INNOVATION

FDA Approves STELARA® (Ustekinumab) for Treatment of Adults With Moderately to Severely Active Crohn's Disease

Horsham, Pa., September 26, 2016 — Janssen Biotech, Inc., announced today that the U.S. Food and Drug Administration (FDA) has approved STELARA® (ustekinumab) for the treatment of moderately to severely active Crohn's disease in adults (18 years or older) who have failed or were intolerant to treatment with immunomodulators or corticosteroids but never failed treatment with a tumor necrosis factor (TNF) blocker, or who failed or were intolerant to treatment with one or more TNF blockers. STELARA® is the first biologic therapy for Crohn's disease targeting interleukin (IL)-12 and IL-23 cytokines, which play a key role in inflammatory and immune responses.

"Crohn's disease is a complex condition to treat, and not all therapies work for every patient," said William J. Sandborn, MD, Chief, Division of Gastroenterology, and Professor of Medicine, UC San Diego School of Medicine, and study investigator. "The FDA approval of STELARA®represents an important advancement in treating patients with Crohn's disease, as this therapy offers an alternate mechanism of action to induce and maintain clinical remission over time. Based on the results of the clinical development program, STELARA® has the potential to benefit many adults living with Crohn's disease."

In clinical studies of patients who were either new to, experienced with, or failed biologic therapy (TNF blockers), between 34% (UNITI-1 study) and 56% (UNITI-2 study) of patients experienced relief from their Crohn's disease symptoms in just six weeks after receiving the one-time intravenous (IV) infusion of STELARA®. Noticeable improvement was observed as early as three weeks. Additionally, the majority of those who responded to induction dosing and continued treatment with STELARA® subcutaneous maintenance doses every 8 weeks were in remission at the end of 44 weeks (52 weeks from initiation of the induction dose).

STELARA® is the only treatment for Crohn's disease that starts with a weight-based, one-time intravenous (IV) infusion induction dose (260 mg [55 kg or less], 390 mg [more than 55 kg to 85 kg], or 520 mg [more than 85 kg]) to help reduce symptoms, followed by 90 mg subcutaneous maintenance injections every 8 weeks to help keep the symptoms under control. The first dose of STELARA® is an induction dose, administered intravenously, under the supervision of a healthcare professional. Subsequent maintenance doses are administered as a subcutaneous injection every 8 weeks, either by a healthcare professional or self-injected by the patient after proper training.

Janssen will work closely with payers, providers and pharmacy benefit managers to ensure STELARA® is broadly accessible and affordable for patients, and that the cost for payers is competitive with currently available biologic therapies for Crohn's disease. Janssen offers a number of patient support programs including a co-pay card for patients with commercial insurance that reduces their out-of-pocket cost for STELARA® to no more than $5 per dose (IV and/or subcutaneous injection), which is also offered for patients with psoriasis and psoriatic arthritis.

"The approval of STELARA® for Crohn's disease underscores our commitment to provide innovative treatment options for people living with chronic inflammatory and immune-mediated diseases," said Andrew Greenspan, MD, vice president of medical affairs at

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Janssen Biotech, Inc. "We are confident STELARA® will improve the lives of many people living with Crohn's disease and are committed to ensuring that it is accessible to patients who qualify for this new therapeutic option."

Clinical Trial Program

The clinical development program for STELARA® for Crohn's disease included more than 1,300 patients across three pivotal Phase 3 studies, which served as the primary basis for FDA approval.

- **The UNITI-1 induction study** found that treatment with STELARA® induced clinical response and clinical remission in patients who had previously failed or were intolerant to treatment with one or more TNF blockers.
- **The UNITI-2 induction study** demonstrated treatment with STELARA® induced clinical response and clinical remission in patients who had previously failed or were intolerant to conventional therapy (immunomodulators or corticosteroids), the majority of whom were naïve to treatment with a TNF blocker.
- **The IM-UNITI maintenance study**, which evaluated patients who achieved clinical response eight weeks after a single intravenous infusion of STELARA® in the UNITI-1 and UNITI-2 Phase 3 induction studies, demonstrated that more than half of patients receiving STELARA®subcutaneous injections every eight weeks were in clinical remission after nearly one year of treatment.

For full Prescribing Information and a Medication Guide, visit www.STELARAINFO.com.

About Crohn's disease

Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract that affects approximately 700,000 Americans. Symptoms of Crohn's disease can vary but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever. Hospitalization is at times required for severe disease, to treat certain complications, and for surgery. There is currently no cure for Crohn's disease.[1]

About STELARA®(ustekinumab)

STELARA® is a prescription medicine used to treat moderately to severely active Crohn's disease in adult patients (18 years and older) who have already taken other medicine 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:
- fever, sweat, or chills
- muscle aches
- cough
- shortness of breath

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- 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. 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®.

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- 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, tiredness, joint pain, nausea, itching, vomiting, vaginal yeast infections, urinary tract infections, and redness at the injection site. 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.

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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/JanssenGlobal.

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1 Crohn's & Colitis Foundation of America. What is Crohn's Disease? Available at http://www.ccfa.org/what-are-crohns-and-colitis/what-is-crohns-disease/. Accessed September 20, 2016.

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