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News Release

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STELARA® PHASE 3 STUDY PUBLISHED IN *THE LANCET* REPORTS ONE YEAR EFFICACY AND SAFETY IN TREATMENT OF ACTIVE PSORIATIC ARTHRITIS

Data Show Interleukin-12/23 Inhibitor STELARA Improved Joint, Soft Tissue and Skin Components of Psoriatic Arthritis

Spring House, Pa., June 13, 2013 — Results from a Janssen Research & Development, LLC (Janssen)-sponsored Phase 3 study published today in *The Lancet* showed patients with active psoriatic arthritis who received either STELARA® (ustekinumab) 45 mg or 90 mg achieved significant improvement in joint symptoms at the study's primary endpoint compared with patients receiving placebo. According to findings from the investigational study, continued treatment with STELARA every 12 weeks resulted in improvements in signs and symptoms of active disease and psoriasis symptoms through one year. In December 2012, Janssen announced submissions to health authorities in the United States and Europe seeking approval of STELARA, an interleukin (IL)-12/IL-23 inhibitor, for the treatment of active psoriatic arthritis. STELARA is approved for the treatment of adults with moderate to severe plaque psoriasis in 72 countries.

"Data from the PSUMMIT I Phase 3 study showed that STELARA significantly improved the joint and skin manifestations of psoriatic arthritis, and a significant proportion of patients maintained improvement in disease symptoms through one year," said lead study investigator Iain B. McInnes, PhD, FRCP, Professor of Medicine, and Director of the Institute of Infection, Immunity, and Inflammation, University of Glasgow, Scotland. "STELARA remains an investigational therapeutic for psoriatic arthritis, and may represent an important future option and alternative mechanism to currently available therapies, pending health authority approval."

During the induction portion of the Phase 3 Multicenter, Randomized, Double-blind, Placebo-controlled trial of Ustekinumab, a Fully Human anti-IL-12/23p40 Monoclonal Antibody, Administered Subcutaneously, in Subjects with Active Psoriatic Arthritis (PSUMMIT I) study, patients were randomized to receive subcutaneous STELARA 45 mg or 90 mg or placebo at weeks 0, 4 and then every 12 weeks. By week 24, all patients receiving placebo were crossed over to receive STELARA. At week 24, 42.4 percent and 49.5 percent of patients receiving STELARA 45 mg and 90 mg, respectively, achieved at least 20 percent improvement in signs and symptoms according to the American College of Rheumatology criteria (ACR 20), the primary endpoint, compared with 22.8 percent of patients receiving placebo ($P < 0.0001$ for both comparisons). Improvement in signs and symptoms continued to increase after week 24, with 55.7 percent and 60.3 percent of patients in the STELARA 45 mg and STELARA 90 mg groups, respectively, demonstrating ACR 20 response at week 52.

ACR 50 (at least a 50 percent improvement in signs and symptoms according to the ACR criteria) and ACR 70 (at least a 70 percent improvement in signs and symptoms according to the ACR criteria) response rates also increased over time among patients receiving STELARA maintenance therapy. At week 24, 24.9 percent and 27.9 percent of patients receiving STELARA 45 mg and 90 mg, respectively, achieved ACR 50 compared with 8.7 percent of patients receiving placebo ($P < 0.0001$ for both comparisons). Improvement in signs and symptoms continued to increase after week 24, with 31.4 percent and 37 percent of patients in the STELARA 45 mg and STELARA 90 mg groups, respectively, demonstrating ACR 50 response at week 52. At week 24, 12.2 percent and 14.2 percent of patients receiving STELARA 45 mg and 90 mg, respectively, achieved ACR 70 compared with 2.4 percent of patients receiving placebo ($P \leq 0.0001$ for both comparisons). Improvement in signs and symptoms continued to increase after week 24, with 18 percent and 21.2 percent of patients in the STELARA 45 mg and STELARA 90 mg groups, respectively, demonstrating ACR 70 response at week 52.

Investigators reported improvements in physical function and skin symptoms throughout the study in both STELARA treatment groups. Nearly half of patients receiving treatment with STELARA demonstrated a clinically meaningful change from baseline in the Health Assessment Questionnaire Disability Index (HAQ-DI) at both weeks 24 and 52. Significantly more patients with at least three percent body surface involvement of psoriasis at baseline achieved at least a 75 percent improvement in psoriasis symptoms as measured by the Psoriasis Area Severity Index (PASI 75) at week 24 [57.2 percent and 62.4 percent of patients receiving STELARA 45 mg and 90 mg, respectively, compared with 11 percent of patients receiving placebo ($P < 0.0001$ for both comparisons), and more than two-thirds of patients across all treatment groups achieved PASI 75 through week 52.

Among study participants affected with enthesitis (inflammation of the entheses, the sites where tendons or ligaments attach to bone, n=425) or dactylitis (inflammation of the finger or toe, n=286) at baseline, patients receiving STELARA achieved clinically relevant improvements in both measures at week 24 and week 52. At week 24, percent improvement in enthesitis scores (median: 42.9 percent for STELARA 45 mg and 50 percent for STELARA 90 mg) and dactylitis scores (75 percent for STELARA 45 mg and 70.8 percent for STELARA 90 mg) were significantly higher than those seen for patients receiving placebo ($P = 0.0019$ and $P < 0.0001$, respectively, for enthesitis comparisons; $P = 0.0003$ for both dactylitis comparisons). Median percent improvements in enthesitis scores (83.3 percent and 74.2 percent) and dactylitis scores (100 in both dose groups) in the STELARA 45 mg and 90 mg groups, respectively, continued through week 52.

