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News Release

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New Analysis Presented by Janssen at United European Gastroenterology Week (UEGW) Demonstrates Long-Term Safety Profile for STELARA® (ustekinumab) in Older Patients Across Approved Indications

First examination of safety events in the 60 and over sub-population across ustekinumab indications, including inflammatory bowel disease where relatively little biologics safety data exists, are generally consistent with placebo

Janssen presents 13 abstracts including four oral presentations and two late breakers at UEGW

BEERSE, BELGIUM, 4 October, 2021 – Today, the Janssen Pharmaceutical Companies of Johnson & Johnson announced a new analysis of STELARA® (ustekinumab) pooled safety data from 13 clinical studies across approved indications.[1] These data show rates of key safety events among adults 60 years and older treated with ustekinumab for up to five years[a] were similar to rates observed with placebo during the control phase of these trials.[1,b] Approved indications included adults with moderately to severely active Crohn's disease (CD), moderately to severely active ulcerative colitis (UC), moderate to severe plaque psoriasis (Pso) and active psoriatic arthritis (PsA) (Oral Presentation OP198).[1] These data represent an

important patient population, as patients 60 years old and older are at a higher risk of disease and therapy-associated morbidity, which can result in disease management challenges.[1]

"Little has been intentionally explored about the safety profile of biologics in patients aged 60 and older with inflammatory bowel disease, as this population is often limited in number in clinical trials," said Professor Subrata Ghosh, Chair and Head of Department of Medicine, University College Cork, Ireland and lead study investigator of the pooled safety analysis.[c] "This analysis arms physicians with data to consider when treating older patients with ustekinumab given the safety profile observed across all approved indications."

Pooled Safety (Oral Presentation OP198) data show:

Data from 13 Phase 2/3 studies including six studies in CD/UC and seven studies in Pso/PsA for ustekinumab were pooled.[1] Of patients 60 years old or older with moderate to severe CD or UC, 214 received ustekinumab, the equivalent of 311 patient years (PYs) of follow up, and 120 received placebo, the equivalent of 97 PYs.[1] Across additional approved indications, 811 received ustekinumab (1,590 PYs) and 272 received placebo (143 PYs).[1] Number of events across pooled indications were as follows:

- Overall rates for adverse events (AEs) per 100 PYs were no greater for ustekinumab (269.12) versus placebo (455.9).[1]
- Overall rates for infections per 100 PYs were similar between ustekinumab (75.49) and placebo (86.44).[1]
- Rates of serious AEs (ustekinumab: 19.88; placebo: 27.19) and serious infections (ustekinumab: 3.33; placebo: 3.49) were similar between ustekinumab and placebo treatment groups.[1]
- No increased risk of malignancy with ustekinumab was observed based on a comparison of observed versus expected malignancies.[1]
- Overall, the safety profile of ustekinumab-treated patients 60 years old and older from the long-term pooled safety dataset across approved indications did not demonstrate higher rates with ustekinumab versus placebo.[1]

"Continuing to follow occurrences of safety events in older adults who are treated with our therapies is valuable information that can help physicians evaluate treatment options for their patients," said Jan Wehkamp, M.D., Ph.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. "These data build on the body of evidence for the safety profile of ustekinumab and underscore our commitment to developing meaningful therapies for people of all ages who are living with an untreated or undertreated immune-mediated disease."

These data are among 13 total abstracts, including three other oral presentations (OP122, OP153, OP199), and two late breakers that Janssen is presenting at UEGW. Late-breaking presentations are:

- The Pharmacokinetics and Immunogenicity of Ustekinumab and Adalimumab in Patients with Moderate to Severe Crohn's Disease: Results from the SEAVUE Study (LB15)
- Clinical and Endoscopic Outcomes with Ustekinumab in Patients with Crohn's Disease: Results from the Long-Term Extension Period of the STARDUST Trial (LB14)

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Editor's Note:

a. Mean patient follow-up was 102 weeks.
b. This analysis compares a shorter follow-up duration on placebo (often due to per-protocol crossover of placebo patients) to the much longer periods of time (including follow-up) that patients receive ustekinumab during the same studies, including long-term extensions of up to five years.
c. Dr Subrata Ghosh is a paid consultant for Janssen. He has not been compensated for any media work.

