



News Release

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STELARA® (ustekinumab) Five-Year Results Presented from Long-term Extension Study of Clinical Response and Remission in Patients with Moderate to Severe Crohn's Disease

Final results of IM-UNITI study presented as an oral presentation at United European Gastroenterology (UEG) Week Virtual 2020 Congress

SPRING HOUSE, PENNSYLVANIA, October 12, 2020 - The Janssen

Pharmaceutical Companies of Johnson & Johnson today announced new, final five-year data from the Phase 3 IM-UNITI open-label, long-term extension (LTE) study which showed treatment of STELARA® (ustekinumab) in patients with moderate to severe Crohn's disease (CD) maintained long-term remission¹ through five years.^{2,i}

These data are being presented today as an oral presentation (Abstract OP110) at the 28th United European Gastroenterology (UEG) Week, which is conducting its annual congress virtually.²

"Crohn's disease is among the most debilitating forms of inflammatory bowel disease, disrupting the lives of millions of patients worldwide," said lead study

investigator William J. Sandbornⁱⁱ, M.D., Chief of Gastroenterology, Professor of Medicine, University of California, San Diego, who is delivering the oral presentation virtually at UEG Week. “Results from the IM-UNITI study showed that patients were able to maintain response with STELARA treatment through five years. Notably, for those patients in clinical remission, the majority (greater than 90 percent) who received continuous treatment with q8w STELARA were steroid-free at five years.”

The key findings showed more than half of the patients with moderately to severely active CD who were randomized to subcutaneous (SC) STELARA every 8 weeks (q8w) and continued to receive this dosage in the LTE study maintained clinical response³ (57 percent) and remission (55 percent) through five years of treatment. Of these patients in clinical remission, 93 percent were steroid-free.²

Additionally, among the subgroup of these patients who had never previously been exposed to anti-tumor necrosis factor alpha (TNF- α) biologics, 59 percent were in clinical remission after five years of receiving SC STELARA q8w maintenance treatment. Further, among the subgroup of these patients who had previously failed (i.e. were refractory to) or who were intolerant to anti TNF- α therapy, 44 percent were in clinical remission after five years of receiving SC STELARA q8w maintenance treatment. Approximately half (51 percent, [290/567]) of all patients (randomized and assigned) who entered the LTE study completed their final dosing visit.²

Through five years, the event rates (per one hundred patient years) for adverse events (AEs), serious AEs, and serious infections for the q8w STELARA group were generally comparable to the event rates in the placebo group. Antibody to STELARA rates through week 272 remained low, occurring in 5 percent of patients assigned to receive STELARA in the maintenance study and continuously receiving the approved 90 mg SC q8w regimen in the LTE. No new safety signals were observed.²

“Crohn’s disease is a chronic, lifelong condition, so it’s important to understand the long-term outcomes of therapies in order to effectively address the disease,” said Jan Wehkamp, M.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. “These results from the LTE study with

STELARA bring us further insights on the long-term management of this chronic disease.”

Janssen is presenting a total of 16 abstracts at this year’s UEG Week congress of which seven are oral presentations.

About the IM-UNITI trial⁴

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 intravenous 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.² 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)

CD is one of the two main forms of inflammatory bowel disease, which affects an estimated 3 million Americans.⁵ 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 diarrhea, rectal bleeding, weight loss and fever.^{6,7} There is currently no cure for CD.⁷

About STELARA® (ustekinumab)⁸

STELARA® (ustekinumab) is a fully human monoclonal antibody and is the first and only 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 or www.twitter.com/JanssenUS.

Janssen Research & Development, LLC is one 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 the Phase 3 five-year long-term extension study of STELARA® (ustekinumab) in Crohn's disease. 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 December 29, 2019, 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.

ⁱIntention-to-treat analysis for patients originally randomized in the maintenance study is available within the abstract:

<https://ueg.eu/week/science/programme>.

ⁱⁱDr William J. Sandborn is a paid consultant for Janssen. He has not been compensated for any media work.

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References

1. Clinical remission is defined as a Crohn's Disease Activity index (CDAI) score of <150.
2. Sandborn, W, *et al.*, Efficacy and Safety of Ustekinumab for Crohn's Disease Through 5 Years: Final Results from the IM-UNITI Long-term Extension (Abstract OP110). Presented at the UEGW Virtual 2020 Congress October 11–13.
3. Clinical response is defined as a decrease in CDAI score from baseline of ≥ 100 points (CDAI100), or a CDAI score of <150.
4. Clinicaltrials.gov. A Study to Evaluate the Safety and Efficacy of Ustekinumab Maintenance Therapy in Patients With Moderately to Severely Active Crohn's Disease (IM-UNITI). Identifier: NCT01369355 Available at: <https://clinicaltrials.gov/ct2/show/NCT01369355>. Accessed September 14, 2020.
5. Crohn's & Colitis Foundation. Overview of Crohn's Disease. Available at: <https://www.crohnscolitisfoundation.org/what-is-crohns-disease/overview>. Accessed September 14, 2020.
6. Crohn's and Colitis Foundation. Causes of Crohn's disease. Available at: <https://www.crohnscolitisfoundation.org/what-is-crohns-disease/causes>. Accessed October 2020.
7. Mayo Clinic. Crohn's disease. Available at <https://www.mayoclinic.org/diseases-conditions/crohns-disease/symptoms-causes/syc-20353304.%20>. Accessed October 2020.
8. STELARA® Prescribing Information. Available at: <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf>. Accessed September 14, 2020.