News Release

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JANSSEN SUBMITS APPLICATIONS SEEKING APPROVAL OF STELARA® IN UNITED STATES AND EUROPEAN UNION FOR CROHN'S DISEASE

Horsham, PA and Beerse, Belgium, November 30, 2015 — Janssen Biotech, Inc. and Janssen-Cilag International NV (Janssen) announced today the submission of a Biologics License Application (BLA) to the United States (U.S.) Food and Drug Administration (FDA) and a Grouped Type II Variation/Extension Application to the European Medicines Agency (EMA) seeking approval of STELARA® (ustekinumab) for the treatment of adult patients with moderately to severely active Crohn's disease. Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract that affects approximately 700,000 Americans[1] and nearly 250,000 Europeans.[2]

"At Janssen, we are committed to addressing the unmet medical needs of patients living with Crohn's disease through the discovery and development of innovative therapeutics," said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. "We are pleased to submit applications seeking approval of STELARA® for the treatment of moderately to severely active Crohn's disease in the U.S. and in Europe, and we look forward to collaborating with health authorities throughout the review process."

Data from the Phase 3 UNITI clinical development program, which includes three studies (UNITI-1, UNITI-2 and IM-UNITI) evaluating the efficacy and safety of STELARA® induction and maintenance treatment in patients with moderately to severely active Crohn's disease, served as the basis for the submissions. Data from the UNITI-2 study were recently presented at the American College of Gastroenterology and United European Gastroenterology Week annual meetings, and results from the UNITI-1 and IM-UNITI studies will be presented at future medical congresses.

STELARA®, approved for the treatment of moderate to severe plaque psoriasis and active psoriatic arthritis in many countries, is a human monoclonal antibody that targets interleukin (IL)-12 and IL-23 cytokines. These cytokines are believed to play an important role in immune-mediated diseases, including Crohn's disease.

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).[3] Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract that affects approximately 700,000 Americans[1] and nearly 250,000 Europeans.[2] 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 IL-12 and IL-23 antagonist, is approved in the United States 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 and can be used alone or in combination with methotrexate (MTX).

In the European Union, STELARA® is approved for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, MTX or psoralen plus ultraviolet A (PUVA). STELARA® is also indicated for the treatment of moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older who are inadequately controlled by or are intolerant to other systemic therapies or phototherapies. In addition, STELARA® is approved alone or in combination with MTX for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying antirheumatic drug (DMARD) therapy has been inadequate.

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 86 countries and psoriatic arthritis in 58 countries.

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.

Important Safety Information (EU)[4]

Special Warnings & Precautions

Infections: Potential to increase risk of infections and reactivate latent infections. Exercise caution in patients with a chronic infection or history of recurrent infection, particularly TB. Patients should be evaluated for tuberculosis and treated for latent TB prior to initiation of STELARA®. Also, consider anti-tuberculosis therapy prior to initiation of STELARA® in patients with past history of latent or active tuberculosis. Patients should seek medical advice if signs or symptoms suggestive of an infection occur. If a serious infection develops, they should be closely monitored and STELARA® should not be administered until infection resolves.

Malignancies: Potential to increase the risk of malignancy. No studies have been conducted in patients with a history of malignancy or in those who continue to receive STELARA® after being diagnosed with a malignancy. Exercise caution when considering STELARA® in these patients. Monitoring for the appearance of non-melanoma skin cancer recommended, in particular for patients greater than 60 years of age, or with a medical history of prolonged immunosuppressant therapy or a history of PUVA treatment.

Hypersensitivity reactions: Serious hypersensitivity reactions (anaphylaxis and angioedema) reported, in some cases several days after treatment. If these occur, institute appropriate therapy and discontinue use of STELARA®.

Vaccinations: Patients receiving STELARA® should not receive concurrent live viral or live bacterial vaccines such as BCG. Before live viral or live bacterial vaccination, treatment with STELARA® should be withheld for at least 15 weeks after the last dose and can be resumed at least 2 weeks after vaccination. Patients receiving STELARA® may receive concurrent inactivated or non-live vaccinations.

Concomitant immunosuppressive therapy: Exercise caution, including when changing immunosuppressive biologic agents. In psoriasis studies, the safety and efficacy of STELARA® in combination with other immunosuppressants, including biologics, or phototherapy have not been evaluated. In psoriatic arthritis studies, concomitant MTX use did not appear to influence the safety or efficacy of STELARA®.

Immunotherapy: Not known whether STELARA® affects allergy immunotherapy.

Serious skin conditions: In patients with psoriasis, exfoliative dermatitis has been reported following STELARA® treatment. Patients with plaque psoriasis may develop erythrodermic psoriasis, with symptoms that may be clinically indistinguishable from exfoliative dermatitis, as part of the natural course of their disease. If these symptoms occur, appropriate therapy should be instituted. STELARA® should be discontinued if a drug reaction is suspected.

Latex sensitivity: Needle cover contains natural rubber (latex), may cause allergic reactions.

Elderly Patients > 65years: Use caution when treating elderly patients.

For complete European Union (EU) prescribing information, please visit:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000958/human_med_001065.jsp&mid=WC0b01ac058001d124

About the Janssen Pharmaceutical Companies of Johnson & Johnson

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 Biotech, Inc., Janssen-Cilag International NV and Janssen Research & Development, LLC are part 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 Biotech, Inc., Janssen-Cilag International NV, 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. The Janssen Pharmaceutical Companies of Johnson & Johnson do not undertake to update any forward-looking statement as a result of new information or future events or developments.

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References

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4. Summary of Product Characteristics Stelara 45 mg solution. Janssen-Cilag International NV. Last updated June 2015.