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News Release

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New Analyses Suggest Favourable Results for STELARA® (ustekinumab) When Used as a First-Line Therapy for Bio-Naïve Patients with Moderately to Severely Active Crohn's Disease and Ulcerative Colitis

Ustekinumab when used as a first-line therapy was associated with longer time in clinical remission or clinical response, including the postponing of surgery, among adult patients with moderately to severely active ulcerative colitis compared with usage as a second- or third-line therapy in a modelled analysis

Bio-naïve patients with moderately to severely active Crohn's disease started on ustekinumab showed higher rates of persistence at one year compared to adalimumab in a retrospective real-world evidence study

BEERSE, BELGIUM, 25 October, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced data from two new analyses of STELARA® (ustekinumab) for the treatment of adults with moderately to severely active Crohn's disease (CD) and ulcerative colitis (UC).[1,2] In a modelled analysis[a] focused on treatment sequencing using data from randomised controlled trials, network meta-analysis and literature, results showed patient time spent in clinical remission

or response was highest when ustekinumab was used as a first-line advanced therapy for bio-naïve patients with moderately to severely active UC relative to outcomes associated with second- or third-line use (P0540).[1] Additionally, in a separate real-world claims analysis, a greater proportion of bio-naïve patients who started biologic therapy with ustekinumab (n=948) for moderately to severely active CD showed persistence at 12 months versus adalimumab (n=4,143) (P0525).[2] These data are among 16 abstracts, including one oral presentation, presented at the 2021 American College of Gastroenterology Annual Scientific Meeting, which is taking place October 22-27 in Las Vegas, Nevada.[1,2]

"Data emerging from these analyses inform physicians with additional evidence to support ustekinumab as a first-line option for patients with moderately to severely active Crohn's disease and ulcerative colitis," said Christopher Gasink, M.D., Head of Immunology Medical Affairs, Gastroenterology, Janssen Scientific Affairs, LLC. "Many patients living with inflammatory bowel disease can cycle through different therapies as a result of loss or lack of treatment response. Studies like these are important in helping guide physicians to select an appropriate therapeutic option for their patients in a first-line setting."

"Identifying the Optimal Treatment Sequence for Ustekinumab in Treatment Algorithms for Advanced Therapies in UC (P0540)" Results Suggested:

Initiating ustekinumab as a first-line advanced therapy for UC in a hybrid decision tree model resulted in more favourable patient outcomes in terms of increased amount of time spent in remission or response and the postponing of surgery compared with second-line and third-line use.[1]

- When used first-line, ustekinumab-treated patients in the cohort model spent on average:
    - 8.5 months (71 percent of the time) in remission or response over one year. [1]
    - 23.1 months (64 percent of the time) in remission or response over three years. [1]

    - 32.2 months (54 percent of the time) in remission or response over five years. [1]
- When ustekinumab was used in the second-line setting, patients spent on average:
    - 7.9 months (66 percent of the time) in remission or response over one year. [1]
    - 14.5 months (40 percent of the time) in remission or response over three years. [1]
    - 17.5 months (29 percent of the time) in remission or response over five years. [1]
- Modelled use of ustekinumab in the first- versus second-line reduced time affected by active UC by 0.6, 8.3, and 13.8 months over one, three, and five years, respectively. When compared to third-line, first-line use of ustekinumab suggested even greater reductions at the one-year (0.9 months), three-year (9 months), and five-year (14.5 months) timepoints.[1]
- Future research is required to generate long-term clinical data to confirm these results. [1]

"Treatment Persistence Among Bio-Naïve Patients with CD Initiated on Ustekinumab or Adalimumab (P0525)" Results Suggested:

A higher proportion of bio-naïve patients selected from the IQVIA PharMetrics® Plus claims database who started on ustekinumab (n=948) were persistent on therapy at 12 months, including persistent and corticosteroid-free and persistent and on monotherapy versus patients who started on adalimumab (n=4,143).[2] Specifically, patients in the ustekinumab versus adalimumab cohort showed:

- 50 percent higher rate of persistence on biologic (hazard ratio [HR] 1.50; 95% confidence interval [CI]: 1.29-1.74).[2]
- 17 percent higher rate of persistence and being corticosteroid-free (HR: 1.17; 95% CI: 1.04-1.31).[2]
- 47 percent higher rate of persistence on monotherapy (HR: 1.47; 95% CI: 1.30-1.65).[2]

"These analyses in ulcerative colitis and Crohn's disease expand the body of data for ustekinumab and give us insight into treatment sequencing and persistence rates, which are important when assessing biologic therapy options for patients. The data are informative because patients with inflammatory bowel disease can demonstrate a short-term clinical response and improvement with therapy and then lose response," said Jan Wehkamp, M.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. "Janssen is committed to conducting analyses that provide additional insight when treating patients with inflammatory bowel disease."

