Meta-analysis to assess cardiovascular safety of mavacamten (CV027-1148)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000234

EU PAS number

EUPAS1000000234

Study ID

1000000234

DARWIN EU® study

No

Study countries

- ☐ Australia
- ☐ Austria
- ☐ Belgium

- [ ] Brazil
- [ ] Canada
- [ ] Chile
- [ ] China
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] India
- [ ] Israel
- [ ] Italy
- [ ] Japan
- [ ] Korea, Democratic People's Republic of
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Spain
- [ ] Switzerland
- [ ] United Kingdom
- [ ] United States

Study description

This meta-analysis study will utilize the patient-level data from pre-existing secondary data sources (studies) from BMS clinical trial repository to assess the risk of major cardiovascular (CV) outcomes associated with mavacamten compared to placebo treatment in adult participants with symptomatic hypertrophic cardiomyopathy (HCM).

Study status

Planned

Research institutions and networks

Institutions

Bristol-Myers Squibb (BMS)

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Institution

Contact details

Study institution contact

Transparency and Disclosure Lead

Study contact

ctt.group@bms.com

Primary lead investigator

Tamara Lesperance

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 13/06/2023

Study start date
Planned: 02/02/2025

Date of final study report
Planned: 01/02/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb (BMS) 100%

Study protocol

CV0271148-protamend01_02Jul2024.pdf(4.05 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Data collection methods:

Secondary use of data

Main study objective:

To assess the risk of major CV events observed under mavacamten treatment is non-inferior to the risk presented under placebo treatment.

Study Design

Non-interventional study design

Other

Systematic review and meta-analysis

Study drug and medical condition

Name of medicine

CAMZYOS

Name of medicine, other

mavacamten

Anatomical Therapeutic Chemical (ATC) code

(C01EB) Other cardiac preparations

Other cardiac preparations

Medical condition to be studied

Hypertrophic cardiomyopathy

Population studied

Short description of the study population

The source population is defined by the parent study protocols, ie, adults 18 years of age or older with symptomatic HCM (oHCM and/or nHCM) in existing Phase 3 and 3b/4 studies.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

964

Study design details

Outcomes

- Time from first dose to the first occurrence of an e-MACE event. e-MACE event defined as a composite of adjudicated events of CV death, non-fatal myocardial infarction (MI), non-fatal stroke, hospitalization for heart failure (HF), hospitalization for arrhythmia, other CV hospitalization (for events other than heart failure or arrhythmia), or appropriate shock therapy from implanted cardiac device (ICD).
- The first occurrence of MACE (4-point), where MACE is defined as a composite of adjudicated event of CV death, non-fatal MI, non-fatal stroke, or hospitalization for HF.
- The first occurrence of MACE-plus, where MACE-plus is defined as a composite of adjudicated event of CV death, non-fatal MI, non-fatal stroke, hospitalization for HF, or hospitalization for arrhythmia, or appropriate shock therapy from ICD.
- Time from first dose to all-cause mortality.
- Time from first dose to CV death.
- Time from first dose to the first occurrence of non-fatal MI.
- Time from first dose to the first occurrence of non-fatal stroke.
- Time from first dose to the first occurrence of hospitalization for HF.
- Time from first dose to the first occurrence of hospitalization for arrhythmia.
- Time from first dose to the first occurrence of other CV hospitalization (for events other than HF or arrhythmia).
- Time from first dose to the first occurrence of appropriate shock therapy from ICD.

Data analysis plan

This meta-analysis will combine evidence using patient-level data from these studies (EXPLORER-HCM, VALOR-HCM, EXPLORER-CN, MEMENTO trials and ODYSSEY-HCM) and appropriate statistical methods will be applied, to allow inference to be made to the population of symptomatic HCM patients. This meta-analysis will be performed within 1 year after the last study is unblinded.

Data management

Data source(s), other

Pre-existing secondary data sources from BMS clinical trial repository

Data sources (types)

Clinical trial

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No