FOR UK MEDICAL AND TRADE MEDIA ONLY

News Release

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JANSSEN RESPONDS TO THE NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) DRAFT GUIDANCE FOR STELARA® (USTEKINUMAB) IN ULCERATIVE COLITIS

Janssen responds to NICE's preliminary decision not to recommend STELARA® (ustekinumab) within its marketing authorisation, for treating moderately to severely active ulcerative colitis (UC)

HIGH WYCOMBE, UK, 23 JANUARY 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the National Institute of Health and Care Excellence (NICE) has issued draft guidance not to recommend STELARA® (ustekinumab) within its marketing authorisation, for treating moderately to severely active ulcerative colitis (UC) in adults when conventional therapy or a biological agent cannot be tolerated, or the disease has responded inadequately, or lost response to treatment.[1] Whilst Janssen is disappointed by the recommendation set out within the Appraisal Consultation Document (ACD), the company is committed to continue collaborating closely with NICE throughout the subsequent stages of this appraisal.

Ustekinumab is the first biologic therapy for UC that targets interleukin (IL)-12 and IL-23 cytokines and has the potential to offer a new mechanism of action for these patients.[2] Ustekinumab is already recommended by NICE as a clinically and cost-

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January 2020

effective option for the treatment of plaque psoriasis, psoriatic arthritis and Crohn's disease.

Janssen welcomes NICE's recognition of the unmet need for new treatment options that reduce the need for corticosteroids or surgery. For up to one-third of people living with UC, current treatments are not completely successful, or complications arise.[3] NICE also recognises the clinical effectiveness of ustekinumab in inducing and maintaining remission and response in patients with moderately to severely active UC. The committee concluded that cost-effectiveness estimates varied from marginally below to above the range that would normally be considered a cost-effective use of NHS resources, and noted uncertainty around some parameters used in the estimates.

"If NICE's decision is upheld, approximately 15,000 people in the UK living with moderately to severely active UC who may be eligible for treatment with ustekinumab, would potentially not have access to an important new treatment option," commented Jennifer Lee, Director of Health Economics, Market Access & Reimbursement (HEMAR) and Advocacy, Janssen-Cilag Limited. "We firmly believe patients living with ulcerative colitis have the right to treatment choices that improve their lives and address their ongoing needs. This initial guidance reinforces the need for reform of existing NICE technology appraisal processes through the NICE Methods Review. We will continue to collaborate closely with NICE throughout the subsequent stages of this appraisal as we believe ustekinumab should become routinely available as an alternative treatment option."

The consultation document represents a first step in the process and NICE's preliminary consultation which may change after further consultation. The Appraisal Consultation Document (ACD) is open to comment until 11th February 2020. A second committee meeting is scheduled for 25th February 2020, and final guidance is expected to be published in May 2020.

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About STELARA® (ustekinumab)[2]

In the European Union, ustekinumab is approved for the treatment of moderate to severe plaque psoriasis in adults and paediatric patients (ages 12 and over) who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or psoralen plus ultraviolet A, and is also indicated for the treatment of moderate to severe plaque psoriasis in adolescent patients aged 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 therapy has been inadequate. In November 2016, the EC 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.

In September 2019, the EC approved the use of ustekinumab for the treatment of moderately to severely active ulcerative colitis in the European Union.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to STELARA®.

About Ulcerative Colitis (UC)
UC is a chronic inflammatory condition affecting approximately 146,000 people in the UK, and can have a significant and often hidden impact on physical and mental wellbeing.[4]

About the Janssen Pharmaceutical Companies of Johnson & Johnson
At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Janssen-Cilag Limited is a Janssen Pharmaceutical Company of Johnson & Johnson. Learn more at www.janssen.com/uk. Follow us at www.twitter.com/JanssenUK.

Cautions Concerning Forward-Looking Statements
This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding NICE's technology appraisal for STELARA® (ustekinumab). 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 healthcare products and services; changes to applicable laws and regulations, including global healthcare reforms; and trends toward healthcare 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, 2018, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Report on Form 10-Q, and in 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.*

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[1] National Institute For Health And Care Excellence. Appraisal consultation document. Available at: https://www.nice.org.uk/guidance/GID-TA10434/documents/129. Accessed January 2020.
[2] European Medicines Agency. Available at: https://www.ema.europa.eu/en/documents/product-information/stelara-epar-product-information_en.pdf. Accessed January 2020.
[3] Crohn's and Colitis Foundation: Treatment Options. Available at: https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis/treatment-options. Accessed January 2020.
[4] NHS. Ulcerative Colitis. Available at: https://www.nhs.uk/conditions/ulcerative-colitis/. Accessed January 2020.

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