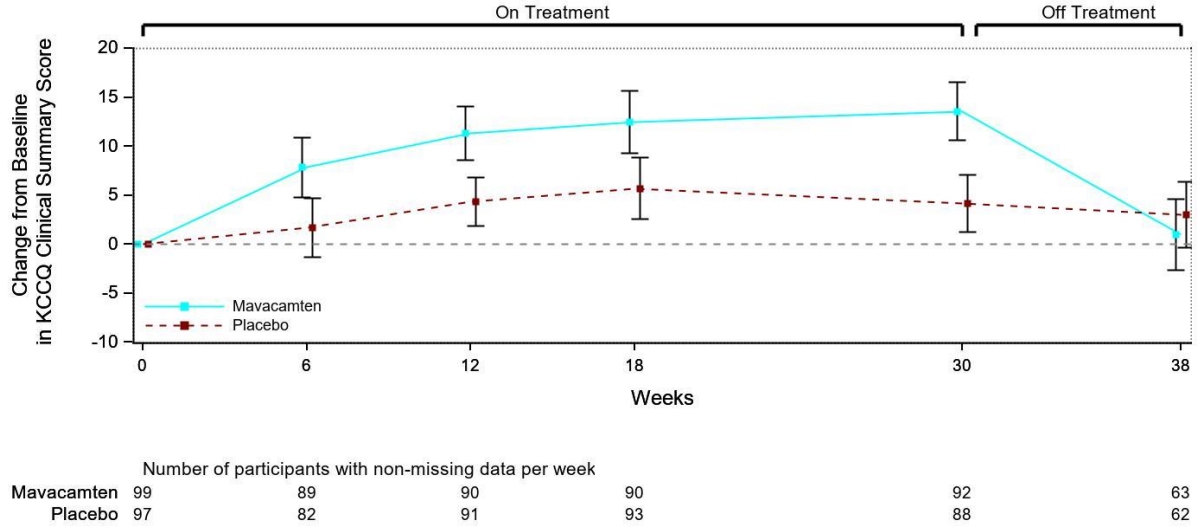

Abbildung 4-39: Mittlere Veränderung des *CSS des KCCQ* gegenüber Baseline im Studienverlauf

4.10.2 Veränderung der einzelnen Domänen und der Summenscores des KCCQ zu Woche 30 gegenüber Baseline mittels MMRM

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Comparison between Mavacamten and Placebo in KCCQ-23 Scores Change from Baseline to Week 30
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten (N =123)			Placebo (N =128)			Mavacamten vs. Placebo	
KCCQ-23	N (A)	Baseline Mean SD	Change from Baseline: LS Mean (95% CI) (B)	N (A)	Baseline Mean SD	Change from Baseline: LS Mean (95% CI) (B)	Difference in LS Mean Change (95% CI); p-value (B)	SMD as Hedge's g (95% CI) (C)
Physical limitation	98	70.44 (18.367)	13.51 (10.09, 16.93)	96	71.53 (19.061)	2.99 (-0.35, 6.34)	10.52 (6.25, 14.79) <0.0001	0.69 (0.40, 0.98)
Symptom frequency	98	70.09 (18.768)	12.80 (9.46, 16.13)	96	67.93 (23.893)	5.86 (2.56, 9.16)	6.94 (2.78, 11.09) 0.0011	0.47 (0.18, 0.75)
Symptom burden	98	72.53 (16.590)	12.04 (8.63, 15.45)	96	70.40 (21.793)	3.61 (0.22, 7.00)	8.43 (4.13, 12.72) 0.0001	0.55 (0.26, 0.84)
Symptom Stability	98	50.26 (14.131)	14.27 (9.27, 19.27)	96	49.22 (12.276)	6.71 (1.71, 11.71)	7.55 (0.96, 14.15) 0.0249	0.32 (0.04, 0.60)
Self-efficacy	98	67.73 (25.882)	11.01 (7.06, 14.95)	96	69.27 (25.644)	11.56 (7.68, 15.43)	-0.55 (-5.53, 4.44)	-0.03 (-0.31, 0.25)

Data Cutoff date: 30Jun2020. SMD = standardized mean difference.
(A) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-treatment assessment.
(B) The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, and the 3 stratification factors (beta blocker use, NYHA class, exercise type based on IXRS) as fixed effect, with visit (within subject) entered as repeat measure. Models run using a CS covariance matrix.
(C) Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmr.sas 24MAR2022:01:30

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Scores Change from Baseline to Week 30
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten (N =123)			Placebo (N =128)			Mavacamten vs. Placebo	
KCCQ-23	N (A)	Baseline Mean SD	Change from Baseline: LS Mean (95% CI) (B)	N (A)	Baseline Mean SD	Change from Baseline: LS Mean (95% CI) (B)	Difference in LS Mean Change (95% CI); p-value (B)	SMD as Hedge's g (95% CI) (C)
Quality of life	98	55.27 (23.184)	18.20 (14.27, 22.13)	96	54.77 (22.580)	8.59 (4.74, 12.44)	9.61 (4.73, 14.48) 0.0001	0.55 (0.27, 0.84)
Social limitation	98	71.83 (21.537)	14.69 (10.88, 18.51)	96	67.32 (24.942)	5.37 (1.56, 9.18)	9.33 (4.53, 14.12) 0.0002	0.55 (0.26, 0.83)
KCCQ Overall Summary Score	98	67.21 (17.241)	15.28 (12.29, 18.28)	96	65.70 (19.565)	6.16 (3.20, 9.11)	9.13 (5.46, 12.80) <0.0001	0.70 (0.41, 0.99)
KCCQ Total Symptom Score	98	71.31 (16.574)	12.62 (9.47, 15.77)	96	69.16 (21.694)	5.02 (1.90, 8.15)	7.60 (3.68, 11.52) 0.0002	0.54 (0.26, 0.83)

Data Cutoff date: 30Jun2020. SMD = standardized mean difference.
(A) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-treatment assessment.
(B) The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, and the 3 stratification factors (beta blocker use, NYHA class, exercise type based on IXRS) as fixed effect, with visit (within subject) entered as repeat measure. Models run using a CS covariance matrix.
(C) Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmr.sas 24MAR2022:01:30

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Scores Change from Baseline to Week 30
Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten (N =123)			Placebo (N =128)			Mavacamten vs. Placebo	
KCCQ-23	N (A)	Baseline Mean SD	Change from Baseline: LS Mean (95% CI) (B)	N (A)	Baseline Mean SD	Change from Baseline: LS Mean (95% CI) (B)	Difference in LS Mean Change (95% CI); p-value (B)	SMD as Hedge's g (95% CI) (C)
KCCQ Clinical Summary Score	98	70.88 (16.320)	13.37 (10.44, 16.30)	96	70.35 (18.992)	4.31 (1.44, 7.18)	9.06 (5.46, 12.66) <0.0001	0.71 (0.42, 1.00)

Data Cutoff date: 30Jun2020. SMD = standardized mean difference.
(A) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-treatment assessment.
(B) The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, and the 3 stratification factors (beta blocker use, NYHA class, exercise type based on IXRS) as fixed effect, with visit (within subject) entered as repeat measure. Models run using a CS covariance matrix.
(C) Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmr.sas 24MAR2022:01:30

4.10.3 Durchschnittliche Veränderung der einzelnen Domänen und der Summenscores des KCCQ im Studienverlauf bis Woche 30 gegenüber Baseline mittels MMRM

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Comparison between Mavacamten and Placebo in KCCQ-23 Scores Change from Baseline to Week 30
Using Mixed Model for Repeated Measurements (MMRM) Sensitivity Analysis - Average Treatment Effect
Intention-to-treat (ITT) population

	Mavacamten (N = 123)			Placebo (N = 128)			Mavacamten vs. Placebo	
KCCQ-23	N (A)	Baseline Mean (SD)	Change from Baseline LS Mean (95% CI) (B)	N (A)	Baseline Mean (SD)	Change from Baseline LS Mean (95% CI) (B)	Difference in LS Mean Change (95% CI) p-value (B)	SMD as Hedge's g (95% CI) (C)
Physical limitation	98	70.44 (18.367)	10.99 (8.01, 13.96)	96	71.53 (19.061)	2.72 (-0.12, 5.56)	8.27 (4.77, 11.77) <0.0001	0.66 (0.37, 0.95)
Symptom frequency	98	70.09 (18.768)	11.31 (8.37, 14.25)	96	67.93 (23.893)	4.81 (1.96, 7.66)	6.50 (3.03, 9.97) 0.0003	0.52 (0.24, 0.81)
Symptom burden	98	72.53 (16.590)	9.81 (6.90, 12.72)	96	70.40 (21.793)	4.19 (1.36, 7.03)	5.62 (2.18, 9.05) 0.0015	0.46 (0.17, 0.74)
Symptom Stability	98	50.26 (14.131)	17.02 (13.36, 20.68)	96	49.22 (12.276)	8.26 (4.73, 11.78)	8.76 (4.37, 13.15) 0.0001	0.56 (0.27, 0.85)
Self-efficacy	98	67.73 (25.882)	10.71 (7.28, 14.15)	96	69.27 (25.644)	10.00 (6.70, 13.30)	0.71 (-3.41, 4.83) 0.7338	0.05 (-0.23, 0.33)

Data Cutoff Date: 30JUN2020; SMD = standardized mean difference.
(A) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-treatment assessment.
(B) The average difference in LS means Change over the entire treatment period will be computed. LS means, p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, and the 3 stratification factors (beta blocker use, NYHA class, exercise type based on IXRS) as fixed effect, with visit (within subject) entered as repeat measure. Models run using a CS covariance matrix.
(C) Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmrate.sas 19OCT2022:05:28

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Comparison between Mavacamten and Placebo in KCCQ-23 Scores Change from Baseline to Week 30
Using Mixed Model for Repeated Measurements (MMRM) Sensitivity Analysis - Average Treatment Effect
Intention-to-treat (ITT) population

	Mavacamten (N = 123)			Placebo (N = 128)			Mavacamten vs. Placebo	
KCCQ-23	N (A)	Baseline Mean (SD)	Change from Baseline LS Mean (95% CI) (B)	N (A)	Baseline Mean (SD)	Change from Baseline LS Mean (95% CI) (B)	Difference in LS Mean Change (95% CI) p-value (B)	SMD as Hedge's g (95% CI) (C)
Quality of life	98	55.27 (23.184)	15.87 (12.41, 19.33)	96	54.77 (22.580)	7.60 (4.29, 10.92)	8.27 (4.20, 12.34) <0.0001	0.57 (0.28, 0.86)
Social limitation	98	71.83 (21.537)	12.92 (9.57, 16.27)	96	67.32 (24.942)	6.47 (3.18, 9.77)	6.45 (2.44, 10.45) 0.0017	0.45 (0.17, 0.74)
KCCQ Overall Summary Score	98	67.21 (17.241)	13.15 (10.43, 15.88)	96	65.70 (19.565)	5.99 (3.34, 8.64)	7.16 (3.96, 10.37) <0.0001	0.63 (0.34, 0.92)
KCCQ Total Symptom Score	98	71.31 (16.574)	10.76 (7.98, 13.54)	96	69.16 (21.694)	4.76 (2.06, 7.47)	6.00 (2.72, 9.27) 0.0004	0.51 (0.23, 0.80)
KCCQ Clinical Summary Score	98	70.88 (16.320)	11.18 (8.55, 13.80)	96	70.35 (18.992)	4.02 (1.48, 6.55)	7.16 (4.07, 10.24) <0.0001	0.65 (0.36, 0.94)

Data Cutoff Date: 30JUN2020; SMD = standardized mean difference.
(A) N is the number of randomized subjects with non-missing baseline and at least one post-baseline on-treatment assessment.
(B) The average difference in LS means Change over the entire treatment period will be computed. LS means, p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, and the 3 stratification factors (beta blocker use, NYHA class, exercise type based on IXRS) as fixed effect, with visit (within subject) entered as repeat measure. Models run using a CS covariance matrix.
(C) Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmrate.sas 19OCT2022:05:28

4.10.4 Veränderung der einzelnen Domänen und der Summenscores des KCCQ zu Woche 30 gegenüber Baseline mittels ANCOVA

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Comparison between Mavacamten and Placebo in KCCQ-23 Scores Change from Baseline to Week 30
Using ANCOVA
Intention-to-treat (ITT) population

	Mavacamten (N = 123)			Placebo (N = 128)			Mavacamten vs. Placebo	
KCCQ	N (A)	Baseline Mean SD	Change from Baseline LS Mean (95% CI) (B)	N (A)	Baseline Mean SD	Change from Baseline LS Mean (95% CI) (B)	Difference in LS Mean Change (95% CI) p-value (B)	SMD as Hedge's g (95% CI) (C)
Physical limitation	92	69.86 (18.675)	14.29 (10.70, 17.88)	88	70.92 (19.307)	3.55 (0.01, 7.09)	10.74 (6.43, 15.04) <0.0001	0.73 (0.42, 1.03)
Symptom frequency	92	69.50 (19.108)	12.87 (9.18, 16.55)	88	68.23 (24.071)	5.23 (1.55, 8.91)	7.64 (3.20, 12.07) 0.0008	0.50 (0.20, 0.80)
Symptom burden	92	72.10 (16.869)	12.25 (8.71, 15.79)	88	70.08 (22.447)	3.66 (0.09, 7.22)	8.59 (4.32, 12.86) 0.0001	0.59 (0.29, 0.88)
Symptom Stability	92	50.00 (13.363)	15.76 (10.11, 21.42)	88	49.15 (12.253)	8.30 (2.69, 13.91)	7.46 (0.59, 14.34) 0.0335	0.32 (0.02, 0.61)
Self-efficacy	92	66.71 (26.028)	11.86 (7.56, 16.16)	88	68.04 (25.698)	11.90 (7.64, 16.16)	-0.04 (-5.28, 5.20) 0.9885	-0.00 (-0.29, 0.29)
Quality of life	92	54.35 (23.456)	18.55 (14.26, 22.84)	88	54.73 (23.084)	8.45 (4.21, 12.69)	10.10 (4.97, 15.24) 0.0001	0.57 (0.27, 0.87)

Data Cutoff date: 30Jun2020. SMD = standardized mean difference.
(A) N is the number of randomized subjects with non-missing baseline and week 30 assessment.
(B) The LS means, its 95% CI and p-values are from the ANCOVA which controls for treatment group (mavacamten vs placebo), baseline value of the corresponding endpoint of interest, and the 3 stratification factors (beta blocker use, NYHA class, ergometer type based on IXRS).
(C) Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-sy-kccqancovar.sas 17AUG2022:06:07

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Scores Change from Baseline to Week 30
Using ANCOVA
Intention-to-treat (ITT) population

	Mavacamten (N = 123)			Placebo (N = 128)			Mavacamten vs. Placebo	
KCCQ	N (A)	Baseline Mean SD	Change from Baseline LS Mean (95% CI) (B)	N (A)	Baseline Mean SD	Change from Baseline LS Mean (95% CI) (B)	Difference in LS Mean Change (95% CI) p-value (B)	SMD as Hedge's g (95% CI) (C)
Social limitation	92	70.88 (21.651)	14.57 (10.15, 18.99)	88	67.19 (25.594)	4.44 (-0.03, 8.90)	10.13 (4.75, 15.50) 0.0003	0.55 (0.25, 0.85)
KCCQ Overall Summary Score	92	66.47 (17.482)	15.53 (12.25, 18.81)	88	65.50 (20.148)	5.93 (2.64, 9.21)	9.60 (5.67, 13.54) <0.0001	0.71 (0.41, 1.01)
KCCQ Total Symptom Score	92	70.80 (16.914)	12.81 (9.48, 16.14)	88	69.15 (22.209)	4.77 (1.42, 8.11)	8.04 (4.04, 12.05) 0.0001	0.58 (0.29, 0.88)
KCCQ Clinical Summary Score	92	70.33 (16.624)	13.80 (10.68, 16.92)	88	70.04 (19.410)	4.42 (1.32, 7.53)	9.37 (5.64, 13.11) <0.0001	0.73 (0.43, 1.03)

Data Cutoff date: 30Jun2020. SMD = standardized mean difference.
(A) N is the number of randomized subjects with non-missing baseline and week 30 assessment.
(B) The LS means, its 95% CI and p-values are from the ANCOVA which controls for treatment group (mavacamten vs placebo), baseline value of the corresponding endpoint of interest, and the 3 stratification factors (beta blocker use, NYHA class, ergometer type based on IXRS).
(C) Hedges g = (mean chg Mava - mean chg Placebo)/pooled-SD, all multiplied by (1-(3/(4*df-1))).
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-sy-kccqancovar.sas 17AUG2022:06:07

4.10.5 Veränderung der einzelnen Domänen des KCCQ im Studienverlauf als mittlere Veränderung der Scores gegenüber Baseline (pro Erhebungszeitpunkt)

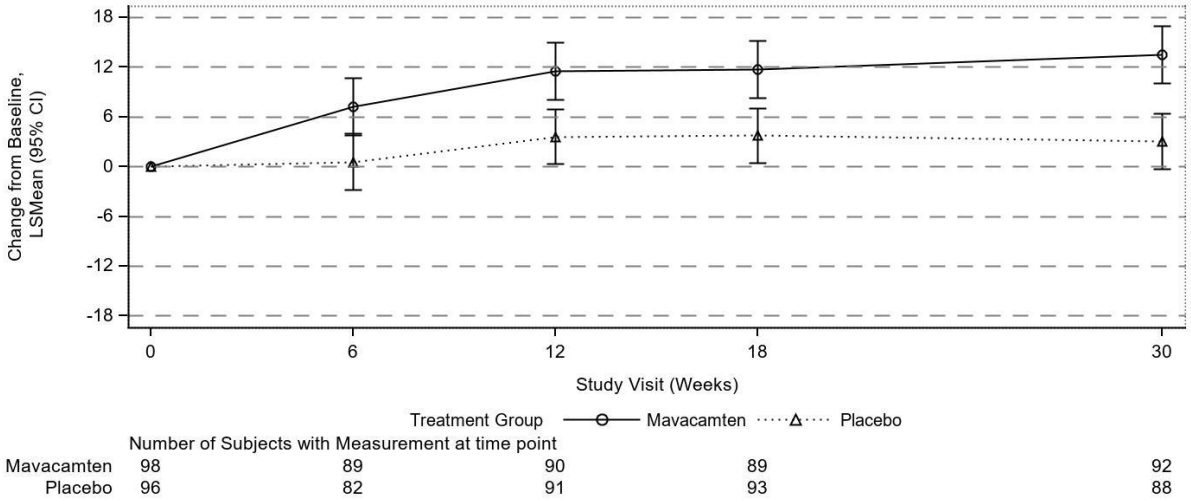

Abbildung 4-40: Mittlere Veränderung der Domäne *körperliche Einschränkung des KCCQ* basierend auf dem MMRM

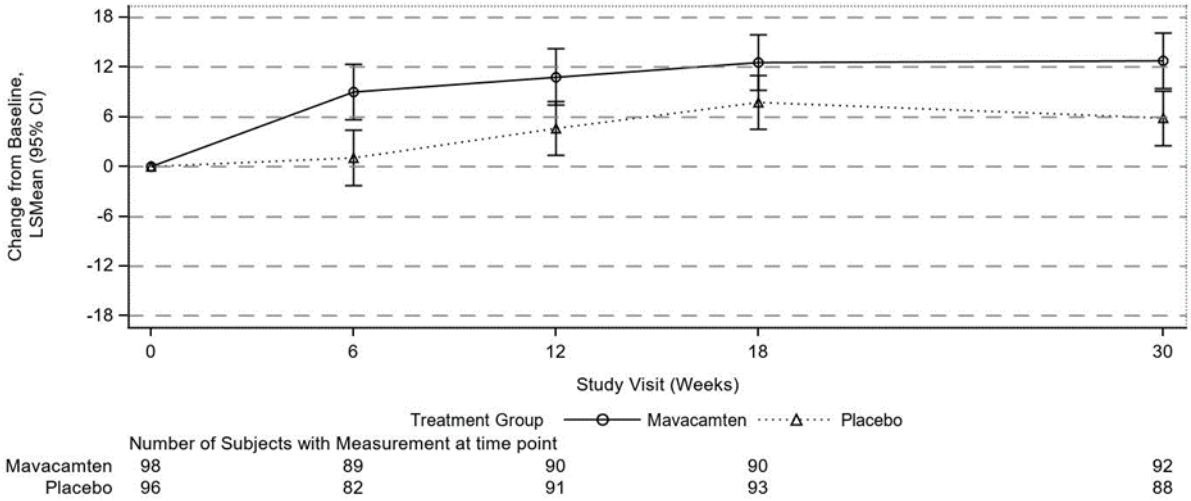

Abbildung 4-41: Mittlere Veränderung der Domäne *Symptomhäufigkeit des KCCQ* basierend auf dem MMRM

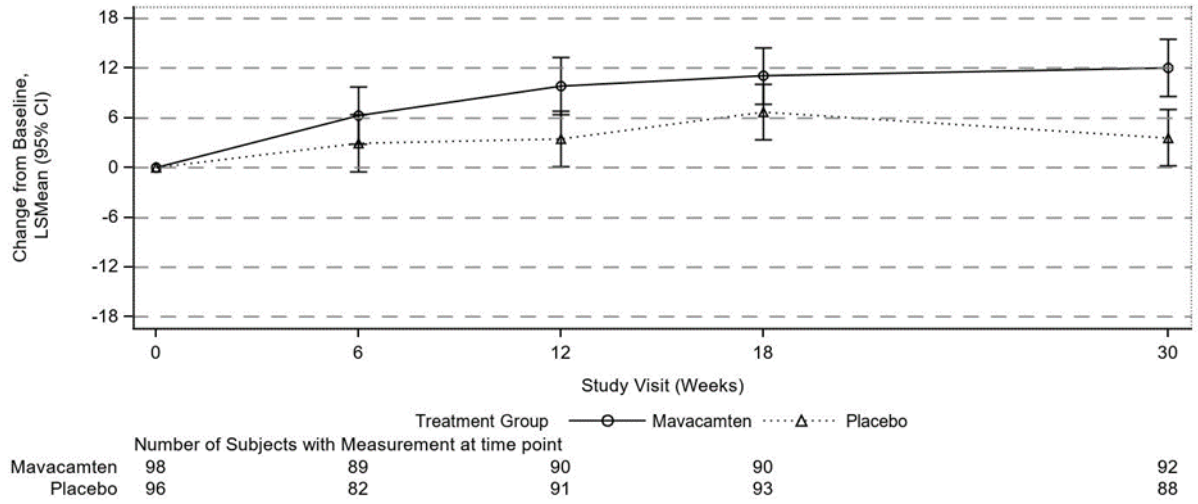

Abbildung 4-42: Mittlere Veränderung der Domäne *Symptomlast des KCCQ* basierend auf dem MMRM

