Johnson & Johnson

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STELARA® (Ustekinumab) Receives FDA Approval To Treat Active Psoriatic Arthritis

First and Only Anti-IL-12/23 Treatment Approved for Adult Patients Living with Psoriatic Arthritis

Horsham, Pa., September 23, 2013 - Janssen Biotech, Inc., announced today that the U.S. Food and Drug Administration (FDA) has approved STELARA® (ustekinumab) alone or in combination with methotrexate for the treatment of adult patients (18 years or older) with active psoriatic arthritis. It is estimated that more than two million people in the U.S. are living with psoriatic arthritis[1], a chronic autoimmune disease characterized by both joint inflammation and psoriasis skin lesions.

"It is critical for dermatologists and rheumatologists to be able to offer new and novel treatment options to our adult patients living with psoriatic arthritis, a disease where additional biologic options are very much needed," said investigator and Steering Committee member Alice B. Gottlieb, triple board certified in dermatology, rheumatology and internal medicine, M.D., Ph.D, Chief and Dermatologist-in-Chief, Department of Dermatology, Tufts Medical Center. "Therapy that targets the cytokines interleukin-12 (IL-12) and interleukin-23 (IL-23), two naturally occurring proteins believed to play a role in the development of this debilitating immune-mediated inflammatory disease, could improve patient care."

For the treatment of psoriatic arthritis, STELARA is administered as a 45 mg subcutaneous injection at weeks 0 and 4, and then every 12 weeks, thereafter. For patients with co-existent moderate to severe plaque psoriasis weighing more than 220 lbs. (100 kg) the recommended dose is 90 mg subcutaneous injection at weeks 0 and 4, and then every 12 weeks, thereafter.

The approval is supported by findings from two pivotal 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 PSUMMIT II), which evaluated the efficacy and safety of subcutaneously-administered STELARA 45 mg or 90 mg at weeks 0, 4 and then every 12 weeks. The trials included 927 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 in spite of previous treatment with conventional therapy. PSUMMIT II also included 180 patients with previous exposure to 1-5 tumor necrosis factor (TNF) inhibitors. Results from PSUMMIT 1 showed that at week 24, 42 percent and 50 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 for both studies. In PSUMMIT II, 44 percent of patients receiving STELARA 45 mg and 44 percent of patients receiving STELARA 90 mg achieved ACR 20 at week 24. Additionally, STELARA improved soft tissue components of the disease, including dactylitis (inflammation of the finger or toe), enthesitis (inflammation of the entheses, the sites where tendons or ligaments attach to bone) and skin component as measured by Psoriasis Area and Severity Index score (PASI) 75.

Data from the PSUMMIT I study was recently published in the June 13 edition of *The Lancet*.

"The Phase 3 PSUMMIT studies demonstrated the efficacy and safety of STELARA in one of the largest clinical development programs ever conducted for the treatment of active psoriatic arthritis," said Jerome A. Boscia, M.D., Vice President, Head of Immunology Development, Janssen Research & Development, LLC. "Today's approval of STELARA is significant for patients and physicians as it marks the first treatment approved for this devastating and complex disease since the introduction of anti-TNF biologic medicines more than a decade ago."

"We're proud to expand our portfolio of biologic treatment options for patients living with psoriatic arthritis to include an anti-IL-12/23 therapy such as STELARA," said Cindy Guzzo, M.D., Vice President, Medical Affairs, Janssen Biotech, Inc. "The efficacy and safety profile of STELARA, coupled with a dosing regimen of every 12 weeks after two starter doses, makes this a meaningful new option for patients battling this chronic condition."

The safety results of STELARA observed in the PSUMMIT studies were consistent with the known safety profile of STELARA in the labeled moderate to severe plaque psoriasis indication, which has five years of safety experience in clinical trials. For more information regarding the safety profile for STELARA, please see "Important Safety Information" below.

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 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 74 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.

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 Biotech, Inc. and 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 our 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 Biotech, Inc. and Janssen Research & Development, LLC 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.

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[1] National Psoriasis Foundation. About Psoriasis: Statistics. Available at: http://www.psoriasis.org/learn_statistics. Accessed April 4, 2013.

[2] National Psoriasis Foundation. About Psoriatic Arthritis. Available at: http://www.psoriasis.org/psoriatic-arthritis. Accessed April 4, 2013.

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