News Release

Media Contact:
Craig Stoltz
Mobile: (215) 986-1975

Investor Contact:
Raychel Kruper
Office: (732) 524-6164

New STELARA® (ustekinumab) Long-Term Data Support its Established Safety Profile in Inflammatory Bowel Disease and Durable Efficacy in Ulcerative Colitis

Final cumulative pooled IBD safety data support the longstanding safety profile of STELARA across all IBD approved indications

Additional long term extension data demonstrate more than half of STELARA-treated patients with ulcerative colitis achieved clinical remission, clinical response, and/or demonstrated endoscopic improvement at four years

SPRING HOUSE, PENNSYLVANIA, March 4, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced final pooled long-term safety results for STELARA® (ustekinumab) through five years in adults with moderately to

severely active Crohn's disease (CD) and four years in adults with moderately to severely active ulcerative colitis (UC), as well as final four-year clinical and endoscopic outcomes from the UNIFI long-term extension (LTE) study evaluating the efficacy of STELARA for the treatment of adults with moderately to severely active UC.[1,2] These data are a part of Janssen's 22 oral and poster presentations at the 18th Congress of the European Crohn's and Colitis Organization (ECCO), taking place in Copenhagen, Denmark, March 1-4.

"These data reinforce the known efficacy and safety profile of STELARA, and demonstrate it can be an effective long-term treatment option for patients living with moderately to severely active ulcerative colitis," said UNIFI study author Waqqas Afif, M.D., Associate Professor, Department of Medicine, Division of Experimental Medicine and Division of Gastroenterology at McGill University Health Centre in Montreal, Canada.[a] "Importantly, clinical and endoscopic outcomes reinforce the durable efficacy of STELARA, as we remain committed to developing therapies that provide patients with lasting remission."

Final STELARA long-term pooled safety analysis (Oral presentation OP39):[1]
A final pooled safety analysis of six Phase 2/3 IBD studies included 2,575 patients treated with STELARA and a total of 4,826 patient-years (PY) of follow-up.

- **Overall safety profile:** Data continue to support a well-established safety experience in adult patients with moderately to severely active ulcerative colitis (UC) through up to four years, and in adult patients with moderately to severely active Crohn's disease (CD) through five years.
- **Key safety events:** Key safety event rates adjusted per 100 PYs for adverse events (AEs), serious AEs, infections, serious infections, major adverse cardiac events (MACE), and malignancies were either similar between placebo and STELARA or lower for STELARA.
- **Adverse events:** The most frequently occurring adverse events (AEs) per 100 PY of follow-up (excluding disease related AEs under study) were headache (11.60 STELARA versus 16.66 placebo), arthralgia (11.23 STELARA versus 15.91 placebo), abdominal pain (9.86 STELARA versus 13.79

placebo), nausea (7.13 STELARA versus 11.35 placebo), and pyrexia (5.91 STELARA versus 11.35 placebo). The most frequently reported serious infections of anal abscess, pneumonia, cellulitis, and abdominal abscess were similar between STELARA and placebo, except gastroenteritis (0.25 STELARA versus 0.11 placebo). The most frequently reported infections were nasopharyngitis (19.10 STELARA versus 17.82 placebo) and upper respiratory tract infection (9.80 STELARA versus 11.78 placebo).

Final UNIFI LTE clinical and endoscopy outcomes through four years from STELARA treatment (Oral presentation OP15):[2] Results from the UNIFI LTE study, among 205 adult patients[b] with a history of moderate to severe UC who had achieved clinical response to treatment with intravenous (IV) STELARA, were randomized to STELARA 90 mg every eight weeks (q8w) or every 12 weeks (q12w)[c] at baseline of the maintenance study, and continued treatment in the LTE, showed that at week 200:[d]

- 58 percent (119/205) of patients were in clinical remission[e]
- 80 percent (164/205) of patients were in clinical response[f]
- 79.5 percent (163/205) of patients were in modified Mayo score response[g]
- 67 percent (138/205) of patients showed endoscopic improvement[h]

"These long-term studies underscore Janssen's commitment to developing novel therapies addressing unmet medical need," said Jan Wehkamp, M.D., Ph.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. "Our findings reinforce our confidence in STELARA as a therapy of choice for patients seeking lasting relief from inflammatory bowel disease."

Editor's Notes:

a. Dr. Afif received grant support from Janssen. He has not been compensated for any media work.

b. Patients were randomized to STELARA at maintenance baseline and continued treatment in the LTE, who either had Mayo score data (including endoscopy) at week 200 or had experienced treatment failure[2]
c. q12w dosing is not currently approved for STELARA in the U.S. Current approved dosing is a subcutaneous 90 mg dose eight weeks after initial intravenous dose, then every eight weeks thereafter[3]
d. Patients who had treatment failure (i.e., had ostomy or colectomy or discontinued STELARA due to lack of therapeutic effect or worsening UC) before week 200 were also included, and were imputed as nonresponders.[2]
e. Clinical remission is defined as a Mayo score ≤2 points and no individual subscore >1[2]
f. Clinical response is defined as a decrease in Mayo score of ≥30% and ≥3 points from induction baseline with either a decrease in rectal bleeding subscore of ≥1 from induction baseline or a rectal bleeding subscore of 0 or 1[2]
g. Modified Mayo score (without Physician's Global Assessment subscore) response is defined as a decrease in modified Mayo score of ≥30% and ≥2 points from induction baseline with either a decrease in rectal bleeding subscore of ≥1 from induction baseline or a rectal bleeding subscore of 0 or 1[2]
h. Endoscopic improvement, endoscopic healing, or mucosal healing is defined as an endoscopy subscore of 0 or 1[2]

