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NEW STELARA® DATA SHOW INHIBITION OF JOINT DESTRUCTION IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS

Integrated Analysis of Two Pivotal Phase 3 Studies Showed STELARA Inhibited the Progression of Structural Damage at Week 24, and Demonstrated Continued Inhibition through Two Years

San Diego, October 28, 2013 - New findings from two integrated Phase 3 Janssen Research & Development, LLC (Janssen)-sponsored studies showed treatment with STELARA® (ustekinumab) resulted in significantly greater inhibition of structural damage in patients with active psoriatic arthritis compared with placebo. Pre-specified integrated analyses from the PSUMMIT I and II trials showed treatment with either STELARA 45 mg or 90 mg resulted in significantly less change from baseline at week 24 in total psoriatic arthritis modified van der Heijde-Sharp (vdH-S) scores compared with placebo. STELARA-treated patients from the combined data analysis of both trials demonstrated continued inhibition through one year and through two years according to findings from the PSUMMIT I trial. These results are being presented during the 2013 Annual Meeting of the American College of Rheumatology (ACR). STELARA recently received approval from the U.S. Food and Drug Administration (FDA) and approval from the European Commission for the treatment of signs and symptoms in adult patients with active psoriatic arthritis.

"Data from the integrated analysis of the Phase 3 clinical program show the efficacy of the interleukin-12/23 antibody STELARA in inhibiting the progression of structural damage in patients with active psoriatic arthritis," said Iain B. McInnes, PhD, FRCP, Professor of Medicine, and Director of the Institute of Infection, Immunity, and Inflammation, University of Glasgow, Scotland, lead study investigator. "These new findings are significant since impeding further joint damage is an important part of the long-term management of this chronic inflammatory disease."

According to a pre-specified integrated analysis of the two Phase 3 Multicenter, Randomised, Double-blind, Placebo-controlled trials of Ustekinumab, a Fully Human anti-IL-12/23p40 Monoclonal Antibody, Administered Subcutaneously, in Subjects with Active Psoriatic Arthritis (PSUMMIT I and II), 927 patients with active psoriatic arthritis despite treatment with disease-modifying antirheumatic drugs (DMARDs), nonsteroidal anti-inflammatory drugs (NSAIDs) and/or tumor necrosis factor (TNF)-alpha inhibitors were randomized to receive STELARA 45 mg, 90 mg or placebo at weeks 0, 4 and then every 12 weeks. Patients with no response to placebo (defined as less than 5 percent improvement in tender and swollen joint count from baseline) at week 16 were crossed over to receive STELARA 45 mg as early escape, and all remaining patients receiving placebo crossed over at week 24 to STELARA 45 mg. Patients receiving STELARA 45 mg who had no response began an increased dose of STELARA 90 mg starting at week 16. Inhibition of radiographic progression was assessed by the change from baseline in total psoriatic arthritis modified vdH-S scores, an X-ray measure of joint destruction, including joint erosion and joint space narrowing. With this method, higher scores indicate greater structural damage while lower scores indicate less structural damage.

In the integrated analysis, at week 24, patients receiving STELARA 45 mg or 90 mg had a mean change (± standard deviation) from baseline in total vdH-S score of 0.40 (±2.11) and 0.39 (±2.40), respectively, compared with a mean change of 0.97 (±3.85) for patients receiving placebo ($P = 0.017$ and $P < 0.001$, respectively). Data through week 52 showed the continued inhibition of radiographic progression with a mean change from baseline of 0.58 (± 2.60) and 0.65 (±3.68) for patients randomized to STELARA 45 mg or 90 mg, respectively. Patients initially randomized to receive placebo who crossed over to STELARA at week 16 or 24 had a mean change of 1.15 (±5.41) from baseline to week 52. When evaluated alone, results from PSUMMIT I were consistent with the pre-specified integrated analysis demonstrating significant inhibition of structural damage at week 24 for both STELARA doses. The effect of STELARA on the inhibition of structural damage progression could not be discerned in the smaller PSUMMIT II study, though a high number of patients who received placebo were missing radiographs (23 percent).

In PSUMMIT I, effects on inhibition of radiographic progression were maintained through week 100 with a mean change from baseline of 0.95 (±3.82), 1.18 (±5.52) and 2.26 (±12.58) for patients receiving STELARA 45 mg or 90 mg, and crossover placebo patients, respectively. Additional measures of clinical response through week 100, as measured by the ACR response criteria (ACR 20: STELARA 45 mg, 56.7 percent; STELARA 90 mg, 63.6 percent), improvements in the Health Assessment Questionnaire Disability Index (HAQ-DI), and improvements in dactylitis and enthesitis indicate maintained clinical efficacy for patients treated with STELARA through week 100.