About Crohn's Disease (CD)

CD is one of the two main forms of inflammatory bowel disease, which affects up to two million people across Europe.[2] CD is a chronic inflammatory condition of the

gastrointestinal tract with no known cause, but the disease is associated with abnormalities of the immune system that could be triggered by a genetic predisposition, diet or other environmental factors.[3] Symptoms of CD can vary but often include abdominal pain and tenderness, frequent diarrhoea, rectal bleeding, weight loss and fever.[4] There is currently no cure for CD.[5]

About Ulcerative Colitis (UC)

UC affects up to 2.6 million people in Europe.[2] It is a chronic disease of the large intestine, also known as the colon, in which the lining becomes inflamed and develops tiny open sores, or ulcers, that produce pus and mucous.[6] UC is the result of an abnormal response by the body's immune system.[6] Symptoms vary, but may include loose and more urgent bowel movements, persistent diarrhoea, abdominal pain, bloody stools, loss of appetite, weight loss and fatigue.[6,7]

About STELARA® (ustekinumab)

Ustekinumab is a fully human monoclonal antibody and is the first biologic treatment to selectively inhibit the interleukin (IL)-12 and IL-23 pathways.[8] 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-α antagonist, or have medical contraindications to such therapies.[8] 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.[8] In addition to CD and UC, ustekinumab has been approved for the treatment of two further immune-mediated conditions in the EU: psoriasis and psoriatic arthritis.[8]

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

Important Safety Information

The most common adverse events (AEs) (>5%) in controlled periods of clinical studies with ustekinumab were nasopharyngitis and headache.[8] Most were considered to be mild and did not necessitate discontinuation of study treatment.[8] The most serious adverse reaction that has been reported for ustekinumab is serious hypersensitivity reactions, including anaphylaxis.[8] The overall safety profile is similar for adult patients with CD, UC, psoriasis, and psoriatic arthritis.[8]

Please refer to the Summary of Product Characteristics for full prescribing information for ustekinumab: https://www.ema.europa.eu/en/documents/product-information/stelara-epar-product-information_en.pdf.

Adverse drug reactions (ADRs) should be reported.

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.

Learn more at www.janssen.com/emea.
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Janssen-Cilag International NV, the marketing authorisation holder for STELARA® in the EU, and Janssen Research & Development, LLC, 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 ongoing and planned development

efforts involving STELARA® (ustekinumab) in inflammatory bowel disease. 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 materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, 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 January 3, 2021, 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. None of 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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References

1. Safety of Ustekinumab in Older IBD Patients (≥60 years): Pooled Safety Analysis Through 5 Years in CD and 2 Years in UC and All Approved Indications (OP198). Presented at UEG Week Virtual 2021, October 3-5, 2021

2. 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.
3. Crohn's & Colitis Foundation. Causes of Crohn's Disease. Available at: https://www.crohnscolitisfoundation.org/what-is-crohns-disease/causes. Accessed September 2021.
4. Crohn's and Colitis Foundation. What is Crohn's disease.. Available at: https://www.crohnscolitisfoundation.org/what-is-crohns-disease/overview. Accessed September 2021.
5. Mayo Clinic. Crohn's disease. Available at: https://www.mayoclinic.org/diseases-conditions/crohns-disease/symptoms-causes/syc-20353304. Accessed September 2021.
6. Crohn's & Colitis UK. What is Ulcerative Colitis?. Available at: https://www.crohnsandcolitis.org.uk/about-inflammatory-bowel-disease/ulcerative-colitis. Accessed September 2021.
7. Crohn's & Colitis Foundation. Living with Ulcerative Colitis. Available at: https://www.crohnscolitisfoundation.org/sites/default/files/legacy/assets/pdfs/living-with-ulcerative.pdf. Accessed September 2021.
8. European Medicines Agency. STELARA Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/stelara-epar-product-information_en.pdf. Accessed September 2021.