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Janssen submits application to EMA seeking approval of STELARA

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If approved, ustekinumab will be the first interleukin (IL)-12/23 inhibitor licensed for the treatment of ulcerative colitis

The Janssen Pharmaceutical Companies of Johnson & Johnson has announced the submission of a Group Type II Variation Application to the European Medicines Agency (EMA) seeking approval of STELARA (ustekinumab) for the treatment of adults with moderately to severely active ulcerative colitis (UC).

Ustekinumab is a human monoclonal antibody that targets the interleukin (IL)-12 and IL-23 cytokines, which are believed to play an important role in the immune and inflammatory responses seen in immune-mediated diseases, such as UC and Crohn's disease.1

This submission follows a supplemental Biologics License Application (sBLA) made to the United States' Food and Drug Administration (FDA) on December 20, 2018, which also seeks approval of ustekinumab for the treatment of adults with moderately to severely active UC.

"Ulcerative colitis (UC) is a chronic, painful and debilitating condition that has a significant impact on quality of life. UC affects up to one million people across Europe, and some of these patients struggle to achieve and maintain high levels of clinical response with currently available therapies. This submission for ustekinumab in UC brings us one step closer to providing a new treatment option to help address this important unmet need," said Jaime Oliver, MD, Janssen Therapeutic Area Lead, Immunology, Europe, Middle East & Africa, Cilag GmbH International. "We look forward to working with the European

Medicines Agency (EMA) as the application process progresses."

This submission is based on data from the Phase 3 UNIFI global clinical development programme, which includes two studies (one induction and one maintenance study) evaluating the efficacy and safety of ustekinumab for the treatment of moderately to severely active UC in adults.

"We're excited to bring this innovative therapy, with a proven track record in Crohn's and other immune diseases, one step closer to being available for people living with ulcerative colitis," said Scott E. Plevy, MD, Gastroenterology Disease Area and IL-23 Pathway Leader, Janssen Research & Development, LLC. "This submission builds upon our 20-year legacy of research and development to address unmet needs of people living with inflammatory bowel diseases."

The common (in ?1% of patients) adverse reactions reported in controlled periods of the adult psoriasis, psoriatic arthritis and Crohn's disease clinical studies with ustekinumab as well as in the post-marketing experience are: arthralgia, back pain, diarrhoea, dizziness, fatigue, headache, injection site erythema, infection site pain, myalgia, nasopharyngitis, nausea, oropharyngeal pain, pruritus, upper respiratory tract infection and vomiting