



News Release

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Janssen Demonstrates Strong Commitment to Inflammatory Bowel Disease with Data from 25 Abstracts Presented at the 2019 Digestive Disease Week Annual Meeting

Phase 3 Data Evaluating STELARA® (ustekinumab) Efficacy and Safety in Patients with Moderate to Severe Ulcerative Colitis Featured in Two Oral Presentations

SAN DIEGO, CALIFORNIA, May 14, 2019 - The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that data from 25 company-sponsored abstracts will be presented at the 2019 Digestive Disease Week (DDW) Annual Meeting in San Diego, California from May 18-21. Results from the Phase 3 UNIFI study evaluating the efficacy and safety of STELARA® (ustekinumab) in patients with moderate to severe ulcerative colitis (UC) – one in the overall UC population and a second in patients who previously failed biologic therapy and those who had not previously failed a biologic therapy – will be shared in oral presentations on May 21.

A Phase 1b study of TD-1473 (JNJ-8398) in moderately to severely active UC will also be featured as an oral presentation on May 20. These data are based on a study sponsored by Theravance Biopharma, Inc., with which Janssen is co-developing this gut-selective pan-JAK inhibitor.

“The presentations at this year’s meeting showcase our steadfast commitment to strengthening and expanding our portfolio in an effort to address the unmet needs for people living with IBD,” said Newman Yeilding, M.D., Vice President, Immunology Clinical Development, Janssen Research & Development, LLC. “The data presented from the Phase 3 UNIFI study of STELARA in ulcerative colitis has been included in our regulatory applications in the U.S., EU, Canada and Japan. There is still a significant unmet need for new treatment options for patients living with moderate to severe UC, and we are excited about the potential of STELARA.”

A listing of abstracts is provided in the table below. Notable data presentations at DDW include the following:

Two oral presentations featuring STELARA data in ulcerative colitis:

- Results from the Phase 3 UNIFI study evaluating the efficacy and safety of STELARA as a maintenance therapy in patients with moderate to severe ulcerative colitis who were in clinical response to a single intravenous induction of STELARA. (Abstract 833)
- Results from the Phase 3 UNIFI study evaluating the efficacy and safety of STELARA induction and maintenance therapy in the subpopulations of patients with moderate to severe ulcerative colitis who had previously failed biologic therapy and those who had not previously failed biologic therapy. (Abstract 833a)
- These data were included in the regulatory applications submitted to health authorities in the U.S., EU, Canada and Japan.

Poster presentation on histologic and endoscopic endpoints in STELARA ulcerative colitis Phase 3:

- Data from the Phase 3 UNIFI study evaluating the effects of STELARA induction therapy on endoscopic improvement, histologic improvement and combined histo-endoscopic mucosal healing (HEMH), in patients with moderate to severe ulcerative colitis will be presented as a poster. These data include an analysis combining endoscopic and histologic findings in a combined endpoint for the first time in a pivotal Phase 3 UC study. 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 and is a major therapeutic goal in treating patients with ulcerative colitis. (Abstract Tu1735)

Abstract No.	Title	Date/Time
833	Efficacy and safety of ustekinumab as maintenance therapy in ulcerative colitis: week 44 results from UNIFI	Oral Presentation Tuesday, May 21, 2019 8:30 AM - 8:45 AM
833a	Efficacy in biologic-failure and nonbiologic-failure populations in a phase 3 study of ustekinumab in moderate-severe ulcerative colitis: UNIFI	Oral Presentation Tuesday, May 21, 2019 8:45 AM - 9:00 AM
Sa1887	General Health Status in Patients with Moderate to Severe Ulcerative Colitis Receiving ustekinumab: results from the phase 3 UNIFI induction and maintenance studies	Poster Presentation Saturday, May 18, 2019 12:00 PM - 2:00 PM
Sa1888	Ustekinumab therapy induced clinically meaningful improvement and remission as measured by the inflammatory bowel disease questionnaire in patients with moderate to severe ulcerative colitis: results from the phase 3 UNIFI induction and maintenance studies	Poster Presentation Saturday, May 18, 2019 12:00 PM - 2:00 PM
Tu1719	Clinical remission by legacy versus FDA definitions: definition justification and results from UNIFI Study	Poster Presentation Tuesday, May 21, 2019 12:00 PM - 2:00 PM
Tu1735	Effects of ustekinumab induction therapy on endoscopic and histologic healing in the UNIFI phase 3 study in ulcerative colitis	Poster Presentation Tuesday, May 21, 2019 12:00 PM - 2:00 PM
Tu1736	Molecular response to ustekinumab in moderate-to-severe ulcerative colitis by serum protein and biopsy gene expression analysis: results from the UNIFI phase 3 induction study	Poster Presentation Tuesday, May 21, 2019 12:00 PM - 2:00 PM
Tu1739	Efficacy and safety of ustekinumab through week 16 in patients with moderate to severe ulcerative colitis randomized to ustekinumab: results from the UNIFI induction trial	Poster Presentation Tuesday, May 21, 2019 12:00 PM - 2:00 PM
Tu1740	Sustained remission in patients with moderate to severe ulcerative colitis: results from the phase 3 UNIFI maintenance study	Poster Presentation Tuesday, May 21, 2019 12:00 PM - 2:00 PM
Tu1749	Pharmacokinetics and exposure-response relationships of intravenously administered ustekinumab during induction treatment in patients with ulcerative colitis: results from the UNIFI induction study	Poster Presentation Tuesday, May 21, 2019 12:00 PM - 2:00 PM
Tu1718	Immunogenicity of ustekinumab in patients with Crohn's disease: results from the IM-UNITI study	Poster Presentation Tuesday, May 21, 2019 12:00 PM - 2:00 PM
Tu1723	Identification of risk factors associated with loss of response to ustekinumab in Crohn's disease	Poster Presentation Tuesday, May 21, 2019 12:00 PM - 2:00 PM

