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## Johnson & Johnson submits regulatory application to European Medicines Agency for STELARA® (ustekinumab) for the treatment of moderately to severely active Crohn's disease in paediatric patients

**Beerse, Belgium (22 July 2024)** – Janssen-Cilag International NV, a Johnson & Johnson company, today announced it has submitted an application to the European Medicines Agency (EMA) seeking to expand the Marketing Authorisation for STELARA® (ustekinumab) to include the treatment of moderately to severely active Crohn's disease (CD) in paediatric patients weighing at least 40 kg, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy or have medical contraindications to such therapies.

The EMA submission was based on data from the Phase 3 UNITI-Jr clinical study<sup>1</sup> and REALITI, an observational non-interventional paediatric IBD real-world evidence study in patients with moderately to severely active Crohn's disease,<sup>2</sup> which was presented at the European Crohn's and Colitis Organisation Congress 2024.

In the UNITI-Jr study, the efficacy and safety of ustekinumab was evaluated in paediatric patients with moderately to severely active Crohn's disease through 52 weeks of treatment.<sup>1</sup> In the real-world evidence study, REALITI, the primary objective was to provide evidence for the clinical effectiveness and safety of ustekinumab in routine clinical practice.<sup>2</sup>

The EMA application has been validated and the review procedure has now started.

### Editor's Notes

#### **ABOUT THE UNITI-Jr PROGRAMME (EudraCT 2019-004225-24)**

UNITI-Jr is a randomised, double-blind Phase 3 study evaluating the efficacy, safety, and pharmacokinetics of ustekinumab in paediatric patients (aged 2-17) with moderately to severely active Crohn's disease.<sup>1</sup> The study included an open-label induction treatment with a single ustekinumab intravenous dose followed by a randomised double-blind subcutaneous maintenance regimen administered either every 8 weeks or every 12 weeks.<sup>1</sup>

#### **ABOUT CROHN'S DISEASE IN PAEDIATRIC PATIENTS**

Crohn's disease is one of the two main forms of inflammatory bowel disease, which affects an estimated two million people across Europe.<sup>3</sup> Crohn's disease within the paediatric population is a rarer form of inflammatory bowel disease,<sup>4</sup> thought to be triggered through a combination of factors including genetic predisposition, diet or other environmental triggers.<sup>5</sup> Symptoms of Crohn's disease may include abdominal pain, rectal bleeding and weight loss,<sup>6</sup> but for the paediatric population, Crohn's disease can delay growth and lead to malnutrition due to essential nutrients not being properly absorbed by the small intestine.<sup>7</sup> In paediatric IBD patients, these chronic symptoms can also lead to higher risk of mental health conditions significantly impacting quality of life.<sup>8,9</sup> There is currently no cure for Crohn's disease.<sup>5</sup>

#### **ABOUT STELARA® (ustekinumab)**

Ustekinumab is a fully human monoclonal antibody and is the first biologic treatment to selectively inhibit the IL-12 and IL-23 pathways.<sup>10,11</sup> In the EU, ustekinumab is approved for the treatment of adult patients with moderate to severe CD 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.<sup>11</sup> Ustekinumab is also approved for the treatment of adults with moderately to severely active UC who have had an inadequate response with, or lost response to, or were intolerant to either conventional

therapy or a biologic, or have medical contraindications to such therapies.<sup>10</sup> In addition to CD and UC, ustekinumab has been approved for the treatment of two further immune-mediated conditions in the EU: plaque psoriasis (Pso) and psoriatic arthritis (PsA).<sup>10</sup>

## ABOUT JOHNSON & JOHNSON

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more at <https://www.jnj.com/emea> or at [www.janssen.com/johnson-johnson-innovative-medicine](http://www.janssen.com/johnson-johnson-innovative-medicine). Follow us on [LinkedIn](#). Janssen Research & Development, LLC and Janssen Biotech, Inc. are Johnson & Johnson companies.

## Cautions Concerning Forward-Looking Statements

*This press release contains “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995 regarding TREMFYA®. 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 Research & Development, LLC, Janssen Biotech, Inc. 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 behavior 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, 2023, including in the sections captioned “Cautionary Note Regarding Forward-Looking Statements” and “Item 1A. Risk Factors,” and in Johnson & Johnson’s subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of Janssen Research & Development, LLC, Janssen Biotech, Inc. 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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<sup>1</sup> Clinical Trials. A Study of Ustekinumab in Pediatric Participants With Moderately to Severely Active Crohn's Disease (UNITI Jr). Identifier: NCT04673357. Available at: <https://classic.clinicaltrials.gov/ct2/show/NCT04673357>

<sup>2</sup> Steiner S, et al. Comparison of paediatric patients and young adults with moderately to severely active Crohn’s disease treated with ustekinumab in the REALITI real-world evidence effectiveness study. Poster presented at ECCO 2024.

<sup>3</sup> Ng SC, et al. Worldwide incidence and prevalence of inflammatory bowel disease in the 21st century: a systematic review of population-based studies. *The Lancet*. 2017;390:2769-78

<sup>4</sup> National Organization for Rare Disorders. Pediatric Crohn’s Disease. Available at: <https://rarediseases.org/rare-diseases/pediatric-crohns-disease/>. Accessed June 2024

<sup>5</sup> Crohn’s & Colitis Foundation. What is Crohn’s disease? Available at: <https://www.crohnscolitisfoundation.org/what-is-crohns-disease/causes>. Accessed June 2024.

<sup>6</sup> Crohn’s & Colitis Foundation. Signs and symptoms of Crohn’s Disease. Available at: <https://www.crohnscolitisfoundation.org/patientsandcaregivers/what-is-crohns-disease/symptoms> Accessed: July 2024

<sup>7</sup> Yale Medicine. Pediatric Crohn’s Disease. Accessed June 18, 2024. Available at: <https://www.yalemedicine.org/conditions/pediatric-crohns-disease>. Accessed June 2024

<sup>8</sup> Keethy D, et al. Pediatric inflammatory bowel disease and depression: treatment implications. *Curr Opin Pediatr*. 2014 Oct;26(5):561-7.

<sup>9</sup> Silva LC, et al. Quality of Life in Children and Adolescents with Inflammatory Bowel Disease: Impact and Predictive Factors. *Pediatr Gastroenterol Hepatol Nutr*. 2020 May;23(3):286-296.

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<sup>10</sup> European Medicines Agency. STELARA Summary of Product Characteristics. Available at: <https://www.ema.europa.eu/en/medicines/human/EPAR/stelara>. Accessed June 2024.

<sup>11</sup> Benson, JM, *et al.* Discovery and mechanism of ustekinumab: a human monoclonal antibody targeting interleukin-12 and interleukin-23 for treatment of immune-mediated disorders. *MAbs*. 2011 3(6):535-545.