



## **News Release**

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## **NEW PHASE 3 STELARA® (USTEKINUMAB) DATA SHOW POSITIVE RESULTS AS MAINTENANCE THERAPY IN ADULTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

*One-year UNIFI data presented for the first time during plenary session at 14th Congress of the European Crohn's and Colitis Organisation (Abstract OP37)*

*New data evaluating STELARA induction therapy on endoscopic and histologic healing featured as a digital oral presentation (Abstract DOP71)*

COPENHAGEN, DENMARK, March 11, 2019 - The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data from the Phase 3 UNIFI study showing that a significantly greater proportion of adult patients with moderate to severe ulcerative colitis (UC) receiving STELARA® (ustekinumab) subcutaneous (SC) maintenance therapy were in clinical remission<sup>1</sup> at one year, the study's primary endpoint, compared to patients receiving placebo. Patients receiving STELARA SC maintenance therapy were in clinical response eight weeks after receiving a single intravenous (IV) induction dose of STELARA.

These data were presented as part of a [plenary session](#) (Abstract OP37) at the 14th Congress of the European Crohn's and Colitis Organisation (ECCO) in Copenhagen, Denmark. At the Congress, Janssen also shared a digital oral presentation with [additional data](#) from the UNIFI induction study evaluating the effects of STELARA on histo-endoscopic mucosal healing, a novel, pre-specified endpoint in this program.

Results from the maintenance phase of the Phase 3 study demonstrated that 44 percent of adult patients with moderate to severe ulcerative colitis receiving STELARA SC injections every 8 weeks (q8w) and 38 percent receiving STELARA SC injections every 12 weeks (q12w) achieved clinical remission, as defined by the Mayo score<sup>1</sup>, at week 44 (52 weeks after IV induction), compared to 24 percent of patients who received placebo (both  $p < 0.001$ ). Patients receiving STELARA had responded to a single IV induction dose. These data were included in submissions to the U.S. Food and Drug Administration and European Medicines Agency seeking approval of STELARA as a treatment for ulcerative colitis.

"Ulcerative colitis is a disruptive, lifelong and potentially debilitating inflammatory bowel disease; however, it is a condition where remission is possible," said lead study investigator William Sandborn, M.D., Chief, Division of Gastroenterology, and Professor of Medicine, University of California, San Diego. "The data suggest the potential of ustekinumab as an effective therapy for helping people living with ulcerative colitis achieve remission, as well as providing other meaningful outcomes, including clinical response, histo-endoscopic improvement and corticosteroid-free remission."

Major secondary endpoints, including maintenance of clinical response, endoscopic improvement, corticosteroid-free remission and maintenance of clinical remission from baseline, were also achieved in greater proportions of patients receiving q8w and q12w injections versus patients receiving placebo. Through one year:

- 71 percent of patients receiving STELARA q8w and 68 percent of patients receiving STELARA q12w maintained clinical response, compared with 44 percent of patients receiving placebo (both  $p > 0.001$ ). Clinical response was defined as a decrease from baseline in the Mayo score by  $\geq 30$  percent

and  $\geq 3$  points, with a rectal bleeding sub-score of 0 or 1 or a decrease in the rectal bleeding sub-score  $\geq 1$ .

- 51 percent of patients receiving STELARA q8w and 44 percent of patients receiving STELARA q12w achieved endoscopic improvement, compared with 29 percent of patients receiving placebo ( $p > 0.001$  and  $p = 0.002$ , respectively). Endoscopic improvement was defined as a Mayo endoscopy sub-score of 0 (normal mucosa or inactive disease) or 1 (mild disease activity).
- 42 percent of patients receiving STELARA q8w and 38 percent of patients receiving STELARA q12w were in clinical remission and were corticosteroid-free, compared with 23 percent of patients receiving placebo ( $p < 0.001$  and  $p = 0.002$ , respectively). The global remission definition was a Mayo score  $\leq 2$  points, with no individual sub-score  $> 1$ .

