News Release

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Janssen Presents Results of First Head-to-Head Study of Biologic Therapies in Patients with Moderate to Severe Crohn's Disease

Late-breaker is one of 20 Janssen abstracts, 16 of which show the safety profile and efficacy of STELARA in treating Crohn's disease and ulcerative colitis at Digestive Disease Week (DDW) Virtual 2021

SPRING HOUSE, PENNSYLVANIA, May 23, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced efficacy and safety data for STELARA® (ustekinumab) in Crohn's disease (CD) and ulcerative colitis (UC),[1-4] including data from the SEAVUE study, the first head-to-head study of biologic therapies in patients with CD, presented in a Clinical Science Late-Breaking Abstract Plenary session.[1] SEAVUE data showed treatment with STELARA demonstrated high rates of clinical remission, corticosteroid-free remission, clinical response and endoscopic response through one year in biologic-naïve patients with moderately to severely active CD, although the primary endpoint of statistical superiority versus adalimumab was not demonstrated.[1] These head-to-head data are one of 20 abstracts Janssen presented from the Company's gastroenterology pipeline and portfolio at DDW Virtual 2021, which took place May 21-23.[1-4]

"As the first head-to-head study of biologic therapies in Crohn's disease, SEAVUE is filling an important knowledge gap in the gastrointestinal community," said Bruce E.

Sands, M.D., M.S., Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at Mount Sinai Hospital and the Dr. Burrill B. Crohn Professor of Medicine (Gastroenterology), at the Icahn Institute for Medicine at Mount Sinai, and SEAVUE study principal investigator.[a] "SEAVUE has generated data that confirm STELARA as an important option for people living with moderately to severely active Crohn's disease who are new to biologic therapy."

STELARA vs. adalimumab efficacy and safety in biologic-naïve CD patients through one year (Presentation #775d):[1] The SEAVUE study examined a total of 386 patients with moderately to severely active CD. Patients were randomized 1:1 to treatment with STELARA approximately 6 mg/kg intravenous (IV) at baseline, then 90 mg subcutaneous (SC) every eight weeks (q8w), or treatment with adalimumab 160/80 mg SC at baseline/week two, then 40 mg SC every two weeks per the U.S. Food and Drug Administration-approved regimens without dose modifications. Results did not show statistically significant differences:

- 64.9 percent of STELARA-treated patients and 61 percent of adalimumab-treated patients achieved clinical remission (Crohn's Disease Activity Index [CDAI] <150) at one year (week 52), the study's primary endpoint.
- Major secondary endpoints were not significantly different between the groups:
    - 60.7 percent of STELARA-treated patients and 57.4 percent of adalimumab-treated patients achieved corticosteroid-free remission.
    - 72.3 percent of STELARA-treated patients and 66.2 percent of adalimumab-treated patients achieved clinical response.
    - 56.5 percent of STELARA-treated patients and 55.4 percent of adalimumab-treated patients achieved patient-reported outcome (PRO)-2 symptom remission.
    - At week 16, 57.1 percent of STELARA-treated patients and 60 percent of adalimumab-treated patients achieved clinical remission.
    - At week 52, in patients with Simple Endoscopic Score for Crohn's Disease (SES-CD)[b] ≥3 at baseline, 28.5 percent of STELARA-treated

patients and 30.7 percent of adalimumab-treated patients achieved endoscopic remission.

- Benefits for both treatments were also demonstrated across additional efficacy endpoints, but did not demonstrate statistically significant differences:
    - At week 52, in patients with SES-CD ≥3 at baseline, 41.9 percent of STELARA-treated patients and 36.9 percent of adalimumab-treated patients achieved endoscopic response.
    - Clinical response achieved at week 16 was maintained at week 52 in 88.6 percent of STELARA-treated patients and 78 percent of adalimumab-treated patients.
    - The mean change from baseline to week 52 in the number of liquid/soft stools in the prior seven days was -19.9 for STELARA-treated patients and -16.2 for adalimumab-treated patients. The mean change from baseline to week 52 in the sum of number of liquid/soft stools and abdominal pain scores in the prior seven days was -29.6 for STELARA-treated patients and -25.1 for adalimumab-treated patients.
- Safety results were consistent with prior experience for both treatments. Discontinuation rates were numerically lower for STELARA-treated patients (15.2 percent) versus adalimumab-treated patients (23.6 percent) who discontinued before week 52. Among STELARA-treated patients and adalimumab-treated patients, 6.3 percent and 11.3 percent had adverse events (AEs) that led to discontinuation of study drug, respectively.

