



News Release

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JANSSEN DEMONSTRATES STRONG COMMITMENT TO RESEARCH AND DEVELOPMENT OF THERAPIES FOR INFLAMMATORY BOWEL DISEASES WITH NINE DATA PRESENTATIONS AT ACG 2020

Final, Five-Year Results of Long-Term Extension Study of Clinical Response and Remission of STELARA® (ustekinumab) in Patients with Moderate-to-Severe Crohn's Disease to be Featured in Oral Presentation

HORSHAM, PENNSYLVANIA, October 19, 2020 - The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that data from nine company-sponsored abstracts will be presented at the 2020 American College of Gastroenterology (ACG) Annual Meeting, being held virtually this year from October 23 – October 28. Featured among the eight poster presentations and one oral presentation are final five-year data from the IM-UNITI open-label long-term extension (LTE) study evaluating the efficacy and safety of STELARA® (ustekinumab) therapy in adult patients with moderately to severely active Crohn's disease, which will be presented via a pre-recorded, on-demand session available to registered attendees.

"While this year's meeting may look different in its virtual setting, our commitment to advancing the science and addressing unmet needs for people living with IBD is unchanged," said Jan Wehkamp, M.D., Vice President, Gastroenterology Disease Area

Leader, Janssen Research & Development, LLC. “Patients with a chronic condition like Crohn’s disease require long-term treatment, so it is critical to conduct studies like the IM-UNITI long-term extension study to gather important data on durability of treatment response and long-term outcomes. We look forward to sharing findings of this STELARA research with the medical community during this year’s congress.”

Other notable presentations at ACG include data from the Phase 3 UNIFI study evaluating the safety and efficacy of STELARA as a maintenance therapy in patients with moderately to severely active ulcerative colitis who previously failed biologic or conventional therapy. Data will be presented from the long-term extension study out to two years, including an abstract showing the effect of the treatment on stool frequency and rectal bleeding.

A listing of all abstracts to be featured at the congress, each available on-demand via the congress’ virtual platform, are provided in the table below.

Abstract No.	Title
P1650	Pharmacokinetics and Immunogenicity of Maintenance Therapy with Ustekinumab: 2-Year Results from the UNIFI Long-Term Extension Study
P1692	Fecal Calprotectin as a Surrogate Marker of Clinical Remission, Clinical Response, Endoscopic Improvement, and Histo-endoscopic Mucosal Healing: UNIFI Induction Study
P1584	Effect of Ustekinumab Maintenance Therapy on Stool Frequency and Rectal Bleeding Through 2 Years in the UNIFI Phase 3 Study in Ulcerative Colitis
OP42	Efficacy and Safety of Ustekinumab for Crohn’s Disease Through 5 Years: Final Results from the IM-UNITI Long-term Extension
P1677	Healthcare Cost Offsets from Reductions in Ulcerative Colitis-Related Hospitalizations and Surgeries in Patients Treated with Ustekinumab in the UNIFI Study

Abstract No.	Title
P1567	Nonbiologic Drug Use One Year Before and Two Years After Initiation of Ustekinumab or Adalimumab for Crohn's Disease Patients
P1676	Costs of Inflammatory Bowel Disease-Related Hospitalizations and Surgeries: A Retrospective Analysis in a Commercially Insured Population
P1100	Economic Costs Associated with Reduction in Work Productivity Loss for Ulcerative Colitis Patients Receiving Ustekinumab Using Results from the UNIFI Clinical Trial
P1101	Cost Reduction Associated With Improvement In Work Productivity Loss From Ustekinumab Treatment By Disease Severity States: Results From The IM-UNITI Clinical Trial

About Inflammatory Bowel Diseases

More than five million people worldwide are living with Crohn's disease and ulcerative colitis—collectively known as IBD.¹ Crohn's disease most commonly affects the end of the small bowel (the ileum) and the beginning of the colon, but it may affect any part of the gastrointestinal (GI) tract, from the mouth to the anus. Ulcerative colitis is limited to the colon, also called the large intestine. Symptoms of Crohn's disease can vary but may include abdominal cramps and pain, frequent diarrhea, rectal bleeding, weight loss and fever. There is currently no cure for Crohn's disease.² Symptoms of ulcerative colitis can vary but may include looser and more urgent bowel movements, bloody stool, crampy abdominal pain, loss of appetite and fatigue. There is currently no cure for ulcerative colitis.³

About STELARA® (ustekinumab)

STELARA® (ustekinumab), a human IL-12 and IL-23 antagonist, is approved in the United States for the treatment of: 1) adults and children 6 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 who have failed or were intolerant to

immunomodulators or corticosteroids; or failed or were intolerant to anti-TNF therapies;
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). 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.

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, 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 read the full [Prescribing Information](#), including the [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, 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 STELARA. 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 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.

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1. World IBD Day. Home. Available at <http://www.worldibdday.org/index.html>. Accessed October 8, 2020.

2. Crohn's & Colitis Foundation of America. What is Crohn's Disease? Available at <http://www.crohnscolitisfoundation.org/what-are-crohns-and-colitis/what-is-crohns-disease/>. Accessed October 8, 2020.
3. Crohn' & Colitis Foundation of America. What is Ulcerative Colitis? Available at <http://www.crohnscolitisfoundation.org/what-are-crohns-and-colitis/what-is-ulcerative-colitis/>. Accessed October 8, 2020.