



News Release

Media Contact:

Craig Stoltz
Mobile: (609) 730-2922

Investor Contact:

Raychel Kruper
Office: (732) 524-6164

STELARA® (ustekinumab) Demonstrated Sustained Symptomatic and Corticosteroid-Free Remission Through Four Years in Adults with Moderately to Severely Active Ulcerative Colitis

55.2 percent of induction responder patients treated with STELARA at the start of maintenance were in symptomatic remission approximately four years later (at week 200), 96.4 percent without corticosteroids

Overall, 79.1 percent of patients treated with STELARA in the long-term extension (LTE) who were receiving corticosteroids at maintenance baseline were no longer receiving corticosteroids by week 200

SPRING HOUSE, PENNSYLVANIA, October 10, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced final data from the long-term extension (LTE) of the Phase 3 UNIFI study demonstrating efficacy and safety of STELARA® (ustekinumab) through four years of treatment in adult patients with moderately to severely active ulcerative colitis (UC).¹ Among all

patients who had achieved clinical response^a with STELARA during induction, 64.9 percent were in symptomatic remission^b after 44 weeks of maintenance. At week 200 (four years), this proportion of patients was 55.2 percent; the majority (96.4 percent [185/192]) were not receiving corticosteroids.¹ Among the 174 patients receiving STELARA as their first biologic for UC (biologic-naïve), 71.8 percent (125) of these patients were in symptomatic remission^b after 44 weeks of maintenance, and 67.2 percent (117) were in remission at week 200. A separate presentation of UNIFI LTE study data showed the majority (79.1 percent) of STELARA randomized patients who received corticosteroids at maintenance baseline and were treated with STELARA in the LTE were able to eliminate the use of corticosteroids by week 200.² These data are being presented at the United European Gastroenterology (UEG) Week 2022 congress taking place in-person in Vienna and virtually from October 8-11.^{1,2}

“The final LTE results of the UNIFI study demonstrated that STELARA can be an effective long-term treatment option for patients living with moderately to severely active ulcerative colitis, including in patients who are biologic-naïve,” said UNIFI presenting 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.^c “Importantly, the vast majority of patients who achieved remission in the study were able to eliminate the use of steroids, which can cause significant side effects and are not a long-term treatment solution for the disease.”

UNIFI LTE Week 200 Efficacy and Safety Data (Poster PO396):¹

At week 200, among all 348 patients who had achieved clinical response to treatment with intravenous (IV) STELARA and were randomized to STELARA 90 mg every eight weeks (q8w) or every 12 weeks (q12w) at baseline of the maintenance study:

- 55.2 percent of patients (192/348) were in symptomatic remission compared to 64.9 percent of patients (226/348) who were in symptomatic remission at week 44 (the end of the primary maintenance treatment study).^{b,d,e}

- 53.2 percent of patients (185/348) achieved corticosteroid-free symptomatic remission compared to 63.5 percent (221/348) at week 44.^{b,d,e,f,g}
- Among the 174 biologic-naïve patients randomized to receive STELARA at maintenance baseline, 67.2 percent (117/174) were in symptomatic remission at week 200 compared to 71.8 percent (125/174) of patients who were in symptomatic remission at week 44.^b
- 72.9 percent of those who were in clinical remission at week 44 were also in symptomatic remission at week 200.^{b,d,e}
- Among the 284 randomized patients who entered the LTE phase of the study after week 44 of the maintenance trial and continued on treatment with STELARA (either q8w or q12w), 67.6 percent (192/284) were in symptomatic remission at week 200.^{b,d,e}

Safety was evaluated for all patients (n=588) who were treated in the LTE, including randomized and non-randomized populations.¹

- Key safety event rates were similar among STELARA-treated patients compared with placebo throughout the study.
- From maintenance week 0 through week 220, STELARA patients and placebo patients had 1,647.4 and 301.7 patient-years (PYs) of follow-up, respectively.
- Numbers of events per 100 PYs of follow-up were as follows: adverse events (AEs) 214.45 for STELARA versus 288.04 for placebo; serious adverse events (SAEs) 7.22 for STELARA versus 10.61 for placebo, and serious infections 2.00 for STELARA versus 3.31 for placebo.
- No new safety signals were observed.^{1,3}