"Until now, there have been no head-to-head trials comparing the safety and efficacy of prescription biologics to treat Crohn's disease, a chronic condition that can cause persistent and debilitating symptoms which can have a profound impact on a person's daily life," said Andrew Greenspan, M.D., Vice President, Immunology Medical Affairs, Janssen Scientific Affairs, LLC. "Armed with this new clinical trial data, doctors have a compelling option in STELARA for appropriate patients living with Crohn's disease."

Additional abstracts are also being presented:

Safety of STELARA in IBD: Pooled Safety Analysis Through Five Years in CD and Two Years in UC (Presentation #129):[2] Safety data from six Phase 2/3 studies in CD patients (through five years) and UC patients (through two years) treated with STELARA (2,575 patients with 3,960 patient-years [PYs] of follow-up) and placebo (1,390 patients with 916 PYs of follow-up) were pooled.

Results showed the STELARA safety profile was favorable and consistent with the previously reported safety profile in inflammatory bowel disease patients through one year and the well-established safety profile across all approved indications for STELARA. Rates for the number of events per 100 PYs of follow-up for AEs (390.70 PYs for STELARA vs. 488.75 PYs for placebo), serious AEs (21.57 PYs for STELARA vs. 29.57 PYs for placebo), infections (98.62 PYs for STELARA vs. 109.56 PYs for placebo), serious infections (4.17 PYs for STELARA vs. 5.35 PYs for placebo), malignancy (0.45 PYs for STELARA vs. 0.33 for placebo), and major adverse cardiac events (MACE) (.30 PYs for STELARA vs. 0.33 PYs for placebo) were similar between placebo and STELARA.

Long-term (Five-Year) Maintenance of Clinically Meaningful Improvement in Health-Related Quality of Life (HRQoL) in Patients with Moderate to Severe CD Treated with STELARA in the IM-UNITI Long-term Extension Study (Presentation #Sa576):[3] Results of the long-term extension of the IM-UNITI placebo-controlled maintenance study showed treatment with STELARA 90 mg every 12 weeks (q12w) or 90 mg q8w was effective at maintaining improvements in HRQoL through five years (252 weeks) that were first achieved during STELARA induction therapy in patients with moderately to severely active CD.

The percentage of patients who achieved clinically meaningful improvement[c] in Inflammatory Bowel Disease Questionnaire (IBDQ)[d] total score at week 252 was 40.8 percent for STELARA 90 mg q12w and 43.2 percent for STELARA 90 mg q8w.

Clinically meaningful improvement was also observed for both STELARA regimens in Medical Outcomes Study 36-Item Short Form (SF-36)[e] Physical and Mental component summary [PCS and MCS] scores.[f] SF-36 PCS scores were: STELARA 90 mg q12w, 37.5 percent; 90 mg q8w, 37.7 percent. MCS scores were: STELARA 90 mg q12w, 33.9 percent; 90 mg q8w, 31 percent during the same period.

The Real-World Effectiveness of STELARA in the Treatment of CD (Presentation #611):[4]

A real-world, retrospective, multicenter, consortium study evaluated cumulative rates of clinical and endoscopic remission of STELARA in a total of 1,113 patients with CD, the largest real-world cohort assessing STELARA effectiveness to date. 90 percent of patients had prior anti-tumor necrosis factor (TNF) exposure and 64.5 percent had prior exposure to treatment with at least two prior biologics, and a median follow-up of 386 days.

Results showed 40 percent of patients achieved clinical remission through 12 months. Cumulative rates of steroid-free, endoscopic, and radiographic remission at 12 months were 32 percent, 39 percent, and 30 percent, respectively. Rates of clinical and endoscopic remission were lower with an increasing number of prior biologic exposures. Notably, the greatest treatment effect of STELARA was seen in biologic-naïve patients with 63 percent and 55 percent of patients achieving clinical and endoscopic remission, respectively, by 12 months.

"We are pleased to continue to build upon and reinforce the strength of Janssen's gastroenterology portfolio with our promise to advance treatment options for patients living with inflammatory bowel disease," said Jan Wehkamp, M.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. "The strong body of scientific evidence for STELARA is the result of our long-term commitment to studying STELARA comparatively and in a variety of clinical settings to provide doctors and their patients with data that can help inform treatment decisions."

