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Takeda files NDA for subcutaneous formulation of Vedolizumab

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Takeda Submits New Drug Application for a Subcutaneous Formulation of Vedolizumab for Patients with Moderately to Severely Active Ulcerative Colitis in Japan



Takeda Pharmaceutical Company Limited has submitted a New Drug Application (NDA) to the Ministry of Health, Labour and Welfare in Japan for a subcutaneous (SC) formulation of vedolizumab, a gut-selective biologic for maintenance therapy in adults with moderately to severely active ulcerative colitis (UC). Takeda proposes to make vedolizumab SC available in both syringe and pen options.

“This NDA filing is an important step in our commitment to deliver innovative medicines and treatment modalities that meet the needs of patients living with ulcerative colitis in Japan,” said Naoyoshi Hirota, Head of the Takeda Development Center Japan. “By making it possible to select the treatment modality that suits a patient's desired administration method and lifestyle, we are aiming to enhance the patient experience and help fulfill their needs.”

This NDA filing is based on the results of the VISIBLE 1 trial, a phase 3 clinical trial that evaluated the efficacy and safety of vedolizumab subcutaneous as maintenance therapy. In the VISIBLE 1 trial conducted in 216 adult patients with moderately to severely active ulcerative colitis, clinical response was obtained at week 6 following two doses of open-label intravenous administrations of vedolizumab as an induction therapy at weeks 0 and 2. The results of the VISIBLE 1 trial were presented at the 2018 United European Gastroenterology Week Congress in Vienna, Austria.