News Release

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STELARA® (ustekinumab) Approved by the U.S. Food and Drug Administration to Treat Pediatric Patients with Active Psoriatic Arthritis

As the first and only biologic targeting both cytokines interleukin (IL)-12 and IL-23, STELARA provides a new therapeutic option for children six years of age and older living with active psoriatic arthritis

Active psoriatic arthritis in pediatric patients is a rare disease affecting five to eight percent of children and adolescents with chronic inflammatory arthritis[1-6]*

HORSHAM, PENNSYLVANIA, August 1, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the U.S. Food and Drug Administration (FDA) has approved STELARA® (ustekinumab) for the treatment of pediatric patients six years of age and older with active psoriatic arthritis (PsA). This rare disease that resembles adult PsA affects five to eight percent of children and adolescents with chronic inflammatory arthritis.*[1-7] Two of the four indications for STELARA now include pediatric patients, further expanding its treatment profile since the first approval in 2009 for adults living with moderate to severe plaque psoriasis (PsO).

STELARA is a fully human monoclonal antibody that selectively inhibits both interleukin (IL)-12 and IL-23, two cytokines thought to play an important role in tempering the overactive inflammatory response in several autoimmune diseases. STELARA is administered as a subcutaneous injection dosed four times per year after two starter doses for the treatment of pediatric patients six years of age and older with active PsA.

"We know active pediatric psoriatic arthritis is a challenging inflammatory disease given its rarity and that symptoms, such as swollen joints and skin lesions, can vary significantly in presentation and severity," said Terence Rooney, M.D., Ph.D., Vice President, Rheumatology and Maternal Fetal Disease Area, Janssen Research & Development, LLC. "With this pediatric approval of STELARA, we're pleased to help address the unmet needs of these young patients and provide physicians with a much-needed treatment option that has an established track record of safety and efficacy."

The FDA's approval was based on pharmacokinetic (PK) data and extrapolation of the established efficacy and existing safety profile of STELARA in multiple Phase 3 studies in adult and pediatric patients with moderate to severe plaque PsO (PSTELLAR, CADMUS, and CADMUS Jr) and adult patients with active PsA (PSUMMIT I and II). With the limited availability of pediatric PsA patients for inclusion in clinical trials, researchers utilized an extrapolation approach based on previous PK, efficacy and safety observations from a closely adjacent population of pediatric patients with moderate to severe plaque PsO who also had active PsA, as well as adult patients with moderate to severe plaque PsO or active PsA. An analysis of the data demonstrated that PK exposure of STELARA in these pediatric PsO patients with active PsA was consistent with that of Phase 3 clinical trials of STELARA in pediatric PsO patients without active PsA, as well as with adult patients with moderate to severe plaque PsO or adult patients with active PsA, while data on common efficacy endpoints were similar in these pediatric PsO patients with active PsA.

"The approval of STELARA for use in children six years of age and older with active psoriatic arthritis, which follows the 2020 approval for moderate to severe plaque psoriasis in this population, is complemented by more than 12 years of clinical trial and real-world evidence across all approved indications demonstrating the safety and efficacy of this biologic therapy," said Jennifer Davidson, DO, Vice President of Immunology Medical Affairs, Janssen Scientific Affairs, LLC. "As a global leader in immunology, Janssen is dedicated to reducing the burden of chronic autoimmune diseases, and this additional approval for STELARA builds on our legacy of bringing important treatment options to younger patients."

Access to STELARA®

Janssen is actively working toward greater patient accessibility through improved commercial first-line formulary coverage, as well as patient-specific support services specifically for patients to start and stay on STELARA® treatment after a prescribing decision has been made.

STELARA withMe offers a comprehensive support program that helps patients get started on STELARA and stay on track. STELARA withMe 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 STELARA withMe Savings Program for commercially insured patients who are eligible.

About Active Psoriatic Arthritis in Pediatric Patients

Active psoriatic arthritis (PsA) in pediatric patients, a rare disease that resembles adult PsA, affects five to eight percent of children and adolescents with chronic inflammatory arthritis.*[1-7] Symptoms of active pediatric PsA can vary significantly in presentation and severity from patient to patient, but often include joint inflammation and skin lesions.[8] PsA can be a challenging disease to treat – especially in younger populations – reinforcing the need for additional treatment options.

About PSTELLAR

PSTELLAR, a Phase 3b, randomized, double-blind, active-controlled, multicenter study assessed the effect of extending maintenance dosing intervals beyond 12 weeks on the clinical efficacy and safety of STELARA in patients with moderate to severe plaque psoriasis. Adults with moderate to severe plaque psoriasis received STELARA at weeks 0, 4 and 16 during open-label treatment. Patients achieving a week-28 Physician's Global Assessment (PGA) score of cleared/minimal (PGA = 0/1) were randomized 1:4 to group 1 [approved every 12 weeks (q12 wk) maintenance] or group 2 (q12-24 wk; response-based dosing determined by time to loss of PGA = 0/1). Key endpoints included the number of visits with PGA = 0/1 (primary end point) and ≥ 75 percent improvement in Psoriasis Area and Severity Index (PASI 75) between weeks 88 and 112, and PGA/PASI responses between weeks 28 and 112.

About CADMUS

CADMUS, a Phase 3, randomized, double-blind, placebo-controlled, parallel, multicenter trial, evaluated the efficacy and safety of STELARA in adolescent 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.

A Phase 3 study, CADMUS Jr, evaluated 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 PSUMMIT

Two Phase 3 multicenter, randomized, double-blind, placebo-controlled trials of STELARA in adult patients with active psoriatic arthritis, PSUMMIT I and PSUMMIT

II, 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 adult 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 despite previous treatment with conventional therapy. PSUMMIT II also included adult patients with previous exposure to tumor necrosis factor (TNF) inhibitors. The primary endpoints for both studies were the proportion of patients demonstrating at least a 20 percent improvement in arthritis signs and symptoms [American College of Rheumatology (ACR) 20] at week 24. Secondary endpoints at week 24 included in the submissions were: improvements in Health Assessment Questionnaire Disability Index (HAQ-DI) scores, a 50 or 70 percent improvement in arthritis signs and symptoms (ACR 50 or ACR 70), and at least a 75 percent improvement in psoriatic skin lesions as measured by the Psoriasis Area Severity Index (PASI 75) in patients with at least three percent body surface area involvement at baseline.

About STELARA® (ustekinumab)[9]

STELARA® (ustekinumab), a human interleukin (IL)-12 and IL-23 antagonist, is approved in the United States for the treatment of: 1) adults and children six years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy; 2) adults and children six years and older with active psoriatic arthritis; 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.

* When other known causes of arthritis have been excluded.[3,5,10]

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.

Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is a rare condition that affects the brain and can cause death. The cause of PRES is not known. If PRES 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 PRES.

- 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.

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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, & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal and www.twitter.com/JanssenUS.

Janssen Research & Development, LLC, Janssen Biotech, Inc. and Janssen Scientific Affairs, 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® (ustekinumab). 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 January 2, 2022, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other 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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