#ENDS#

Editor's Note:

a. A hybrid model with decision tree for induction and a Markov cohort model for maintenance was developed to assess clinical efficacy of ustekinumab therapy when used 1st, 2nd, or 3rd line. Transition probabilities for remission, response and surgery were derived from randomised controlled trials, network meta-analysis, and the literature. Full details are available in the poster.[1]

About (P0540): Identifying the Optimal Treatment Sequence for Ustekinumab in Treatment Algorithms for Advanced Therapies in UC[1]

In the hybrid model described in the editor's note, the treatment basket for first- and second-line UC was represented by infliximab (33 percent), adalimumab (33 percent), and vedolizumab (33 percent), and third-line treatment was comprised of vedolizumab (50 percent) and tofacitinib (50 percent). Patients moved to next line of treatment upon loss of response, and those failing the first three lines of advanced therapy moved to conventional treatment (e.g., aminosalicylates and/or immunosuppressants, corticosteroids). The model estimated time spent in remission, response, active UC (Mayo score 6-12), surgery, as well as occurrences of death over one, three and five years. Transition probabilities for remission, response and surgery were derived from randomised controlled trials, network meta-analysis, and the literature. These are modelled results based on input

assumptions largely from clinical trials and a network meta-analysis.

About (P0525): **Treatment Persistence Among Bio-Naïve Patients with CD Initiated on Ustekinumab or Adalimumab[2]**

Bio-naïve adults with CD initiated on ustekinumab or adalimumab between September 23, 2016 and August 1, 2019 were selected from a de-identified health insurance claims data from the IQVIA PharMetrics® Plus. Bio-naïve patients were defined as patients with no medical or pharmacy claim for biologics indicated for CD during the baseline period (12 months before the initiation of the index agent). Baseline characteristics were balanced in weighted ustekinumab (n=948) and adalimumab (n=4,143) cohorts using inverse probability of treatment weights. Persistence on index agent was defined as absence of gaps >120 days (ustekinumab) or >60 days (adalimumab) between days of therapy supply. Composite endpoints of being persistent on index biologic and corticosteroid-free (<14 days of supply after day 90 post-index) and persistent and on monotherapy (no immunomodulators or non-index biologics) were assessed. All endpoints were estimated at 12 months post-index using weighted Kaplan-Meier and Cox's proportional hazards model analyses. Analyses of claims database depend on correct diagnosis, procedure, and drug codes, and misclassification may have occurred. All patients are assumed to have moderate to severe disease since they started biologic treatment.

Modelling and Real-World Data Limitations

Modelling and real-world data have the potential to supplement randomised controlled trial data by providing additional information about how a medicine performs across all available Phase 2 and 3 clinical trials and in routine clinical practice. There are limitations, however, and these data cannot be used as stand-alone evidence to validate the efficacy or safety of a treatment.

About Ulcerative Colitis (UC)

UC affects up to 2.6 million people in Europe.[3] 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.[4] UC is the result of an abnormal response by the body's immune system.[4] Symptoms vary, but may include loose and more urgent bowel movements, persistent diarrhoea, abdominal pain, bloody stools, loss of appetite, weight loss, and fatigue.[4,5]

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.[3] 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.[6] Symptoms of CD can vary, but often include abdominal pain and tenderness, frequent diarrhoea, rectal bleeding, weight loss, and fever.[7] There is currently no cure for CD.[8]

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.[9] 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.[9] 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.[9] 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.[9]

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

USTEKINUMAB 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; Janssen Research & Development, LLC; and Janssen Scientific Affairs, LLC are each 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 STELARA® (ustekinumab)

product development. 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, and 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 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 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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