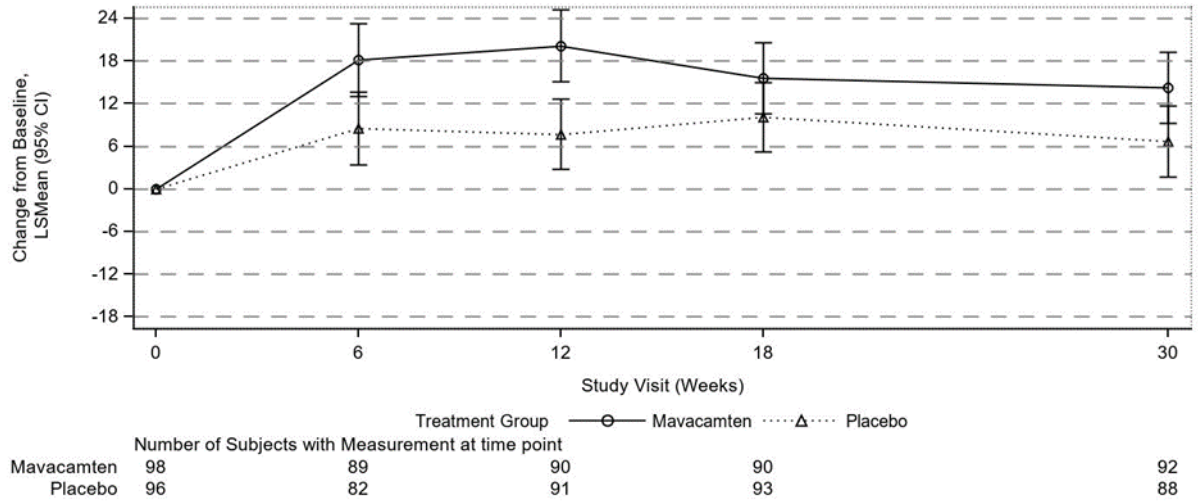

Abbildung 4-43: Mittlere Veränderung der Domäne *Symptomstabilität des KCCQ* basierend auf dem MMRM

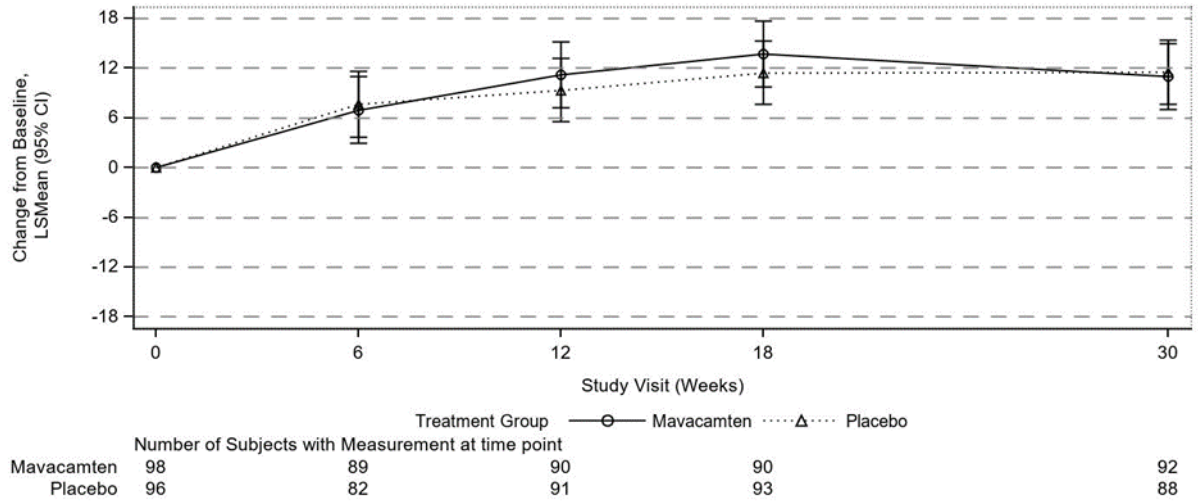

Abbildung 4-44: Mittlere Veränderung der Domäne *Selbsteffektivität des KCCQ* basierend auf dem MMRM

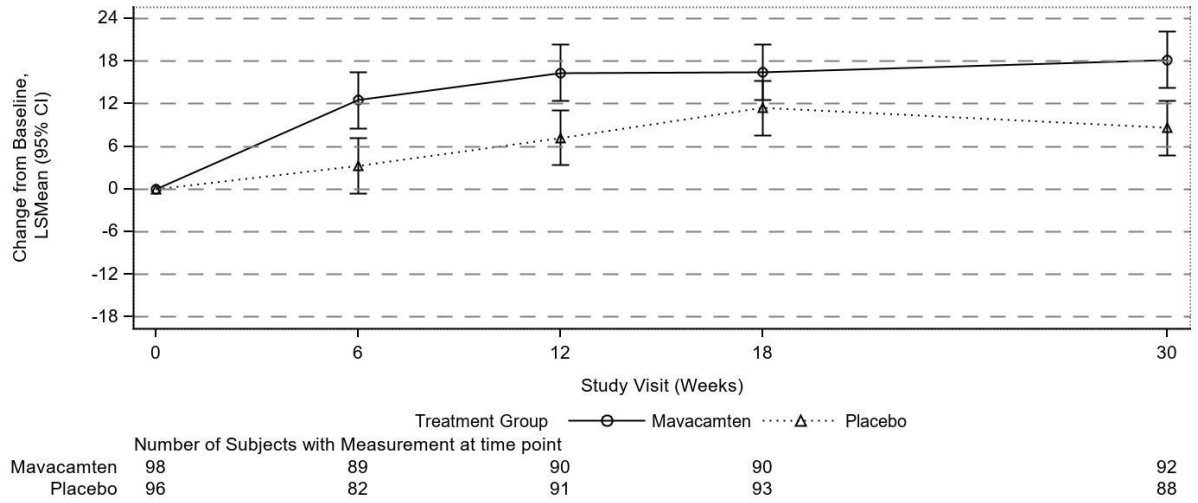

Abbildung 4-45: Mittlere Veränderung der Domäne *Lebensqualität des KCCQ* basierend auf dem MMRM

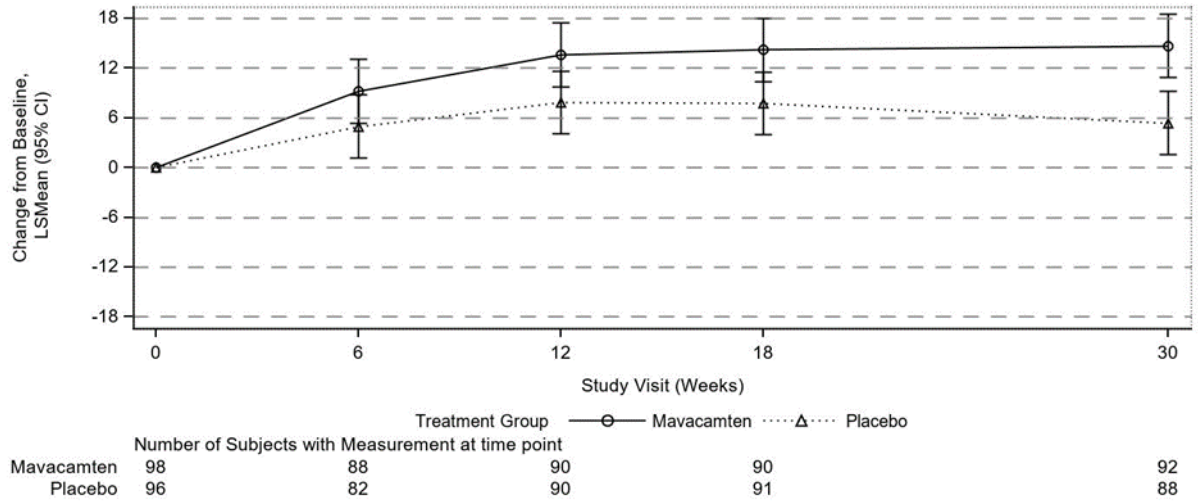

Abbildung 4-46: Mittlere Veränderung der Domäne soziale Einschränkung *des KCCQ* basierend auf dem MMRM

4.10.6 Subgruppenanalyse für die KCCQ-Summenscores TSS, CSS und OSS zu Woche 30 gegenüber Baseline mittels MMRM

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Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
KCCQ OVERALL SUMMARY SCORE									
BETA-BLOCKER USE									0.3990
YES	79	67.63 (18.266)	15.38 (12.59, 18.18)	69	67.46 (19.683)	5.49 (2.52, 8.45)	9.90 (5.82, 13.97) <0.0001	0.78 (0.45, 1.12)	
NO	19	65.49 (12.337)	12.58 (7.35, 17.81)	27	61.19 (18.871)	5.94 (1.47, 10.40)	6.65 (-0.23, 13.52) 0.0579	0.56 (-0.04, 1.16)	
TYPE OF EXERCISE TESTING									0.1056
EXERCISE BICYCLE	45	66.38 (18.802)	15.88 (12.37, 19.39)	46	66.14 (16.415)	3.90 (0.41, 7.40)	11.98 (7.02, 16.93) <0.0001	0.99 (0.55, 1.42)	
TREADMILL	53	67.92 (15.946)	13.94 (10.65, 17.22)	50	65.29 (22.234)	7.20 (3.82, 10.57)	6.74 (2.03, 11.45) 0.0052	0.55 (0.15, 0.94)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmrsubsum.sas 25MAY2023:01:59

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NYHA CLASS									0.6994
CLASS II	70	72.48 (14.139)	14.99 (11.99, 17.99)	71	70.51 (17.976)	5.39 (2.43, 8.35)	9.60 (5.44, 13.75) <0.0001	0.76 (0.42, 1.10)	
CLASS III	28	54.05 (17.473)	14.45 (9.91, 18.99)	25	52.01 (17.581)	6.25 (1.42, 11.08)	8.19 (1.84, 14.55) 0.0118	0.68 (0.13, 1.24)	
CONSENT FOR THE CMR SUBSTUDY									0.9418
YES	19	66.87 (18.339)	11.12 (5.95, 16.30)	19	64.28 (21.881)	2.15 (-3.06, 7.36)	8.97 (1.62, 16.32) 0.0170	0.76 (0.10, 1.42)	
NO	79	67.30 (17.089)	15.73 (12.96, 18.50)	77	66.05 (19.092)	6.47 (3.65, 9.28)	9.26 (5.32, 13.21) <0.0001	0.73 (0.41, 1.06)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmrsubsum.sas 25MAY2023:01:59

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
SEX									0.2481
MALE	56	70.95 (16.981)	13.84 (10.61, 17.08)	62	69.76 (18.615)	6.15 (3.06, 9.25)	7.69 (3.24, 12.14) 0.0008	0.62 (0.25, 0.99)	
FEMALE	42	62.24 (16.494)	16.15 (12.50, 19.80)	34	58.29 (19.339)	4.62 (0.52, 8.71)	11.53 (6.10, 16.97) <0.0001	0.95 (0.47, 1.43)	
AGE									0.1827
<= 49	25	66.70 (16.883)	16.38 (11.81, 20.95)	18	62.29 (20.926)	7.50 (2.09, 12.90)	8.88 (1.80, 15.96) 0.0142	0.75 (0.12, 1.37)	
50 - 64	37	69.39 (15.408)	16.71 (12.87, 20.54)	49	65.95 (19.511)	4.46 (1.07, 7.85)	12.25 (7.13, 17.37) <0.0001	1.01 (0.56, 1.47)	
>=65	36	65.33 (19.375)	11.82 (7.94, 15.71)	29	67.38 (19.232)	6.43 (2.14, 10.71)	5.40 (-0.39, 11.19) 0.0673	0.45 (-0.04, 0.95)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmrsubsum.sas 25MAY2023:01:59

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
BMI									0.6837
<30	63	67.48 (16.929)	16.35 (13.32, 19.39)	56	63.93 (19.861)	6.83 (3.62, 10.05)	9.52 (5.10, 13.94) <0.0001	0.77 (0.40, 1.14)	
>=30	35	66.74 (18.032)	12.09 (8.18, 16.00)	40	68.17 (19.118)	3.92 (0.22, 7.62)	8.17 (2.79, 13.56) 0.0031	0.68 (0.21, 1.15)	
RACE									0.3607
NON-WHITE	6	70.03 (14.032)	11.99 (2.80, 21.17)	9	58.37 (27.257)	8.02 (0.45, 15.60)	3.96 (-7.96, 15.88) 0.5130	0.32 (-0.72, 1.36)	
WHITE	92	67.03 (17.478)	15.02 (12.39, 17.65)	87	66.45 (18.643)	5.37 (2.67, 8.07)	9.65 (5.88, 13.42) <0.0001	0.75 (0.44, 1.05)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmrsubsum.sas 25MAY2023:01:59

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
REGION									0.0336*
US	45	67.60 (16.869)	13.32 (9.82, 16.82)	39	67.76 (19.475)	8.05 (4.31, 11.80)	5.27 (0.14, 10.39) 0.0441	0.44 (0.00, 0.87)	
EX-US	53	66.89 (17.706)	16.13 (12.86, 19.39)	57	64.29 (19.674)	3.94 (0.76, 7.12)	12.18 (7.63, 16.74) <0.0001	0.99 (0.60, 1.39)	
CALCIUM CHANNEL BLOCKER USE									0.2047
YES	16	63.59 (11.944)	11.20 (5.55, 16.85)	15	61.23 (18.663)	6.64 (0.79, 12.49)	4.56 (-3.56, 12.67) 0.2695	0.39 (-0.33, 1.10)	
NO	82	67.92 (18.068)	15.55 (12.81, 18.30)	81	66.52 (19.728)	5.42 (2.65, 8.19)	10.13 (6.23, 14.03) <0.0001	0.79 (0.48, 1.11)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmrsubsum.sas 25MAY2023:01:59

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
PRESENCE OF HCM PATHOGENIC MUTATION									0.1547
PATHOGENIC OR LIKELY PATHOGENIC	21	65.99 (12.260)	14.29 (9.09, 19.48)	17	63.55 (20.779)	11.26 (5.54, 16.99)	3.02 (-4.70, 10.75) 0.4411	0.24 (-0.40, 0.89)	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	26	69.10 (17.744)	14.10 (9.39, 18.81)	33	67.03 (19.243)	6.16 (1.94, 10.39)	7.93 (1.61, 14.26) 0.0142	0.64 (0.11, 1.16)	
NEGATIVE	24	65.17 (21.519)	15.87 (10.98, 20.76)	25	67.18 (17.145)	3.13 (-1.64, 7.91)	12.74 (5.90, 19.57) 0.0003	1.03 (0.43, 1.62)	
TIME FROM DIAGNOSIS OF OHCM									0.2314
<=5	50	69.88 (13.424)	13.94 (10.56, 17.32)	38	60.84 (19.905)	6.92 (3.08, 10.77)	7.01 (1.87, 12.16) 0.0078	0.57 (0.14, 1.00)	
>5	48	64.43 (20.253)	15.76 (12.32, 19.19)	58	68.88 (18.835)	4.77 (1.58, 7.95)	10.99 (6.30, 15.69) <0.0001	0.89 (0.49, 1.29)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmrsubsum.sas 25MAY2023:01:59

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Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
SEPTAL REDUCTION THERAPY (SRT) HISTORY									0.0521
YES	8	55.18 (16.081)	7.12 (-0.83, 15.07)	7	62.69 (22.794)	8.71 (0.31, 17.11)	-1.59 (-13.13, 9.94) 0.7856	-0.13 (-1.15, 0.88)	
NO	90	68.28 (17.014)	15.54 (12.90, 18.17)	89	65.93 (19.418)	5.36 (2.70, 8.02)	10.17 (6.43, 13.92) <0.0001	0.79 (0.49, 1.10)	
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED									0.7751
YES	22	67.09 (19.758)	15.94 (11.04, 20.85)	21	61.20 (21.461)	5.86 (0.84, 10.88)	10.08 (3.06, 17.11) 0.0051	0.84 (0.22, 1.47)	
NO	76	67.25 (16.588)	14.52 (11.69, 17.35)	75	66.95 (18.964)	5.55 (2.68, 8.41)	8.97 (4.94, 13.00) <0.0001	0.71 (0.38, 1.04)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
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Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
HISTORY OF HYPERTENSION									0.2821
YES	51	67.92 (18.700)	13.45 (10.11, 16.79)	43	66.55 (18.326)	5.94 (2.34, 9.54)	7.51 (2.60, 12.42) 0.0029	0.62 (0.20, 1.03)	
NO	47	66.45 (15.671)	16.34 (12.88, 19.80)	53	65.01 (20.664)	5.35 (2.04, 8.66)	10.99 (6.20, 15.78) <0.0001	0.89 (0.48, 1.31)	
RESTING LVEF									0.6413
<75%	56	70.47 (15.158)	14.95 (11.71, 18.19)	51	66.04 (19.894)	5.02 (1.66, 8.39)	9.92 (5.25, 14.60) <0.0001	0.80 (0.41, 1.19)	
>=75%	42	62.87 (19.008)	14.68 (11.03, 18.34)	45	65.30 (19.403)	6.28 (2.73, 9.83)	8.40 (3.31, 13.49) 0.0013	0.69 (0.26, 1.12)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
LVOT RESTING PEAK GRADIENT									0.3261
<=50	47	65.54 (17.781)	15.24 (11.76, 18.71)	49	67.54 (17.448)	4.44 (1.03, 7.85)	10.80 (5.93, 15.67) <0.0001	0.88 (0.46, 1.30)	
>50	51	68.75 (16.757)	14.46 (11.13, 17.80)	47	63.77 (21.575)	6.86 (3.37, 10.35)	7.61 (2.77, 12.44) 0.0022	0.62 (0.21, 1.02)	
LVOT RESTING PEAK GRADIENT									0.2858
<=30	25	63.75 (19.335)	16.37 (11.76, 20.99)	29	64.48 (19.359)	4.36 (0.06, 8.67)	12.01 (5.70, 18.31) 0.0002	1.00 (0.44, 1.57)	
>30	73	68.40 (16.440)	14.31 (11.44, 17.19)	67	66.22 (19.776)	6.16 (3.16, 9.16)	8.15 (4.00, 12.30) 0.0001	0.65 (0.31, 0.99)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL									0.0180*
<=14	44	68.38 (16.228)	17.74 (14.19, 21.29)	54	65.04 (18.262)	4.60 (1.32, 7.88)	13.14 (8.30, 17.98) <0.0001	1.07 (0.65, 1.50)	
>14	50	66.35 (18.721)	12.57 (9.22, 15.93)	36	66.48 (22.728)	7.37 (3.49, 11.24)	5.21 (0.08, 10.33) 0.0466	0.43 (-0.00, 0.86)	
E/E' SEPTAL									0.0150*
<=14	14	68.85 (15.253)	21.77 (15.84, 27.70)	20	63.61 (18.943)	3.82 (-1.21, 8.86)	17.95 (10.16, 25.74) <0.0001	1.54 (0.76, 2.31)	
>14	84	66.94 (17.619)	13.67 (10.98, 16.36)	76	66.25 (19.812)	6.08 (3.27, 8.90)	7.59 (3.70, 11.48) 0.0002	0.60 (0.28, 0.92)	

Data Cutoff Date: 30JUN2020.
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KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE									0.0124*
<=14	21	69.33 (15.035)	20.23 (15.32, 25.15)	22	65.19 (18.806)	3.47 (-1.35, 8.29)	16.76 (9.88, 23.65) <0.0001	1.43 (0.76, 2.10)	
>14	77	66.64 (17.842)	13.37 (10.60, 16.15)	74	65.85 (19.908)	6.24 (3.40, 9.08)	7.13 (3.16, 11.10) 0.0005	0.57 (0.24, 0.90)	
LEFT ATRIAL VOLUME INDEX									0.9427
<=MEDIAN	45	66.04 (16.541)	13.85 (10.30, 17.39)	47	68.47 (19.390)	4.53 (1.03, 8.02)	9.32 (4.34, 14.30) 0.0003	0.76 (0.34, 1.18)	
>MEDIAN	52	68.22 (18.086)	15.74 (12.42, 19.07)	49	63.03 (19.558)	6.66 (3.23, 10.09)	9.09 (4.30, 13.87) 0.0002	0.74 (0.33, 1.14)	

Data Cutoff Date: 30JUN2020.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NT-PROBNP									0.1327
<=MEDIAN	43	65.52 (17.721)	14.43 (10.84, 18.02)	53	66.06 (17.353)	3.16 (-0.12, 6.44)	11.27 (6.41, 16.13) <0.0001	0.92 (0.50, 1.35)	
>MEDIAN	53	68.53 (17.201)	14.78 (11.51, 18.05)	42	66.31 (21.327)	8.42 (4.78, 12.06)	6.36 (1.46, 11.26) 0.0111	0.52 (0.11, 0.93)	
HS-CARDIAC TROPONIN-I									0.0443*
<=ULN	74	67.93 (17.614)	15.35 (12.53, 18.17)	74	65.64 (19.500)	5.43 (2.58, 8.28)	9.92 (5.91, 13.93) <0.0001	0.79 (0.46, 1.13)	
>ULN	22	64.61 (16.808)	11.96 (7.16, 16.76)	16	68.50 (18.791)	10.21 (4.65, 15.78)	1.75 (-5.61, 9.10) 0.6402	0.15 (-0.50, 0.79)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0285*
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	33	68.72 (17.067)	18.28 (14.24, 22.31)	44	64.30 (19.249)	4.67 (1.07, 8.27)	13.61 (8.19, 19.02) <0.0001	1.12 (0.64, 1.61)	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	61	66.46 (17.894)	12.70 (9.60, 15.80)	43	66.18 (21.478)	6.60 (3.00, 10.20)	6.10 (1.35, 10.86) 0.0121	0.50 (0.10, 0.89)	
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0255*
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	12	68.65 (16.572)	21.48 (15.06, 27.90)	15	63.28 (20.421)	3.11 (-2.70, 8.91)	18.37 (9.72, 27.03) <0.0001	1.56 (0.70, 2.43)	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	86	67.01 (17.417)	13.90 (11.23, 16.57)	80	65.96 (19.552)	5.94 (3.17, 8.72)	7.96 (4.11, 11.81) <0.0001	0.63 (0.31, 0.94)	

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Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0278*
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	18	68.32 (15.766)	20.11 (14.81, 25.41)	15	63.28 (20.421)	3.10 (-2.70, 8.90)	17.01 (9.15, 24.87) <0.0001	1.45 (0.68, 2.22)	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	80	66.96 (17.640)	13.65 (10.90, 16.40)	79	65.84 (19.647)	6.08 (3.30, 8.86)	7.57 (3.66, 11.48) 0.0002	0.60 (0.28, 0.92)	
CREATININE CLEARANCE (CRCL)									0.5705
<60	12	63.29 (12.946)	15.24 (8.69, 21.80)	11	60.05 (17.485)	8.61 (1.78, 15.44)	6.63 (-2.82, 16.08) 0.1678	0.55 (-0.28, 1.39)	
>=60	85	67.73 (17.853)	14.71 (11.99, 17.42)	85	66.43 (19.795)	5.22 (2.49, 7.96)	9.48 (5.63, 13.34) <0.0001	0.74 (0.43, 1.05)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
KCCQ TOTAL SYMPTOM SCORE									
BETA-BLOCKER USE									0.7111
YES	79	71.90 (16.993)	13.28 (10.32, 16.25)	69	70.74 (21.040)	5.32 (2.18, 8.47)	7.96 (3.64, 12.28) 0.0003	0.59 (0.26, 0.92)	
NO	19	68.86 (14.869)	10.52 (5.11, 15.93)	27	65.12 (23.198)	4.02 (-0.61, 8.66)	6.50 (-0.61, 13.61) 0.0731	0.53 (-0.07, 1.12)	
TYPE OF EXERCISE TESTING									0.0728
EXERCISE BICYCLE	45	70.90 (17.932)	13.42 (9.76, 17.08)	46	69.72 (18.884)	2.54 (-1.12, 6.19)	10.88 (5.71, 16.05) <0.0001	0.86 (0.43, 1.29)	
TREADMILL	53	71.66 (15.494)	12.15 (8.70, 15.59)	50	68.65 (24.173)	7.19 (3.65, 10.73)	4.96 (0.01, 9.90) 0.0493	0.38 (-0.01, 0.77)	