Editor's Note:

a. Dr. Bruce Sands is a paid consultant for Janssen. He has not been compensated for any media work.
b. SES-CD evaluates the presence or absence of endoscopic healing of the intestinal mucosa. The SES-CD is scored based on four endoscopic variables (area of affected surface, presence and size of ulcers, extent of ulcerated surface, and presence of stenoses) in the five intestinal segments. The total SES-CD score range is 0–60, with each section ranging from 0 to 12 points.[5]
c. Clinically meaningful improvement is defined as an IBDQ change ≥16 points or change in SF-36 MCS or PCS score ≥5 points.[3]
d. IBDQ is a 32-item questionnaire with four dimensions (bowel symptoms, systemic symptoms, emotional function, and social function [total score 32 to 224]).[3]
e. SF-36 is a set of generic, coherent, and easily administered quality-of-life measures reliant upon patient self-reporting.[6]
f. PCS and MCS are each scored 0 to 100; higher scores indicate better quality of life.[3]

About DDW

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is a fully virtual meeting from May 21-23, 2021. The meeting showcases more than 2,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

About SEAVUE[7]

SEAVUE is a Phase 3b, multicenter, randomized, blinded, active-controlled study to compare the efficacy and safety of STELARA to adalimumab in the treatment of

biologic-naïve patients with moderately to severely active Crohn's disease. The study consists of screening (within 1 to 5 weeks prior to week 0), treatment phase (weeks 0 to 52), and follow-up phase (up to week 76). Study assessments include Crohn's Disease Activity Index (CDAI), video ileocolonoscopy; CD-related healthcare utilization; patient-reported outcomes (PROs); laboratory evaluations; biomarkers; review of concomitant medications and adverse events (AEs); and evaluation of serum concentrations of study agent as well as development of antibodies to study agent. All participants were randomly assigned to receive either ustekinumab or adalimumab. No participants were treated with placebo only.

About IM-UNITI[8]

IM-UNITI, a Phase 3, multicenter, randomized, double-blind, placebo-controlled, parallel group study, evaluated the efficacy and safety of STELARA maintenance therapy in adult patients with moderate to severe Crohn's disease. Patients who had responded to a single IV dose of STELARA in the UNITI-1 or UNITI-2 induction studies were randomized equally to receive maintenance SC STELARA 90 mg q8w or q12w, or placebo. There were 1,281 patients enrolled in the maintenance study. In randomized patients who met loss of response criteria between weeks 8–32, a one-time dose adjustment to 90 mg q8w occurred. All patients completing week 44 were eligible to enter the long-term extension program, continuing their current regimen up to week 252.

About Crohn's disease

CD is one of the two main forms of inflammatory bowel disease, which affects an estimated three million Americans.[9] 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.[10] Symptoms of CD can vary but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss and fever.[11] There is currently no cure for CD.[12]

About Ulcerative Colitis

More than five million people worldwide are living with CD and UC—commonly known as inflammatory bowel disease. UC affects nearly 907,000 people in the U.S., with

approximately 38,000 new cases diagnosed each year.[13] 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.[14] Symptoms vary but may include loose and more urgent bowel movements, persistent diarrhea, abdominal pain, bloody stool, loss of appetite, weight loss and fatigue.[15]

About STELARA® (ustekinumab)[16]

STELARA® (ustekinumab) is a fully human monoclonal antibody and is the first biologic treatment to selectively inhibit the interleukin (IL)-12 and IL-23 pathways. STELARA is approved in the United States for the treatment of: 1) adults and children six years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy; 2) adult patients (18 years or older) with active psoriatic arthritis, used alone or in combination with methotrexate (MTX); 3) adult patients (18 years and older) with moderately to severely active Crohn's disease; 4) adult patients (18 years and older) with moderately to severely active ulcerative colitis.

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

IMPORTANT SAFETY INFORMATION

STELARA® is a prescription medicine that affects your immune system. STELARA® can increase your chance of having serious side effects including:

Serious Infections

STELARA® may lower your ability to fight infections and may increase your risk of infections. While taking STELARA®, some people have serious infections, which may require hospitalization, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses.

- Your doctor should check you for TB before starting STELARA® and watch you closely for signs and symptoms of TB during treatment with STELARA®.

- If your doctor feels that you are at risk for TB, you may be treated for TB before and during treatment with STELARA®.

