



STELARA™ (ustekinumab) Receives FDA Approval For Treatment Of Moderate To Severe Plaque Psoriasis With Four-Times-A-Year Maintenance Dosing

First-in-Class Anti-IL-12/23 Biologic Targets Proteins Believed to Play a Role in Psoriasis

HORSHAM, Pa., September 25, 2009 -- Centocor Ortho Biotech Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved STELARA (ustekinumab) for the treatment of adult patients 18 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. The efficacy and safety of STELARA were evaluated in one of the largest clinical development programs for a biologic medication in the treatment of psoriasis.

STELARA is a first-in-class human monoclonal antibody that selectively targets the cytokines interleukin-12 (IL-12) and interleukin-23 (IL-23), naturally occurring proteins that are believed to play a role in the development of psoriasis.

"Findings from clinical studies showed that approximately seven out of 10 patients receiving STELARA achieved 75 percent skin clearance after just two doses, and maintained response for one year with continued treatment," said Mark Lebwohl, MD, professor and chairman of the Department of Dermatology, The Mount Sinai School of Medicine, and study investigator. "STELARA is a meaningful new option for patients with psoriasis that offers maintenance dosing every 12 weeks following two starter doses."

Psoriasis is an inflammatory disorder characterized by raised, inflamed, red lesions, or plaques, which can cause physical pain. It is estimated that as many as 7.5 million Americans have psoriasis, which can present in various forms, ranging from mild to severe and disabling.

The clinical development program for STELARA included more than 2,200 patients, with two pivotal Phase 3 trials serving as the primary basis for FDA approval. In each of these trials, a significantly higher proportion of patients receiving either STELARA 45 mg or 90 mg achieved at least a 75 percent reduction in psoriasis as measured by the Psoriasis Area and Severity Index (PASI), or PASI 75, at week 12 compared to patients receiving placebo. With every-12-week STELARA maintenance therapy, the majority of patients achieving a PASI 75 improvement maintained substantial skin clearance for one year.

STELARA is a subcutaneous injection given at weeks 0 and 4, followed by every-12-week dosing. The recommended starting dose of STELARA is 45 mg for patients weighing 220 lbs. (100 kg) or less, and 90 mg for patients weighing more than 220 lbs.

"We are pleased to be in the position to make STELARA available to patients living with this chronic, lifelong inflammatory disease and for dermatologists treating these individuals," said Kim Taylor, President, Centocor Ortho Biotech Inc. "We have collaborated with the FDA to ensure that STELARA is supported by a Risk Evaluation and Mitigation Strategy, which will allow physicians to make treatment decisions based on the most comprehensive risk-benefit information. Importantly, we have already compiled three years of safety data from our ongoing five-year extension studies, which will aid in establishing the long-term safety profile of STELARA."

"Psoriasis is a serious disease that affects millions of Americans," said Randy Beranek, President and CEO of the National Psoriasis Foundation. "The approval of STELARA represents an important new treatment option for people who are living with this chronic condition."

About Psoriasis

Psoriasis is a chronic, immune-mediated disease that results from the overproduction of skin cells, resulting in their accumulation on the surface of the skin, which causes red, scaly plaques that may bleed. It is estimated that approximately 7.5 million Americans and nearly 3 percent of the world's population are living with psoriasis and nearly one-quarter of those people have cases that are considered moderate to severe.

About STELARA (ustekinumab)

STELARA, a human interleukin (IL)-12 and IL-23 antagonist, is approved for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. IL-12 and IL-23 are naturally occurring proteins that are believed to play a role in psoriasis. For more information about STELARA, visit www.STELARAinfo.com.

Centocor Ortho Biotech Inc. discovered STELARA and has exclusive marketing rights to the product in the United States.

Janssen-Cilag companies have exclusive marketing rights in all countries outside of the United States.

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 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. It is not known if people who take STELARA™ will get any of these infections because of the effects of STELARA™ on these proteins.

Cancer

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.

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.

Before receiving STELARA™, tell your doctor if you:

- have any of the conditions or symptoms listed above for serious infections, cancer, or RPLS
- 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™**
- receive phototherapy for your psoriasis
- have any other medical conditions
- are pregnant or plan to become pregnant, or are breast-feeding or plan to breast-feed

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you take:

- other medicines that affect your immune system
- certain medicines that can affect how your liver breaks down other medicines

Common side effects of STELARA™ include upper respiratory infections, headache and tiredness.

These are not all of the side effects with STELARA™. Tell your doctor about any side effect that bothers you or does not go away. Ask your doctor or pharmacist for more information.

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.

Please read the Medication Guide for STELARA™ and discuss any questions you have with your doctor.

About Centocor Ortho Biotech Inc.

Centocor Ortho Biotech Inc. redefines the standard of care in immunology, nephrology and oncology. The company was formed when Centocor, Inc. and Ortho Biotech Inc. were consolidated in late 2008, and was renamed Centocor Ortho Biotech Inc. Built upon a pioneering history, Centocor Ortho Biotech Inc. harnesses innovations in large-molecule and small-molecule research to create important new therapeutic options. Beyond its innovative medicines, Centocor Ortho Biotech is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates and healthcare professionals have access to the latest treatment information, support services and quality care. For more information about Centocor Ortho Biotech, visit www.CentocorOrthoBiotech.com. Centocor Ortho Biotech is a wholly-owned subsidiary of Johnson & Johnson.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Centocor Ortho Biotech Inc. and/or Johnson & Johnson's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 28, 2008. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Centocor Ortho Biotech Inc. nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)