News Release

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Janssen Announces U.S. FDA Approval of STELARA® (ustekinumab) for the Treatment of Adults with Moderately to Severely Active Ulcerative Colitis

In the Phase 3 pivotal trial, more than 40 percent of patients receiving STELARA subcutaneous (SC) injections every 8 weeks were in clinical remission at one year and not taking corticosteroids

STELARA is the first and only approved treatment for ulcerative colitis to demonstrate improvement of the colon as measured by a novel histologic-endoscopic mucosal improvement endpoint

HORSHAM, PENNSYLVANIA, October 21, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the U.S. Food and Drug Administration's (FDA) approval of STELARA® (ustekinumab) for the treatment of adult patients with moderately to severely active ulcerative colitis. The approval for this new indication is based on the pivotal Phase 3 UNIFI clinical trial which achieved its primary endpoint of clinical remission. Results from UNIFI demonstrate that treatment with STELARA both induced and maintained clinical remission in a significantly greater proportion of adult patients with moderately to severely active ulcerative colitis (UC) compared to placebo.

UC is a serious, chronic and progressive immune-mediated inflammatory disease of the large intestine, affecting approximately 910,000 people in the United States. STELARA is the first and only approved biologic therapy for UC that targets the interleukin (IL)-12 and IL-23 cytokines. The IL-12 and IL-23 cytokines have been shown to play an important role in inflammatory and immune responses.

The pivotal trial included an initial Induction study (UNIFI-I) where patients received a single dose of STELARA 6 mg/kg intravenous (IV) infusion. It was followed 8 weeks later by a Maintenance study (UNIFI-M) where patients received STELARA 90 mg subcutaneous (SC) injections every 8 weeks for 44 weeks. Both studies demonstrated the safety and efficacy of STELARA as a treatment option for patients with moderately to severely active UC, and the design and complete results were recently published in the *New England Journal of Medicine*.

In the Induction study, 19 percent of patients receiving STELARA achieved clinical remission in just 8 weeks. In addition, STELARA provided patients with rapid relief of their symptoms as 58 percent of patients receiving STELARA experienced a clinical response at Week 8.

In the Maintenance study, 45 percent of patients receiving STELARA were in remission at one year. STELARA also helped patients achieve clinical remission without the use of corticosteroids. At 1 year, 43 percent of patients treated with STELARA were in clinical remission and not receiving steroids.

STELARA is the first and only approved UC treatment to provide improvement of the intestinal lining as assessed by a novel histologic-endoscopic mucosal improvement endpoint. In the Induction study, 17 percent of patients receiving STELARA achieved histologic-endoscopic mucosal improvement at Week 8. In the Maintenance study, 44 percent of patients receiving STELARA achieved histologic-endoscopic mucosal improvement at 1 year. Histologic-endoscopic mucosal improvement is a combined measure that assesses the improvement of the colon at the cellular level through histologic examination and through images observed during colonoscopy. The relationship of histologic-endoscopic mucosal improvement to long-term outcomes was not studied in the clinical trial.

"Ulcerative colitis is a chronic and progressive disease that can have a significant impact on patients, often disrupting their day-to-day lives with frequent and urgent needs for bowel movements that can be accompanied by pain and cramping," said William J. Sandborn, M.D., Chief, Division of Gastroenterology, and Professor of Medicine, UC San Diego School of Medicine, and study investigator.[*] "The FDA approval of STELARA for UC represents an exciting milestone, offering patients a new option that has demonstrated improvement of the histology and endoscopic appearance of the intestinal lining, while also offering patients the potential for response and remission without the need for steroids."

Since receiving approval in September 2009 for the treatment of adults living with moderate to severe plaque psoriasis, STELARA has received approval for four additional indications: adolescent patients with moderate to severe plaque psoriasis, adults with active psoriatic arthritis, adults with moderately to severely active Crohn's disease (CD), and now adults with moderately to severely active ulcerative colitis. More than 45,000 patients have been treated with STELARA for CD to-date. Consistent with the approved dosing in CD, STELARA for UC starts with a weight-based, one-time IV infusion induction dose followed by a convenient maintenance dosing schedule of a 90 mg SC maintenance injection every 8 weeks.

Click to Tweet:#BREAKING: The @US_FDA has approved a new indication for STELARA® (ustekinumab). Read more: https://ctt.ac/6HpG2+

"Because of the individual nature of ulcerative colitis, what works for one patient may not work for another. That is why it is so critical that our ulcerative colitis patients have many different treatment options available to them," said Caren Heller, M.D., MBA, Chief Scientific Officer at the Crohn's & Colitis Foundation.[†] "The approval of STELARA is extremely important for patients living with moderate to severe ulcerative colitis. STELARA gives patients another option to, hopefully, induce remission and help manage their disease."