You should not start taking STELARA® if you have any kind of infection unless your doctor says it is okay.

Before starting STELARA®, tell your doctor if you:

- think you have an infection or have symptoms of an infection such as:
    - fever, sweats, or chills
    - muscle aches
    - cough
    - shortness of breath
    - blood in phlegm
    - weight loss
    - warm, red, or painful skin or sores on your body
    - diarrhea or stomach pain
    - burning when you urinate or urinate more often than normal
    - feel very tired
- are being treated for an infection.
- get a lot of infections or have infections that keep coming back.
- have TB, or have been in close contact with someone with TB.

After starting STELARA®, call your doctor right away if you have any symptoms of an infection (see above). STELARA® can make you more likely to get infections or make an infection that you have worse. People who have a genetic problem where the body does not make any of the proteins interleukin 12 (IL-12) and interleukin 23 (IL-23) are at a higher risk for certain serious infections that can spread throughout the body and cause death. People who take STELARA® may also be more likely to get these infections.

Cancers

STELARA® may decrease the activity of your immune system and increase your risk for certain types of cancer. Tell your doctor if you have ever had any type of

cancer. Some people who had risk factors for skin cancer developed certain types of skin cancers while receiving STELARA®. Tell your doctor if you have any new skin growths.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

RPLS is a rare condition that affects the brain and can cause death. The cause of RPLS is not known. If RPLS is found early and treated, most people recover. Tell your doctor right away if you have any new or worsening medical problems including: headache, seizures, confusion, and vision problems.

Serious Allergic Reactions

Serious allergic reactions can occur. Stop using STELARA® and get medical help right away if you have any symptoms of a serious allergic reaction such as: feeling faint, swelling of your face, eyelids, tongue, or throat, chest tightness, or skin rash.

Lung Inflammation

Cases of lung inflammation have happened in some people who receive STELARA® and may be serious. These lung problems may need to be treated in a hospital. Tell your doctor right away if you develop shortness of breath or a cough that doesn't go away during treatment with STELARA®**.**

Before receiving STELARA®, tell your doctor about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed above for serious infections, cancers, or RPLS.
- ever had an allergic reaction to STELARA® or any of its ingredients. Ask your doctor if you are not sure.
- are allergic to latex. The needle cover on the prefilled syringe contains latex.
- have recently received or are scheduled to receive an immunization (vaccine). People who take STELARA® should not receive live vaccines. Tell your doctor if anyone in your house needs a live vaccine. The viruses used in some types of live vaccines can spread to people with a weakened immune system, and can

cause serious problems. **You should not receive the BCG vaccine during the one year before receiving STELARA® or one year after you stop receiving STELARA®.**

- have any new or changing lesions within psoriasis areas or on normal skin.
- are receiving or have received allergy shots, especially for serious allergic reactions.
- receive or have received phototherapy for your psoriasis.
- are pregnant or plan to become pregnant. It is not known if STELARA® can harm your unborn baby. You and your doctor should decide if you will receive STELARA®.
- are breastfeeding or plan to breastfeed. It is thought that STELARA® passes into your breast milk. Talk to your doctor about the best way to feed your baby if you receive STELARA®.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

When prescribed STELARA®:

- Use STELARA® exactly as your doctor tells you to.
- STELARA® is intended for use under the guidance and supervision of your doctor. In children 6 years and older, it is recommended that STELARA® be administered by a healthcare provider. If your doctor decides that you or a caregiver may give your injections of STELARA® at home, you should receive training on the right way to prepare and inject STELARA®. Your doctor will determine the right dose of STELARA® for you, the amount for each injection, and how often you should receive it. Do not try to inject STELARA® yourself until you or your caregiver have been shown how to inject STELARA® by your doctor or nurse.

Common side effects of STELARA® include: nasal congestion, sore throat, and runny nose, upper respiratory infections, fever, headache, tiredness, itching, nausea and vomiting, redness at the injection site, vaginal yeast infections, urinary tract infections, sinus infection, stomach pain, diarrhea, and joint pain. These are not all of the possible side effects with STELARA®. Tell your doctor about any side effect that you experience. Ask your doctor or pharmacist for more information.

Please read the full Prescribing Information and Medication Guide for STELARA® and discuss any questions you have with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

cp-113880v1

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. Follow us at www.twitter.com/JanssenGlobal.

Janssen Research & Development, LLC is a 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 Crohn's disease and 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 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 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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