Omvoh® (mirikizumab-mrkz) – New indication

- On January 15, 2025, Eli Lilly announced the FDA approval of Omvoh (mirikizumab-mrkz), for the treatment of **moderately to severely active Crohn's disease (CD) in adults**.

- Omvoh is also approved for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

- The approval of Omvoh for the new indication was based on a randomized, double-blind, placebo-controlled study in 679 adult patients with moderately to severely active CD who had an inadequate response, loss of response, or intolerance to corticosteroids, immunomodulators, and/or biologics. Patients received Omvoh or placebo. The co-primary endpoints were clinical remission by Crohn's Disease Activity Index (CDAI) and endoscopic response by Simple Endoscopic Score for Crohn's disease (SES-CD) at week 52.

    - Clinical remission was achieved in 53% and 36% of patients with Omvoh and placebo, respectively (treatment difference 17, 95% CI: 9, 25; $p < 0.001$).
    - Endoscopic response was achieved in 46% and 23% of patients with Omvoh and placebo, respectively (treatment difference 23, 95% CI: 15, 30; $p < 0.001$).

- The most common adverse reactions (≥ 5%) with Omvoh use for CD were upper respiratory tract infections, injection site reactions, headache, arthralgia, and elevated liver tests.

- The recommended induction dose of Omvoh for the treatment of CD is 900 mg intravenously over at least 90 minutes at week 0, week 4, and week 8. The maintenance dosage (week 12 and every 4 weeks thereafter) is 300 mg subcutaneously (given as two consecutive injections of 100 mg and 200 mg in any order).

    - Refer to the Omvoh drug label for dosing for UC.