On 26 April 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Camzyos, intended for the treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM). The applicant for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

Camzyos will be available as 2.5 mg, 5 mg, 10 mg and 15 mg hard capsules. The active substance of Camzyos is mavacamten, a reversible cardiac myosin inhibitor (ATC code: C01EB24). By modulating the number of myosin heads that can enter power-generating states, Camzyos inhibits cardiac myosin, thereby normalising cardiac muscle contractility, reducing dynamic left ventricular outflow tract obstruction and improving cardiac filling pressures in patients with oHCM.

The benefits of Camzyos, as shown in two phase 3, randomised, placebo-controlled trials, are an improvement in exercise capacity (as measured by pVO2max) and reduced need for septal reduction therapy in oHCM patients administered mavacamten compared with placebo. The most common side effects are dizziness, dyspnoea, systolic dysfunction and syncope.

The full indication is:

CAMZYOS is indicated for the treatment of symptomatic (New York Heart Association, NYHA, class II-III) obstructive hypertrophic cardiomyopathy (oHCM) in adult patients (see section 5.1).

Treatment with Camzyos should be initiated under the supervision of a physician experienced in the management of patients with cardiomyopathy.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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1 Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.