The overall safety profile of STELARA in UC was consistent with what has been observed across all approved indications of STELARA.

"At Janssen, we have a longstanding commitment to developing innovative new options that can help address the unmet treatment needs for those living with immune-mediated diseases," said David M. Lee, M.D., Ph.D., Therapeutic Area Head, Immunology, Janssen Research & Development, LLC. "With today's milestone, STELARA has received its fifth FDA approval since 2009, a testament to our unwavering focus on delivering treatments for patients who have limited therapeutic options."

Janssen will work closely with payers, providers and pharmacy benefit managers to ensure STELARA is broadly accessible and affordable for patients living with UC. 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 UNIFI

UNIFI is a Phase 3 clinical trial program designed to evaluate the safety and efficacy of STELARA induction and maintenance therapy for the treatment of adults with moderately to severely active ulcerative colitis who demonstrated an inadequate response to or were unable to tolerate conventional (i.e., corticosteroids, immunomodulators) or biologic (i.e., one or more TNF blockers and/or vedolizumab) therapies. Both the Induction and Maintenance studies were randomized, double-blind, placebo-controlled, parallel group, multi-center studies. The Induction (UNIFI-I) study was 8 weeks duration and patients achieving clinical response at Week 8 during the Induction study were eligible to enter the Maintenance study. The Maintenance study (UNIFI-M) was 44 weeks duration. The primary endpoint of the Induction study was clinical remission at Week 8 and the primary endpoint for the maintenance study was clinical remission at Week 44 (1 year after the induction dose) among responders to a single IV STELARA induction infusion.

After completion of the Maintenance study, a long-term extension continues to follow eligible participants for an additional 3 years.

About Ulcerative Colitis

Ulcerative Colitis (UC) is a chronic, progressive inflammatory bowel disease (IBD) that causes ulcerations and inflammation in the large intestine (colon and rectum).[1,2] UC affects approximately 910,000 adults in the U.S. and men are more likely than women to be diagnosed.[3] The disease is more common among Caucasian people, although it can affect people of any racial or ethnic group. Diagnosis tends to peak between the ages of 15 and 35, although the disease itself can occur at any age.[4] Symptoms of ulcerative colitis can vary but may include diarrhea and more urgent bowel movements, bloody stool, crampy abdominal pain, and fatigue. There is currently no cure for ulcerative colitis.[5]

About STELARA® (ustekinumab)

STELARA® (ustekinumab), a human IL-12 and IL-23 antagonist, is approved in the United States for the treatment of: 1) adults and children 12 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.

STELARA Dosing for Ulcerative Colitis

Adults with ulcerative colitis will receive the first dose of STELARA through a vein in the arm (intravenous infusion) in a healthcare facility by a healthcare provider. It takes at least 1 hour to receive the full dose of medicine. STELARA will then be given as an injection under the skin (subcutaneous injection) 8 weeks after the first dose of STELARA, then every 8 weeks thereafter.

See full Prescribing Information for Dosing Information for other indications.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to STELARA®.

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.
- 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). 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 12 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, stomach pain, diarrhea, 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 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 30, 2018, 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. Hendrickson BA, Gokhale R, Cho JH. Clinical aspects and pathophysiology of inflammatory bowel disease. *Clin Microbiol Rev*. 2002;15(1):79-94.
2. Crohn's & Colitis Foundation of America. Inflammatory bowel disease and irritable bowel syndrome: similarities and differences. www.crohnscolitisfoundation.org/assets/pdfs/ibd-and-irritable-bowel.pdf. Published July 2014. Accessed July 7, 2019.
3. Molodecky NA, Soon IS, Rabi DM, et al. Increasing incidence and prevalence of the inflammatory bowel diseases with time, based on systematic review. *Gastroenterology*. 2012;142(1):46-54.
4. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG clinical guideline: Ulcerative colitis in adults. *Am J Gastroenterol.* 2019;114(3)384-413.
5. Danese S, Allex M, van Bodegraven AA, et al. Unmet medical needs in ulcerative colitis: an expert group consensus. *Digestive Diseases*. 2019;37(4)266-283.

*Dr. William Sandborn was compensated for his work as an investigator on the UNIFI study.

†Johnson & Johnson Healthcare Systems, Inc. is a corporate sponsor for the Crohn's & Colitis Foundation.