The trial had a placebo-controlled period of 16 weeks after which some non-responding, placebo-treated patients were switched to the STELARA 45 mg regimen. Through this 16-week placebo-controlled period, 40 percent and 43.6 percent of patients receiving STELARA 45 mg or STELARA 90 mg, respectively, experienced at least one adverse event (AE) compared with 42 percent of patients receiving placebo. Through week 16, the percentages of patients experiencing at least one serious AE were reported as 2 percent in the STELARA 45 mg group, 1.5 percent in the STELARA 90 mg group and 2 percent in the placebo group. Safety through week 52 was consistent with that observed during the placebo-controlled period. No malignancies, cases of tuberculosis (TB), opportunistic infections or deaths occurred through week 52. After the placebo-controlled period, major adverse cardiovascular events (MACE) were reported in three patients with multiple pre-existing cardiovascular risk factors who were receiving STELARA 45 mg dosing.

About PSUMMIT I

The PSUMMIT I trial is a Phase 3, multicenter, randomized, double-blind, placebo-controlled study including 615 adults with active psoriatic arthritis designed to evaluate the efficacy and safety of STELARA. The trial included patients diagnosed with active psoriatic arthritis who had at least five tender and five swollen joints and C-reactive protein (CRP) levels of at least 0.3 mg/dL (upper limit of normal [ULN] 1.0 mg/dL) despite treatment with disease-modifying antirheumatic drugs (DMARDs) and/or nonsteroidal anti-inflammatory drugs (NSAIDs). Patients were naïve to treatment with anti-TNF-alpha therapies and/or IL-12/23 inhibitors.

Patients were randomized to three groups: STELARA 45 mg or STELARA 90 mg at weeks 0, 4 and then every 12 weeks or placebo. Patients with less than a five percent improvement in tender and swollen joint counts at week16 were considered non-responders for the primary and major secondary analyses at week 24. Patients with less than a five percent improvement in tender and swollen joint counts at week16 who were receiving placebo were switched to STELARA 45 mg, and patients receiving STELARA 45 mg were switched to 90 mg. Patients receiving STELARA 90 mg remained on the 90 mg dosing regimen. The primary endpoint was ACR

20 response at week 24. Secondary endpoints at week 24 included ACR 50 and ACR 70 response, Disease Activity Score (DAS) 28-CRP response, PASI 75 in patients with at least three percent body surface area involvement at baseline, improvements in enthesitis and dactylitis scores and improvements in Health Assessment Questionnaire-Disability Index (HAQ-DI) scores.

Following week 24 assessment, patients receiving STELARA 45 mg and 90 mg continued to receive every-12-week maintenance therapy, and placebo patients were crossed over to receive STELARA 45 mg induction (at weeks 24 and 28) and maintenance therapy every 12 weeks thereafter. Safety and efficacy results were reported through week 52 in the trial.

About Psoriatic Arthritis

Psoriatic arthritis is a chronic immune-mediated inflammatory disease characterized by both joint inflammation and the skin lesions associated with psoriasis that affects up to 37 million people worldwide.[1] While estimates of the prevalence of psoriatic arthritis among people living with psoriasis vary, up to 30 percent may develop inflammatory arthritis.[1] The disease causes pain, stiffness and swelling in and around the joints and commonly appears between the ages of 30 and 50, but can develop at any time.[2] Though the exact cause of psoriatic arthritis is unknown, genes, the immune system and environmental factors are all believed to play a role in the onset of the 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. IL-12 and IL-23 are naturally occurring proteins that are believed to play a role in inflammatory conditions such as psoriasis and psoriatic arthritis.

Janssen Biotech, Inc. discovered STELARA and has exclusive marketing rights to the product in the United States. The Janssen Pharmaceutical Companies maintain exclusive worldwide marketing rights to STELARA, which is currently approved for the treatment of moderate to severe plaque psoriasis in 72 countries. For more information about STELARA, visit www.STELARAinfo.com.

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 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.

Cancer
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, cancer, or RPLS
- 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®.** Non-live vaccinations received while taking STELARA® may not fully protect you from disease.
- are receiving or have received allergy shots, especially for serious allergic reactions
- ever had an allergic reaction to STELARA®
- 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 non-prescription medicines, vitamins, and herbal supplements**.** Especially tell your doctor if you take:

- other medicines that affect your immune system
- certain medicines that can affect how your liver breaks down other medicines

Common side effects of STELARA® include: upper respiratory infections, headache, and tiredness

These are not all of the side effects with STELARA®. Tell your doctor about any side effect that bothers you or does not go away. 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 Medication Guide for STELARA® and discuss any questions you have with your doctor.

The U.S. full prescribing information for STELARA® can be accessed at the following link: http://www.stelarainfo.com/pdf/PrescribingInformation.pdf.

About Janssen Research & Development, LLC

At Janssen Research & Development, LLC, we are united and energized by one mission—to discover and develop innovative medicines that ease patients' suffering, and solve the most important unmet medical needs of our time. As one of the Janssen Pharmaceutical Companies of Johnson & Johnson, our strategy is to identify the biggest unmet medical needs and match them with the best science, internal or external, to find solutions for patients worldwide. We leverage our world-class discovery and development expertise, and operational excellence, to bring innovative, effective treatments in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. For more information on Janssen R&D, visit http://www.janssenrnd.com/.

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[1] National Psoriasis Foundation. About Psoriasis: Statistics. www.psoriasis.org/learn_statistics. Accessed April 4, 2013.
[2] National Psoriasis Foundation. About Psoriatic Arthritis. www.psoriasis.org/psoriatic-arthritis. Accessed April 4, 2013.