UNIFI LTE Week 200 Corticosteroid-Sparing Data (Poster PO395):²

Results from a separate presentation on corticosteroid-sparing effects within the UNIFI LTE study show 79.1 percent of STELARA randomized patients who received corticosteroids at maintenance baseline and were treated with STELARA in the LTE were no longer receiving corticosteroids at week 200.⁹ Among patients who were

randomized to STELARA at maintenance baseline and treated in the LTE phase of the study:

- Rates of corticosteroid-free symptomatic remission^b at week 200 were generally similar between the q8w group (63.6 percent [91/143]) and the q12w group (66.7 percent [94/141]).^{e,f,g,h}
- Among patients treated with STELARA who were in symptomatic remission^b at week 200, 94.8 percent (91/96) in the q8w group and 97.9 percent (94/96) in the q12w group were corticosteroid-free.

“STELARA is a well-established therapy, and the final results of the UNIFI LTE study demonstrate sustained, long-term clinical benefit in moderately to severely active ulcerative colitis,” said Jan Wehkamp, M.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. “We hope this is welcome news for patients who are seeking long-term treatment options that may provide enduring relief from the debilitating symptoms of the disease.”

Editor’s Note:

- a. Clinical response is defined as a decrease from baseline in the Mayo score by ≥ 30 percent and ≥ 3 points, with either a decrease from baseline in the rectal bleeding subscore ≥ 1 or a rectal bleeding subscore of 0 or 1.⁴
- b. Symptomatic remission is defined as a stool frequency subscore of 0 or 1 and a rectal bleeding subscore of 0. Symptomatic remission results refer to the STELARA 90 mg q8w and q12w combined group.¹
- c. Dr. Afif received grant support from Janssen. He has not been compensated for any media work.
- d. Patients who had an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC after week 44 and prior to week 200, were considered not to be in symptomatic remission at week 200.¹
- e. Patients who had both stool frequency and rectal bleeding subscores missing at a visit were considered not to be in symptomatic remission for that visit.¹

- f. Patients who had a missing value in corticosteroid use had their last value carried forward.¹
- g. During the maintenance study, all patients receiving corticosteroids at maintenance baseline were required to initiate tapering.²
- h. Patients who had an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect or due to an AE of worsening of UC prior to the designated visit were considered not to be in symptomatic remission.¹

About UNIFI (NCT02407236)⁵

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^a 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. 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. Randomized 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. Efficacy was evaluated in randomized patients using symptomatic

remission.^b Safety was evaluated for all 588 patients who were treated in the LTE, including the randomized and nonrandomized populations. The nonrandomized population included STELARA induction non-responders at week 8 who received SC STELARA and responded eight weeks later, and responders to placebo induction.

About Ulcerative Colitis

Inflammatory bowel disease (IBD), which includes Crohn's disease and UC, affect as many as 1.6 million people in the United States.⁶ 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.⁷ It is the result of the immune system's overactive response.⁷ Symptoms vary, but may include loose and more urgent bowel movements, persistent diarrhea, abdominal pain, bloody stool, loss of appetite, weight loss and fatigue.⁸

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.

cp-124932v6

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 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, 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 2, 2022, 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. Afif, W, *et al.* Efficacy and Safety of Ustekinumab for Ulcerative Colitis Through 4 Years: Final Results from the UNIFI Long-term Extension. Presented at UEG Week 2022, October 8-11.
2. Arasaradnam, RP, *et al.* Corticosteroid-Sparing Effects of Ustekinumab Therapy for Ulcerative Colitis Through 4 Years: UNIFI Long-term Extension. Presented at UEG Week 2022, October 8-11.
3. STELARA® Prescribing Information. Available at: <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf>. Accessed September 2022.
4. Sands, BE, *et al.* Safety and Efficacy of Ustekinumab Induction Therapy in Patients with Moderate to Severe Ulcerative Colitis: Results from the Phase 3 UNIFI Study. Presented at ACG 2018, October 9.
5. 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 September 2022.
6. 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 2022.
7. Crohn's & Colitis Foundation. What is Ulcerative Colitis? Available at: <https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis>. Accessed September 2022.
8. Crohn's & Colitis Foundation. Signs and Symptoms of Ulcerative Colitis. Available at: <https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis/symptoms>. Accessed September 2022.