News Release

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U.S. Food and Drug Administration Approves STELARA® (ustekinumab) for Treatment of Pediatric Patients with Moderate to Severe Plaque Psoriasis

STELARA is the first and only biologic to target interleukin (IL)-12 and IL-23 approved for pediatric psoriasis use, providing a new proven treatment for children (6-11 years of age) who have had few available options

HORSHAM, PA, JULY 30, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the U.S. Food and Drug Administration (FDA) has approved an expanded indication for STELARA® (ustekinumab) as a treatment for pediatric patients (6-11 years of age) who struggle with the skin lesions or plaques associated with moderate to severe plaque psoriasis (PsO). Plaque psoriasis is the most common form of psoriasis in adults and children.[1] STELARA targets both interleukin (IL)-12 and IL-23, two cytokines thought to play an important role in modulating the overactive inflammatory response in a number of autoimmune conditions, including PsO. STELARA is administered as an injection given under

the skin, dosed four times per year after two starter doses.

"We are thrilled that the latest approval for STELARA will bring an alternative class of medication to this patient population and that we are able to deliver on our promise to find meaningful solutions for people afflicted with immune-mediated diseases," said Lloyd Miller, M.D., Ph.D., Vice President, Immunodermatology Disease Area Leader, Janssen Research & Development, LLC. "While STELARA is currently available for adults and adolescents 12 years and older, children with plaque psoriasis have had more limited treatment options."

The FDA approval of STELARA for pediatric use is based on results from the CADMUS Junior study, an open-label, single-arm, multicenter phase 3 clinical trial, of 44 patients with moderate to severe plaque psoriasis in which 77 percent of patients achieved clear or almost clear skin, at week 12 after two doses. Secondary endpoints included the proportion of patients achieving 75 percent or 90 percent improvement in their Psoriasis Area and Severity Index (PASI) score at week 12 compared to baseline. Study results showed 84 percent and 64 percent of patients achieved a PASI 75 response and PASI 90 response, respectively. In general, the safety profile observed in CADMUS Junior was similar to the safety profile from studies in adults with plaque psoriasis.[1] Patients knew they were on STELARA for the entirety of the study, which may affect results.

Click to Tweet: #BREAKING: The @US_FDA approves expanded indication for STELARA® (ustekinumab). Read more: https://bit.ly/395z0bK

"Plaque psoriasis presents differently in all patients, making it a challenging disease to both diagnose and treat. Especially in the pediatric population, it is important for patients, parents and physicians to work together to identify an appropriate treatment," said Stacie Bell, Ph.D., Chief Scientific and Medical Officer, National Psoriasis Foundation. "The approval of new treatment options is an exciting step forward to address the unmet needs of children living with psoriasis."

Access for STELARA

Janssen will work closely with payers, providers and pharmacy benefit managers in an effort to help ensure STELARA is broadly accessible and affordable for patients living with PsO.

Janssen CarePath offers a comprehensive support program that helps patients get started on STELARA and stay on track. Janssen CarePath provides information on insurance coverage, potential out-of-pocket costs and treatment support, and identifies options that may help make treatment more affordable, including the Janssen CarePath Savings Program for commercially insured patients who are eligible.

About Psoriasis

Plaque psoriasis (PsO) is the most common form of psoriasis in adults and children. It is an inflammatory, immune-mediated disease resulting in overproduction of skin cells which causes raised, red, scaly plaques that may be itchy or painful.[2] It is estimated that more than 8 million Americans and about 125 million people worldwide live with the disease. Nearly one-quarter of all people with PsO have cases that are considered moderate to severe.[3] About one-third of people with psoriasis first have symptoms before the age of 20 years and approximately 20,000 children under the age of 10 are diagnosed with psoriasis.[2]

About STELARA® (ustekinumab)

STELARA® (ustekinumab), is the first and only biologic treatment in this patient population to target the interleukin (IL) 12/IL-23 pathways, an important therapeutic target for the condition.[4] With this approval, STELARA is now the only IL-12/IL-23 inhibitor approved in the United States for the treatment of: 1) adults and pediatric patients 6 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 4) adult patients (18 years and older) with moderately to severely active ulcerative colitis.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive

worldwide marketing rights to STELARA.

IMPORTANT SAFETY INFORMATION

INDICATIONS

STELARA® is a prescription medicine used to treat:

- adults and children 6 years and older with moderate or severe psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
- adults 18 years and older with active psoriatic arthritis. STELARA® can be used alone or with the medicine methotrexate.
- adults 18 years and older with moderately to severely active Crohn's disease.
- adults 18 years and older with moderately to severely active ulcerative colitis.

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 or have any open cuts.
- 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). These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications. 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. In children 6 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: nasal congestion, sore throat, and runny nose, upper respiratory infections, fever, headache, tiredness, itching, nausea and vomiting, redness at the injection site, vaginal yeast infections, urinary tract infections, sinus infection, bronchitis, diarrhea, stomach pain, and joint pain. 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 click to 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 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 or www.twitter.com/JanssenUS. 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 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 29, 2019, 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. None of 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] Philipp S, Menter A, Nikkels A. Ustekinumab for the treatment of moderate-to-severe plaque psoriasis in pediatric

patients (≥6 to <12 years of age): efficacy, safety, pharmacokinetic, and biomarker results from the open-label CADMUS Jr study. [published online ahead of print March 16, 2020]. Br J Dermatol. doi: 10.1111/Bjd.19018.
[2] National Psoriasis Foundation. About Psoriasis. Available at: https://www.psoriasis.org/about-psoriasis. Accessed June 2020.
[3] National Psoriasis Foundation. Statistics. Available at: https://www.psoriasis.org/content/statistics. Accessed June 2020.
[4] Benson J, et al. Discovery and mechanism of ustekinumab. MAbs 2011;3:535–45.