



News Release

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STELARA® (ustekinumab) Demonstrated Sustained Symptomatic and Corticosteroid-Free Remission Rates in Adults with Moderately to Severely Active Ulcerative Colitis at Nearly Three Years in Long-Term Extension of Phase 3 Trial

55.2 percent of patients were in symptomatic remission and 96.4 percent of patients were corticosteroid-free at week 152

New data from the UNIFI study is one of 22 Janssen abstracts, including five oral and three digital oral presentations, at the 16th Congress of the European Crohn's and Colitis Organisation

SPRING HOUSE, PENNSYLVANIA, July 9, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new three-year data from the long-term extension (LTE) of the STELARA® (ustekinumab) Phase 3 UNIFI study. The data demonstrated the majority (55.2 percent) of adult patients with moderately to severely active ulcerative colitis (UC) who initially responded to treatment with STELARA sustained symptomatic remission^a rates at nearly three years (week 152).¹ Furthermore, a majority (96.4 percent) of the patients in symptomatic remission^a at week 152 were corticosteroid-free. These data are being

presented today as a digital oral presentation (DOP83) at the 16th Congress of the European Crohn's and Colitis Organisation.¹

"Despite recent substantial therapeutic gains, many patients living with ulcerative colitis still struggle to find lasting relief from their disease symptoms, especially without the use of steroids that can be associated with debilitating side effects when used long-term," 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.^b "The LTE of the UNIFI study underscores the importance of studying therapies long-term, with results showing ustekinumab as both an effective and enduring treatment option for patients living with moderately to severely active ulcerative colitis."

Of the 348 patients in the intent-to-treat population^c who had achieved clinical response at maintenance baseline and were randomized to STELARA 90 mg every eight weeks (q8w) or every 12 weeks (q12w):¹

- 55.2 percent of patients were in symptomatic remission^a at week 152.
- 96.4 percent (185/192) of patients in symptomatic remission^a at week 152 were not receiving corticosteroids.

Of the 248 patients randomized to STELARA 90 mg q8w or q12w at maintenance baseline and treated in the LTE:^{1,d}

- 67.6 percent of patients were in symptomatic remission^a at week 152.
- 76.4 percent of patients in clinical remission^e at week 44 were in symptomatic remission^a at week 152.

Safety was evaluated at week 156 for all patients (n=588) who were treated in the LTE. From maintenance week 0 through week 156, combined STELARA patients and placebo patients had 1,281.6 and 425 patient-years (PYs) of follow-up, respectively. Safety events per 100 PYs of follow-up were as follows: adverse events (AEs) 235.81 for STELARA vs 204.48 for placebo; serious adverse events

(SAEs) 7.73 for STELARA vs 7.53 for placebo, and serious infections 2.34 for STELARA vs 2.35 for placebo. No new safety signals were observed.^{1,2}

Results from a separate digital oral presentation (DOP86) on corticosteroid-sparing effects within the UNIFI LTE show 91.4 percent of STELARA patients (n=139) receiving corticosteroids at maintenance baseline were no longer receiving corticosteroids at week 152 (patients were randomized to STELARA at the start of the LTE of the study).³

“Janssen is relentlessly focused on unmet patient needs and committed to improving the standard of care in ulcerative colitis,” said Jan Wehkamp, M.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. “We are proud to share these long-term data among the gastrointestinal community, especially for patients who are still struggling to manage their disease and achieve remission.”

Editor’s Note:

- a. Symptomatic remission is defined as a Mayo 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
- b. Dr. Sands is a paid consultant for Janssen. He has not been compensated for any media work.
- c. All patients were randomized to STELARA at maintenance baseline with non-responder importation (NRI) and treatment failure criteria.¹
- d. Included treatment failure and missing data utilizing NRI.¹
- e. Clinical remission is defined as a Mayo score ≤ 2 points, with no individual subscore >1 .¹

About the UNIFI Trial⁴

UNIFI is 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 UC 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 are randomized, double-blind, placebo-controlled, parallel group, multi-center studies.

The induction study was of at least eight 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 duration. The primary endpoint of the induction study was clinical remission at week eight, 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. Starting at week 56, randomized patients with UC worsening could adjust to q8w dosing. Efficacy was evaluated in randomized patients using symptomatic remission.^a Safety was evaluated for all 588 patients who were treated in the LTE, including the randomized and nonrandomized populations. Through week 156, 131 patients continued on placebo and 457 patients received STELARA. The nonrandomized population included STELARA induction non-responders at week eight who received SC STELARA and responded eight weeks later, and responders to placebo induction.

About Ulcerative Colitis

More than five million people worldwide are living with Crohn's disease (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.⁵ 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.⁶ Symptoms vary but may include loose and more urgent bowel movements, persistent diarrhea, abdominal pain, bloody stool, loss of appetite, weight loss and fatigue.⁷

About STELARA® (ustekinumab)²

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 CD; 4) adult patients (18 years and older) with moderately to severely active UC.

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.

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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 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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References

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