About UNIFI (NCT02407236)[2,4]

UNIFI was a Phase 3 protocol designed to evaluate the safety and efficacy of STELARA induction and maintenance dosing for the treatment of moderately to severely active ulcerative colitis in adults who demonstrated an inadequate response to or were unable to tolerate conventional (i.e., corticosteroids, immunomodulators) or biologic (i.e., one or more TNF blockers or vedolizumab) therapies. Both the induction and maintenance studies were

randomized, double-blind, placebo-controlled, parallel group, multi-center studies.

The induction study was of at least 8 weeks duration for each participant. Participants achieving clinical response in the induction study were eligible for the maintenance study. The maintenance study was 44 weeks in duration. The primary endpoint of the induction study was clinical remission at week 8, and the primary endpoint for the maintenance study was clinical remission at week 44 among responders to a single intravenous (IV) STELARA infusion (130 mg or ~6 mg/kg). Overall, 523 IV STELARA induction responders were randomized to subcutaneous (SC) maintenance therapy (175 SC placebo; 172 STELARA 90 mg q12w; 176 STELARA 90 mg q8w). 284 STELARA patients who completed week 44 entered the LTE. Placebo patients were discontinued after week 44 unblinding. The long-term extension of UNIFI followed eligible participants for an additional three years upon completion of the maintenance study.

Starting at week 56, randomized patients with UC worsening could adjust to q8w dosing. Outcomes based on the Mayo score (including endoscopy assessed by a local reader) were evaluated in the final efficacy visit at week 200. Patients who had treatment failure (i.e., had ostomy or colectomy, or discontinued STELARA due to lack of therapeutic effect or worsening UC) before week 200 were also included, and were imputed as non-responders.

About Ulcerative Colitis

Ulcerative Colitis (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.[5] It is the result of the immune system's overactive response.[5] Symptoms vary, but may include loose and more urgent bowel movements, persistent diarrhea, abdominal pain, bloody stool, loss of appetite, weight loss and fatigue.[6]

About Crohn's Disease

CD is one of the two main forms of IBD, which affects an estimated three million Americans.[7] 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.[8] Symptoms of CD can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss and fever.[9]

About STELARA® (ustekinumab)[3]

STELARA® (ustekinumab), a human interleukin (IL)-12 and IL-23 antagonist, 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) adults and children six years and older with active psoriatic arthritis; 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 or have any open cuts.
- 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). These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications. 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.

Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is a rare condition that affects the brain and can cause death. The cause of PRES is not known. If PRES 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 PRES.
- 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, bronchitis, diarrhea, stomach pain, 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 click to 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.

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 & Retina; 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 product development of 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 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 1, 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, 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.

# # #

References

1. Ghosh, S, *et al.* Safety of Ustekinumab in IBD: Final Pooled Long-Term Safety Analysis Through 5 Years in CD and 4 Years in UC. Presented at 18th Congress of ECCO, March 1-4.

2. Danese, S, *et al.* Efficacy of Ustekinumab for Ulcerative Colitis Through 4 Years: Final Clinical and Endoscopy Outcomes from the UNIFI Long-Term Extension. Presented at the 18th Congress of ECCO, March 1-4.
3. STELARA® Prescribing Information. Available at: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf. Accessed January 2023.
4. National Institutes of Health: Clinicaltrials.gov. A Study to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Participants With Moderately to Severely Active Ulcerative Colitis (UNIFI). Identifier: NCT02407236. Available at: https://clinicaltrials.gov/ct2/show/NCT02407236. Accessed January 2023.
5. Crohn's & Colitis Foundation of America. The Facts About Inflammatory Bowel Diseases. Available at https://www.crohnscolitisfoundation.org/sites/default/files/2019-02/Updated%20IBD%20Factbook.pdf. Accessed September January 2023.
6. Crohn's & Colitis Foundation. What is Ulcerative Colitis? Available at: https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis. Accessed January 2023.
7. Crohn's & Colitis Foundation. Overview of Crohn's disease. Available at: https://www.crohnscolitisfoundation.org/what-is-crohns-disease/overview. Accessed January 2023.
8. Crohn's & Colitis Foundation. What is Crohn's disease? Available at: https://www.crohnscolitisfoundation.org/what-is-crohns-disease/causes. Accessed January 2023.
9. Crohn's & Colitis Foundation. Signs and Symptoms of Crohn's Disease. Available at: https://www.crohnscolitisfoundation.org/what-is-crohns-disease/symptoms. Accessed January 2023.
10.