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Takeda's BLA for Vedolizumab gets approval by U.S. FDA

14 May 2019 | News

Takeda proposes to make vedolizumab SC available in both pre-filled syringe and pen options.

Takeda Pharmaceutical Company has announced that the U.S. Food & Drug Administration (FDA) has accepted for review a Biologics License Application (BLA) for a subcutaneous (SC) formulation of vedolizumab for maintenance therapy in adults with moderately to severely active ulcerative colitis (UC). Takeda proposes to make vedolizumab SC available in both pre-filled syringe and pen options.

“Acceptance of this regulatory submission for review brings us one step closer to our goal of better meeting the diverse needs of patients with ulcerative colitis in the U.S. The availability of a subcutaneous option for maintenance therapy with vedolizumab, in addition to the currently approved intravenous formulation, would provide physicians and patients with greater flexibility on route of administration, if approved,” said Uthra Sundaram, Senior Vice President, GI Business Unit, Takeda Pharmaceuticals U.S.A.

The application is based on the pivotal VISIBLE 1 phase 3 study, which assessed the safety and efficacy of a SC formulation of vedolizumab as maintenance therapy in 216 adult patients with moderately to severely active UC who achieved clinical response at week 6 following two doses of open-label vedolizumab intravenous (IV) therapy at weeks 0 and 2.[1] The results of VISIBLE 1 were presented at the 2018 United European Gastroenterology (UEG) Week Congress in Vienna, Austria.

In evaluating the primary endpoint of VISIBLE 1, a statistically significant proportion of patients receiving vedolizumab SC 108 mg maintenance therapy administered every two weeks achieved clinical remission compared to patients receiving placebo (46.2% vs. 14.3%; $p<0.001$) at week 52. A similar rate of clinical remission was observed in the vedolizumab IV 300 mg reference arm (42.6%) at week 52. Furthermore, adverse event rates, including severe adverse events and infections, were similar between the SC and IV groups at week 52. Injection-site reactions were generally mild and experienced by 10.4% of patients in the vedolizumab SC treatment arm (vs. 0% in the placebo group), with none leading to treatment discontinuation.

“The VISIBLE 1 study provides us with important knowledge on the characterization of the efficacy and safety profile for the investigational subcutaneous formulation of vedolizumab,” said Karen Lasch, M.D., Medical Head, Specialty GI, U.S. Medical Office, Takeda. “Takeda is deeply committed to bringing innovative medicines and treatment modalities to patients living with gastrointestinal diseases.”