NEWS RELEASE

Phase 3 Data Show STELARA® Induced Clinical Response And Remission In The Treatment Of Patients With Moderate To Severe Crohn's Disease

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Efficacy and Safety Results from First STELARA® Phase 3 Induction Study (UNITI-2) Presented at the American College of Gastroenterology Annual Meeting

Honolulu, HI, October 19, 2015 - Phase 3 data presented for the first time showed treatment with STELARA® (ustekinumab) induced clinical response and clinical remission in patients with moderate to severe Crohn's disease who had previously failed conventional therapy, the majority of whom were naïve to treatment with anti-tumor necrosis factor (TNF)-alpha therapy. The Phase 3 Janssen Research & Development, LLC-sponsored UNITI-2 study achieved its primary endpoint with STELARA® treatment groups demonstrating significantly higher rates of clinical response at week 6 when compared with the placebo group. Major secondary endpoints of clinical response and clinical remission at week 8 were also significantly higher among patients receiving STELARA® compared with patients receiving placebo. STELARA®, approved for the treatment of moderate to severe plaque psoriasis and active psoriatic arthritis in many countries, is a monoclonal antibody that targets interleukin (IL)-12 and IL-23 cytokines believed to play a role in immune-mediated diseases, including Crohn's disease.

"The UNITI-2 study results show STELARA® induced clinical response and remission in patients with moderate to severe Crohn's disease who had failed steroids and/or immunosuppressive therapy, but had not failed TNF inhibitors," said Brian Feagan, M.D., Professor of Medicine, Chief Executive Officer and Senior Medical Director, Robarts Research Institute, University of Western Ontario, and study investigator. "Findings from this Phase 3 program provide an important first look into the efficacy and safety of STELARA® induction therapy in the treatment of inflammatory bowel disease-a disease where new therapeutic options are needed as the incidence continues to

rise globally."

Patients participating in the Phase 3 UNITI-2 study received a single intravenous (I.V.) infusion of placebo, STELARA® 130 mg or STELARA® ~6 mg/kg (weight-tiered dosing: patients weighing less than or equal to 55 kg received 260 mg; patients weighing more than 55 kg and less than or equal to 85 kg received 390 mg; and patients weighing more than 85 kg received 520 mg) at week 0. Enrolled patients had previously failed steroids and/or immunomodulators and were either naïve to or had been exposed to anti-TNF-alpha therapy, but had not failed such biologic therapy.

At week 6, 52 percent of patients receiving STELARA® 130 mg and 56 percent of patients receiving STELARA® ~6 mg/kg achieved clinical response, as defined by a reduction from baseline in the Crohn's Disease Activity Index (CDAI) score of at least 100 points, compared with 29 percent of patients receiving placebo ($P < 0.001$). CDAI is a symptom-based disease assessment tool commonly used in clinical trials to quantify Crohn's disease activity.

At week 8, 47 percent and 58 percent of patients receiving STELARA® 130 mg and STELARA® ~6 mg/kg, respectively, achieved clinical response, compared with 32 percent of patients receiving placebo ($P < 0.001$). In addition, 31 percent of patients receiving STELARA® 130 mg and 40 percent of patients receiving STELARA® ~6 mg/kg achieved clinical remission at week 8, as defined by a CDAI score of less than 150 points, compared with 20 percent of patients receiving placebo ($P = 0.009$ for STELARA® 130 mg; $P < 0.001$ for STELARA® ~6 mg/kg).

In addition to significant improvements in signs and symptoms as measured by CDAI, both doses of STELARA® resulted in statistically significant improvements in the Inflammatory Bowel Disease Questionnaire (IBDQ), a health-related quality of life measure for patients with IBD, as well as markers of inflammation, including C-reactive protein (CRP), fecal lactoferrin and calprotectin.

Through week 8, adverse events (AEs), serious AEs and infections (including serious infections) were reported in similar proportions across STELARA® and placebo treatment groups. No malignancies, deaths, opportunistic infections, cases of tuberculosis or major adverse cardiovascular events (MACE) were observed in patients treated with STELARA®.

"The STELARA® Phase 3 UNITI-2 induction results are important findings, as induction of clinical response and clinical remission are important goals in the management of Crohn's disease," said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. "We look forward to filing applications this year seeking approval of STELARA® for the treatment of moderate to severe Crohn's disease and remain committed to the continued development of this innovative medicine for the treatment of immune-mediated diseases."