Tu1724	Association of ustekinumab serum concentrations and perianal fistula resolution in the Crohn's Disease UNITI program	Poster Presentation Tuesday, May 21, 2019 12:00 PM – 2:00 PM
Tu1725	Characterization of patients with delayed response to ustekinumab for Crohn's disease	Poster Presentation Tuesday, May 21, 2019 12:00 PM – 2:00 PM
Sa1906	Dose escalation with originator infliximab is more common than standard dosing in pediatric IBD: the DEVELOP experience	Poster Presentation Saturday, May 18, 2019 12:00 PM – 2:00 PM
Su1842	Characteristics of hepatosplenic T-cell lymphoma in patients exposed to infliximab: analysis of a company global safety database	Poster Presentation Sunday, May 19, 2019 12:00 PM – 2:00 PM
801	Clinical, endoscopic, histologic and biomarker activity following treatment with the gut-selective, pan-JAK inhibitor TD-1473 in moderately-to-severely active ulcerative colitis	Oral Presentation Monday, May 20, 2019 5:15 PM - 5:30 PM
Su1781	The economic burden of ulcerative colitis in the United States	Poster of Distinction Sunday, May 19, 2019 12:00 PM – 2:00 PM
Su1872	Evaluation of real-world maintenance dosing for ustekinumab and adalimumab among patients with Crohn's disease with at least one-year follow-up in the symphony health database	Poster Presentation Sunday, May 19, 2019 12:00 PM – 2:00 PM
Mo1779	Trends in emergency department visits and hospital admissions for patients with abdominal pain and history of inflammatory bowel disease	Poster Presentation Monday, May 20, 2019 12:00 PM – 2:00 PM
Mo1907	Evaluation of ustekinumab treatment patterns among Crohn's disease patients in three large US commercial claims databases	Poster Presentation Monday, May 20, 2019 12:00 PM – 2:00 PM
Mo1908	Nonbiologic drug use before and after initiation of ustekinumab or adalimumab for Crohn's disease patients	Poster Presentation Monday, May 20, 2019 12:00 PM – 2:00 PM
Mo1909	Evaluation of health care utilization, hospitalization/ emergency room costs, and other medication use among Crohn's disease patients using ustekinumab in three large United States commercial claims databases	Poster Presentation Monday, May 20, 2019 12:00 PM – 2:00 PM
Mo1993	Healthcare utilization and comorbidities among people with refractory and non-responsive celiac disease: findings from 4 large US administrative claims databases	Poster Presentation Monday, May 20, 2019 12:00 PM – 2:00 PM
Tu1839	Impact of ustekinumab TDM on clinical practice: a multicenter, prospective, cross-sectional observational trial	Poster Presentation Tuesday, May 21, 2019 12:00 PM – 2:00 PM

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 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®, 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.
- 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 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. Follow us at www.twitter.com/JanssenGlobal or www.twitter.com/JanssenUS.

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1. World IBD Day. Home. Available at <http://www.worldibdday.org/index.html>. Accessed February 2019.
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 February 2019.
3. 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 February 2019.