Media Enquiries:
Emily Bone
Phone: +44 787-639-4360
ebone1@its.jnj.com

Investor Relations:
Christopher DelOrefice
Phone: +1 732-524-2955

Lesley Fishman
Phone: +1 732-524-3922

JANSSEN SUBMITS APPLICATION TO EUROPEAN MEDICINES AGENCY SEEKING APPROVAL OF STELARA® (USTEKINUMAB) FOR TREATMENT OF ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS

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

BEERSE, BELGIUM, Monday January 7, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today 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. Data from the Phase 3 induction study were recently presented at the 2018 American College of Gastroenterology (ACG) and United European Gastroenterology Week (UEGW) annual meetings, indicating that treatment with a single intravenous (IV) dose of ustekinumab induces clinical remission and response in adults with moderately to severely active UC who previously experienced an inadequate response or intolerance to conventional or biologic therapies.[2] Results from the Phase 3 maintenance study will be presented at future scientific meetings.

"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.[3]

#ENDS#

Information for Editors

About ulcerative colitis

Crohn's disease and ulcerative colitis (UC), collectively known as inflammatory bowel disease (IBD), affect approximately three million people in Europe; of these, one million are living with UC.[4] UC is a chronic disease of the large intestine, also known as the colon, in which the lining of the colon becomes inflamed and develops tiny open sores, or ulcers, that produce pus and mucus. It is the result of an abnormal response by the body's immune system. Symptoms vary, but may include loose and more urgent bowel movements, persistent diarrhoea, abdominal pain, bloody stools, loss of appetite, weight loss and fatigue.[5]

About the UNIFI trial programme

UNIFI is a Phase 3 programme, designed to evaluate the safety and efficacy of ustekinumab induction and maintenance dosing for the treatment of moderately to severely active UC in

adults who demonstrated an inadequate response to, or were unable to tolerate, conventional (i.e. corticosteroids, immunomodulators) or biologic (i.e. one or more tumour necrosis factor [TNF]-alpha antagonists and/or vedolizumab) therapies. Both the induction and maintenance studies were randomised, double-blind, placebo-controlled, parallel group, multicentre studies. The induction study was of at least 8 weeks duration. Participants achieving clinical response in the induction study were eligible to enter into the maintenance study. The maintenance study was 44 weeks in duration, representing a total treatment duration of 1 year. The primary endpoint of the induction study was clinical remission at week 8, and the primary endpoint for the maintenance study was clinical remission at week 44 among responders to a single intravenous (IV) ustekinumab infusion. After completion of the maintenance study, eligible participants are continuing in a long-term extension study for an additional three years.

About STELARA® (ustekinumab)[3]

In the European Union, ustekinumab is approved for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or psoralen plus ultraviolet A (PUVA), and is also indicated for the treatment of moderate-to-severe plaque psoriasis in adolescent patients from the age of 12 years and older who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. In addition, ustekinumab is approved alone or in combination with MTX for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying antirheumatic drug (DMARD) therapy has been inadequate. In November 2016, the European Commission approved ustekinumab for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF-alpha antagonist or have medical contraindications to such therapies.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to ustekinumab, which is currently approved for the treatment of moderate to severe plaque psoriasis in 90 countries, paediatric psoriasis in 43 countries, psoriatic arthritis in 83 countries and Crohn's disease in 62 countries.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science.

We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com/EMEA. Follow us on Twitter: @JanssenEMEA.

Janssen-Cilag International NV; Janssen Research & Development, LLC and Cilag GmbH International are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding 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. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialise, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behaviour and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

# # #

References

1. Croxford A, Kulig P, *et al*. IL-23 and IL-23 in health and disease. *Cytokine Growth Factor Rev.* 2014;25(4):415–21.
2. Sands B, Sandborn W, *et al*. Safety and efficacy of ustekinumab induction therapy in patients with moderate to severe ulcerative colitis: results from the Phase 3 UNIFI study. *United Europe Gastroenterology Week (UEGW) 2018, Vienna, Austria.* 20–24 Oct 2018: LB01.

3. European Medicines Agency. Ustekinumab Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/stelara. Last updated December 2018; last accessed December 2018.
4. Janssen Disease Lens. Available at: http://www.diseaselens.com/disease/ulcerative_colitis/. Accessed December 2018.
5. Crohn's and Colitis UK. Ulcerative colitis. Available at: https://www.crohnsandcolitis.org.uk/about-inflammatory-bowel-disease/ulcerative-colitis. Accessed December 2018.