About the UNITI-2 Trial

UNITI-2, a Phase 3, multicenter, randomized, double-blind, placebo-controlled, parallel group study, evaluated the

efficacy and safety of STELARA® induction therapy in patients with moderate to severe Crohn's disease. Patients (n=628) were randomized equally to receive a single I.V. infusion of placebo, STELARA® 130 mg or STELARA® ~6 mg/kg (weight-tiered dosing: patients weighing less than or equal to 55 kg received 260 mg; patients weighing more than 55 kg and less than or equal to 85 kg received 390 mg; and patients weighing more than 85 kg received 520 mg) at week 0. All participating patients had previously failed steroids and/or immunomodulators and were either naïve to or had been exposed to anti-TNF-alpha therapy, but had not failed such biologic therapy. The primary endpoint was clinical response at week 6, measured by the proportion of patients who achieved at least a 100-point reduction from baseline CDAI scores. Major secondary endpoints at week 8 included clinical response and clinical remission (defined by CDAI scores less than 150 points). At week 8, patients either transitioned to the IM-UNITI maintenance study or participated in safety follow-up through week 20.

UNITI-2 is part of a comprehensive Phase 3 clinical development program investigating STELARA® for the treatment of moderate to severe Crohn's disease. Data from the UNITI-1 induction study in anti-TNF-alpha refractory patients and the IM-UNITI maintenance study will be presented at future medical congresses.

About Crohn's Disease

More than five million people worldwide are living with Crohn's disease and ulcerative colitis-collectively known as inflammatory bowel disease (IBD).[1] Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract that affects approximately 700,000 Americans[2] and nearly 250,000 Europeans.[3] The cause of Crohn's disease is not known, but the disease is associated with abnormalities of the immune system that could be triggered by a genetic predisposition or diet and other environmental factors. Symptoms of Crohn's disease can vary but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss and fever. There is currently no cure for Crohn's disease.[2]

About STELARA® (ustekinumab)

STELARA®, a human interleukin (IL)-12 and IL-23 antagonist, is approved for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

STELARA® is also approved for the treatment of adult patients (18 years or older) with active psoriatic arthritis. STELARA® can be used alone or in combination with methotrexate (MTX).

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to STELARA®.

Important Safety Information (U.S.)

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 your 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 who has 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. It is not known if people who take STELARA® will get any of these infections because of the effects of STELARA® on these proteins.

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. Get medical help right away if you have any symptoms such as: feeling faint, swelling of your face, eyelids, tongue, or throat, trouble breathing, throat or chest tightness, or skin rash.

Before receiving STELARA®, tell your doctor 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 vaccine. The viruses used in some types of 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 taking STELARA® or one year after you stop taking 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
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if STELARA® will harm your unborn baby. You and your doctor should decide if you will take STELARA®
- are breast-feeding or plan to breast-feed. It is thought that STELARA® passes into your breast milk. You should not breast-feed while taking STELARA® without first talking to your doctor.

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 prescribed by your doctor
- 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®. Do not try to inject STELARA® yourself until you or your caregiver has been shown how to inject STELARA® by your doctor or nurse.

Common side effects of STELARA® include: upper respiratory infections, headache, tiredness, joint pain and nausea. 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.

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.

Please read the **Full Prescribing Information**, including the **Medication Guide** for STELARA®, and discuss any questions you have with your doctor.

About Janssen Research & Development, LLC

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people with serious diseases throughout the world. Beyond its innovative medicines, Janssen is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates and healthcare professionals have access to the latest treatment information, support services and quality care.

Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit **www.janssen.com** for more information. Follow us on Twitter at **https://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 product development. 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/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in new product development, including the uncertainty of clinical success and of obtaining regulatory approvals; competition, including technological advances,

new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and description 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 28, 2014, including in Exhibit 99 thereto, 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. Neither Janssen Research & Development, LLC nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

References

World IBD Day. Home. Available at **http://www.worldibdday.org/index.html**. Accessed October 9, 2015.

Crohn's & Colitis Foundation of America. What is Crohn's Disease?. Available at **http://www.ccfa.org/what-are-crohns-and-colitis/what-is-crohns-disease/**. Accessed October 9, 2015.

European Federation of Pharmaceutical Industries and Associations. Inflammatory Bowel Disease. Available at **http://www.efpia.eu/diseases/78/59/Inflammatory-Bowel-Disease**. Accessed October 9, 2015.

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