Optum Rx®

Velsipity™ (etrasimod) – New drug approval

- On October 13, 2023, Pfizer announced the FDA approval of Velsipity (etrasimod), for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

- UC is a chronic inflammatory bowel disease characterized by chronic diarrhea with blood and mucus, abdominal pain, and urgency. UC affects an estimated 1.25 million people in the U.S.

- Velsipity is a selective sphingosine-1-phosphate (S1P) receptor modulator. It is the second drug in the class approved for UC. BMS' Zeposia (ozanimod) was approved for the same indication in 2021.

- The efficacy of Velsipity was established in two randomized, double-blind, placebo-controlled studies (UC-1 and UC-2) in adults with moderately to severely active UC who had an inadequate response, loss of response, or intolerance to one or more of the following treatment options: oral aminosalicylates, corticosteroids, thiopurines, Janus kinase (JAK) inhibitors, or biologic therapies. In both studies, patients were randomized to receive Velsipity or placebo.

- In UC-1 (N = 408), the primary endpoints were the proportion of patients achieving clinical remission at week 12 and at week 52.

    — At week 12, clinical remission was achieved in 27% and 7% of patients with Velsipity and placebo, respectively (treatment difference 20, 95% CI: 13, 27; $p < 0.001$).
    — At week 52, clinical remission was achieved in 32% and 7% of patients with Velsipity and placebo, respectively (treatment difference 26, 95% CI: 19, 33; $p < 0.001$).

- In UC-2 (N = 333), the primary endpoint was the proportion of patients achieving clinical remission at week 12.

    — At week 12, clinical remission was achieved in 26% and 15% of patients with Velsipity and placebo, respectively (treatment difference 11, 95% CI: 3, 20; $p < 0.05$).

- Velsipity is contraindicated in patients who:

    — In the last 6 months, have experienced a myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure
    — Have a history or presence of Mobitz type II second-degree or third-degree AV block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker.

- Warnings and precautions for Velsipity include infections; bradyarrhythmia and atrioventricular conduction delays; liver injury; macular edema; increased blood pressure; fetal risk; malignancies; posterior reversible encephalopathy syndrome; respiratory effects; unintended additive immune system effects from prior treatment with immunosuppressive or immune-modulating drugs; and immune system effects after stopping Velsipity.

- The most common adverse reactions (≥ 5%) with Velsipity use were headache, elevated liver tests, and dizziness.

- The recommended dose of Velsipity is 2 mg orally once daily.

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- The wholesale acquisition cost (WAC) of Velsipity will be approximately $75,000 per year.
- Pfizer's launch plans for Velsipity are pending. Velsipity will be available as a 2 mg tablet.

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