Omvoh™ (mirikizumab-mrkz) – New drug approval

- On October 26, 2023, Eli Lilly announced the FDA approval of Omvoh (mirikizumab-mrkz), for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

- Omvoh is a monoclonal antibody that selectively binds to the p19 subunit of human interleukin (IL)-23 cytokine and inhibits its interaction with the IL-23 receptor. Inflammation due to over-activation of the IL-23 pathway plays a role in the pathogenesis of UC.

- The efficacy of Omvoh was established in two randomized, double-blind, placebo-controlled studies, one induction study and one maintenance study in adult patients with moderately to severely active UC. The 12-week intravenous (IV) induction study (UC-1) was followed by the 40-week subcutaneous (SC) randomized withdrawal maintenance study (UC-2).

- In UC-1, efficacy was evaluated in 1,062 patients who were randomized to receive 300 mg Omvoh or placebo by IV infusion at week 0, week 4, and week 8. The primary endpoint was clinical remission at week 12.

    — Clinical remission was achieved in 24% and 15% of patients with Omvoh and placebo, respectively (treatment difference 10, 95% CI: 5, 15; $p < 0.001$).

- The maintenance study (UC-2) evaluated 506 patients who achieved clinical response at week 12 in Study UC-1. These patients were randomized to receive 200 mg Omvoh or placebo subcutaneously (SC) every 4 weeks for 40 weeks in UC2, for a total of 52 weeks of treatment. The primary endpoint was clinical remission at week 40.

    — Clinical remission was achieved in 51% and 27% of patients with Omvoh and placebo, respectively (treatment difference 22, 95% CI: 14, 31; $p < 0.001$).

- Warnings and precautions for Omvoh include hypersensitivity reactions, infections, tuberculosis, hepatotoxicity, and immunizations.

- The most common adverse reactions (≥ 2%) with Omvoh use during induction therapy were upper respiratory tract infections and arthralgia. The most common adverse reactions (≥ 2%) during maintenance therapy were upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection.

- For induction therapy, the recommended dose of Omvoh is 300 mg administered by IV infusion over at least 30 minutes at week 0, week 4, and week 8.

    — Omvoh for IV use is intended for administration by a healthcare provider using aseptic technique.

- The recommended maintenance dosage of Omvoh is 200 mg administered by SC injection (given as two consecutive injections of 100 mg each) at week 12, and every 4 weeks thereafter.

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  - — Omvoh is intended for use under the guidance and supervision of a healthcare professional. Patients may self-inject Omvoh after training in SC injection technique.

- Eli Lilly plans to launch Omvoh in the coming weeks. Omvoh will be available as a 300 mg/15 mL (20 mg/mL) solution in a single-dose vial (for IV infusion) and a 100 mg/mL solution in a single-dose prefilled pen (for SC injection).

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