Through one year, the proportions of patients with adverse events (AEs), serious AEs, infections, and serious infections in the STELARA groups were generally comparable to the placebo group. The proportions of patients who discontinued the study agent were lower with STELARA q8w and q12w versus placebo. Among the primary population in the maintenance study, no deaths occurred. Two malignancies other than non-melanoma skin cancer (NMSC) (one colon cancer, q8w; one papillary renal cell carcinoma, q12w) were reported. One patient reported NMSC (two squamous cell carcinoma events, q12w). Overall, the safety for STELARA in ulcerative colitis patients was consistent with the known safety profile of STELARA in Crohn's disease.

"The UNIFI maintenance data further build the case for STELARA as a potential new treatment option for ulcerative colitis and illustrate our ongoing commitment to researching and developing meaningful therapies for people living with inflammatory bowel diseases," said Scott E. Plevy, M.D., Gastroenterology Disease Area and IL-23 Pathway Leader, Janssen Research & Development, LLC. "Furthermore, we are proud that UNIFI is the first Phase 3 study to report a combined histo-endoscopic endpoint in patients with ulcerative colitis."

In the abstract (DOP71) presenting induction study colonic mucosal healing results, patients achieved higher rates of endoscopic improvement, histologic improvement and

the combined endpoint of histo-endoscopic mucosal healing (HEMH), versus placebo, eight weeks after receiving a single IV induction dose of STELARA. Histo-endoscopic mucosal healing assesses how the colon is responding both histologically and endoscopically to therapy and both have been associated with improved long-term clinical outcomes, such as reduced risk of relapse and need for surgery/hospitalization, and reduced risk of developing cancer.<sup>2</sup>

### **About the UNIFI Trial**

UNIFI is a Phase 3 protocol designed to evaluate the safety and efficacy of STELARA induction and maintenance dosing for the treatment of moderate to severe 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 are 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 duration. The primary endpoint of the induction study is clinical remission at week 8 and the primary endpoint for the maintenance study is clinical remission at week 44 among responders to a single IV STELARA infusion.

After completion of the maintenance study, a long-term extension will follow eligible participants for an additional 3 years.

### **About Ulcerative Colitis**

More than five million people worldwide are living with Crohn's disease and ulcerative colitis—commonly known as inflammatory bowel disease. Ulcerative colitis, or UC, affects nearly 907,000 people in the United States, with approximately 38,000 new cases diagnosed each year.<sup>3</sup> 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. Symptoms vary but may include loose and more urgent

bowel movements, persistent diarrhea, abdominal pain, bloody stool, loss of appetite, weight loss and fatigue.<sup>4</sup>

### **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 12 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.

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<sup>®</sup>, call your doctor right away** if you have any symptoms of an infection (see above). STELARA<sup>®</sup> 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<sup>®</sup> may also be more likely to get these infections.

### **Cancers**

STELARA<sup>®</sup> 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<sup>®</sup>. 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.
- STELARA® is intended for use under the guidance and supervision of your doctor. In children 12 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:** upper respiratory infections, headache, and tiredness **in psoriasis** patients; joint pain and nausea **in psoriatic arthritis patients**; and upper respiratory infections, redness at the injection site, vaginal yeast infections, itching, urinary tract infections, and vomiting **in Crohn's disease** patients. 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](http://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. Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Learn more at [www.janssen.com](http://www.janssen.com). Follow us at [www.twitter.com/JanssenGlobal](https://www.twitter.com/JanssenGlobal).

### **Cautions Concerning Forward-Looking Statements**

*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding new study data on 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 30, 2018, 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](http://www.sec.gov), [www.jnj.com](http://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. Remission was defined as a Mayo score  $\leq 2$  points, with no individual subscore  $> 1$ .
2. GI Health Foundation. What is Mucosal Healing? Available at [http://www.gihealthfoundation.org/GI\\_news\\_and\\_library/library/ppts/IBD/WhatisMucosalHealing.pdf](http://www.gihealthfoundation.org/GI_news_and_library/library/ppts/IBD/WhatisMucosalHealing.pdf). Accessed February 21, 2019.
3. World IBD Day. Home. Available at <http://www.worldibdday.org/index.html>. Accessed September 11, 2018.
4. Crohn's & Colitis Foundation of America. What is Ulcerative Colitis? Available at <http://www.crohnscolitisfoundation.org/what-are-crohns-and-colitis/what-is-ulcerative-colitis/>. Accessed September 11, 2018.