Data Cutoff Date: 30JUN2020.
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Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
NYHA CLASS									0.3288
CLASS II	70	76.07 (14.473)	13.29 (10.14, 16.45)	71	74.81 (19.789)	4.51 (1.38, 7.65)	8.78 (4.39, 13.17) 0.0001	0.66 (0.32, 1.00)	
CLASS III	28	59.41 (15.684)	11.37 (6.72, 16.02)	25	53.13 (18.932)	6.23 (1.17, 11.28)	5.14 (-1.47, 11.75) 0.1268	0.41 (-0.13, 0.96)	
CONSENT FOR THE CMR SUBSTUDY									0.9745
YES	19	68.64 (19.100)	10.28 (4.89, 15.68)	19	67.32 (23.855)	2.62 (-2.82, 8.06)	7.67 (0.01, 15.32) 0.0497	0.62 (-0.03, 1.27)	
NO	79	71.95 (15.977)	13.33 (10.38, 16.29)	77	69.62 (21.270)	5.53 (2.52, 8.54)	7.80 (3.58, 12.02) 0.0003	0.58 (0.26, 0.90)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
SEX									0.2580
MALE	56	74.81 (16.282)	12.09 (8.69, 15.50)	62	73.59 (21.633)	5.77 (2.51, 9.04)	6.32 (1.63, 11.01) 0.0085	0.48 (0.12, 0.85)	
FEMALE	42	66.64 (15.973)	13.60 (9.79, 17.41)	34	61.09 (19.641)	3.42 (-0.87, 7.71)	10.18 (4.49, 15.87) 0.0005	0.80 (0.33, 1.27)	
AGE									0.0257*
<= 49	25	71.79 (18.791)	14.41 (9.75, 19.06)	18	67.07 (20.754)	9.95 (4.46, 15.45)	4.45 (-2.75, 11.66) 0.2246	0.37 (-0.24, 0.98)	
50 - 64	37	72.38 (14.046)	15.65 (11.73, 19.58)	49	70.09 (21.911)	3.00 (-0.49, 6.50)	12.65 (7.39, 17.91) <0.0001	1.02 (0.56, 1.47)	
>=65	36	69.88 (17.685)	8.55 (4.56, 12.53)	29	68.89 (22.534)	5.25 (0.86, 9.63)	3.30 (-2.62, 9.22) 0.2735	0.27 (-0.22, 0.76)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmrsubsum.sas 25MAY2023:01:59

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Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
BMI									0.6079
<30	63	73.00 (15.251)	13.86 (10.63, 17.09)	56	67.71 (21.866)	5.53 (2.12, 8.94)	8.33 (3.62, 13.03) 0.0006	0.63 (0.26, 1.00)	
>=30	35	68.27 (18.568)	10.72 (6.61, 14.84)	40	71.20 (21.559)	4.15 (0.26, 8.05)	6.57 (0.90, 12.24) 0.0232	0.52 (0.06, 0.98)	
RACE									0.3246
NON-WHITE	6	73.44 (6.995)	8.23 (-1.22, 17.68)	9	63.08 (25.087)	6.31 (-1.49, 14.10)	1.93 (-10.34, 14.19) 0.7572	0.15 (-0.88, 1.19)	
WHITE	92	71.17 (17.024)	13.03 (10.23, 15.83)	87	69.79 (21.379)	4.82 (1.94, 7.70)	8.21 (4.19, 12.23) <0.0001	0.60 (0.30, 0.90)	

Data Cutoff Date: 30JUN2020.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
REGION									0.1578
US	45	69.33 (16.248)	12.53 (8.85, 16.21)	39	71.07 (21.626)	7.53 (3.60, 11.46)	5.00 (-0.39, 10.38) 0.0687	0.39 (-0.04, 0.83)	
EX-US	53	73.00 (16.815)	12.92 (9.47, 16.37)	57	67.85 (21.834)	3.19 (-0.18, 6.56)	9.73 (4.90, 14.56) <0.0001	0.75 (0.36, 1.14)	
CALCIUM CHANNEL BLOCKER USE									0.2839
YES	16	66.73 (13.952)	9.30 (3.46, 15.13)	15	63.82 (24.523)	5.54 (-0.51, 11.60)	3.76 (-4.63, 12.14) 0.3785	0.31 (-0.40, 1.02)	
NO	82	72.21 (16.969)	13.42 (10.50, 16.34)	81	70.15 (21.149)	4.85 (1.89, 7.80)	8.58 (4.42, 12.73) <0.0001	0.63 (0.32, 0.95)	

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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
PRESENCE OF HCM PATHOGENIC MUTATION									0.0670
PATHOGENIC OR LIKELY PATHOGENIC	21	75.05 (13.182)	11.16 (5.85, 16.46)	17	66.79 (22.993)	12.87 (7.05, 18.68)	-1.71 (-9.60, 6.18) 0.6695	-0.14 (-0.78, 0.50)	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	26	71.39 (17.180)	12.38 (7.58, 17.18)	33	69.19 (21.833)	5.80 (1.46, 10.14)	6.58 (0.11, 13.06) 0.0463	0.52 (-0.01, 1.04)	
NEGATIVE	24	68.40 (18.721)	12.82 (7.83, 17.82)	25	71.71 (21.702)	2.88 (-1.99, 7.76)	9.94 (2.96, 16.92) 0.0055	0.78 (0.20, 1.37)	
TIME FROM DIAGNOSIS OF OHCM									0.1658
<=5	50	74.04 (14.579)	12.24 (8.70, 15.78)	38	63.82 (22.082)	7.21 (3.20, 11.22)	5.03 (-0.36, 10.41) 0.0671	0.39 (-0.04, 0.82)	
>5	48	68.47 (18.143)	13.23 (9.64, 16.83)	58	72.67 (20.887)	3.49 (0.14, 6.85)	9.74 (4.82, 14.66) 0.0001	0.75 (0.36, 1.15)	

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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
SEPTAL REDUCTION THERAPY (SRT) HISTORY									0.0327*
YES	8	65.76 (16.791)	2.39 (-5.70, 10.48)	7	68.60 (23.427)	6.69 (-1.89, 15.27)	-4.30 (-16.08, 7.48) 0.4727	-0.35 (-1.37, 0.67)	
NO	90	71.81 (16.559)	13.68 (10.88, 16.47)	89	69.21 (21.693)	4.81 (1.99, 7.64)	8.86 (4.89, 12.84) <0.0001	0.65 (0.35, 0.95)	
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED									0.6923
YES	22	69.74 (16.097)	14.65 (9.57, 19.73)	21	67.41 (22.624)	5.65 (0.47, 10.83)	9.00 (1.74, 16.25) 0.0153	0.73 (0.11, 1.35)	
NO	76	71.77 (16.787)	12.19 (9.19, 15.19)	75	69.65 (21.557)	4.77 (1.73, 7.81)	7.42 (3.15, 11.69) 0.0007	0.55 (0.23, 0.88)	

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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
HISTORY OF HYPERTENSION									0.2429
YES	51	71.04 (17.889)	11.49 (7.98, 14.99)	43	68.48 (21.647)	5.66 (1.88, 9.43)	5.83 (0.68, 10.99) 0.0267	0.46 (0.04, 0.87)	
NO	47	71.61 (15.206)	14.09 (10.47, 17.72)	53	69.71 (21.922)	4.38 (0.90, 7.87)	9.71 (4.68, 14.74) 0.0002	0.75 (0.35, 1.16)	
RESTING LVEF									0.4461
<75%	56	74.05 (14.290)	13.43 (10.03, 16.83)	51	70.30 (22.204)	4.52 (0.98, 8.06)	8.91 (4.01, 13.82) 0.0004	0.68 (0.29, 1.07)	
>=75%	42	67.66 (18.763)	11.82 (8.01, 15.63)	45	67.87 (21.275)	5.45 (1.73, 9.18)	6.37 (1.05, 11.69) 0.0191	0.50 (0.07, 0.93)	

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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
LVOT RESTING PEAK GRADIENT									0.2916
<=50	47	68.95 (16.404)	13.44 (9.79, 17.09)	49	70.26 (20.533)	3.91 (0.33, 7.48)	9.53 (4.42, 14.64) 0.0003	0.74 (0.33, 1.15)	
>50	51	73.49 (16.591)	12.10 (8.60, 15.60)	47	68.02 (23.008)	6.08 (2.42, 9.74)	6.02 (0.94, 11.10) 0.0203	0.47 (0.06, 0.87)	
LVOT RESTING PEAK GRADIENT									0.4004
<=30	25	67.46 (16.864)	14.11 (9.32, 18.91)	29	67.49 (21.826)	4.08 (-0.41, 8.56)	10.04 (3.48, 16.60) 0.0029	0.81 (0.25, 1.36)	
>30	73	72.63 (16.381)	12.27 (9.22, 15.32)	67	69.88 (21.761)	5.35 (2.17, 8.52)	6.92 (2.52, 11.33) 0.0022	0.52 (0.18, 0.86)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL									0.0575
<=14	44	72.16 (16.955)	15.91 (12.25, 19.57)	54	69.29 (21.071)	4.74 (1.34, 8.14)	11.17 (6.18, 16.17) <0.0001	0.88 (0.47, 1.30)	
>14	50	70.46 (16.997)	10.25 (6.78, 13.71)	36	69.16 (24.212)	5.44 (1.46, 9.42)	4.81 (-0.47, 10.08) 0.0741	0.39 (-0.05, 0.82)	
E/E' SEPTAL									0.0960
<=14	14	76.34 (14.886)	18.78 (12.61, 24.95)	20	66.61 (20.087)	4.76 (-0.50, 10.01)	14.02 (5.90, 22.15) 0.0008	1.15 (0.42, 1.89)	
>14	84	70.47 (16.773)	11.72 (8.85, 14.60)	76	69.83 (22.174)	5.00 (1.99, 8.01)	6.72 (2.57, 10.88) 0.0016	0.50 (0.18, 0.81)	

Data Cutoff Date: 30JUN2020.
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Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE									0.0740
<=14	21	73.96 (16.870)	17.89 (12.77, 23.02)	22	69.27 (20.991)	4.56 (-0.46, 9.58)	13.34 (6.16, 20.51) 0.0003	1.09 (0.45, 1.73)	
>14	77	70.59 (16.530)	11.35 (8.39, 14.30)	74	69.13 (22.038)	5.07 (2.04, 8.10)	6.28 (2.05, 10.51) 0.0038	0.47 (0.15, 0.79)	
LEFT ATRIAL VOLUME INDEX									0.2072
<=MEDIAN	45	67.06 (16.001)	12.92 (9.21, 16.63)	47	71.83 (21.975)	3.01 (-0.64, 6.67)	9.91 (4.69, 15.12) 0.0002	0.77 (0.35, 1.19)	
>MEDIAN	52	75.16 (16.401)	12.49 (8.99, 15.98)	49	66.60 (21.330)	6.83 (3.24, 10.43)	5.66 (0.62, 10.70) 0.0280	0.43 (0.04, 0.83)	

Data Cutoff Date: 30JUN2020.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NT-PROBNP									0.0711
<=MEDIAN	43	69.60 (16.392)	13.37 (9.62, 17.12)	53	69.04 (19.290)	2.57 (-0.87, 6.02)	10.80 (5.70, 15.89) <0.0001	0.85 (0.43, 1.27)	
>MEDIAN	53	72.74 (17.046)	11.93 (8.50, 15.36)	42	70.54 (23.494)	7.17 (3.36, 10.98)	4.76 (-0.37, 9.89) 0.0687	0.37 (-0.04, 0.78)	
HS-CARDIAC TROPONIN-I									0.2780
<=ULN	74	72.41 (16.433)	12.89 (9.88, 15.89)	74	68.78 (21.649)	5.10 (2.05, 8.15)	7.79 (3.50, 12.08) 0.0004	0.58 (0.25, 0.91)	
>ULN	22	67.61 (17.642)	10.98 (5.97, 16.00)	16	72.92 (20.750)	7.73 (1.93, 13.52)	3.25 (-4.42, 10.92) 0.4041	0.27 (-0.38, 0.91)	

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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.1916
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	33	72.29 (18.061)	15.95 (11.81, 20.09)	44	68.04 (21.531)	5.34 (1.61, 9.07)	10.60 (5.03, 16.18) 0.0002	0.85 (0.38, 1.32)	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	61	70.75 (16.389)	10.59 (7.36, 13.82)	43	69.31 (23.431)	4.46 (0.74, 8.19)	6.12 (1.19, 11.06) 0.0151	0.48 (0.09, 0.88)	
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.2270
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	12	75.52 (15.112)	18.01 (11.36, 24.67)	15	65.90 (20.524)	5.00 (-1.03, 11.04)	13.01 (4.01, 22.01) 0.0048	1.06 (0.25, 1.87)	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	86	70.72 (16.765)	12.00 (9.14, 14.86)	80	69.51 (21.984)	4.77 (1.81, 7.74)	7.23 (3.11, 11.35) 0.0006	0.53 (0.22, 0.84)	

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Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.2050
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	18	72.51 (17.328)	17.46 (11.94, 22.97)	15	65.90 (20.524)	5.02 (-1.02, 11.05)	12.44 (4.25, 20.62) 0.0031	1.02 (0.29, 1.74)	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	80	71.04 (16.501)	11.68 (8.74, 14.61)	79	69.22 (21.980)	4.82 (1.85, 7.80)	6.85 (2.67, 11.03) 0.0014	0.51 (0.19, 0.82)	
CREATININE CLEARANCE (CRCL)									0.2034
<60	12	68.32 (11.161)	10.06 (3.30, 16.83)	11	63.16 (22.661)	8.09 (1.05, 15.13)	1.97 (-7.78, 11.72) 0.6908	0.16 (-0.66, 0.98)	
>=60	85	71.47 (17.135)	13.07 (10.19, 15.96)	85	69.94 (21.582)	4.55 (1.63, 7.46)	8.53 (4.42, 12.63) <0.0001	0.62 (0.31, 0.93)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmrsubsum.sas 25MAY2023:01:59

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
KCCQ CLINICAL SUMMARY SCORE									
BETA-BLOCKER USE									0.2041
YES	79	70.95 (17.258)	14.31 (11.59, 17.03)	69	72.18 (18.718)	4.16 (1.27, 7.06)	10.14 (6.17, 14.11) <0.0001	0.82 (0.48, 1.16)	
NO	19	70.57 (12.028)	10.29 (5.25, 15.32)	27	65.66 (19.233)	4.85 (0.54, 9.15)	5.44 (-1.19, 12.07) 0.1071	0.47 (-0.12, 1.07)	
TYPE OF EXERCISE TESTING									0.0445*
EXERCISE BICYCLE	45	69.59 (17.770)	14.39 (11.00, 17.78)	46	71.93 (16.377)	1.95 (-1.43, 5.34)	12.43 (7.64, 17.23) <0.0001	1.06 (0.62, 1.50)	
TREADMILL	53	71.97 (15.067)	12.77 (9.59, 15.95)	50	68.89 (21.177)	6.58 (3.30, 9.85)	6.19 (1.62, 10.76) 0.0081	0.52 (0.13, 0.91)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NYHA CLASS									0.9238
CLASS II	70	75.62 (13.336)	13.91 (11.00, 16.82)	71	75.48 (17.272)	4.61 (1.71, 7.52)	9.29 (5.24, 13.34) <0.0001	0.75 (0.41, 1.09)	
CLASS III	28	59.02 (17.274)	12.57 (8.19, 16.95)	25	55.78 (16.085)	3.61 (-1.08, 8.31)	8.96 (2.81, 15.11) 0.0045	0.77 (0.21, 1.33)	
CONSENT FOR THE CMR SUBSTUDY									0.8113
YES	19	68.88 (18.604)	10.95 (5.94, 15.97)	19	69.74 (18.580)	1.06 (-3.99, 6.11)	9.90 (2.78, 17.02) 0.0067	0.87 (0.20, 1.53)	
NO	79	71.36 (15.817)	14.14 (11.43, 16.85)	77	70.50 (19.209)	5.17 (2.41, 7.93)	8.97 (5.10, 12.84) <0.0001	0.72 (0.40, 1.05)	

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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
SEX									0.0952
MALE	56	75.08 (15.389)	12.39 (9.24, 15.53)	62	75.15 (18.047)	5.30 (2.28, 8.32)	7.09 (2.77, 11.41) 0.0014	0.59 (0.22, 0.96)	
FEMALE	42	65.28 (16.007)	15.02 (11.47, 18.57)	34	61.59 (17.718)	2.60 (-1.39, 6.58)	12.42 (7.17, 17.68) <0.0001	1.06 (0.58, 1.54)	
AGE									0.0874
<= 49	25	72.65 (17.772)	14.64 (10.25, 19.04)	18	68.86 (19.279)	8.09 (2.91, 13.28)	6.55 (-0.25, 13.35) 0.0591	0.57 (-0.05, 1.19)	
50 - 64	37	72.77 (13.031)	15.55 (11.85, 19.24)	49	71.08 (19.003)	2.65 (-0.63, 5.93)	12.90 (7.96, 17.83) <0.0001	1.10 (0.65, 1.56)	
>=65	36	67.71 (18.182)	10.64 (6.88, 14.39)	29	70.04 (19.406)	4.99 (0.86, 9.12)	5.65 (0.07, 11.23) 0.0473	0.49 (-0.01, 0.99)	

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Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
BMI									0.7101
<30	63	72.09 (15.312)	14.63 (11.66, 17.61)	56	69.23 (19.619)	5.17 (2.02, 8.31)	9.47 (5.14, 13.80) <0.0001	0.78 (0.41, 1.16)	
>=30	35	68.68 (18.019)	11.51 (7.69, 15.33)	40	71.91 (18.209)	3.23 (-0.38, 6.84)	8.28 (3.02, 13.54) 0.0021	0.71 (0.24, 1.17)	
RACE									0.3173
NON-WHITE	6	74.43 (10.718)	10.39 (1.54, 19.23)	9	63.62 (22.761)	6.77 (-0.53, 14.06)	3.62 (-7.87, 15.10) 0.5350	0.31 (-0.73, 1.35)	
WHITE	92	70.65 (16.635)	13.73 (11.15, 16.30)	87	71.04 (18.575)	4.11 (1.46, 6.76)	9.61 (5.92, 13.31) <0.0001	0.76 (0.46, 1.06)	

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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
REGION									0.0541
US	45	70.10 (16.324)	12.85 (9.45, 16.25)	39	71.25 (17.607)	7.20 (3.56, 10.83)	5.65 (0.67, 10.63) 0.0263	0.48 (0.05, 0.92)	
EX-US	53	71.54 (16.444)	14.09 (10.92, 17.26)	57	69.73 (20.014)	2.41 (-0.68, 5.51)	11.67 (7.24, 16.11) <0.0001	0.98 (0.58, 1.37)	
CALCIUM CHANNEL BLOCKER USE									0.1031
YES	16	69.04 (11.629)	8.95 (3.52, 14.37)	15	63.44 (20.762)	5.54 (-0.10, 11.18)	3.41 (-4.41, 11.22) 0.3912	0.30 (-0.41, 1.01)	
NO	82	71.23 (17.121)	14.42 (11.75, 17.09)	81	71.63 (18.501)	4.14 (1.43, 6.84)	10.29 (6.48, 14.09) <0.0001	0.83 (0.51, 1.15)	

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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
PRESENCE OF HCM PATHOGENIC MUTATION									0.0437*
PATHOGENIC OR LIKELY PATHOGENIC	21	73.60 (12.066)	11.50 (6.60, 16.40)	17	68.96 (18.667)	10.21 (4.83, 15.59)	1.29 (-5.99, 8.58) 0.7269	0.11 (-0.53, 0.75)	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	26	72.41 (17.150)	12.90 (8.45, 17.34)	33	71.33 (19.088)	5.71 (1.71, 9.72)	7.19 (1.21, 13.17) 0.0188	0.61 (0.08, 1.14)	
NEGATIVE	24	67.24 (18.582)	14.53 (9.90, 19.16)	25	72.90 (18.446)	1.40 (-3.11, 5.91)	13.13 (6.65, 19.61) <0.0001	1.12 (0.52, 1.72)	
TIME FROM DIAGNOSIS OF OHCM									0.2933
<=5	50	72.83 (12.979)	13.09 (9.81, 16.37)	38	67.37 (18.797)	5.84 (2.13, 9.55)	7.25 (2.29, 12.21) 0.0044	0.61 (0.18, 1.04)	
>5	48	68.84 (19.126)	13.97 (10.63, 17.30)	58	72.30 (19.027)	3.39 (0.28, 6.49)	10.58 (6.02, 15.14) <0.0001	0.88 (0.48, 1.28)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Inter-action p-value
SEPTAL REDUCTION THERAPY (SRT) HISTORY									0.0651
YES	8	59.96 (16.670)	6.90 (-0.78, 14.57)	7	67.34 (20.632)	7.64 (-0.47, 15.75)	-0.74 (-11.88, 10.39) 0.8956	-0.06 (-1.08, 0.95)	
NO	90	71.85 (16.024)	14.12 (11.53, 16.70)	89	70.58 (18.963)	4.10 (1.49, 6.71)	10.02 (6.35, 13.69) <0.0001	0.80 (0.49, 1.10)	
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED									0.5606
YES	22	68.74 (18.366)	15.57 (10.83, 20.31)	21	68.19 (21.983)	4.72 (-0.11, 9.55)	10.85 (4.09, 17.61) 0.0018	0.94 (0.31, 1.57)	
NO	76	71.50 (15.758)	12.93 (10.17, 15.69)	75	70.95 (18.187)	4.26 (1.46, 7.05)	8.68 (4.75, 12.60) <0.0001	0.70 (0.37, 1.03)	

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Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
HISTORY OF HYPERTENSION									0.7792
YES	51	69.87 (17.947)	12.87 (9.61, 16.12)	43	71.10 (18.174)	4.09 (0.59, 7.60)	8.77 (3.99, 13.56) 0.0004	0.74 (0.32, 1.16)	
NO	47	71.97 (14.463)	14.23 (10.85, 17.60)	53	69.73 (19.782)	4.58 (1.35, 7.81)	9.65 (4.98, 14.32) <0.0001	0.81 (0.40, 1.21)	
RESTING LVEF									0.8053
<75%	56	74.16 (14.217)	13.67 (10.52, 16.82)	51	70.85 (19.255)	4.15 (0.88, 7.43)	9.51 (4.97, 14.06) <0.0001	0.79 (0.39, 1.18)	
>=75%	42	66.50 (18.018)	13.32 (9.77, 16.88)	45	69.77 (18.890)	4.59 (1.14, 8.04)	8.74 (3.79, 13.68) 0.0006	0.74 (0.30, 1.17)	

