A Prospective Registry Study to Assess Real-world Patient Characteristics, Treatment Patterns, and Longitudinal Outcomes in Patients Receiving Mavacamten and Other Treatments for Symptomatic Obstructive Hypertrophic Cardiomyopathy (Obstructive-HCM)

Status: RECRUITING

## Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria \* ≥ 18 years of age at the time of informed consent. \* Willing and able to provide written informed consent form (ICF) and any required privacy authorization prior to the initiation of study procedures (or in those situations where consent cannot be given by participants, consent provided by their legally acceptable representatives) United States Sub-Study \* Diagnosis of obstructive HCM consistent with 2020 American Heart Association/American College of Cardiology (AHA/ACC) guidelines. \* Obstructive HCM is defined clinically by the presence of increased LV wall thickness ≥ 15 mm (or ≥ 13 mm with positive family history of HCM) in a nondilated ventricular chamber that is not solely explained by abnormal loading conditions (eg, another cardiac or systemic disease) and peak LVOT gradient of ≥ 30 mmHq at rest or with provocation. \* Has documented LVEF of ≥ 55% recorded by echocardiography within the last 6 months. \* Symptoms consistent with NYHA functional class II-IV. \* Receiving beta blocker (BB)s, non-dihydropyridine calcium. channel blockers (nonDHP CCBs), disopyramide, and/or mavacamten (once available) as part of routine clinical care; or currently receiving no treatment due to intolerance or failure of prior treatment (eg, BBs, non-DHP CCBs, or disopyramide) for obstructive HCM. European Sub-study \* Diagnosis of obstructive HCM consistent with the most recent European Society of Cardiology (ESC) and American Heart Association/American College of Cardiology (AHA/ACC) guidelines \* Documented LVEF of ≥55% recorded by TTE \* Documented symptoms consistent with NYHA functional class II-III at enrollment or within 6 months prior to enrollment (if not available at enrollment). \* As part of routine clinical care for obstructive HCM: receiving BBs, non-DHP CCBs, disopyramide; initiating mavacamten at enrollment; or currently receiving no treatment due to intolerance or failure of prior treatment (e.g., BBs, non-DHP CCBs, or disopyramide). Exclusion Criteria \* Known phenocopy disease (e.g., Fabry disease, amyloidosis) or LV hypertrophy associated with hypertension. \* Documentation of any fixed obstruction of the outflow tract such as aortic valve stenosis or replacement. \* Prior treatment of obstructive HCM with invasive septal reduction (surgical myectomy or percutaneous alcohol septal ablation \[ASA\]) within 6 months prior to enrollment; participants with an unsuccessful myectomy or percutaneous ASA performed >> 6 months prior to enrollment may be enrolled. \* Naïve to treatment for obstructive HCM (ie, never treated with BBs, nonDHP CCBs, or disopyramide). United States Sub-Study \* Receiving an investigational therapeutic agent for obstructive HCM (eg, myosin-inhibitors other than mavacamten) in an interventional clinical trial at participant enrollment. \* Previously or currently enrolled in a long-term safety extension study of mavacamten (eg, EXPLORER-HCM \ [ClinicalTrials.gov, NCT03470545\], MAVA-LTE \[NCT03723655\], PIONEER-OLE \[NCT03496168\], VALORHCM \[NCT04349072\], or MAVERICK \[NCT037423655\] European Sub-study \* Receiving an investigational therapeutic agent or any cardiac myosin inhibitor and/or modulators for obstructive HCM at patient enrolment \* Previously or currently enrolled in other HCM registry studies (e.g., TORCH, REMY, EU-PASS) \* Previously or currently enrolled in a study of mavacamten (e.g., EXPLORER-HCM \[ClinicalTrials.gov, NCT03470545\], MAVA-LTE \[NCT03723655\], PIONEER-OLE \[NCT03496168\], VALOR-HCM \[NCT04349072\], MAVERICK \ [NCT03442764\], or MEMENTO \[NCT2264899\]) \* Previously treated with mavacamten

## Conditions & Interventions

Interventions:

DRUG: Mavacamten, DRUG: Non-mavacamten symptomatic oHCM therapy

Conditions:

Obstructive Hypertrophic Cardiomyopathy

Keywords:

Obstructive hypertrophic cardiomyopathy, Obstructive HCM (oHCM), Mavacamten, Heart failure, oHCM

## More Information

 $\textbf{Contact(s):} \ \textbf{BMS Study Connect Contact Center www.BMSStudyConnect.com - Clinical.Trials@bms.com - Clinical.Trials$ 

**Principal Investigator:** 

Phase: IRB Number:

System ID: NCT05489705

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