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Camzyos™ (mavacamten) – New orphan drug approval

- On April 28, 2022, Bristol Myers Squibb announced the FDA approval of Camzyos (mavacamten), for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.

- In obstructive HCM, the wall (septum) between the two bottom chambers of the heart thickens. The walls of the pumping chamber can also become stiff. It may block or reduce the blood flow from the left ventricle to the aorta. People with HCM are at higher risk for developing atrial fibrillation, which can lead to blood clots, stroke, and other heart-related complications. HCM may also lead to heart failure.

- Camzyos is a first-in-class cardiac myosin inhibitor and the first FDA approved treatment for obstructive HCM.

- The efficacy of Camzyos was established in EXPLORER-HCM, a double-blind, randomized, placebo-controlled study in 251 adults with symptomatic NYHA class II and III obstructive HCM. Patients were randomized to receive Camzyos or placebo once daily for 30 weeks. The primary composite functional endpoint, assessed at 30 weeks, was defined as the proportion of patients who achieved either improvement of mixed venous oxygen tension (pVO_2) by ≥ 1.5 mL/kg/min plus improvement in NYHA class by at least 1 or improvement of pVO_2 by ≥ 3.0 mL/kg/min plus no worsening in NYHA class.

    - Overall, 37% of patients met the primary endpoint with Camzyos vs. 17% with placebo (treatment difference 19, 95% CI: 9, 30; p = 0.0005).
    - Although the benefit of Camzyos was smaller in patients on background beta blocker therapy compared to those who were not, analyses of other secondary endpoints (symptoms, left ventricular outflow tract gradient) suggest that patients might benefit from Camzyos treatment regardless of beta blocker use.

- Camzyos carries a boxed warning for risk of heart failure.

    - Because of the risk of heart failure due to systolic dysfunction, Camzyos is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called Camzyos REMS Program.

- Camzyos is contraindicated with concomitant use of:

    - Moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors
    - Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers.

- Additional warnings and precautions for Camzyos include CYP450 drug interactions leading to heart failure or loss of effectiveness and embryo-fetal toxicity.

- The most common adverse reactions (> 5% and more commonly on Camzyos than on placebo) with Camzyos use were dizziness and syncope.

- The recommended starting dose of Camzyos is 5 mg orally once daily; allowable subsequent doses with titration are 2.5, 5, 10, or 15 mg once daily.

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  - Dosage must be individualized based on clinical status and echocardiographic assessment of patient response.
  - Refer to the Camzyos drug label for additional dosing and administration recommendations.

- Bristol Myers Squibb launch plans for Camzyos are pending. Camzyos will be available as 2.5 mg, 5 mg, 10 mg, and 15 mg capsules.

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