Data Cutoff Date: 30JUN2020.
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Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
LVOT RESTING PEAK GRADIENT									0.3517
<=50	47	69.52 (16.305)	14.34 (10.96, 17.73)	49	71.95 (16.909)	3.71 (0.39, 7.02)	10.64 (5.90, 15.38) <0.0001	0.89 (0.47, 1.31)	
>50	51	72.13 (16.396)	12.78 (9.54, 16.01)	47	68.68 (21.000)	5.05 (1.65, 8.44)	7.73 (3.03, 12.42) 0.0014	0.65 (0.24, 1.05)	
LVOT RESTING PEAK GRADIENT									0.4245
<=30	25	67.05 (17.627)	15.65 (11.18, 20.12)	29	69.19 (18.073)	4.41 (0.25, 8.58)	11.24 (5.13, 17.34) 0.0004	0.97 (0.41, 1.54)	
>30	73	72.19 (15.762)	12.80 (9.99, 15.60)	67	70.85 (19.488)	4.34 (1.41, 7.26)	8.46 (4.41, 12.51) <0.0001	0.69 (0.35, 1.03)	

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Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL									0.0131*
<=14	44	71.77 (14.898)	16.69 (13.27, 20.10)	54	70.40 (18.301)	3.61 (0.45, 6.78)	13.07 (8.42, 17.73) <0.0001	1.11 (0.68, 1.54)	
>14	50	70.15 (18.041)	11.01 (7.78, 14.24)	36	69.51 (21.378)	5.84 (2.12, 9.56)	5.17 (0.25, 10.10) 0.0397	0.45 (0.01, 0.88)	
E/E' SEPTAL									0.0543
<=14	14	75.73 (12.523)	19.31 (13.54, 25.07)	20	68.73 (15.425)	3.44 (-1.46, 8.33)	15.87 (8.30, 23.44) <0.0001	1.40 (0.64, 2.16)	
>14	84	70.07 (16.796)	12.54 (9.90, 15.19)	76	70.77 (19.893)	4.60 (1.83, 7.36)	7.95 (4.12, 11.77) <0.0001	0.64 (0.32, 0.96)	

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Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
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Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE									0.0224*
<=14	21	73.43 (14.334)	19.09 (14.34, 23.84)	22	71.01 (16.528)	3.30 (-1.35, 7.96)	15.79 (9.13, 22.44) <0.0001	1.39 (0.73, 2.06)	
>14	77	70.18 (16.840)	12.01 (9.30, 14.72)	74	70.15 (19.765)	4.67 (1.89, 7.44)	7.35 (3.47, 11.23) 0.0002	0.60 (0.27, 0.93)	
LEFT ATRIAL VOLUME INDEX									0.4117
<=MEDIAN	45	67.71 (16.324)	13.81 (10.36, 17.27)	47	73.10 (18.365)	3.31 (-0.09, 6.71)	10.50 (5.64, 15.36) <0.0001	0.88 (0.45, 1.30)	
>MEDIAN	52	73.66 (16.120)	13.26 (10.02, 16.50)	49	67.71 (19.395)	5.36 (2.02, 8.70)	7.90 (3.24, 12.57) 0.0010	0.66 (0.26, 1.06)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmrsubsum.sas 25MAY2023:01:59

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
NT-PROBNP									0.1143
<=MEDIAN	43	69.66 (15.884)	13.62 (10.14, 17.10)	53	70.93 (15.679)	2.06 (-1.13, 5.25)	11.56 (6.84, 16.28) <0.0001	0.98 (0.55, 1.40)	
>MEDIAN	53	71.99 (17.030)	13.08 (9.91, 16.26)	42	70.73 (21.673)	6.48 (2.95, 10.01)	6.61 (1.86, 11.36) 0.0066	0.56 (0.15, 0.97)	
HS-CARDIAC TROPONIN-I									0.2798
<=ULN	74	71.35 (16.622)	13.78 (11.00, 16.55)	74	69.61 (19.246)	4.52 (1.71, 7.34)	9.25 (5.30, 13.21) <0.0001	0.75 (0.42, 1.08)	
>ULN	22	69.19 (16.183)	11.75 (7.06, 16.44)	16	75.16 (17.219)	6.75 (1.31, 12.19)	5.00 (-2.19, 12.19) 0.1721	0.44 (-0.21, 1.09)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmrsubsum.sas 25MAY2023:01:59

Protocol: MYK-461-005

Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0369*
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	33	71.43 (16.188)	17.26 (13.38, 21.14)	44	69.30 (18.897)	3.96 (0.48, 7.43)	13.31 (8.10, 18.52) <0.0001	1.14 (0.66, 1.63)	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	61	70.75 (16.901)	11.28 (8.28, 14.28)	43	69.89 (20.534)	4.78 (1.30, 8.26)	6.50 (1.90, 11.09) 0.0058	0.55 (0.15, 0.94)	
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.1549
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	12	75.50 (13.417)	18.31 (12.07, 24.55)	15	67.88 (15.499)	3.42 (-2.22, 9.05)	14.90 (6.47, 23.32) 0.0006	1.30 (0.47, 2.14)	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	86	70.23 (16.650)	12.84 (10.21, 15.47)	80	70.58 (19.635)	4.36 (1.63, 7.09)	8.49 (4.70, 12.28) <0.0001	0.68 (0.37, 0.99)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmrsubsum.sas 25MAY2023:01:59

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Comparison between Mavacamten and Placebo in KCCQ-23 Summary Scores Change from Baseline to Week 30,
Subgroup Analysis Using Mixed Model for Repeated Measurements (MMRM)
Intention-to-treat (ITT) population

	Mavacamten			Placebo			Mavacamten vs Placebo		
Subgroup	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	N	Baseline Mean(SD)	Change from Baseline: LS Mean (95% CI)	Difference in LS Mean Change (95% CI) p-value	SMD as Hedge's g (95% CI)	Interaction p-value
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS									0.0826
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	18	72.41 (15.127)	18.57 (13.44, 23.71)	15	67.88 (15.499)	3.42 (-2.19, 9.04)	15.15 (7.53, 22.77) 0.0001	1.33 (0.57, 2.09)	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	80	70.53 (16.648)	12.38 (9.69, 15.08)	79	70.36 (19.666)	4.41 (1.67, 7.14)	7.98 (4.14, 11.81) <0.0001	0.64 (0.32, 0.96)	
CREATININE CLEARANCE (CRCL)									0.7695
<60	12	65.37 (12.074)	13.58 (7.23, 19.92)	11	66.51 (19.116)	5.76 (-0.83, 12.34)	7.82 (-1.30, 16.95) 0.0926	0.68 (-0.17, 1.52)	
>=60	85	71.52 (16.799)	13.41 (10.75, 16.07)	85	70.84 (19.033)	4.17 (1.49, 6.85)	9.24 (5.46, 13.01) <0.0001	0.73 (0.42, 1.04)	

Data Cutoff Date: 30JUN2020.
Note: The LS means (95% CI) and the p-values are based on Mixed Model for Repeated Measurements with data up to Week 30 which includes baseline value, treatment group, visit, interaction between treatment group and visit, subgroup, and treatment*subgroup interaction as fixed effect and Subject will be treated as a random effect, and compound symmetric variance covariance component will be used.
Subjects with non-missing baseline and at least one post-baseline assessments are included in this analysis.
KCCQ is 23-item Kansas City Cardiomyopathy Questionnaire.
Program Source: BMS_GMA\MYK_MMA\HAB57330\Biostatistics\Production\Tables\EBR567\rt-sy-kccqmmrmrsubsum.sas 25MAY2023:01:59

4.11 Analysen für den Endpunkt Verträglichkeit

4.11.1 Schwere UE nach SOC/PT

Auf Ebene der SOC und PT traten keine schweren UE bei mindestens 5 % der Patient:innen bzw. mindestens 1 % der Patient:innen und mit einer Häufigkeit von mindestens 10 Ereignissen in mindestens einem Studienarm auf, sodass gemäß Dossiervorlage keine schweren UE nach SOC und PT dargestellt werden.

4.11.2 SUE nach SOC/PT

Auf Ebene der SOC und PT traten keine SUE bei mindestens 5 % der Patient:innen bzw. mindestens 1 % der Patient:innen und mit einer Häufigkeit von mindestens 10 Ereignissen in mindestens einem Studienarm auf, sodass gemäß Dossiervorlage keine SUE nach SOC und PT dargestellt werden.

4.11.3 Jegliche UE

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Analysis of Treatment-Emergent Adverse Events
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE) (A)	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)(C)	Odds Ratio (95% CI) p-value (B)(D)	Risk Difference (95% CI) p-value (B)(C)
PATIENTS WITH ANY TEAEs	108 (87.8)	104 (81.3)	1.08 (0.97, 1.20) 0.1619	1.64 (0.78, 3.53) 0.1712	6.47 (-2.51, 15.44) 0.1580

Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
(B) The analysis is stratified on baseline NYHA class, beta blocker use, and exercise type (per IXRS).
(C) Risk ratio /Risk Difference is based on Mantel-Haenszel method. p-value and 95% CI are derived using normal approximation.
(D) Odds ratio is based on Cochran-Mantel-Haenszel method.
95% CI are derived using the exact method. p-value is calculated from the Cochrane-Mantel-Haenszel-Test using the exact method.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ae-aeteaetbin.sas 30AUG2022:07:39

4.11.4 Jegliche UE nach SOC/PT

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Incidence of Treatment-Emergent Adverse Events by SOC/PT
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)(C)	 Odds Ratio (95% CI) p-value (B)(D)	 Risk Difference (95% CI) p-value (B)(C)
TOTAL SUBJECTS WITH AN EVENT (A)	108 (87.8)	104 (81.3)	1.08 (0.97, 1.20) 0.1619	1.64 (0.78, 3.53) 0.1712	6.47 (-2.51, 15.44) 0.1580
CARDIAC DISORDERS	30 (24.4)	34 (26.6)	0.91 (0.59, 1.39) 0.6505	0.88 (0.48, 1.61) 0.6664	-2.51 (-13.29, 8.28) 0.6490
ATRIAL FIBRILLATION	10 (8.1)	10 (7.8)	1.01 (0.44, 2.32) 0.9807	1.01 (0.36, 2.82) 1.0000	0.08 (-6.57, 6.73) 0.9807
PALPITATIONS	7 (5.7)	10 (7.8)	0.72 (0.28, 1.87) 0.5040	0.71 (0.22, 2.14) 0.6200	-2.15 (-8.34, 4.05) 0.4972
GASTROINTESTINAL DISORDERS	26 (21.1)	26 (20.3)	1.06 (0.65, 1.72) 0.8204	1.07 (0.55, 2.09) 0.8758	1.17 (-8.89, 11.22) 0.8203
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	29 (23.6)	28 (21.9)	1.08 (0.68, 1.72) 0.7462	1.10 (0.58, 2.09) 0.7635	1.72 (-8.59, 12.02) 0.7439

Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
(B) The analysis is stratified on baseline NYHA class, beta blocker use, and exercise type (per IXRS).
(C) Risk ratio /Risk Difference is based on Mantel-Haenszel method. p-value and 95% CI are derived using normal approximation.

(D) Odds ratio is based on Cochran-Mantel-Haenszel method.
95% CI are derived using the exact method. p-value is calculated from the Cochrane-Mantel-Haenszel-Test using the exact method.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ae-teaesoctbin.sas
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Incidence of Treatment-Emergent Adverse Events by SOC/PT
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)(C)	 Odds Ratio (95% CI) p-value (B)(D)	 Risk Difference (95% CI) p-value (B)(C)
INFECTIONS AND INFESTATIONS	48 (39.0)	51 (39.8)	0.98 (0.72, 1.32) 0.8709	0.96 (0.56, 1.64) 0.8978	-1.00 (-13.18, 11.17) 0.8717
NASOPHARYNGITIS	15 (12.2)	19 (14.8)	0.81 (0.44, 1.49) 0.5042	0.78 (0.34, 1.75) 0.5706	-2.81 (-11.04, 5.42) 0.5038
UPPER RESPIRATORY TRACT INFECTION	10 (8.1)	6 (4.7)	1.75 (0.67, 4.58) 0.2539	1.81 (0.58, 6.33) 0.3058	3.58 (-2.58, 9.74) 0.2540
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	14 (11.4)	12 (9.4)	1.19 (0.57, 2.51) 0.6441	1.21 (0.50, 2.99) 0.6846	1.80 (-5.80, 9.40) 0.6423
INVESTIGATIONS	8 (6.5)	14 (10.9)	0.57 (0.25, 1.33) 0.1968	0.55 (0.19, 1.47) 0.2671	-4.71 (-11.65, 2.24) 0.1842
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	40 (32.5)	29 (22.7)	1.43 (0.95, 2.14) 0.0847	1.66 (0.90, 3.03) 0.0884	9.69 (-1.14, 20.51) 0.0795

Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
(B) The analysis is stratified on baseline NYHA class, beta blocker use, and exercise type (per IXRS).
(C) Risk ratio /Risk Difference is based on Mantel-Haenszel method. p-value and 95% CI are derived using normal approximation.
(D) Odds ratio is based on Cochran-Mantel-Haenszel method.
95% CI are derived using the exact method. p-value is calculated from the Cochrane-Mantel-Haenszel-Test using the exact method.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ae-teaesoctbin.sas
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Incidence of Treatment-Emergent Adverse Events by SOC/PT
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)(C)	 Odds Ratio (95% CI) p-value (B)(D)	 Risk Difference (95% CI) p-value (B)(C)
BACK PAIN	10 (8.1)	8 (6.3)	1.26 (0.51, 3.10) 0.6187	1.28 (0.43, 3.91) 0.6323	1.62 (-4.70, 7.93) 0.6157
NERVOUS SYSTEM DISORDERS	46 (37.4)	36 (28.1)	1.32 (0.92, 1.90) 0.1263	1.53 (0.86, 2.70) 0.1368	9.08 (-2.38, 20.53) 0.1204
DIZZINESS	26 (21.1)	17 (13.3)	1.61 (0.91, 2.86) 0.1000	1.76 (0.86, 3.67) 0.0988	8.01 (-1.33, 17.34) 0.0928
HEADACHE	15 (12.2)	10 (7.8)	1.53 (0.71, 3.31) 0.2788	1.59 (0.64, 4.12) 0.3003	4.17 (-3.29, 11.64) 0.2730
PSYCHIATRIC DISORDERS	11 (8.9)	5 (3.9)	2.27 (0.81, 6.40) 0.1201	2.37 (0.74, 9.05) 0.1256	4.99 (-1.11, 11.09) 0.1086
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	36 (29.3)	26 (20.3)	1.44 (0.92, 2.25) 0.1122	1.61 (0.87, 3.03) 0.1087	8.81 (-1.86, 19.48) 0.1056

Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
(B) The analysis is stratified on baseline NYHA class, beta blocker use, and exercise type (per IXRS).
(C) Risk ratio /Risk Difference is based on Mantel-Haenszel method. p-value and 95% CI are derived using normal approximation.
(D) Odds ratio is based on Cochran-Mantel-Haenszel method.
95% CI are derived using the exact method. p-value is calculated from the Cochrane-Mantel-Haenszel-Test using the exact method.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ae-teaesoctbin.sas
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Incidence of Treatment-Emergent Adverse Events by SOC/PT
Safety Analysis (SAF) population

System Organ Class Preferred Term	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)(C)	 Odds Ratio (95% CI) p-value (B)(D)	 Risk Difference (95% CI) p-value (B)(C)
DYSPNOEA	18 (14.6)	13 (10.2)	1.44 (0.72, 2.88) 0.3063	1.49 (0.66, 3.49) 0.3404	4.37 (-3.86, 12.60) 0.2983
COUGH	10 (8.1)	4 (3.1)	2.81 (0.85, 9.22) 0.0892	2.93 (0.79, 12.51) 0.1004	5.21 (-0.45, 10.86) 0.0711
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	10 (8.1)	15 (11.7)	0.68 (0.32, 1.47) 0.3286	0.65 (0.25, 1.65) 0.3975	-3.71 (-11.05, 3.62) 0.3210
VASCULAR DISORDERS	13 (10.6)	10 (7.8)	1.36 (0.62, 2.96) 0.4400	1.42 (0.54, 3.80) 0.5088	2.77 (-4.21, 9.76) 0.4363

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Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
(B) The analysis is stratified on baseline NYHA class, beta blocker use, and exercise type (per IXRS).
(C) Risk ratio /Risk Difference is based on Mantel-Haenszel method. p-value and 95% CI are derived using normal approximation.
(D) Odds ratio is based on Cochran-Mantel-Haenszel method.
95% CI are derived using the exact method. p-value is calculated from the Cochrane-Mantel-Haenszel-Test using the exact method.
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4.11.5 UESI

4.11.5.1 Jegliche UESI

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Incidence of Treatment-Emergent Adverse Events of Special Interest
Safety Analysis (SAF) population

	Mavacamten (N = 123)	Placebo (N = 128)	Mavacamten vs Placebo		
	Patients with event n (%)	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)(C)	Odds Ratio (95% CI) p-value (B)(D)	Risk Difference (95% CI) p-value (B)(C)
TOTAL SUBJECTS WITH AN EVENT (A)	18 (14.6)	29 (22.7)	0.63 (0.38, 1.07) 0.0858	0.55 (0.27, 1.14) 0.0960	-8.34 (-17.56, 0.89) 0.0767
LVEF <= 30%	0	0	NA	NA	NA
OVERDOSE	18 (14.6)	29 (22.7)	0.63 (0.38, 1.07) 0.0858	0.55 (0.27, 1.14) 0.0960	-8.34 (-17.56, 0.89) 0.0767
PREGNANCY	0	0	NA	NA	NA

Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
(B) The analysis is stratified on baseline NYHA class, beta blocker use, and exercise type (per IXRS).
(C) Risk ratio /Risk Difference is based on Mantel-Haenszel method. p-value and 95% CI are derived using normal approximation.
(D) Odds ratio is based on Cochran-Mantel-Haenszel method.
95% CI are derived using the exact method. p-value is calculated from the Cochrane-Mantel-Haenszel-Test using the exact method.
NA= Not Applicable.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ae-teaessoctbin.sas 30AUG2022:07:40

4.11.5.2 Schwere UESI

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Incidence of Treatment-Emergent Adverse Events of Special Interest with Severe Intensity
Safety Analysis (SAF) population

	Mavacamten (N = 123)	Placebo (N = 128)	Mavacamten vs Placebo		
	Patients with event n (%)	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)(C)	Odds Ratio (95% CI) p-value (B)(D)	Risk Difference (95% CI) p-value (B)(C)
TOTAL SUBJECTS WITH AN EVENT (A)	1 (0.8)	5 (3.9)	0.21 (0.02, 1.71) 0.1431	0.19 (0.00, 1.82) 0.2114	-3.13 (-6.84, 0.57) 0.0975
LVEF <= 30%	0	0	NA	NA	NA
OVERDOSE	1 (0.8)	5 (3.9)	0.21 (0.02, 1.71) 0.1431	0.19 (0.00, 1.82) 0.2114	-3.13 (-6.84, 0.57) 0.0975
PREGNANCY	0	0	NA	NA	NA

Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
(B) The analysis is stratified on baseline NYHA class, beta blocker use, and exercise type (per IXRS).
(C) Risk ratio /Risk Difference is based on Mantel-Haenszel method. p-value and 95% CI are derived using normal approximation.
(D) Odds ratio is based on Cochran-Mantel-Haenszel method.
95% CI are derived using the exact method. p-value is calculated from the Cochrane-Mantel-Haenszel-Test using the exact method.
Severe includes severe, life-threatening and fatal.
NA= Not Applicable.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ae-aegr345ssoctbin.sas

4.11.5.3 Schwerwiegende UESI

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Incidence of Serious Treatment-Emergent Adverse Events of Special Interest
Safety Analysis (SAF) population

	Mavacamten (N = 123)	Placebo (N = 128)	Mavacamten vs Placebo		
	Patients with event n (%)	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)(C)	Odds Ratio (95% CI) p-value (B)(D)	Risk Difference (95% CI) p-value (B)(C)
TOTAL SUBJECTS WITH AN EVENT (A)	0	5 (3.9)	0.00 (NE, NE) NE	0.00 (0.00, 0.83) 0.0600	-3.94 (-7.31, -0.57) 0.0221
LVEF <= 30%	0	0	NA	NA	NA
OVERDOSE	0	5 (3.9)	0.00 (NE, NE) NE	0.00 (0.00, 0.83) 0.0600	-3.94 (-7.31, -0.57) 0.0221
PREGNANCY	0	0	NA	NA	NA

Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
(B) The analysis is stratified on baseline NYHA class, beta blocker use, and exercise type (per IXRS).
(C) Risk ratio /Risk Difference is based on Mantel-Haenszel method. p-value and 95% CI are derived using normal approximation.
(D) Odds ratio is based on Cochran-Mantel-Haenszel method.
95% CI are derived using the exact method. p-value is calculated from the Cochrane-Mantel-Haenszel-Test using the exact method.
NA = Not Applicable. NE = Not Estimable.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ae-saessoctbin.sas 30AUG2022:07:41

4.11.6 UE von klinischem Interesse

4.11.6.1 Jegliche UE von klinischem Interesse

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Analysis of Treatment-Emergent Adverse Events of Clinical Interest
Safety Analysis (SAF) population

TEAEs (A) of Clinical Interest	Mavacamten (N = 123) n (%)	Placebo (N = 128) n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)(C)	Odds Ratio (95% CI) p-value (B)(D)	Risk Difference (95% CI) p-value (B)(C)
PATIENTS WITH ANY TEAEs OF CLINICAL INTEREST	53 (43.1)	47 (36.7)	1.17 (0.86, 1.58) 0.3254	1.29 (0.75, 2.20) 0.3678	6.08 (-5.95, 18.10) 0.3221
PATIENTS WITH MAJOR CARDIAC EVENTS (MACE)	2 (1.6)	3 (2.3)	0.69 (0.12, 3.96) 0.6807	0.68 (0.06, 6.15) 1.0000	-0.72 (-4.15, 2.71) 0.6792
PATIENTS WITH ATRIAL FIBRILLATION TEAEs	10 (8.1)	10 (7.8)	1.01 (0.44, 2.32) 0.9807	1.01 (0.36, 2.82) 1.0000	0.08 (-6.57, 6.73) 0.9807
PATIENTS WITH SYNCOPE/PRESYNCOPE (BROAD) TEAEs	30 (24.4)	25 (19.5)	1.26 (0.78, 2.04) 0.3368	1.34 (0.71, 2.56) 0.3638	5.08 (-5.19, 15.34) 0.3323
PATIENTS WITH SYNCOPE/PRESYNCOPE [NARROW] TEAEs	8 (6.5)	7 (5.5)	1.21 (0.45, 3.29) 0.7030	1.23 (0.37, 4.10) 0.7931	1.14 (-4.70, 6.99) 0.7012

Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
(B) The analysis is stratified on baseline NYHA class, beta blocker use, and exercise type (per IXRS).
(C) Risk ratio /Risk Difference is based on Mantel-Haenszel method. p-value and 95% CI are derived using normal approximation.
(D) Odds ratio is based on Cochran-Mantel-Haenszel method.
95% CI are derived using the exact method. p-value is calculated from the Cochrane-Mantel-Haenszel-Test using the exact method.
Non-Severe includes severity of mild or moderate. Severe includes severe, life-threatening and fatal.
NA = Not Applicable. NE = Not Estimable.
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Analysis of Treatment-Emergent Adverse Events of Clinical Interest
Safety Analysis (SAF) population

	Mavacamten (N = 123)	Placebo (N = 128)	Mavacamten vs Placebo		
TEAEs (A) of Clinical Interest	n (%)	n (%)	Risk Ratio (95% CI) p-value (B)(C)	Odds Ratio (95% CI) p-value (B)(D)	Risk Difference (95% CI) p-value (B)(C)
PATIENTS WITH CARDIAC FAILURE TEAEs	3 (2.4)	5 (3.9)	0.57 (0.14, 2.29) 0.4313	0.55 (0.08, 3.03) 0.4818	-1.73 (-5.98, 2.51) 0.4234
PATIENTS WITH QTC PROLONGATION	0	1 (0.8)	0.00 (NE, NE) NE	0.00 (0.00, 19.58) 1.0000	-0.79 (-2.32, 0.75) 0.3142
PATIENTS WITH HEPATIC EVENTS	4 (3.3)	4 (3.1)	1.02 (0.25, 4.23) 0.9789	1.02 (0.19, 5.61) 1.0000	0.06 (-4.31, 4.43) 0.9786
PATIENTS WITH AUTOIMMUNE DISORDERS	1 (0.8)	1 (0.8)	0.91 (0.06, 14.53) 0.9463	0.91 (0.01, 71.36) 1.0000	-0.08 (-2.29, 2.14) 0.9463
PATIENTS WITH DIZZINESS, SYNCOPE/PRESYNCOPE, AND FALL-RELATED AEs	42 (34.1)	30 (23.4)	1.46 (0.97, 2.19) 0.0667	1.69 (0.93, 3.02) 0.0723	10.68 (-0.48, 21.85) 0.0608
PATIENTS WITH RHABDOMYOLYSIS/MYOPATHY	0	0	NA	NA	NA

Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
(B) The analysis is stratified on baseline NYHA class, beta blocker use, and exercise type (per IXRS).
(C) Risk ratio /Risk Difference is based on Mantel-Haenszel method. p-value and 95% CI are derived using normal approximation.
(D) Odds ratio is based on Cochran-Mantel-Haenszel method.
95% CI are derived using the exact method. p-value is calculated from the Cochrane-Mantel-Haenszel-Test using the exact method.
Non-Severe includes severity of mild or moderate. Severe includes severe, life-threatening and fatal.
NA = Not Applicable. NE = Not Estimable.
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4.11.6.2 Schwere UE von klinischem Interesse

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest with Severe Intensity
by Categories
Safety Analysis (SAF) population

	Mavacamten (N = 123)	Placebo (N = 128)	Mavacamten vs Placebo		
TEAEs (A) of Clinical Interest	Patients with event n (%)	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)(C)	Odds Ratio (95% CI) p-value (B)(D)	Risk Difference (95% CI) p-value (B)(C)
PATIENTS WITH ANY TEAEs OF CLINICAL INTEREST WITH SEVERE INTENSITY	7 (5.7)	8 (6.3)	0.89 (0.33, 2.38) 0.8101	0.88 (0.26, 2.86) 1.0000	-0.72 (-6.57, 5.13) 0.8094
PATIENTS WITH MAJOR CARDIAC EVENTS (MACE)	1 (0.8)	2 (1.6)	0.48 (0.04, 5.29) 0.5515	0.46 (0.01, 9.78) 0.6172	-0.81 (-3.39, 1.76) 0.5357
PATIENTS WITH ATRIAL FIBRILLATION TEAEs	3 (2.4)	4 (3.1)	0.75 (0.17, 3.39) 0.7075	0.74 (0.11, 4.52) 1.0000	-0.78 (-4.79, 3.22) 0.7024
PATIENTS WITH SYNCOPE/PRESYNCOPE (BROAD) TEAEs	4 (3.3)	1 (0.8)	4.13 (0.47, 36.26) 0.2001	4.22 (0.41, 209.32) 0.2075	2.47 (-1.03, 5.97) 0.1664
PATIENTS WITH SYNCOPE/PRESYNCOPE [NARROW] TEAEs	3 (2.4)	1 (0.8)	3.08 (0.33, 29.15) 0.3263	3.14 (0.25, 166.53) 0.3646	1.64 (-1.48, 4.77) 0.3032

Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
(B) The analysis is stratified on baseline NYHA class, beta blocker use, and exercise type (per IXRS).
(C) Risk ratio /Risk Difference is based on Mantel-Haenszel method. p-value and 95% CI are derived using normal approximation.
(D) Odds ratio is based on Cochran-Mantel-Haenszel method.
95% CI are derived using the exact method. p-value is calculated from the Cochrane-Mantel-Haenszel-Test using the exact method.
Severe includes severe, life-threatening and fatal.
NA= Not Applicable.
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Incidence of Treatment-Emergent Adverse Events of Clinical Interest with Severe Intensity
by Categories
Safety Analysis (SAF) population

TEAEs (A) of Clinical Interest	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)(C)	Odds Ratio (95% CI) p-value (B)(D)	Risk Difference (95% CI) p-value (B)(C)
PATIENTS WITH CARDIAC FAILURE TEAEs	1 (0.8)	1 (0.8)	0.91 (0.06, 14.53) 0.9463	0.91 (0.01, 71.36) 1.0000	-0.08 (-2.29, 2.14) 0.9463
PATIENTS WITH QTC PROLONGATION	0	0	NA	NA	NA
PATIENTS WITH HEPATIC EVENTS	0	0	NA	NA	NA
PATIENTS WITH AUTOIMMUNE DISORDERS	1 (0.8)	1 (0.8)	0.91 (0.06, 14.53) 0.9463	0.91 (0.01, 71.36) 1.0000	-0.08 (-2.29, 2.14) 0.9463
PATIENTS WITH DIZZINESS, SYNCOPE/PRESYNCOPE, AND FALL-RELATED AEs	4 (3.3)	1 (0.8)	4.13 (0.47, 36.26) 0.2001	4.22 (0.41, 209.32) 0.2075	2.47 (-1.03, 5.97) 0.1664
PATIENTS WITH RHABDOMYOLYSIS/MYOPATHY	0	0	NA	NA	NA

Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
(B) The analysis is stratified on baseline NYHA class, beta blocker use, and exercise type (per IXRS).
(C) Risk ratio /Risk Difference is based on Mantel-Haenszel method. p-value and 95% CI are derived using normal approximation.
(D) Odds ratio is based on Cochran-Mantel-Haenszel method.
95% CI are derived using the exact method. p-value is calculated from the Cochrane-Mantel-Haenszel-Test using the exact method.
Severe includes severe, life-threatening and fatal.
NA= Not Applicable.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ae-aegr345csoctbin.sas 16SEP2022:06:18

4.11.6.3 Schwerwiegende UE von klinischem Interesse

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Incidence of Serious Treatment-Emergent Adverse Events of Clinical Interest by Categories
Safety Analysis (SAF) population

	Mavacamten (N = 123)	Placebo (N = 128)	Mavacamten vs Placebo		
TEAEs (A) of Clinical Interest	Patients with event n (%)	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)(C)	Odds Ratio (95% CI) p-value (B)(D)	Risk Difference (95% CI) p-value (B)(C)
PATIENTS WITH ANY SERIOUS TEAEs OF CLINICAL INTEREST	8 (6.5)	8 (6.3)	1.01 (0.39, 2.65) 0.9813	1.01 (0.32, 3.19) 1.0000	0.07 (-6.04, 6.18) 0.9813
PATIENTS WITH MAJOR CARDIAC EVENTS (MACE)	1 (0.8)	2 (1.6)	0.48 (0.04, 5.29) 0.5515	0.46 (0.01, 9.78) 0.6172	-0.81 (-3.39, 1.76) 0.5357
PATIENTS WITH ATRIAL FIBRILLATION TEAEs	3 (2.4)	5 (3.9)	0.60 (0.14, 2.55) 0.4868	0.59 (0.09, 3.13) 0.7238	-1.57 (-5.87, 2.73) 0.4748
PATIENTS WITH SYNCOPE/PRESYNCOPE (BROAD) TEAEs	3 (2.4)	1 (0.8)	3.08 (0.33, 29.15) 0.3263	3.14 (0.25, 166.53) 0.3646	1.64 (-1.48, 4.77) 0.3032
PATIENTS WITH SYNCOPE/PRESYNCOPE [NARROW] TEAEs	3 (2.4)	1 (0.8)	3.08 (0.33, 29.15) 0.3263	3.14 (0.25, 166.53) 0.3646	1.64 (-1.48, 4.77) 0.3032
PATIENTS WITH CARDIAC FAILURE TEAEs	1 (0.8)	1 (0.8)	0.91 (0.06, 14.53) 0.9463	0.91 (0.01, 71.36) 1.0000	-0.08 (-2.29, 2.14) 0.9463

Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
(B) The analysis is stratified on baseline NYHA class, beta blocker use, and exercise type (per IXRS).
(C) Risk ratio /Risk Difference is based on Mantel-Haenszel method. p-value and 95% CI are derived using normal approximation.
(D) Odds ratio is based on Cochran-Mantel-Haenszel method.
95% CI are derived using the exact method. p-value is calculated from the Cochrane-Mantel-Haenszel-Test using the exact method.
NA= Not Applicable.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ae-saecsoctbin.sas 16SEP2022:06:20

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Incidence of Serious Treatment-Emergent Adverse Events of Clinical Interest by Categories
Safety Analysis (SAF) population

TEAEs (A) of Clinical Interest	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)(C)	Odds Ratio (95% CI) p-value (B)(D)	Risk Difference (95% CI) p-value (B)(C)
PATIENTS WITH QTC PROLONGATION	0	0	NA	NA	NA
PATIENTS WITH HEPATIC EVENTS	0	0	NA	NA	NA
PATIENTS WITH AUTOIMMUNE DISORDERS	1 (0.8)	1 (0.8)	0.91 (0.06, 14.53) 0.9463	0.91 (0.01, 71.36) 1.0000	-0.08 (-2.29, 2.14) 0.9463
PATIENTS WITH DIZZINESS, SYNCOPE/PRESYNCOPE, AND FALL-RELATED AEs	5 (4.1)	1 (0.8)	5.14 (0.61, 43.49) 0.1332	5.25 (0.58, 261.58) 0.1134	3.26 (-0.56, 7.08) 0.0941
PATIENTS WITH RHABDOMYOLYSIS/MYOPATHY	0	0	NA	NA	NA

Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
(B) The analysis is stratified on baseline NYHA class, beta blocker use, and exercise type (per IXRS).
(C) Risk ratio /Risk Difference is based on Mantel-Haenszel method. p-value and 95% CI are derived using normal approximation.
(D) Odds ratio is based on Cochran-Mantel-Haenszel method.
95% CI are derived using the exact method. p-value is calculated from the Cochrane-Mantel-Haenszel-Test using the exact method.
NA= Not Applicable.
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4.11.7 Therapieabbrüche aufgrund von UE nach SOC/PT

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Treatment Emergent Adverse Events Leading to Discontinuation of Study Therapy Summary
Safety Analysis (SAF) population

System Organ Class (%) Preferred Term (%)	Mavacamten (N = 123)			Placebo (N = 128)		
	Any Grade	Non-Severe	Severe	Any Grade	Non-Severe	Severe
TOTAL SUBJECTS WITH AN EVENT	2 (1.6)	0	2 (1.6)	1 (0.8)	0	1 (0.8)
Cardiac disorders	1 (0.8)	0	1 (0.8)	0	0	0
Atrial fibrillation	1 (0.8)	0	1 (0.8)	0	0	0
General disorders and administration site conditions	0	0	0	1 (0.8)	0	1 (0.8)
Sudden death	0	0	0	1 (0.8)	0	1 (0.8)
Nervous system disorders	1 (0.8)	0	1 (0.8)	0	0	0
Syncope	1 (0.8)	0	1 (0.8)	0	0	0

Data Cutoff Date: 30JUN2020.
MedDRA version 21.0 CTC Version 4.0
TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
Non-Severe includes severity of mild or moderate. Severe includes severe, life-threatening, and fatal.
At each level of subject summarization, a subject is counted only once for the most severe event if the subject reported the same event multiple times.
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4.11.8 Subgruppenanalyse für den Endpunkt Verträglichkeit

4.11.8.1 Subgruppenanalyse für schwere UE

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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
PATIENTS WITH ANY TEAEs WITH SEVERE INTENSITY(A)								
OVERALL	123	12 (9.8)	128	14 (10.9)	0.89 (0.43, 1.85) 0.7590	0.88 (0.35, 2.15) 0.8373	-1.18 (-8.71, 6.35) 0.7585	
BETA-BLOCKER USE								0.6690
YES	94	8 (8.5)	95	10 (10.5)	0.81 (0.33, 1.96) 0.6378	0.79 (0.26, 2.35) 0.8051	-2.02 (-10.38, 6.35) 0.6366	
NO	29	4 (13.8)	33	4 (12.1)	1.14 (0.31, 4.15) 0.8447	1.16 (0.19, 6.91) 1.0000	1.67 (-15.11, 18.45) 0.8452	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
Severe includes severe, life-threatening and fatal.
NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
TYPE OF EXERCISE TESTING								0.7198
EXERCISE BICYCLE	55	5 (9.1)	58	5 (8.6)	1.05 (0.32, 3.44) 0.9299	1.06 (0.23, 4.91) 1.0000	0.47 (-10.01, 10.95) 0.9299	
TREADMILL	68	7 (10.3)	70	9 (12.9)	0.80 (0.32, 2.03) 0.6393	0.78 (0.23, 2.52) 0.7916	-2.56 (-13.22, 8.10) 0.6375	
NYHA CLASS								0.7570
CLASS II	88	8 (9.1)	95	9 (9.5)	0.96 (0.39, 2.38) 0.9290	0.96 (0.30, 2.94) 1.0000	-0.38 (-8.79, 8.03) 0.9289	
CLASS III	35	4 (11.4)	33	5 (15.2)	0.75 (0.22, 2.57) 0.6521	0.72 (0.13, 3.75) 0.7304	-3.72 (-19.87, 12.42) 0.6514	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
Severe includes severe, life-threatening and fatal.
NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
Program Source: BMS_GMA\MYK_Pub\HAB21481\Biostatistics\Production\Tables\EBR567\rt-ae-aegr345subtbisub.sas 29AUG2022:09:41

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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CONSENT FOR THE CMR SUBSTUDY								NE
YES	20	0	24	2 (8.3)	NA	NA	NA	
NO	103	12 (11.7)	104	12 (11.5)	1.01 (0.48, 2.14) 0.9799	1.01 (0.39, 2.60) 1.0000	0.11 (-8.61, 8.84) 0.9799	
SEX								0.3133
FEMALE	57	6 (10.5)	45	8 (17.8)	0.59 (0.22, 1.58) 0.2964	0.54 (0.14, 1.97) 0.3870	-7.25 (-20.97, 6.47) 0.3003	
MALE	66	6 (9.1)	83	6 (7.2)	1.26 (0.43, 3.72) 0.6787	1.28 (0.32, 5.06) 0.7661	1.86 (-7.03, 10.76) 0.6816	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
Severe includes severe, life-threatening and fatal.
NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
AGE								0.1129
<= 49	27	4 (14.8)	25	1 (4.0)	3.70 (0.44, 30.94) 0.2267	4.17 (0.37, 213.95) 0.3517	10.81 (-4.63, 26.26) 0.1699	
50 - 64	51	5 (9.8)	63	5 (7.9)	1.24 (0.38, 4.03) 0.7263	1.26 (0.27, 5.83) 0.7505	1.87 (-8.68, 12.41) 0.7285	
>= 65	45	3 (6.7)	40	8 (20.0)	0.33 (0.09, 1.17) 0.0866	0.29 (0.05, 1.33) 0.1046	-13.33 (-27.71, 1.05) 0.0692	
BMI								0.6007
<30	77	6 (7.8)	77	8 (10.4)	0.75 (0.27, 2.06) 0.5768	0.73 (0.20, 2.54) 0.7803	-2.60 (-11.67, 6.47) 0.5747	
>=30	46	6 (13.0)	51	6 (11.8)	1.11 (0.38, 3.20) 0.8486	1.13 (0.28, 4.58) 1.0000	1.28 (-11.87, 14.43) 0.8488	

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The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
Severe includes severe, life-threatening and fatal.
NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
RACE								0.2077
NON-WHITE	8	2 (25.0)	14	1 (7.1)	3.50 (0.37, 32.80) 0.2725	4.33 (0.18, 274.85) 0.5273	17.86 (-15.04, 50.76) 0.2874	
WHITE	115	10 (8.7)	114	13 (11.4)	0.76 (0.35, 1.67) 0.4972	0.74 (0.28, 1.92) 0.5184	-2.71 (-10.49, 5.07) 0.4953	
REGION								0.1153
US	53	7 (13.2)	55	4 (7.3)	1.82 (0.56, 5.85) 0.3172	1.94 (0.46, 9.58) 0.3551	5.93 (-5.48, 17.34) 0.3080	
EX-US	70	5 (7.1)	73	10 (13.7)	0.52 (0.19, 1.45) 0.2118	0.48 (0.12, 1.67) 0.2766	-6.56 (-16.49, 3.37) 0.1957	

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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CALCIUM CHANNEL BLOCKER USE								0.2384
YES	25	4 (16.0)	17	1 (5.9)	2.72 (0.33, 22.28) 0.3510	3.05 (0.26, 159.30) 0.6323	10.12 (-8.09, 28.33) 0.2762	
NO	98	8 (8.2)	111	13 (11.7)	0.70 (0.30, 1.61) 0.3984	0.67 (0.23, 1.84) 0.4914	-3.55 (-11.62, 4.52) 0.3890	
PRESENCE OF HCM PATHOGENIC MUTATION								N.M.E.
PATHOGENIC OR LIKELY PATHOGENIC	28	2 (7.1)	22	2 (9.1)	N.M.E.	N.M.E.	N.M.E.	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	32	2 (6.3)	43	6 (14.0)	N.M.E.	N.M.E.	N.M.E.	
NEGATIVE	30	4 (13.3)	35	1 (2.9)	N.M.E.	N.M.E.	N.M.E.	

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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
TIME FROM DIAGNOSIS OF OHCM (Years)								0.8177
<=5	65	5 (7.7)	55	4 (7.3)	1.06 (0.30, 3.75) 0.9307	1.06 (0.22, 5.65) 1.0000	0.42 (-9.02, 9.86) 0.9306	
>5	58	7 (12.1)	73	10 (13.7)	0.88 (0.36, 2.17) 0.7832	0.86 (0.26, 2.73) 1.0000	-1.63 (-13.14, 9.88) 0.7814	
SEPTAL REDUCTION THERAPY(SRT) HISTORY								NE
YES	11	0	8	1 (12.5)	NA	NA	NA	
NO	112	12 (10.7)	120	13 (10.8)	0.99 (0.47, 2.08) 0.9767	0.99 (0.39, 2.47) 1.0000	-0.12 (-8.10, 7.86) 0.9767	

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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
IMPLANTABLE CARDIOVERTERDEFIBRILLATOR (ICD) IMPLANTED								0.4481
YES	27	3 (11.1)	29	2 (6.9)	1.61 (0.29, 8.91) 0.5848	1.69 (0.18, 21.61) 0.6642	4.21 (-10.80, 19.23) 0.5823	
NO	96	9 (9.4)	99	12 (12.1)	0.77 (0.34, 1.75) 0.5379	0.75 (0.26, 2.06) 0.6459	-2.75 (-11.43, 5.93) 0.5352	
HISTORY OF HYPERTENSION								0.7870
YES	60	4 (6.7)	59	5 (8.5)	0.79 (0.22, 2.79) 0.7100	0.77 (0.15, 3.80) 0.7430	-1.81 (-11.31, 7.70) 0.7093	
NO	63	8 (12.7)	69	9 (13.0)	0.97 (0.40, 2.37) 0.9529	0.97 (0.30, 3.06) 1.0000	-0.35 (-11.78, 11.09) 0.9528	

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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
RESTING LVEF								0.2012
<75%	69	5 (7.2)	70	9 (12.9)	0.56 (0.20, 1.60) 0.2805	0.53 (0.13, 1.89) 0.3989	-5.61 (-15.56, 4.33) 0.2688	
>=75%	54	7 (13.0)	58	5 (8.6)	1.50 (0.51, 4.46) 0.4617	1.58 (0.40, 6.73) 0.5480	4.34 (-7.17, 15.85) 0.4596	
LVOT RESTING PEAK GRADIENT (mmHg)								0.4761
<=50	60	4 (6.7)	67	7 (10.4)	0.64 (0.20, 2.07) 0.4548	0.61 (0.12, 2.57) 0.5376	-3.78 (-13.45, 5.89) 0.4434	
>50	63	8 (12.7)	61	7 (11.5)	1.11 (0.43, 2.87) 0.8347	1.12 (0.33, 3.91) 1.0000	1.22 (-10.25, 12.69) 0.8345	

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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
LVOT RESTING PEAK GRADIENT (mmHg)								0.7299
<=30	35	1 (2.9)	41	2 (4.9)	0.59 (0.06, 6.19) 0.6565	0.57 (0.01, 11.55) 1.0000	-2.02 (-10.62, 6.58) 0.6451	
>30	88	11 (12.5)	87	12 (13.8)	0.91 (0.42, 1.94) 0.8003	0.89 (0.33, 2.36) 0.8266	-1.29 (-11.31, 8.72) 0.8002	
E/E' LATERAL								0.5286
<=14	56	3 (5.4)	67	6 (9.0)	0.60 (0.16, 2.28) 0.4522	0.58 (0.09, 2.87) 0.5080	-3.60 (-12.63, 5.43) 0.4348	
>14	62	8 (12.9)	55	7 (12.7)	1.01 (0.39, 2.61) 0.9773	1.02 (0.30, 3.56) 1.0000	0.18 (-11.96, 12.31) 0.9773	

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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
E/E' SEPTAL								NE
<=14	17	0	28	0	NA	NA	NA	
>14	106	12 (11.3)	99	14 (14.1)	0.80	0.78	-2.82	
					(0.39, 1.65)	(0.31, 1.92)	(-11.96, 6.32)	
					0.5452	0.6752	0.5452	
E/E' AVERAGE								NE
<=14	26	0	33	0	NA	NA	NA	
>14	97	12 (12.4)	95	14 (14.7)	0.84	0.82	-2.37	
					(0.41, 1.72)	(0.32, 2.03)	(-12.05, 7.32)	
					0.6325	0.6773	0.6320	

