Entyvio® (vedolizumab) – New indication for subcutaneous use

- On April 19, 2024, Takeda announced the FDA approval of the subcutaneous (SC) formulation of Entyvio (vedolizumab), for maintenance treatment in adults with moderately to severely active Crohn's disease (CD) after induction therapy with intravenous (IV) Entyvio.
- The SC formulation of Entyvio was approved for ulcerative colitis (UC) in September 2023.
- The IV formulation of Entyvio is also approved for both UC and CD.
- The approval of SC Entyvio for the new indication was based on a randomized, double-blind, placebo-controlled study in adult patients with moderately to severely active CD. All patients received open-label IV Entyvio at week 0 and week 2. In order to be randomized to treatment in the SC study, patients had to be in clinical response at week 6. A total of 409 patients were randomized at week 6 to SC Entyvio or placebo every 2 weeks. The primary endpoint was the proportion of patients with clinical remission at week 52.
    - Clinical remission was achieved in 48% of patients with Entyvio vs. 34% with placebo (treatment difference 14, 95% CI: 4, 24; $p < 0.01$).
- The recommended SC maintenance dose of Entyvio for the treatment of both CD and UC is 108 mg SC once every 2 weeks.
    - Patients may self-inject or caregivers may inject SC Entyvio using either the Entyvio prefilled syringe or Entyvio Pen after training in SC injection technique.