News Release

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JANSSEN SUBMITS APPLICATION SEEKING FDA APPROVAL OF STELARA® (USTEKINUMAB) FOR THE TREATMENT OF ADOLESCENTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS

Horsham, PA, December 15, 2016 — Janssen Biotech, Inc. (Janssen) announced today the submission of a Supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) seeking approval of STELARA® (ustekinumab) for the treatment of adolescents (12 to 17 years of age) with moderate to severe plaque psoriasis. It is estimated that 7.5 million Americans have psoriasis, which can range from mild to severe and disabling, and approximately one-third of those affected develop the immune-mediated disease before 20 years of age.[2] STELARA®, a human monoclonal antibody that targets interleukin (IL)-12 and IL-23 cytokines, has been approved in the United States for the treatment of adults with moderate to severe plaque psoriasis since September 2009.

“Adolescence is an important developmental period, and a diagnosis of moderate to severe plaque psoriasis can present physical and emotional challenges for girls and boys,” said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. “We look forward to collaborating with the FDA on this application with the hope that in the future, we may be able to offer STELARA® to dermatologists and their adolescent patients as a new treatment option for moderate to severe plaque psoriasis."

The application is supported by data from the Phase 3 CADMUS registration study, which evaluated the efficacy and safety of STELARA® in the treatment of adolescents (12 to 17 years of age) with moderate to severe plaque psoriasis. Results from the CADMUS study have been previously published in the *Journal of the American Academy of Dermatology* in May 2015. The efficacy and safety profile of STELARA® in the CADMUS trial was consistent with the profile of this anti-IL-12/23 monoclonal antibody as previously observed in adult patients receiving STELARA®.

About CADMUS

CADMUS, a Phase 3, randomized, double-blind, placebo-controlled, parallel, multicenter trial, evaluated the efficacy and safety of STELARA® in pediatric patients 12 to 17 years of age with moderate to severe plaque psoriasis. Patients (N=110) had been diagnosed with psoriasis more than six months prior to first study agent administration and had a Psoriasis Area Severity Index (PASI) score greater than or equal to 12, a Physician's Global Assessment (PGA) score greater than or equal to 3 and body surface area (BSA) involvement of at least 10 percent. In addition, patients were inadequately controlled with topical therapy or were candidates for systemic/phototherapy.

Patients were randomized 1:1:1 to receive subcutaneous injections of placebo, STELARA® standard dosing (SD) [intended to achieve exposures comparable to adults] or STELARA® half standard dosing (HSD) [intended to achieve exposures half of those seen in adults]. STELARA® dosing tiers were determined by body weight. Patients receiving placebo crossed over to receive STELARA® SD or HSD at weeks 12 and 16; all patients continued with maintenance dosing every 12 weeks through week 40. Final efficacy and safety evaluations were made at weeks 52 and 60, respectively. The primary endpoint of the study was a PGA score of cleared (0) or minimal (1) at week 12. Secondary endpoints at week 12 included at least a 75 or 90 percent improvement in psoriatic skin lesions, as measured by PASI 75 or PASI 90, and improvement in quality of life, as measured by the Children's Dermatology Life Quality Index (CDLQI) [patient-reported outcome].

A Phase 3 study, CADMUS Jr, is currently ongoing to evaluate the efficacy and safety of STELARA® in the treatment of pediatric patients 6 to 11 years of age living with moderate to severe plaque psoriasis.

About STELARA® (ustekinumab)

STELARA® is a human interleukin (IL)-12 and IL-23 antagonist indicated in the U.S. for the treatment of adult patients with: moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy; active psoriatic arthritis, alone or in combination with methotrexate; and moderately to severely active Crohn's disease who have failed or were intolerant to treatment with immunomodulators or corticosteroids but never failed treatment with a tumor necrosis factor (TNF) blocker, or who failed or were intolerant to treatment with one or more TNF blockers.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to STELARA®, which is currently approved for the treatment of moderate to severe plaque psoriasis in 88 countries, active psoriatic arthritis in 75 countries, pediatric psoriasis in 38 countries and moderately to severely active Crohn's disease in 32 countries.

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. 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 such as: feeling faint, swelling of your face, eyelids, tongue, or throat, 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. Talk to your doctor about the best way to feed your baby if you take 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 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, nausea, itching, vomiting, vaginal yeast infections, urinary tract infections, and redness at the injection site. 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 and 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 Psoriasis

Psoriasis is a chronic, autoimmune inflammatory disorder that results in the overproduction of skin cells, characterized by raised, inflamed, red lesions, or plaques, which can cause physical pain. It is estimated that as many as 125 million people worldwide have psoriasis, including 7.5 million Americans.[1,3-7] The disease symptoms can range from mild, to moderate, to severe and disabling. It is estimated that nearly three percent of the world's population is living with psoriasis.[6]

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at Twitter.com/JanssenGlobal.

Janssen Biotech, Inc. and Janssen Research & Development, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development of STELARA®, including potential approval of an expanded indication. 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 Biotech, Inc., Janssen Research & Development, LLC and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; competition, including technological advances, new products and patents attained by competitors; challenges to patents; manufacturing difficulties or delays; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions 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 January 3, 2016, 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. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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