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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
LEFT ATRIAL VOLUME INDEX								0.6953
<=MEDIAN	60	3 (5.0)	65	5 (7.7)	0.65 (0.16, 2.60) 0.5429	0.63 (0.09, 3.43) 0.7193	-2.69 (-11.20, 5.82) 0.5351	
>MEDIAN	62	8 (12.9)	63	9 (14.3)	0.90 (0.37, 2.19) 0.8218	0.89 (0.28, 2.82) 1.0000	-1.38 (-13.39, 10.63) 0.8215	
NT-PROBNP								0.4355
<=MEDIAN	55	5 (9.1)	68	9 (13.2)	0.69 (0.24, 1.93) 0.4764	0.66 (0.16, 2.36) 0.5741	-4.14 (-15.22, 6.93) 0.4632	
>MEDIAN	65	7 (10.8)	58	5 (8.6)	1.25 (0.42, 3.72) 0.6895	1.28 (0.33, 5.43) 0.7676	2.15 (-8.29, 12.59) 0.6866	

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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
HS-CARDIAC TROPONIN-I								0.9113
<=ULN	88	8 (9.1)	96	11 (11.5)	0.79 (0.33, 1.88) 0.5994	0.77 (0.26, 2.24) 0.6359	-2.37 (-11.12, 6.39) 0.5962	
>ULN	32	3 (9.4)	23	3 (13.0)	0.72 (0.16, 3.25) 0.6678	0.69 (0.08, 5.72) 0.6862	-3.67 (-20.74, 13.40) 0.6736	
E/E' LATERAL >14 OR HS-CARDIACTROPONIN >ULN VS OTHERS								0.7162
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	41	3 (7.3)	55	6 (10.9)	0.67 (0.18, 2.52) 0.5548	0.64 (0.10, 3.27) 0.7283	-3.59 (-15.06, 7.87) 0.5391	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	78	8 (10.3)	62	7 (11.3)	0.91 (0.35, 2.37) 0.8442	0.90 (0.27, 3.11) 1.0000	-1.03 (-11.40, 9.33) 0.8450	

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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

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E/E' SEPTAL >14 OR HS-CARDIACTROPONIN >ULN VS OTHERS								NE
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	14	0	22	0	NA	NA	NA	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	109	12 (11.0)	104	14 (13.5)	0.82 (0.40, 1.68) 0.5855	0.80 (0.32, 1.97) 0.6770	-2.45 (-11.26, 6.35) 0.5852	
E/E' AVERAGE >14 OR HS-CARDIACTROPONIN >ULN VS OTHERS								NE
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	21	0	24	0	NA	NA	NA	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	102	12 (11.8)	100	14 (14.0)	0.84 (0.41, 1.73) 0.6358	0.82 (0.33, 2.03) 0.6786	-2.24 (-11.47, 7.00) 0.6353	

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(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
Severe includes severe, life-threatening and fatal.
NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
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Incidence of Treatment-Emergent Adverse Events with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CREATININE CLEARANCE (CRCL) (mL/min)								NE
<60	14	0	16	0	NA	NA	NA	
>=60	108	12 (11.1)	112	14 (12.5)	0.89 (0.43, 1.83) 0.7499	0.88 (0.35, 2.16) 0.8358	-1.39 (-9.91, 7.13) 0.7494	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
Severe includes severe, life-threatening and fatal.
NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
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4.11.8.2 Subgruppenanalyse für SUE

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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
PATIENTS WITH ANY SERIOUS TEAEs(A)								
OVERALL	123	14 (11.4)	128	12 (9.4)	1.21 (0.58, 2.52) 0.6026	1.24 (0.51, 3.08) 0.6807	2.01 (-5.54, 9.56) 0.6023	
BETA-BLOCKER USE								0.5638
YES	94	11 (11.7)	95	8 (8.4)	1.39 (0.59, 3.30) 0.4559	1.44 (0.50, 4.34) 0.4791	3.28 (-5.29, 11.85) 0.4529	
NO	29	3 (10.3)	33	4 (12.1)	0.85 (0.21, 3.50) 0.8258	0.84 (0.11, 5.47) 1.0000	-1.78 (-17.49, 13.94) 0.8246	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
TYPE OF EXERCISE TESTING								0.0979
EXERCISE BICYCLE	55	9 (16.4)	58	4 (6.9)	2.37 (0.78, 7.26) 0.1300	2.64 (0.68, 12.42) 0.1454	9.47 (-2.29, 21.22) 0.1144	
TREADMILL	68	5 (7.4)	70	8 (11.4)	0.64 (0.22, 1.87) 0.4176	0.62 (0.15, 2.28) 0.5622	-4.08 (-13.77, 5.62) 0.4101	
NYHA CLASS								0.1850
CLASS II	88	11 (12.5)	95	7 (7.4)	1.70 (0.69, 4.18) 0.2509	1.80 (0.60, 5.73) 0.3218	5.13 (-3.55, 13.81) 0.2466	
CLASS III	35	3 (8.6)	33	5 (15.2)	0.57 (0.15, 2.18) 0.4082	0.53 (0.08, 3.01) 0.4705	-6.58 (-21.93, 8.77) 0.4009	

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(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CONSENT FOR THE CMR SUBSTUDY								0.5316
YES	20	1 (5.0)	24	2 (8.3)	0.60 (0.06, 6.14) 0.6669	0.58 (0.01, 12.09) 1.0000	-3.33 (-17.95, 11.28) 0.6548	
NO	103	13 (12.6)	104	10 (9.6)	1.31 (0.60, 2.86) 0.4932	1.36 (0.52, 3.64) 0.5157	3.01 (-5.55, 11.56) 0.4912	
SEX								0.0618
FEMALE	57	6 (10.5)	45	8 (17.8)	0.59 (0.22, 1.58) 0.2964	0.54 (0.14, 1.97) 0.3870	-7.25 (-20.97, 6.47) 0.3003	
MALE	66	8 (12.1)	83	4 (4.8)	2.52 (0.79, 7.99) 0.1178	2.72 (0.69, 12.88) 0.1333	7.30 (-1.82, 16.42) 0.1167	

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(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
AGE								0.0706
<= 49	27	6 (22.2)	25	1 (4.0)	5.56 (0.72, 42.98) 0.1004	6.86 (0.72, 328.26) 0.1013	18.22 (0.76, 35.68) 0.0408	
50 - 64	51	5 (9.8)	63	4 (6.3)	1.54 (0.44, 5.45) 0.4998	1.60 (0.32, 8.52) 0.5107	3.45 (-6.69, 13.60) 0.5044	
>= 65	45	3 (6.7)	40	7 (17.5)	0.38 (0.11, 1.38) 0.1406	0.34 (0.05, 1.64) 0.1792	-10.83 (-24.68, 3.01) 0.1252	
BMI								0.8466
<30	77	9 (11.7)	77	7 (9.1)	1.29 (0.50, 3.28) 0.5987	1.32 (0.41, 4.43) 0.7926	2.60 (-7.03, 12.23) 0.5970	
>=30	46	5 (10.9)	51	5 (9.8)	1.11 (0.34, 3.59) 0.8632	1.12 (0.24, 5.25) 1.0000	1.07 (-11.08, 13.21) 0.8635	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
RACE								NE
NON-WHITE	8	0	14	1 (7.1)	NA	NA	NA	
WHITE	115	14 (12.2)	114	11 (9.6)	1.26 (0.60, 2.66) 0.5414	1.30 (0.52, 3.32) 0.6725	2.52 (-5.54, 10.59) 0.5396	
REGION								0.8355
US	53	4 (7.5)	55	3 (5.5)	1.38 (0.33, 5.89) 0.6604	1.41 (0.23, 10.12) 0.7135	2.09 (-7.21, 11.40) 0.6594	
EX-US	70	10 (14.3)	73	9 (12.3)	1.16 (0.50, 2.68) 0.7306	1.19 (0.40, 3.54) 0.8079	1.96 (-9.18, 13.10) 0.7306	

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The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CALCIUM CHANNEL BLOCKER USE								0.6186
YES	25	3 (12.0)	17	1 (5.9)	2.04 (0.23, 18.00) 0.5211	2.18 (0.16, 121.58) 0.6355	6.12 (-10.83, 23.07) 0.4794	
NO	98	11 (11.2)	111	11 (9.9)	1.13 (0.51, 2.50) 0.7574	1.15 (0.43, 3.08) 0.8233	1.31 (-7.05, 9.68) 0.7580	
PRESENCE OF HCM PATHOGENIC MUTATION								N.M.E.
PATHOGENIC OR LIKELY PATHOGENIC	28	4 (14.3)	22	1 (4.5)	N.M.E.	N.M.E.	N.M.E.	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	32	2 (6.3)	43	5 (11.6)	N.M.E.	N.M.E.	N.M.E.	
NEGATIVE	30	3 (10.0)	35	1 (2.9)	N.M.E.	N.M.E.	N.M.E.	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
TIME FROM DIAGNOSIS OF OHCM (Years)								0.8912
<=5	65	5 (7.7)	55	3 (5.5)	1.41 (0.35, 5.64) 0.6268	1.44 (0.27, 9.72) 0.7252	2.24 (-6.59, 11.07) 0.6194	
>5	58	9 (15.5)	73	9 (12.3)	1.26 (0.53, 2.97) 0.5989	1.31 (0.42, 4.02) 0.6188	3.19 (-8.80, 15.18) 0.6022	
SEPTAL REDUCTION THERAPY(SRT)								NE
HISTORY								
YES	11	1 (9.1)	8	0	NA	NA	NA	
NO	112	13 (11.6)	120	12 (10.0)	1.16 (0.55, 2.44) 0.6935	1.18 (0.47, 2.98) 0.8327	1.61 (-6.39, 9.61) 0.6938	

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(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
IMPLANTABLE CARDIOVERTERDEFIBRILLATOR (ICD) IMPLANTED								0.4282
YES	27	4 (14.8)	29	2 (6.9)	2.15 (0.43, 10.79) 0.3533	2.35 (0.30, 27.77) 0.4141	7.92 (-8.35, 24.19) 0.3401	
NO	96	10 (10.4)	99	10 (10.1)	1.03 (0.45, 2.37) 0.9421	1.03 (0.37, 2.92) 1.0000	0.32 (-8.20, 8.83) 0.9421	
HISTORY OF HYPERTENSION								0.2021
YES	60	2 (3.3)	59	4 (6.8)	0.49 (0.09, 2.58) 0.4016	0.47 (0.04, 3.48) 0.4390	-3.45 (-11.31, 4.41) 0.3901	
NO	63	12 (19.0)	69	8 (11.6)	1.64 (0.72, 3.76) 0.2393	1.79 (0.62, 5.46) 0.3313	7.45 (-4.84, 19.75) 0.2346	

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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
RESTING LVEF								0.0897
<75%	69	5 (7.2)	70	8 (11.4)	0.63 (0.22, 1.84) 0.4025	0.61 (0.15, 2.24) 0.5619	-4.18 (-13.82, 5.46) 0.3953	
>=75%	54	9 (16.7)	58	4 (6.9)	2.42 (0.79, 7.39) 0.1219	2.70 (0.69, 12.70) 0.1426	9.77 (-2.12, 21.66) 0.1072	
LVOT RESTING PEAK GRADIENT (mmHg)								0.8000
<=50	60	6 (10.0)	67	5 (7.5)	1.34 (0.43, 4.17) 0.6131	1.38 (0.33, 6.03) 0.7550	2.54 (-7.32, 12.40) 0.6140	
>50	63	8 (12.7)	61	7 (11.5)	1.11 (0.43, 2.87) 0.8347	1.12 (0.33, 3.91) 1.0000	1.22 (-10.25, 12.69) 0.8345	

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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
LVOT RESTING PEAK GRADIENT (mmHg)								0.6222
<=30	35	3 (8.6)	41	2 (4.9)	1.76 (0.31, 9.93) 0.5234	1.83 (0.20, 22.96) 0.6567	3.69 (-7.69, 15.07) 0.5247	
>30	88	11 (12.5)	87	10 (11.5)	1.09 (0.49, 2.43) 0.8379	1.10 (0.40, 3.07) 1.0000	1.01 (-8.62, 10.63) 0.8377	
E/E' LATERAL								0.6852
<=14	56	4 (7.1)	67	5 (7.5)	0.96 (0.27, 3.39) 0.9459	0.95 (0.18, 4.69) 1.0000	-0.32 (-9.54, 8.90) 0.9458	
>14	62	9 (14.5)	55	6 (10.9)	1.33 (0.51, 3.50) 0.5626	1.39 (0.40, 5.09) 0.5931	3.61 (-8.42, 15.64) 0.5568	

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The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
E/E' SEPTAL								NE
<=14	17	0	28	0	NA	NA	NA	
>14	106	14 (13.2)	99	12 (12.1)	1.09	1.10	1.09	
					(0.53, 2.24)	(0.45, 2.77)	(-8.02, 10.19)	
					0.8154	0.8370	0.8151	
E/E' AVERAGE								NE
<=14	26	1 (3.8)	33	0	NA	NA	NA	
>14	97	13 (13.4)	95	12 (12.6)	1.06	1.07	0.77	
					(0.51, 2.21)	(0.42, 2.73)	(-8.75, 10.29)	
					0.8740	1.0000	0.8739	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
LEFT ATRIAL VOLUME INDEX								0.8074
<=MEDIAN	60	5 (8.3)	65	5 (7.7)	1.08 (0.33, 3.56) 0.8950	1.09 (0.24, 5.01) 1.0000	0.64 (-8.89, 10.17) 0.8951	
>MEDIAN	62	9 (14.5)	63	7 (11.1)	1.31 (0.52, 3.29) 0.5705	1.36 (0.42, 4.61) 0.6031	3.41 (-8.30, 15.11) 0.5687	
NT-PROBNP								0.6928
<=MEDIAN	55	6 (10.9)	68	7 (10.3)	1.06 (0.38, 2.97) 0.9122	1.07 (0.28, 3.98) 1.0000	0.61 (-10.34, 11.57) 0.9124	
>MEDIAN	65	8 (12.3)	58	5 (8.6)	1.43 (0.49, 4.12) 0.5102	1.49 (0.40, 6.14) 0.5683	3.69 (-7.08, 14.46) 0.5022	

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(D) Interaction p value is derived from Cochran's Q heterogeneity test.
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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
HS-CARDIAC TROPONIN-I								0.5543
<=ULN	88	10 (11.4)	96	9 (9.4)	1.21 (0.52, 2.84) 0.6584	1.24 (0.43, 3.64) 0.8092	1.99 (-6.84, 10.82) 0.6589	
>ULN	32	3 (9.4)	23	3 (13.0)	0.72 (0.16, 3.25) 0.6678	0.69 (0.08, 5.72) 0.6862	-3.67 (-20.74, 13.40) 0.6736	
E/E' LATERAL >14 OR HS-CARDIACTROPONIN >ULN VS OTHERS								0.8966
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	41	4 (9.8)	55	5 (9.1)	1.07 (0.31, 3.75) 0.9119	1.08 (0.20, 5.41) 1.0000	0.67 (-11.18, 12.51) 0.9123	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	78	9 (11.5)	62	6 (9.7)	1.19 (0.45, 3.17) 0.7244	1.22 (0.36, 4.42) 0.7891	1.86 (-8.36, 12.08) 0.7211	

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The subgroups by stratification factors were determined using the data in eCRF.
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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
E/E' SEPTAL >14 OR HS-CARDIACTROPONIN >ULN VS OTHERS								NE
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	14	0	22	0	NA	NA	NA	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	109	14 (12.8)	104	12 (11.5)	1.11 (0.54, 2.29) 0.7713	1.13 (0.46, 2.83) 0.8360	1.31 (-7.48, 10.09) 0.7708	
E/E' AVERAGE >14 OR HS-CARDIACTROPONIN >ULN VS OTHERS								NE
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	21	1 (4.8)	24	0	NA	NA	NA	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	102	13 (12.7)	100	12 (12.0)	1.06 (0.51, 2.21) 0.8723	1.07 (0.42, 2.72) 1.0000	0.75 (-8.33, 9.83) 0.8722	

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(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
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Incidence of Serious Treatment-Emergent Adverse Events by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CREATININE CLEARANCE (CRCL) (mL/min)								NE
<60	14	0	16	0	NA	NA	NA	
>=60	108	14 (13.0)	112	12 (10.7)	1.21 (0.59, 2.50) 0.6062	1.24 (0.50, 3.10) 0.6785	2.25 (-6.29, 10.79) 0.6058	

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The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
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4.11.8.3 Subgruppenanalyse für UESI

4.11.8.3.1 Subgruppenanalyse für jegliche UESI

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Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
PATIENTS WITH ANY TEAEs OF SPECIAL INTEREST(A)								
OVERALL	123	18 (14.6)	128	29 (22.7)	0.65 (0.38, 1.10) 0.1083	0.59 (0.29, 1.17) 0.1090	-8.02 (-17.59, 1.55) 0.1004	
BETA-BLOCKER USE								0.2075
YES	94	17 (18.1)	95	23 (24.2)	0.75 (0.43, 1.31) 0.3058	0.69 (0.32, 1.48) 0.3738	-6.13 (-17.73, 5.48) 0.3010	
NO	29	1 (3.4)	33	6 (18.2)	0.19 (0.02, 1.48) 0.1132	0.16 (0.00, 1.50) 0.1090	-14.73 (-29.47, 0.01) 0.0501	

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The subgroups by stratification factors were determined using the data in eCRF.
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Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
TYPE OF EXERCISE TESTING								0.6302
EXERCISE BICYCLE	55	4 (7.3)	58	5 (8.6)	0.84 (0.24, 2.98) 0.7917	0.83 (0.16, 4.11) 1.0000	-1.35 (-11.31, 8.62) 0.7909	
TREADMILL	68	14 (20.6)	70	24 (34.3)	0.60 (0.34, 1.06) 0.0786	0.50 (0.21, 1.14) 0.0873	-13.70 (-28.39, 1.00) 0.0678	
NYHA CLASS								0.4259
CLASS II	88	10 (11.4)	95	20 (21.1)	0.54 (0.27, 1.09) 0.0849	0.48 (0.19, 1.16) 0.1090	-9.69 (-20.23, 0.86) 0.0717	
CLASS III	35	8 (22.9)	33	9 (27.3)	0.84 (0.37, 1.91) 0.6748	0.79 (0.23, 2.74) 0.7819	-4.42 (-25.02, 16.19) 0.6744	

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Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CONSENT FOR THE CMR SUBSTUDY								0.4888
YES	20	2 (10.0)	24	6 (25.0)	0.40 (0.09, 1.77) 0.2269	0.33 (0.03, 2.25) 0.2591	-15.00 (-36.75, 6.75) 0.1764	
NO	103	16 (15.5)	104	23 (22.1)	0.70 (0.39, 1.25) 0.2301	0.65 (0.30, 1.39) 0.2864	-6.58 (-17.19, 4.03) 0.2240	
SEX								0.6505
FEMALE	57	10 (17.5)	45	11 (24.4)	0.72 (0.33, 1.54) 0.3935	0.66 (0.22, 1.93) 0.4630	-6.90 (-22.87, 9.07) 0.3972	
MALE	66	8 (12.1)	83	18 (21.7)	0.56 (0.26, 1.20) 0.1374	0.50 (0.17, 1.32) 0.1360	-9.57 (-21.42, 2.29) 0.1139	

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(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
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Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
AGE								0.5089
<= 49	27	2 (7.4)	25	4 (16.0)	0.46 (0.09, 2.31) 0.3479	0.42 (0.04, 3.32) 0.4109	-8.59 (-26.03, 8.85) 0.3342	
50 - 64	51	4 (7.8)	63	12 (19.0)	0.41 (0.14, 1.20) 0.1040	0.36 (0.08, 1.31) 0.1078	-11.20 (-23.39, 0.98) 0.0715	
>= 65	45	12 (26.7)	40	13 (32.5)	0.82 (0.42, 1.59) 0.5563	0.76 (0.27, 2.14) 0.6364	-5.83 (-25.27, 13.60) 0.5563	
BMI								0.2294
<30	77	10 (13.0)	77	20 (26.0)	0.50 (0.25, 1.00) 0.0490	0.43 (0.16, 1.05) 0.0659	-12.99 (-25.33, -0.65) 0.0392	
>=30	46	8 (17.4)	51	9 (17.6)	0.99 (0.41, 2.34) 0.9736	0.98 (0.30, 3.20) 1.0000	-0.26 (-15.40, 14.89) 0.9736	

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Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
RACE								0.4199
NON-WHITE	8	3 (37.5)	14	5 (35.7)	1.05 (0.34, 3.28) 0.9330	1.08 (0.12, 8.87) 1.0000	1.79 (-40.11, 43.68) 0.9334	
WHITE	115	15 (13.0)	114	24 (21.1)	0.62 (0.34, 1.12) 0.1122	0.56 (0.26, 1.20) 0.1167	-8.01 (-17.70, 1.68) 0.1052	
REGION								0.3424
US	53	7 (13.2)	55	15 (27.3)	0.48 (0.21, 1.09) 0.0808	0.41 (0.13, 1.20) 0.0945	-14.07 (-28.95, 0.82) 0.0641	
EX-US	70	11 (15.7)	73	14 (19.2)	0.82 (0.40, 1.68) 0.5868	0.79 (0.30, 2.04) 0.6625	-3.46 (-15.88, 8.96) 0.5846	

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Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CALCIUM CHANNEL BLOCKER USE								0.1732
YES	25	1 (4.0)	17	4 (23.5)	0.17 (0.02, 1.39) 0.0986	0.14 (0.00, 1.63) 0.1397	-19.53 (-41.11, 2.05) 0.0761	
NO	98	17 (17.3)	111	25 (22.5)	0.77 (0.44, 1.34) 0.3548	0.72 (0.34, 1.51) 0.3902	-5.18 (-15.97, 5.62) 0.3475	
PRESENCE OF HCM PATHOGENIC MUTATION								0.6209
PATHOGENIC OR LIKELY PATHOGENIC	28	3 (10.7)	22	3 (13.6)	0.79 (0.18, 3.52) 0.7526	0.76 (0.09, 6.36) 1.0000	-2.92 (-21.28, 15.43) 0.7550	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	32	7 (21.9)	43	8 (18.6)	1.18 (0.48, 2.91) 0.7259	1.23 (0.33, 4.44) 0.7759	3.27 (-15.18, 21.72) 0.7283	
NEGATIVE	30	4 (13.3)	35	8 (22.9)	0.58 (0.19, 1.75) 0.3354	0.52 (0.10, 2.25) 0.3587	-9.52 (-28.00, 8.96) 0.3124	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
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Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
TIME FROM DIAGNOSIS OF OHCM (Years)								0.8177
<=5	65	8 (12.3)	55	11 (20.0)	0.62 (0.27, 1.42) 0.2555	0.56 (0.18, 1.69) 0.3177	-7.69 (-20.94, 5.56) 0.2551	
>5	58	10 (17.2)	73	18 (24.7)	0.70 (0.35, 1.40) 0.3108	0.64 (0.24, 1.63) 0.3918	-7.42 (-21.28, 6.45) 0.2945	
SEPTAL REDUCTION THERAPY (SRT) HISTORY								NE
YES	11	1 (9.1)	8	0	NA	NA	NA	
NO	112	17 (15.2)	120	29 (24.2)	0.63 (0.37, 1.08) 0.0917	0.56 (0.27, 1.14) 0.1003	-8.99 (-19.13, 1.15) 0.0823	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
NA = Not Applicable. NE = Not Estimable.
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Protocol: MYK-461-005

Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED								0.1473
YES	27	6 (22.2)	29	5 (17.2)	1.29 (0.44, 3.74) 0.6404	1.37 (0.30, 6.55) 0.7425	4.98 (-15.87, 25.84) 0.6397	
NO	96	12 (12.5)	99	24 (24.2)	0.52 (0.27, 0.97) 0.0404	0.45 (0.19, 1.01) 0.0424	-11.74 (-22.47, -1.02) 0.0319	
HISTORY OF HYPERTENSION								0.8663
YES	60	10 (16.7)	59	16 (27.1)	0.61 (0.30, 1.24) 0.1751	0.54 (0.20, 1.42) 0.1891	-10.45 (-25.20, 4.30) 0.1649	
NO	63	8 (12.7)	69	13 (18.8)	0.67 (0.30, 1.52) 0.3408	0.63 (0.21, 1.79) 0.3537	-6.14 (-18.50, 6.22) 0.3300	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
NA = Not Applicable. NE = Not Estimable.
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Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
RESTING LVEF								0.7404
<75%	69	10 (14.5)	70	17 (24.3)	0.60 (0.29, 1.21) 0.1523	0.53 (0.20, 1.35) 0.1982	-9.79 (-22.83, 3.24) 0.1409	
>=75%	54	8 (14.8)	58	12 (20.7)	0.72 (0.32, 1.62) 0.4214	0.67 (0.22, 1.97) 0.4668	-5.87 (-19.96, 8.21) 0.4137	
LVOT RESTING PEAK GRADIENT (mmHg)								0.3977
<=50	60	6 (10.0)	67	14 (20.9)	0.48 (0.20, 1.17) 0.1049	0.42 (0.12, 1.28) 0.1421	-10.90 (-23.24, 1.45) 0.0837	
>50	63	12 (19.0)	61	15 (24.6)	0.77 (0.40, 1.52) 0.4567	0.72 (0.28, 1.85) 0.5174	-5.54 (-20.06, 8.98) 0.4543	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
NA = Not Applicable. NE = Not Estimable.
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Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
LVOT RESTING PEAK GRADIENT (mmHg)								0.3455
<=30	35	4 (11.4)	41	11 (26.8)	0.43 (0.15, 1.22) 0.1118	0.35 (0.07, 1.37) 0.1475	-15.40 (-32.58, 1.78) 0.0789	
>30	88	14 (15.9)	87	18 (20.7)	0.77 (0.41, 1.45) 0.4155	0.73 (0.31, 1.68) 0.4402	-4.78 (-16.22, 6.66) 0.4127	
E/E' LATERAL								0.0352*
<=14	56	3 (5.4)	67	15 (22.4)	0.24 (0.07, 0.78) 0.0183	0.20 (0.03, 0.76) 0.0096	-17.03 (-28.62, -5.44) 0.0040	
>14	62	15 (24.2)	55	13 (23.6)	1.02 (0.54, 1.96) 0.9438	1.03 (0.40, 2.66) 1.0000	0.56 (-14.93, 16.04) 0.9438	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
NA = Not Applicable. NE = Not Estimable.
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Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
E/E' SEPTAL								0.5221
<=14	17	1 (5.9)	28	5 (17.9)	0.33 (0.04, 2.59) 0.2909	0.29 (0.01, 3.00) 0.3846	-11.97 (-30.04, 6.09) 0.1939	
>14	106	17 (16.0)	99	24 (24.2)	0.66 (0.38, 1.16) 0.1465	0.60 (0.28, 1.26) 0.1640	-8.20 (-19.16, 2.75) 0.1422	
E/E' AVERAGE								0.1842
<=14	26	1 (3.8)	33	7 (21.2)	0.18 (0.02, 1.38) 0.0994	0.15 (0.00, 1.33) 0.0668	-17.37 (-33.15, -1.58) 0.0311	
>14	97	17 (17.5)	95	22 (23.2)	0.76 (0.43, 1.33) 0.3347	0.71 (0.32, 1.52) 0.3726	-5.63 (-17.00, 5.73) 0.3315	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
NA = Not Applicable. NE = Not Estimable.
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Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
LEFT ATRIAL VOLUME INDEX								0.3886
<=MEDIAN	60	8 (13.3)	65	10 (15.4)	0.87 (0.37, 2.05) 0.7446	0.85 (0.27, 2.60) 0.8029	-2.05 (-14.34, 10.23) 0.7435	
>MEDIAN	62	10 (16.1)	63	19 (30.2)	0.53 (0.27, 1.06) 0.0716	0.45 (0.17, 1.14) 0.0894	-14.03 (-28.60, 0.54) 0.0591	
NT-PROBNP								0.3432
<=MEDIAN	55	5 (9.1)	68	14 (20.6)	0.44 (0.17, 1.15) 0.0942	0.39 (0.10, 1.25) 0.1307	-11.50 (-23.75, 0.75) 0.0659	
>MEDIAN	65	13 (20.0)	58	15 (25.9)	0.77 (0.40, 1.49) 0.4403	0.72 (0.28, 1.82) 0.5201	-5.86 (-20.75, 9.02) 0.4402	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
NA = Not Applicable. NE = Not Estimable.
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Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
HS-CARDIAC TROPONIN-I								0.5971
<=ULN	88	14 (15.9)	96	24 (25.0)	0.64 (0.35, 1.15) 0.1347	0.57 (0.25, 1.25) 0.1471	-9.09 (-20.64, 2.46) 0.1229	
>ULN	32	4 (12.5)	23	3 (13.0)	0.96 (0.24, 3.88) 0.9524	0.95 (0.14, 7.23) 1.0000	-0.54 (-18.45, 17.37) 0.9526	
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.0638
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	41	2 (4.9)	55	13 (23.6)	0.21 (0.05, 0.86) 0.0309	0.17 (0.02, 0.82) 0.0206	-18.76 (-31.78, -5.74) 0.0047	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	78	16 (20.5)	62	14 (22.6)	0.91 (0.48, 1.71) 0.7669	0.88 (0.36, 2.17) 0.8369	-2.07 (-15.80, 11.67) 0.7679	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
NA = Not Applicable. NE = Not Estimable.
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Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.4781
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	14	1 (7.1)	22	5 (22.7)	0.31 (0.04, 2.42) 0.2661	0.26 (0.01, 2.86) 0.3705	-15.58 (-37.69, 6.52) 0.1670	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	109	17 (15.6)	104	24 (23.1)	0.68 (0.39, 1.18) 0.1705	0.62 (0.29, 1.30) 0.2234	-7.48 (-18.06, 3.10) 0.1659	
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.2908
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	21	1 (4.8)	24	5 (20.8)	0.23 (0.03, 1.80) 0.1614	0.19 (0.00, 1.99) 0.1927	-16.07 (-34.70, 2.56) 0.0908	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	102	17 (16.7)	100	23 (23.0)	0.72 (0.41, 1.27) 0.2621	0.67 (0.31, 1.42) 0.2921	-6.33 (-17.30, 4.64) 0.2578	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
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Incidence of Treatment-Emergent Adverse Events of Special Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95 %CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CREATININE CLEARANCE (CRCL) (mL/min)								0.2407
<60	14	5 (35.7)	16	5 (31.3)	1.14 (0.42, 3.14) 0.7957	1.22 (0.20, 7.26) 1.0000	4.46 (-29.39, 38.31) 0.7960	
>=60	108	13 (12.0)	112	24 (21.4)	0.56 (0.30, 1.05) 0.0687	0.50 (0.22, 1.10) 0.0725	-9.39 (-19.16, 0.38) 0.0595	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
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4.11.8.3.2 Subgruppenanalyse für schwere UESI

Subgruppenanalysen für schwere UESI wurden nicht berechnet, da ≥ 10 Ereignisse in maximal einer Subgruppe auftraten.

4.11.8.3.1 Subgruppenanalyse für schwerwiegende UESI

Subgruppenanalysen für schwerwiegende UESI wurden nicht berechnet, da ≥ 10 Ereignisse in maximal einer Subgruppe auftraten.

4.11.8.4 Subgruppenanalyse für UE von klinischem Interesse

4.11.8.4.1 Subgruppenanalyse für jegliche UE von klinischem Interesse

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
Treatment Emergent Adverse event (TEAE)	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
PATIENTS WITH ANY TEAEs OF CLINICAL INTEREST(A)								
OVERALL	123	53 (43.1)	128	47 (36.7)	1.17 (0.87, 1.59) 0.3038	1.30 (0.76, 2.24) 0.3667	6.37 (-5.73, 18.47) 0.3020	
BETA-BLOCKER USE								0.3179
YES	94	43 (45.7)	95	34 (35.8)	1.28 (0.90, 1.81) 0.1667	1.51 (0.81, 2.83) 0.1843	9.96 (-3.99, 23.90) 0.1616	
NO	29	10 (34.5)	33	13 (39.4)	0.88 (0.45, 1.69) 0.6909	0.81 (0.25, 2.57) 0.7943	-4.91 (-28.94, 19.11) 0.6887	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
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Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
TYPE OF EXERCISE TESTING								0.8288
EXERCISE BICYCLE	55	22 (40.0)	58	19 (32.8)	1.22 (0.75, 1.99) 0.4250	1.37 (0.59, 3.17) 0.4410	7.24 (-10.47, 24.95) 0.4228	
TREADMILL	68	31 (45.6)	70	28 (40.0)	1.14 (0.77, 1.68) 0.5078	1.26 (0.61, 2.61) 0.6060	5.59 (-10.90, 22.08) 0.5065	
NYHA CLASS								0.6911
CLASS II	88	36 (40.9)	95	32 (33.7)	1.21 (0.83, 1.77) 0.3133	1.36 (0.72, 2.60) 0.3593	7.22 (-6.77, 21.22) 0.3116	
CLASS III	35	17 (48.6)	33	15 (45.5)	1.07 (0.64, 1.77) 0.7972	1.13 (0.39, 3.27) 0.8130	3.12 (-20.61, 26.84) 0.7968	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
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Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CONSENT FOR THE CMR SUBSTUDY								0.4517
YES	20	9 (45.0)	24	7 (29.2)	1.54 (0.70, 3.40) 0.2818	1.99 (0.48, 8.30) 0.3520	15.83 (-12.56, 44.22) 0.2744	
NO	103	44 (42.7)	104	40 (38.5)	1.11 (0.80, 1.55) 0.5334	1.19 (0.66, 2.16) 0.5727	4.26 (-9.11, 17.62) 0.5325	
SEX								0.0087*
FEMALE	57	19 (33.3)	45	21 (46.7)	0.71 (0.44, 1.16) 0.1713	0.57 (0.24, 1.38) 0.2210	-13.33 (-32.37, 5.70) 0.1697	
MALE	66	34 (51.5)	83	26 (31.3)	1.64 (1.11, 2.44) 0.0136	2.33 (1.13, 4.81) 0.0183	20.19 (4.54, 35.84) 0.0115	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
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Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
AGE								0.9602
<= 49	27	11 (40.7)	25	8 (32.0)	1.27 (0.61, 2.64) 0.5170	1.46 (0.41, 5.35) 0.5737	8.74 (-17.29, 34.78) 0.5105	
50 - 64	51	20 (39.2)	63	22 (34.9)	1.12 (0.69, 1.81) 0.6357	1.20 (0.52, 2.77) 0.6981	4.30 (-13.54, 22.13) 0.6369	
>= 65	45	22 (48.9)	40	17 (42.5)	1.15 (0.72, 1.84) 0.5577	1.29 (0.50, 3.33) 0.6637	6.39 (-14.78, 27.55) 0.5541	
BMI								0.4376
<30	77	32 (41.6)	77	30 (39.0)	1.07 (0.73, 1.57) 0.7426	1.11 (0.56, 2.23) 0.8696	2.60 (-12.89, 18.08) 0.7424	
>=30	46	21 (45.7)	51	17 (33.3)	1.37 (0.83, 2.26) 0.2177	1.68 (0.68, 4.15) 0.2977	12.32 (-7.04, 31.67) 0.2122	

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
RACE								0.3968
NON-WHITE	8	7 (87.5)	14	8 (57.1)	1.53 (0.91, 2.59) 0.1109	5.25 (0.42, 275.32) 0.1932	30.36 (-4.24, 64.96) 0.0855	
WHITE	115	46 (40.0)	114	39 (34.2)	1.17 (0.83, 1.64) 0.3660	1.28 (0.72, 2.28) 0.4125	5.79 (-6.70, 18.28) 0.3636	
REGION								0.5823
US	53	26 (49.1)	55	21 (38.2)	1.28 (0.83, 1.98) 0.2577	1.56 (0.68, 3.60) 0.3319	10.87 (-7.73, 29.48) 0.2518	
EX-US	70	27 (38.6)	73	26 (35.6)	1.08 (0.71, 1.66) 0.7146	1.14 (0.54, 2.37) 0.7323	2.95 (-12.88, 18.79) 0.7145	

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Protocol: MYK-461-005

Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CALCIUM CHANNEL BLOCKER USE								0.8281
YES	25	8 (32.0)	17	5 (29.4)	1.09 (0.43, 2.76) 0.8592	1.13 (0.25, 5.53) 1.0000	2.59 (-25.76, 30.93) 0.8580	
NO	98	45 (45.9)	111	42 (37.8)	1.21 (0.88, 1.67) 0.2372	1.39 (0.77, 2.52) 0.2622	8.08 (-5.29, 21.45) 0.2362	
PRESENCE OF HCM PATHOGENIC MUTATION								0.7853
PATHOGENIC OR LIKELY PATHOGENIC	28	11 (39.3)	22	8 (36.4)	1.08 (0.53, 2.22) 0.8332	1.13 (0.31, 4.23) 1.0000	2.92 (-24.12, 29.96) 0.8323	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	32	13 (40.6)	43	15 (34.9)	1.16 (0.65, 2.09) 0.6097	1.28 (0.45, 3.63) 0.6370	5.74 (-16.45, 27.93) 0.6121	
NEGATIVE	30	15 (50.0)	35	12 (34.3)	1.46 (0.82, 2.61) 0.2037	1.92 (0.63, 5.87) 0.2186	15.71 (-8.11, 39.53) 0.1960	

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
TIME FROM DIAGNOSIS OF OHCM (Years)								0.7316
<=5	65	24 (36.9)	55	18 (32.7)	1.13 (0.69, 1.85) 0.6326	1.20 (0.53, 2.76) 0.7026	4.20 (-12.88, 21.27) 0.6300	
>5	58	29 (50.0)	73	29 (39.7)	1.26 (0.86, 1.84) 0.2382	1.52 (0.71, 3.23) 0.2890	10.27 (-6.80, 27.35) 0.2383	
SEPTAL REDUCTION THERAPY (SRT) HISTORY								0.5913
YES	11	5 (45.5)	8	4 (50.0)	0.91 (0.35, 2.35) 0.8438	0.83 (0.09, 7.33) 1.0000	-4.55 (-50.00, 40.91) 0.8446	
NO	112	48 (42.9)	120	43 (35.8)	1.20 (0.87, 1.65) 0.2745	1.34 (0.77, 2.36) 0.2849	7.02 (-5.53, 19.58) 0.2728	

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The subgroups by stratification factors were determined using the data in eCRF.
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Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED								0.7628
YES	27	11 (40.7)	29	11 (37.9)	1.07 (0.56, 2.06) 0.8296	1.13 (0.34, 3.76) 1.0000	2.81 (-22.79, 28.41) 0.8297	
NO	96	42 (43.8)	99	36 (36.4)	1.20 (0.85, 1.70) 0.2941	1.36 (0.74, 2.52) 0.3094	7.39 (-6.33, 21.11) 0.2914	
HISTORY OF HYPERTENSION								0.4835
YES	60	28 (46.7)	59	21 (35.6)	1.31 (0.85, 2.03) 0.2244	1.58 (0.71, 3.53) 0.2651	11.07 (-6.49, 28.64) 0.2167	
NO	63	25 (39.7)	69	26 (37.7)	1.05 (0.69, 1.62) 0.8135	1.09 (0.51, 2.33) 0.8591	2.00 (-14.63, 18.64) 0.8136	

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(D) Interaction p value is derived from Cochran's Q heterogeneity test.
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Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
RESTING LVEF								0.7960
<75%	69	30 (43.5)	70	25 (35.7)	1.22 (0.80, 1.84) 0.3514	1.38 (0.66, 2.90) 0.3885	7.76 (-8.45, 23.98) 0.3479	
>=75%	54	23 (42.6)	58	22 (37.9)	1.12 (0.71, 1.76) 0.6152	1.21 (0.53, 2.77) 0.7007	4.66 (-13.50, 22.82) 0.6149	
LVOT RESTING PEAK GRADIENT (mmHg)								0.6578
<=50	60	27 (45.0)	67	24 (35.8)	1.26 (0.82, 1.92) 0.2932	1.47 (0.68, 3.18) 0.3650	9.18 (-7.86, 26.22) 0.2910	
>50	63	26 (41.3)	61	23 (37.7)	1.09 (0.71, 1.69) 0.6852	1.16 (0.53, 2.54) 0.7164	3.56 (-13.63, 20.76) 0.6845	

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
LVOT RESTING PEAK GRADIENT (mmHg)								0.2659
<=30	35	17 (48.6)	41	13 (31.7)	1.53 (0.87, 2.69) 0.1383	2.03 (0.72, 5.75) 0.1618	16.86 (-4.98, 38.71) 0.1302	
>30	88	36 (40.9)	87	34 (39.1)	1.05 (0.73, 1.51) 0.8051	1.08 (0.56, 2.07) 0.8777	1.83 (-12.69, 16.34) 0.8050	
E/E' LATERAL								0.1028
<=14	56	19 (33.9)	67	26 (38.8)	0.87 (0.54, 1.40) 0.5781	0.81 (0.36, 1.81) 0.7072	-4.88 (-21.90, 12.15) 0.5745	
>14	62	32 (51.6)	55	19 (34.5)	1.49 (0.97, 2.31) 0.0713	2.02 (0.90, 4.57) 0.0923	17.07 (-0.61, 34.75) 0.0585	

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
E/E' SEPTAL								0.8665
<=14	17	6 (35.3)	28	9 (32.1)	1.10 (0.47, 2.54) 0.8271	1.15 (0.26, 4.85) 1.0000	3.15 (-25.40, 31.70) 0.8287	
>14	106	47 (44.3)	99	37 (37.4)	1.19 (0.85, 1.65) 0.3136	1.33 (0.74, 2.43) 0.3236	6.97 (-6.46, 20.39) 0.3092	
E/E' AVERAGE								0.3452
<=14	26	9 (34.6)	33	13 (39.4)	0.88 (0.45, 1.73) 0.7081	0.81 (0.24, 2.68) 0.7898	-4.78 (-29.52, 19.97) 0.7051	
>14	97	44 (45.4)	95	34 (35.8)	1.27 (0.90, 1.79) 0.1804	1.49 (0.80, 2.77) 0.1890	9.57 (-4.25, 23.39) 0.1747	

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
LEFT ATRIAL VOLUME INDEX								0.7142
<=MEDIAN	60	25 (41.7)	65	22 (33.8)	1.23 (0.78, 1.94) 0.3684	1.40 (0.63, 3.08) 0.4601	7.82 (-9.15, 24.79) 0.3664	
>MEDIAN	62	27 (43.5)	63	25 (39.7)	1.10 (0.72, 1.66) 0.6613	1.17 (0.54, 2.54) 0.7183	3.87 (-13.40, 21.14) 0.6609	
NT-PROBNP								0.3543
<=MEDIAN	55	26 (47.3)	68	23 (33.8)	1.40 (0.91, 2.16) 0.1306	1.75 (0.79, 3.88) 0.1425	13.45 (-3.89, 30.79) 0.1284	
>MEDIAN	65	27 (41.5)	58	23 (39.7)	1.05 (0.68, 1.61) 0.8321	1.08 (0.49, 2.37) 0.8560	1.88 (-15.50, 19.26) 0.8318	

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(D) Interaction p value is derived from Cochran's Q heterogeneity test.
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Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
HS-CARDIAC TROPONIN-I								0.6328
<=ULN	88	35 (39.8)	96	31 (32.3)	1.23 (0.84, 1.81) 0.2917	1.38 (0.72, 2.65) 0.3561	7.48 (-6.38, 21.34) 0.2900	
>ULN	32	16 (50.0)	23	11 (47.8)	1.05 (0.60, 1.81) 0.8741	1.09 (0.33, 3.64) 1.0000	2.17 (-24.60, 28.95) 0.8736	
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.5252
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	41	13 (31.7)	55	17 (30.9)	1.03 (0.56, 1.87) 0.9334	1.04 (0.39, 2.70) 1.0000	0.80 (-17.96, 19.56) 0.9335	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	78	39 (50.0)	62	24 (38.7)	1.29 (0.88, 1.90) 0.1913	1.58 (0.76, 3.30) 0.2315	11.29 (-5.15, 27.73) 0.1782	

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.9033
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	14	4 (28.6)	22	5 (22.7)	1.26 (0.41, 3.90) 0.6917	1.36 (0.21, 8.03) 0.7115	5.84 (-23.59, 35.28) 0.6972	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	109	49 (45.0)	104	40 (38.5)	1.17 (0.85, 1.61) 0.3390	1.31 (0.73, 2.34) 0.4045	6.49 (-6.72, 19.71) 0.3356	
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.8693
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	21	6 (28.6)	24	6 (25.0)	1.14 (0.43, 3.01) 0.7869	1.20 (0.26, 5.55) 1.0000	3.57 (-22.38, 29.52) 0.7874	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	102	47 (46.1)	100	37 (37.0)	1.25 (0.89, 1.73) 0.1937	1.46 (0.80, 2.66) 0.2019	9.08 (-4.45, 22.61) 0.1885	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
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Incidence of Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CREATININE CLEARANCE (CRCL) (mL/min)								0.0556
<60	14	4 (28.6)	16	9 (56.3)	0.51 (0.20, 1.29) 0.1553	0.31 (0.05, 1.77) 0.1590	-27.68 (-61.60, 6.25) 0.1098	
>=60	108	49 (45.4)	112	38 (33.9)	1.34 (0.96, 1.86) 0.0854	1.62 (0.91, 2.89) 0.0982	11.44 (-1.41, 24.29) 0.0809	

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4.11.8.4.2 Subgruppenanalyse für schwere UE von klinischem Interesse

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest with Severe Intensity by Subgroups
Safety Analysis (SAF) population

	Mavacamten (N = 123)		Placebo (N = 128)		Mavacamten vs Placebo			
Treatment Emergent Adverse event (TEAE)	N	Patients with event n (%)	N	Patients with event n (%)	Risk Ratio (95% CI) p-value (B)	Odds Ratio (95% CI) p-value (C)	Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
PATIENTS WITH ANY TEAEs OF CLINICAL INTEREST WITH SEVERE INTENSITY(A)								
OVERALL	123	7 (5.7)	128	8 (6.3)	0.91 (0.34, 2.44) 0.8519	0.91 (0.27, 2.96) 1.0000	-0.56 (-6.42, 5.30) 0.8517	
BETA-BLOCKER USE								0.3603
YES	94	6 (6.4)	95	5 (5.3)	1.21 (0.38, 3.84) 0.7428	1.23 (0.30, 5.27) 0.7670	1.12 (-5.56, 7.80) 0.7424	
NO	29	1 (3.4)	33	3 (9.1)	0.38 (0.04, 3.45) 0.3894	0.36 (0.01, 4.82) 0.6157	-5.64 (-17.49, 6.20) 0.3505	

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MedDRA version 21.0 CTC Version 4.0
Severe includes severe, life-threatening and fatal. NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
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Incidence of Treatment-Emergent Adverse Events of Clinical Interest with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
TYPE OF EXERCISE TESTING								0.4431
EXERCISE BICYCLE	55	3 (5.5)	58	2 (3.4)	1.58 (0.27, 9.11) 0.6077	1.62 (0.18, 19.97) 0.6736	2.01 (-5.61, 9.63) 0.6058	
TREADMILL	68	4 (5.9)	70	6 (8.6)	0.69 (0.20, 2.33) 0.5454	0.67 (0.13, 2.97) 0.7448	-2.69 (-11.31, 5.93) 0.5409	
NYHA CLASS								N.M.E.
CLASS II	88	4 (4.5)	95	3 (3.2)	N.M.E.	N.M.E.	N.M.E.	
CLASS III	35	3 (8.6)	33	5 (15.2)	N.M.E.	N.M.E.	N.M.E.	
CONSENT FOR THE CMR SUBSTUDY								NE
YES	20	0	24	1 (4.2)	NA	NA	NA	
NO	103	7 (6.8)	104	7 (6.7)	1.01 (0.37, 2.78) 0.9851	1.01 (0.29, 3.52) 1.0000	0.07 (-6.78, 6.91) 0.9851	
SEX								N.M.E.
FEMALE	57	3 (5.3)	45	6 (13.3)	N.M.E.	N.M.E.	N.M.E.	
MALE	66	4 (6.1)	83	2 (2.4)	N.M.E.	N.M.E.	N.M.E.	

