



NEWS RELEASE

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JANSSEN ANNOUNCES U.S. FDA APPROVAL OF STELARA® (USTEKINUMAB) FOR THE TREATMENT OF ADOLESCENTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS

- *Approval of STELARA® for adolescents 12 years or older provides an important new treatment option for adolescent plaque psoriasis patients*
- *Findings from a registrational study showed STELARA® led to significant skin clearance results at week 12*

Horsham, Pa., October 13, 2017 — Janssen Biotech, Inc., announced today that the U.S. Food and Drug Administration (FDA) has approved an expanded indication for STELARA® (ustekinumab) for the treatment of adolescents (12 years of age or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Today's approval marks a significant milestone for this age group as approximately one-third of individuals who develop plaque psoriasis do so before 20 years of age, and there are limited treatment options for adolescents.¹ Since receiving approval in September 2009 for the treatment of adults living with moderate to severe plaque psoriasis, STELARA® has become a leading therapeutic option for dermatologists and their patients, with only four doses a year after two starter doses.

"Psoriasis can affect many aspects of everyday life and the visible plaques, itching and discomfort can take a particular toll on adolescents," said Andrew Greenspan, M.D., Vice President of Medical Affairs at Janssen. "With today's approval, STELARA® has the potential to make a meaningful difference in the lives of these young adults."

The approval of [STELARA® for the adolescent indication](#) in moderate to severe plaque psoriasis is based on data from a Phase 3 study designed to evaluate the efficacy and safety of subcutaneous administration of STELARA® in patients aged 12 years or older. At least two-thirds of patients receiving STELARA® were responders at the week 12 primary endpoint after just two doses at weeks 0 and 4, defined by achieving a Physician's Global Assessment (PGA) score of 0 or 1 (cleared or minimal psoriasis). Safety findings for adolescent patients treated with STELARA® were consistent with those seen in studies in adults with plaque psoriasis.

"Psoriasis is a highly visible disease, and it is essential that these younger patients and their caregivers have options that can effectively reduce the difficult-to-conceal and often misunderstood plaques," said Michael Siegel, Ph.D., Senior Vice President of Research and Clinical Affairs for the National

Psoriasis Foundation. "It is encouraging to have new treatment options where few exist for adolescents living with psoriasis during such formative times in their lives."²

What is Psoriasis?

Psoriasis is a chronic, autoimmune inflammatory disorder that results in the overproduction of skin cells.³ It is estimated that more than 7.5 million Americans live with the disease.⁴ The most common form of psoriasis, affecting about 80 to 90 percent of psoriasis patients, is plaque psoriasis characterized by raised, inflamed, red lesions, or plaques, which can cause physical pain.³ Approximately 80 percent of those affected with psoriasis have mild to moderate disease, while 20 percent have moderate to severe plaque psoriasis.⁴ The scalp and face are the most affected areas in adolescents.⁵ This can lead to emotional and social complications in this population.⁵

What is STELARA® (ustekinumab)?

STELARA®, a fully human interleukin (IL)-12 and IL-23 antagonist, is a prescription medicine used to treat adults and children 12 years of age 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). STELARA® is administered subcutaneously at weeks 0 and 4, and then every 12 weeks thereafter.

STELARA® is also indicated for the treatment of adult patients 18 years and older with active psoriatic arthritis, alone or with the medicine methotrexate, and for the treatment of adult patients 18 years or older with moderately to severely active Crohn's disease who have already taken other medicines that did not work well enough or they could not tolerate it.

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:
 - o fevers, sweats or chills
 - o muscle aches
 - o cough
 - o shortness of breath
 - o blood in your phlegm
 - o weight loss
 - o warm, red, or painful skin or sores on your body
 - o diarrhea or stomach pain
 - o burning when you urinate or urinate more often than normal
 - o 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, 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 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

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 on Twitter at <https://twitter.com/JanssenUS> or <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 benefits of an expanded indication for 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 Biotech, Inc., any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of commercial success for new indications; 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 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including in the section captioned "Cautionary Note Regarding Forward-Looking Statements," 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 World Health Organization. Psoriasis. http://apps.who.int/gb/ebwha/pdf_files/EB133/B133_5-en.pdf. Accessed October 10, 2017.

² National Center for Biotechnology Information. Management of Psoriasis in Adolescence. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3961070/>. Accessed October 10, 2017

³ National Psoriasis Foundation. About Psoriasis. <https://www.psoriasis.org/about-psoriasis>. Accessed October 10, 2017.

⁴ American Academy of Dermatology. Psoriasis. <https://www.aad.org/media/stats/conditions/psoriasis>. Accessed October 10, 2017.

⁵ National Center for Biotechnology Information. Psoriasis in Children and Adolescents: Diagnosis, Management and Comorbidities. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4744260/#CR7>. Accessed October 10, 2017.