News Release

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Janssen Submits Application to U.S. FDA Seeking Approval of STELARA® (ustekinumab) for the Treatment of Pediatric Patients with Moderate to Severe Plaque Psoriasis

SPRING HOUSE, PENNSYLVANIA, October 7, 2019 - The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the submission of a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) seeking expanded approval of STELARA® (ustekinumab) to treat pediatric (ages 6-11) patients with moderate to severe plaque psoriasis (PsO).

STELARA is the first and only biologic targeting both cytokines interleukin (IL)-12 and IL-23, which evidence suggests play an important role in inflammation associated with auto-immune conditions, such as PsO, and is the only drug that blocks these cytokines that is approved for adolescent use. STELARA is currently approved in many countries for the treatment of adolescents and adults with moderate to severe plaque psoriasis

(ages 12+), adults with active psoriatic arthritis, adults with moderate to severe Crohn's disease and adults with moderate to severe ulcerative colitis in the EU.

The STELARA sBLA is based on results from the Phase 3 CADMUS Jr study, in which the primary endpoint of the proportion of patients achieving a Physician's Global Assessment (PGA) score of Cleared (0) or Minimal (1) at week 12 was met. At week 12, 77 percent of patients (confidence interval [CI]: 62 percent, 89 percent) achieved PGA 0/1 response. The safety profile observed for STELARA in CADMUS Jr was generally consistent with previous studies as well as the current prescribing information for STELARA. The results of the study were presented earlier this year at the Skin Inflammation & Psoriasis International Network (SPIN) Annual Congress.

"Children with psoriasis struggle to manage its symptoms, while their families struggle to find an efficacious and safe treatment option," said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. "We're eager to bring this therapy, with a well-established safety and efficacy profile in plaque psoriasis and other immune diseases, one step closer to being available to children living with this chronic disease."

In addition to the primary endpoint, multiple secondary endpoints were assessed in the CADMUS Jr study. These include the proportions of patients achieving 75 percent or 90 percent improvement in their Psoriasis Area and Severity Index score at week 12 compared to baseline, and the change in Children's Dermatology Life Quality Index score at week 12 compared to baseline. Safety was evaluated through week 56.

CADMUS Jr was an open-label, single-arm, multicenter Phase 3 study designed to evaluate the efficacy and safety of STELARA administered by subcutaneous injection in pediatric patients with moderate to severe PsO. The study evaluated 44 participants and continued through 56 weeks.

Janssen also submitted a marketing application this year to the European Medicines Agency seeking approval of STELARA as a treatment for pediatric PsO patients.

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 and itching.[1] It is estimated that 125 million people worldwide live with the disease.[2] Nearly one-quarter of people with psoriasis have cases that are considered moderate to severe.[2] In the United States, about one-third of people with psoriasis experience symptoms before the age of 20 years.[3]

About STELARA® (ustekinumab)

STELARA® (ustekinumab), a human IL-12 and IL-23 antagonist, is approved in the United States for the treatment of: 1) adults and children 12 years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy; 2) adult patients (18 years or older) with active psoriatic arthritis, used alone or in combination with methotrexate (MTX); 3) adult patients (18 years and older) with moderately to severely active Crohn's disease who have failed or were intolerant to immunomodulators or corticosteroids, or failed or were intolerant to anti-TNF therapies.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to STELARA®.

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 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 with 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 of a serious allergic reaction such as: feeling faint, swelling of your face, eyelids, tongue, or throat, chest tightness, or skin rash.

Lung Inflammation

Cases of lung inflammation have happened in some people who receive STELARA® and may be serious. These lung problems may need to be treated in a hospital. Tell your doctor right away if you develop shortness of breath or a cough that doesn't go away during treatment with STELARA®.

Before receiving STELARA®, tell your doctor about all of your medical conditions, including 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 live vaccine. The viruses used in some types of live 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 receiving STELARA® or one year after you stop receiving 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.
- are pregnant or plan to become pregnant. It is not known if STELARA® can harm your unborn baby. You and your doctor should decide if you will receive STELARA®.
- are breastfeeding or plan to breastfeed. It is thought that STELARA® passes into your breast milk. Talk to your doctor about the best way to feed your baby if you receive 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 your doctor tells you to. STELARA® is intended for use under the guidance and supervision of your doctor.
- STELARA® is intended for use under the guidance and supervision of your doctor. In children 12 years and older, it is recommended that STELARA® be administered by a healthcare provider. 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®. Your doctor will determine the right dose of STELARA® for you, the amount for each injection, and how often you should receive it. Do not try to inject STELARA® yourself until you or your caregiver have been shown how to inject STELARA® by your doctor or nurse.

Common side effects of STELARA® include: upper respiratory infections, headache, and tiredness **in psoriasis** patients; joint pain and nausea **in psoriatic arthritis patients**; and upper respiratory infections, redness at the injection site, vaginal yeast infections, itching, urinary tract infections, and vomiting **in Crohn's**

disease patients. 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, including the 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 the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal. Janssen Research & Development, LLC is one 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 new study data on STELARA. 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 Research & Development, LLC, any of the other Janssen

Pharmaceutical Companies 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; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; 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 December 30, 2018, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, 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. Neither the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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1. American Academy of Dermatology. What is Psoriasis? https://www.aad.org/public/diseases/scaly-skin/psoriasis/what-is-psoriasis. Accessed September 23, 2019
2. National Psoriasis Foundation. https://www.psoriasis.org/content/statistics. Accessed September 23, 2019.
3. Medical News Today. What to know about psoriasis in children. https://www.medicalnewstoday.com/articles/319656.php. Accessed September 23, 2019