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
AGE								N.M.E.
<= 49	27	2 (7.4)	25	1 (4.0)	N.M.E.	N.M.E.	N.M.E.	
50 - 64	51	3 (5.9)	63	3 (4.8)	N.M.E.	N.M.E.	N.M.E.	
>= 65	45	2 (4.4)	40	4 (10.0)	N.M.E.	N.M.E.	N.M.E.	
BMI								N.M.E.
<30	77	3 (3.9)	77	5 (6.5)	N.M.E.	N.M.E.	N.M.E.	
>=30	46	4 (8.7)	51	3 (5.9)	N.M.E.	N.M.E.	N.M.E.	
RACE								NE
NON-WHITE	8	1 (12.5)	14	0	NA	NA	NA	
WHITE	115	6 (5.2)	114	8 (7.0)	0.74 (0.27, 2.07) 0.5713	0.73 (0.20, 2.49) 0.5947	-1.80 (-8.01, 4.41) 0.5696	
REGION								N.M.E.
US	53	4 (7.5)	55	2 (3.6)	N.M.E.	N.M.E.	N.M.E.	
EX-US	70	3 (4.3)	73	6 (8.2)	N.M.E.	N.M.E.	N.M.E.	

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CALCIUM CHANNEL BLOCKER USE								0.8099
YES	25	1 (4.0)	17	1 (5.9)	0.68 (0.05, 10.14) 0.7797	0.67 (0.01, 55.57) 1.0000	-1.88 (-15.45, 11.69) 0.7857	
NO	98	6 (6.1)	111	7 (6.3)	0.97 (0.34, 2.79) 0.9562	0.97 (0.26, 3.50) 1.0000	-0.18 (-6.74, 6.37) 0.9562	
PRESENCE OF HCM PATHOGENIC MUTATION								N.M.E.
PATHOGENIC OR LIKELY PATHOGENIC	28	0	22	1 (4.5)	N.M.E.	N.M.E.	N.M.E.	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	32	2 (6.3)	43	3 (7.0)	N.M.E.	N.M.E.	N.M.E.	
NEGATIVE	30	3 (10.0)	35	0	N.M.E.	N.M.E.	N.M.E.	

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
TIME FROM DIAGNOSIS OF OHCM (Years)								0.4579
<=5	65	2 (3.1)	55	3 (5.5)	0.56 (0.10, 3.26) 0.5220	0.55 (0.04, 5.02) 0.6596	-2.38 (-9.70, 4.95) 0.5246	
>5	58	5 (8.6)	73	5 (6.8)	1.26 (0.38, 4.14) 0.7050	1.28 (0.28, 5.88) 0.7496	1.77 (-7.49, 11.03) 0.7077	
SEPTAL REDUCTION THERAPY (SRT) HISTORY								NE
YES	11	0	8	0	NA	NA	NA	
NO	112	7 (6.3)	120	8 (6.7)	0.94 (0.35, 2.50) 0.8974	0.93 (0.28, 3.06) 1.0000	-0.42 (-6.74, 5.91) 0.8973	
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED								NE
YES	27	0	29	2 (6.9)	NA	NA	NA	
NO	96	7 (7.3)	99	6 (6.1)	1.20 (0.42, 3.45) 0.7309	1.22 (0.34, 4.57) 0.7806	1.23 (-5.78, 8.24) 0.7307	

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
HISTORY OF HYPERTENSION								N.M.E.
YES	60	3 (5.0)	59	3 (5.1)	N.M.E.	N.M.E.	N.M.E.	
NO	63	4 (6.3)	69	5 (7.2)	N.M.E.	N.M.E.	N.M.E.	
RESTING LVEF								N.M.E.
<75%	69	1 (1.4)	70	5 (7.1)	N.M.E.	N.M.E.	N.M.E.	
>=75%	54	6 (11.1)	58	3 (5.2)	N.M.E.	N.M.E.	N.M.E.	
LVOT RESTING PEAK GRADIENT (mmHg)								N.M.E.
<=50	60	2 (3.3)	67	4 (6.0)	N.M.E.	N.M.E.	N.M.E.	
>50	63	5 (7.9)	61	4 (6.6)	N.M.E.	N.M.E.	N.M.E.	
LVOT RESTING PEAK GRADIENT (mmHg)								0.6929
<=30	35	1 (2.9)	41	2 (4.9)	0.59 (0.06, 6.19) 0.6565	0.57 (0.01, 11.55) 1.0000	-2.02 (-10.62, 6.58) 0.6451	
>30	88	6 (6.8)	87	6 (6.9)	0.99 (0.33, 2.95) 0.9836	0.99 (0.25, 3.86) 1.0000	-0.08 (-7.57, 7.41) 0.9836	

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(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
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Incidence of Treatment-Emergent Adverse Events of Clinical Interest with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
E/E' LATERAL								0.9216
<=14	56	2 (3.6)	67	3 (4.5)	0.80 (0.14, 4.61) 0.8005	0.79 (0.06, 7.18) 1.0000	-0.91 (-7.84, 6.03) 0.7980	
>14	62	5 (8.1)	55	5 (9.1)	0.89 (0.27, 2.90) 0.8430	0.88 (0.19, 4.06) 1.0000	-1.03 (-11.21, 9.15) 0.8434	
E/E' SEPTAL								NE
<=14	17	0	28	0	NA	NA	NA	
>14	106	7 (6.6)	99	8 (8.1)	0.82 (0.31, 2.17) 0.6854	0.80 (0.24, 2.65) 0.7909	-1.48 (-8.63, 5.68) 0.6857	
E/E' AVERAGE								NE
<=14	26	0	33	0	NA	NA	NA	
>14	97	7 (7.2)	95	8 (8.4)	0.86 (0.32, 2.27) 0.7561	0.85 (0.25, 2.80) 0.7939	-1.20 (-8.80, 6.39) 0.7560	

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
LEFT ATRIAL VOLUME INDEX								0.7393
<=MEDIAN	60	1 (1.7)	65	2 (3.1)	0.54 (0.05, 5.82) 0.6128	0.53 (0.01, 10.56) 1.0000	-1.41 (-6.71, 3.89) 0.6022	
>MEDIAN	62	5 (8.1)	63	6 (9.5)	0.85 (0.27, 2.63) 0.7737	0.83 (0.19, 3.49) 1.0000	-1.46 (-11.38, 8.46) 0.7732	
NT-PROBNP								N.M.E.
<=MEDIAN	55	3 (5.5)	68	4 (5.9)	N.M.E.	N.M.E.	N.M.E.	
>MEDIAN	65	4 (6.2)	58	4 (6.9)	N.M.E.	N.M.E.	N.M.E.	
HS-CARDIAC TROPONIN-I								0.3995
<=ULN	88	6 (6.8)	96	6 (6.3)	1.09 (0.37, 3.26) 0.8761	1.10 (0.28, 4.28) 1.0000	0.57 (-6.59, 7.72) 0.8763	
>ULN	32	1 (3.1)	23	2 (8.7)	0.36 (0.03, 3.73) 0.3913	0.34 (0.01, 7.03) 0.5652	-5.57 (-18.57, 7.43) 0.4009	

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Incidence of Treatment-Emergent Adverse Events of Clinical Interest with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								0.9129
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	41	2 (4.9)	55	3 (5.5)	0.89 (0.16, 5.11) 0.9000	0.89 (0.07, 8.16) 1.0000	-0.58 (-9.49, 8.34) 0.8992	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	78	5 (6.4)	62	5 (8.1)	0.79 (0.24, 2.62) 0.7063	0.78 (0.17, 3.58) 0.7502	-1.65 (-10.34, 7.03) 0.7090	
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								NE
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	14	0	22	0	NA	NA	NA	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	109	7 (6.4)	104	8 (7.7)	0.83 (0.31, 2.22) 0.7176	0.82 (0.24, 2.71) 0.7926	-1.27 (-8.16, 5.61) 0.7177	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
Severe includes severe, life-threatening and fatal. NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
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Incidence of Treatment-Emergent Adverse Events of Clinical Interest with Severe Intensity by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								NE
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	21	0	24	0	NA	NA	NA	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	102	7 (6.9)	100	8 (8.0)	0.86 (0.32, 2.28) 0.7582	0.85 (0.25, 2.80) 0.7944	-1.14 (-8.37, 6.10) 0.7580	
CREATININE CLEARANCE (CRCL) (mL/min)								NE
<60	14	0	16	0	NA	NA	NA	
>=60	108	7 (6.5)	112	8 (7.1)	0.91 (0.34, 2.42) 0.8458	0.90 (0.27, 2.96) 1.0000	-0.66 (-7.32, 6.00) 0.8456	

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(D) Interaction p value is derived from Cochran's Q heterogeneity test.
MedDRA version 21.0 CTC Version 4.0
Severe includes severe, life-threatening and fatal. NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
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4.11.8.4.3 Subgruppenanalyse für schwerwiegende UE von klinischem Interesse

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Incidence of Serious Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
PATIENTS WITH ANY SERIOUS TEAEs OF CLINICAL INTEREST(A)								
OVERALL	123	8 (6.5)	128	8 (6.3)	1.04 (0.40, 2.69) 0.9344	1.04 (0.33, 3.31) 1.0000	0.25 (-5.79, 6.30) 0.9344	
BETA-BLOCKER USE								NE
YES	94	8 (8.5)	95	5 (5.3)	1.62 (0.55, 4.76) 0.3833	1.67 (0.46, 6.75) 0.4058	3.25 (-3.96, 10.46) 0.3773	
NO	29	0	33	3 (9.1)	NA	NA	NA	
TYPE OF EXERCISE TESTING								N.M.E.
EXERCISE BICYCLE	55	6 (10.9)	58	2 (3.4)	N.M.E.	N.M.E.	N.M.E.	
TREADMILL	68	2 (2.9)	70	6 (8.6)	N.M.E.	N.M.E.	N.M.E.	

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The subgroups by stratification factors were determined using the data in eCRF.
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Incidence of Serious Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) (B)	Interaction p-value for Risk Ratio (D)
NYHA CLASS								N.M.E.
CLASS II	88	6 (6.8)	95	3 (3.2)	N.M.E.	N.M.E.	N.M.E.	
CLASS III	35	2 (5.7)	33	5 (15.2)	N.M.E.	N.M.E.	N.M.E.	
CONSENT FOR THE CMR SUBSTUDY								NE
YES	20	0	24	1 (4.2)	NA	NA	NA	
NO	103	8 (7.8)	104	7 (6.7)	1.15 (0.43, 3.07) 0.7739	1.17 (0.35, 3.94) 0.7956	1.04 (-6.03, 8.10) 0.7737	
SEX								N.M.E.
FEMALE	57	2 (3.5)	45	6 (13.3)	N.M.E.	N.M.E.	N.M.E.	
MALE	66	6 (9.1)	83	2 (2.4)	N.M.E.	N.M.E.	N.M.E.	
AGE								N.M.E.
<= 49	27	4 (14.8)	25	1 (4.0)	N.M.E.	N.M.E.	N.M.E.	
50 - 64	51	3 (5.9)	63	3 (4.8)	N.M.E.	N.M.E.	N.M.E.	
>= 65	45	1 (2.2)	40	4 (10.0)	N.M.E.	N.M.E.	N.M.E.	

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Incidence of Serious Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
BMI								N.M.E.
<30	77	4 (5.2)	77	5 (6.5)	N.M.E.	N.M.E.	N.M.E.	
>=30	46	4 (8.7)	51	3 (5.9)	N.M.E.	N.M.E.	N.M.E.	
RACE								NE
NON-WHITE	8	0	14	0	NA	NA	NA	
WHITE	115	8 (7.0)	114	8 (7.0)	0.99 (0.39, 2.55) 0.9855	0.99 (0.31, 3.15) 1.0000	-0.06 (-6.66, 6.54) 0.9856	
REGION								0.9965
US	53	2 (3.8)	55	2 (3.6)	1.04 (0.15, 7.10) 0.9699	1.04 (0.07, 14.83) 1.0000	0.14 (-6.99, 7.26) 0.9699	
EX-US	70	6 (8.6)	73	6 (8.2)	1.04 (0.35, 3.08) 0.9395	1.05 (0.26, 4.14) 1.0000	0.35 (-8.74, 9.45) 0.9395	

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Incidence of Serious Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
CALCIUM CHANNEL BLOCKER USE								NE
YES	25	0	17	1 (5.9)	NA	NA	NA	
NO	98	8 (8.2)	111	7 (6.3)	1.29 (0.49, 3.44) 0.6047	1.32 (0.40, 4.46) 0.7893	1.86 (-5.20, 8.92) 0.6062	
PRESENCE OF HCM PATHOGENIC MUTATION								N.M.E.
PATHOGENIC OR LIKELY PATHOGENIC	28	1 (3.6)	22	1 (4.5)	N.M.E.	N.M.E.	N.M.E.	
VARIANT OF UNCERTAIN SIGNIFICANCE (VUS)	32	2 (6.3)	43	3 (7.0)	N.M.E.	N.M.E.	N.M.E.	
NEGATIVE	30	3 (10.0)	35	0	N.M.E.	N.M.E.	N.M.E.	
TIME FROM DIAGNOSIS OF OHCM (Years)								0.3554
<=5	65	2 (3.1)	55	3 (5.5)	0.56 (0.10, 3.26) 0.5220	0.55 (0.04, 5.02) 0.6596	-2.38 (-9.70, 4.95) 0.5246	
>5	58	6 (10.3)	73	5 (6.8)	1.51 (0.49, 4.70) 0.4767	1.57 (0.37, 6.86) 0.5362	3.50 (-6.25, 13.24) 0.4821	

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Incidence of Serious Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
SEPTAL REDUCTION THERAPY (SRT) HISTORY								NE
YES	11	0	8	0	NA	NA	NA	
NO	112	8 (7.1)	120	8 (6.7)	1.07 (0.42, 2.76) 0.8863	1.08 (0.34, 3.42) 1.0000	0.48 (-6.06, 7.01) 0.8864	
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) IMPLANTED								0.5382
YES	27	1 (3.7)	29	2 (6.9)	0.54 (0.05, 5.59) 0.6030	0.52 (0.01, 10.66) 1.0000	-3.19 (-14.85, 8.46) 0.5913	
NO	96	7 (7.3)	99	6 (6.1)	1.20 (0.42, 3.45) 0.7309	1.22 (0.34, 4.57) 0.7806	1.23 (-5.78, 8.24) 0.7307	
HISTORY OF HYPERTENSION								0.5140
YES	60	2 (3.3)	59	3 (5.1)	0.66 (0.11, 3.78) 0.6368	0.64 (0.05, 5.86) 0.6794	-1.75 (-8.97, 5.46) 0.6342	
NO	63	6 (9.5)	69	5 (7.2)	1.31 (0.42, 4.10) 0.6375	1.35 (0.32, 5.89) 0.7565	2.28 (-7.21, 11.76) 0.6379	

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Incidence of Serious Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
RESTING LVEF								N.M.E.
<75%	69	2 (2.9)	70	5 (7.1)	N.M.E.	N.M.E.	N.M.E.	
>=75%	54	6 (11.1)	58	3 (5.2)	N.M.E.	N.M.E.	N.M.E.	
LVOT RESTING PEAK GRADIENT (mmHg)								N.M.E.
<=50	60	3 (5.0)	67	4 (6.0)	N.M.E.	N.M.E.	N.M.E.	
>50	63	5 (7.9)	61	4 (6.6)	N.M.E.	N.M.E.	N.M.E.	
LVOT RESTING PEAK GRADIENT (mmHg)								0.8797
<=30	35	2 (5.7)	41	2 (4.9)	1.17 (0.17, 7.89) 0.8708	1.18 (0.08, 17.10) 1.0000	0.84 (-9.29, 10.97) 0.8715	
>30	88	6 (6.8)	87	6 (6.9)	0.99 (0.33, 2.95) 0.9836	0.99 (0.25, 3.86) 1.0000	-0.08 (-7.57, 7.41) 0.9836	
E/E' LATERAL								N.M.E.
<=14	56	4 (7.1)	67	3 (4.5)	N.M.E.	N.M.E.	N.M.E.	
>14	62	4 (6.5)	55	5 (9.1)	N.M.E.	N.M.E.	N.M.E.	

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Incidence of Serious Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
E/E' SEPTAL								NE
<=14	17	0	28	0	NA	NA	NA	
>14	106	8 (7.5)	99	8 (8.1)	0.93	0.93	-0.53	
					(0.36, 2.39)	(0.29, 2.97)	(-7.89, 6.82)	
					0.8868	1.0000	0.8869	
E/E' AVERAGE								NE
<=14	26	1 (3.8)	33	0	NA	NA	NA	
>14	97	7 (7.2)	95	8 (8.4)	0.86	0.85	-1.20	
					(0.32, 2.27)	(0.25, 2.80)	(-8.80, 6.39)	
					0.7561	0.7939	0.7560	
LEFT ATRIAL VOLUME INDEX								0.5408
<=MEDIAN	60	3 (5.0)	65	2 (3.1)	1.63	1.66	1.92	
					(0.28, 9.39)	(0.18, 20.43)	(-5.01, 8.85)	
					0.5876	0.6703	0.5866	
>MEDIAN	62	5 (8.1)	63	6 (9.5)	0.85	0.83	-1.46	
					(0.27, 2.63)	(0.19, 3.49)	(-11.38, 8.46)	
					0.7737	1.0000	0.7732	

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Incidence of Serious Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
NT-PROBNP								N.M.E.
<=MEDIAN	55	3 (5.5)	68	4 (5.9)	N.M.E.	N.M.E.	N.M.E.	
>MEDIAN	65	5 (7.7)	58	4 (6.9)	N.M.E.	N.M.E.	N.M.E.	
HS-CARDIAC TROPONIN-I								0.3340
<=ULN	88	7 (8.0)	96	6 (6.3)	1.27 (0.44, 3.64) 0.6530	1.30 (0.36, 4.87) 0.7760	1.70 (-5.74, 9.15) 0.6536	
>ULN	32	1 (3.1)	23	2 (8.7)	0.36 (0.03, 3.73) 0.3913	0.34 (0.01, 7.03) 0.5652	-5.57 (-18.57, 7.43) 0.4009	
E/E' LATERAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								N.M.E.
RESTING LATERAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	41	4 (9.8)	55	3 (5.5)	N.M.E.	N.M.E.	N.M.E.	
RESTING LATERAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	78	4 (5.1)	62	5 (8.1)	N.M.E.	N.M.E.	N.M.E.	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
(D) Interaction p value is derived from Cochran's Q heterogeneity test.
Severe includes severe, life-threatening and fatal. NE= Not Estimable. NA= Not Applicable. N.M.E.= Non-meaningful Estimate.
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Incidence of Serious Treatment-Emergent Adverse Events of Clinical Interest by Subgroups
Safety Analysis (SAF) population

Treatment Emergent Adverse event (TEAE)	Mavacamten (N = 123) N	Mavacamten (N = 123) Patients with event n (%)	Placebo (N = 128) N	Placebo (N = 128) Patients with event n (%)	Mavacamten vs Placebo Risk Ratio (95% CI) p-value (B)	Mavacamten vs Placebo Odds Ratio (95% CI) p-value (C)	Mavacamten vs Placebo Risk Difference (95% CI) p-value (B)	Interaction p-value for Risk Ratio (D)
E/E' SEPTAL >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								NE
RESTING SEPTAL E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	14	0	22	0	NA	NA	NA	
RESTING SEPTAL E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	109	8 (7.3)	104	8 (7.7)	0.95 (0.37, 2.45) 0.9222	0.95 (0.30, 3.03) 1.0000	-0.35 (-7.44, 6.73) 0.9222	
E/E' AVERAGE >14 OR HS-CARDIAC TROPONIN >ULN VS OTHERS								NE
RESTING AVERAGE E/E' <=14 AND HS-CARDIAC TROPONIN-I <=ULN	21	1 (4.8)	24	0	NA	NA	NA	
RESTING AVERAGE E/E' >14 OR HS-CARDIAC TROPONIN-I >ULN	102	7 (6.9)	100	8 (8.0)	0.86 (0.32, 2.28) 0.7582	0.85 (0.25, 2.80) 0.7944	-1.14 (-8.37, 6.10) 0.7580	
CREATININE CLEARANCE (CRCL) (mL/min)								NE
<60	14	0	16	0	NA	NA	NA	
>=60	108	8 (7.4)	112	8 (7.1)	1.04 (0.40, 2.66) 0.9398	1.04 (0.33, 3.31) 1.0000	0.26 (-6.60, 7.13) 0.9398	

Data Cutoff Date: 30JUN2020. N is the number of subjects within the defined subgroup for the corresponding treatment group.
(A) TEAEs is defined as any AE happened after the first dose of study drug and before the last dose + 56 days.
The subgroups by stratification factors were determined using the data in eCRF.
(B) RR/RD 95% CI and p-value is based on normal approximation.(C) OR 95% CIs and p-value are based on Fisher exact test.
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