Entyvio® (vedolizumab) – New formulation approval

- On September 27, 2023, Takeda announced the FDA approval of a subcutaneous (SC) formulation of Entyvio (vedolizumab), for the maintenance treatment of moderately to severely active ulcerative colitis (UC).

- Entyvio was previously available as an intravenous (IV) formulation. The IV formulation is also approved for treatment of moderately to severely active Crohn's disease (CD).

    — A Biologics License Application (BLA) for SC administration of Entyvio for CD is currently under review by the FDA.

- The efficacy of Entyvio was established in the SC UC Trial, a randomized, double-blind, placebo-controlled study in adult patients with moderately to severely active UC. All patients received open-label IV Entyvio at week 0 and week 2. In order to be randomized to treatment in SC UC Trial, patients had to be in clinical response at week 6. A total of 162 patients were randomized at week 6 to SC Entyvio or placebo every 2 weeks. The primary endpoint was the proportion of patients in clinical remission defined as a Mayo score of ≤ 2 points and no individual subscore > 1 point at week 52.

    — A statistically significant proportion of patients receiving Entyvio SC maintenance therapy achieved clinical remission compared to patients receiving placebo (46% vs. 14%). The estimate of treatment difference was 32% (95% CI: 20, 45; $p < 0.001$).

- Warnings and precautions for Entyvio include infusion-related reactions and hypersensitivity reactions; infections; progressive multifocal leukoencephalopathy; liver injury; and live and oral vaccines.

- Adverse reactions with SC Entyvio are similar to those reported with IV Entyvio with the exception of injection site reactions reported with subcutaneous Entyvio.

- Following the first two Entyvio IV doses administered at week 0 and week 2, Entyvio may be switched to SC injection at week 6. From week 6 and thereafter, Entyvio can be administered as a 108 mg SC dose once every 2 weeks.

    — Therapy should be discontinued in patients who show no evidence of therapeutic benefit by week 14.
    — Entyvio may be switched from IV infusion to SC injection, for patients in clinical response or remission beyond week 6. To switch patients to Entyvio SC injection, the first SC dose should be administered in place of the next scheduled IV infusion and every two weeks thereafter.
    — Patients or caregivers may self-inject SC Entyvio after training in SC injection technique.

- Refer to the Entyvio drug label for additional dosing and administration recommendations for UC and CD.

- Takeda plans to launch Entyvio SC by the end of October 2023. Entyvio SC will be available as a 108 mg/0.68 mL solution in a single-dose prefilled syringe and in a single-dose prefilled pen.