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Takeda takes step towards EU Entyvio extension

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European Medicines Agency accepts Takeda's Marketing Authorization Application for a subcutaneous formulation of Vedolizumab for maintenance therapy in moderately to severely active Ulcerative Colitis and Crohn's Disease

Takeda Pharmaceutical Company Limited announced that the European Medicines Agency (EMA) has accepted a Marketing Authorization Line Extension Application for a subcutaneous (SC) formulation of the gut-selective biologic vedolizumab for maintenance therapy in adults with moderately to severely active ulcerative colitis (UC) or Crohn's disease (CD). Takeda proposes to make vedolizumab SC available in both pre-filled syringe and pen options.

"This regulatory application marks an important milestone in our continued commitment to delivering innovative medicines and treatment modalities that meet the diverse needs of patients living with ulcerative colitis and Crohn's disease across Europe," said Adam Zaeske, Head, GI Franchise, Europe and Canada Business Unit, Takeda. "If approved, a subcutaneous formulation of vedolizumab, together with the currently available intravenous option, will provide greater choice, enhancing the patient experience in line with their treatment preferences and lifestyle."

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) induction therapy at weeks 0 and 2.