"Ustekinumab has demonstrated clinical efficacy across multiple areas of psoriatic arthritis disease activity, including not only joint and skin, but also in joint tissues, including dactylitis and enthesitis. Now there is data suggesting efficacy inhibiting the progression of joint damage as assessed on X-rays," said Arthur Kavanaugh, MD, Director of the Center for Innovative

Therapy, and Professor of Medicine at the University of California, San Diego School of Medicine, and co-principal study investigator. "Long-term findings from the PSUMMIT I trial offer important insights into the efficacy and safety of ustekinumab as a new treatment option for patients with psoriatic arthritis."

In PSUMMIT I and PSUMMIT II, similar proportions of patients receiving STELARA or placebo experienced at least one adverse event (AE) or serious AE through week 16, the placebo-controlled period of both trials. Safety through week 52 among patients receiving STELARA 45 mg or 90 mg was consistent with that observed during the placebo-controlled period with AE incidence of 66.8 percent and 64.7 percent, respectively, in PSUMMIT I; 78.6 percent and 77.9 percent, respectively, in PSUMMIT II. The incidence of serious AEs among patients receiving STELARA 45 or 90 mg were 5.9 percent and 3.4 percent, respectively, in PSUMMIT I; 5.8 percent in both dose groups, in PSUMMIT II. STELARA continued to be well-tolerated through week 108 in PSUMMIT I, with a safety profile similar to that observed in the placebo-controlled portion of the trial and through week 52.

About PSUMMIT I

The PSUMMIT I trial is a Phase 3, multicenter, randomized, double-blind, placebo-controlled study including 615 adults with psoriatic arthritis designed to evaluate the efficacy and safety of STELARA in adults with psoriatic arthritis. 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 despite treatment with DMARDs and/or NSAIDs. Patients were naive to treatment with anti-TNF-alpha therapies and/or IL-12/23 inhibitors. Concurrent methotrexate use was permitted but not mandated. PSUMMIT I evaluated the efficacy and safety of STELARA for approximately two years.

Patients were randomized to three groups: STELARA 45 mg or STELARA 90 mg at weeks 0, 4 and then every 12 weeks or placebo. At week 16, patients with less than a 5 percent improvement in tender and swollen joint counts were entered into blinded early escape to receive STELARA 45 mg (patients receiving placebo) or STELARA 90 mg (patients receiving STELARA 45 mg). 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 using CRP (DAS28-CRP) response, at least a 75 percent improvement in the Psoriasis Activity Severity Index (PASI 75) in patients with at least 3 percent body surface area involvement at baseline, improvements in enthesitis and dactylitis scores, improvements in HAQ-DI scores and change from baseline in total vdH-S scores.

About PSUMMIT II

The PSUMMIT II trial is a Phase 3, multicenter, randomized, double-blind, placebo-controlled study including 312 adults with psoriatic arthritis designed to evaluate the efficacy and safety of STELARA in adults with psoriatic arthritis. The trial included patients diagnosed with active psoriatic arthritis who had at least five tender and five swollen joints and CRP levels of at least 0.3 mg/dL despite treatment with DMARDs and/or NSAIDs and/or prior exposure to anti-TNF treatment, including 8 to 14 weeks of exposure to currently available anti-TNF-alpha treatments or documented evidence of anti-TNF-alpha intolerance/toxicity with less than 8 to 14 weeks' exposure. Concurrent methotrexate use was permitted but not mandated. Within the trial, 180 patients had prior exposure to anti-TNF-alpha treatments and 132 patients were anti-TNF-alpha naïve. PSUMMIT II evaluated the efficacy and safety of STELARA for approximately one year.

Patients were randomized to three groups: STELARA 45 mg or STELARA 90 mg at weeks 0, 4, and then every 12 weeks or placebo. At week 16, patients with less than a 5 percent improvement in tender and swollen joint counts were entered into blinded early escape to receive STELARA 45 mg (patients receiving placebo) or STELARA 90 mg (patients receiving STELARA 45 mg). The primary endpoint was ACR 20 response at week 24. Secondary endpoints at week 24 included ACR 50 and ACR 70 response, DAS28-CRP response, PASI 75 in patients with at least 3 percent body surface area involvement at baseline, improvements in enthesitis and dactylitis scores, improvements in HAQ-DI scores and change from baseline in total vdH-S scores.

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, and alone or in combination with methotrexate for the treatment of adult patients (18 years or older) with active psoriatic arthritis. IL-12 and IL-23 are naturally occurring proteins that are believed to play a role in inflammatory conditions such as psoriasis, psoriatic arthritis and other inflammatory diseases.

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 74 countries.

For more information about STELARA in the U.S., 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, 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 and Janssen Biotech, Inc.

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 and Janssen Biotech, Inc. are two of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit www.janssen.com for more information. Follow us on Twitter at www.twitter.com/JanssenUS.

References

[1] National Psoriasis Foundation. About Psoriasis: Statistics. http://www.psoriasis.org/learn_statistics. Accessed September 6, 2013.

[2] National Psoriasis Foundation. About Psoriatic Arthritis. http://www.psoriasis.org/psoriatic-arthritis. Accessed September 6, 2013.