News Release

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NEW PHASE 3 DATA SHOW SINGLE DOSE OF STELARA® (USTEKINUMAB) INDUCES CLINICAL REMISSION AND RESPONSE IN ADULTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

Janssen presents 8-week induction data from pivotal Phase 3 UNIFI study during plenary session at the American College of Gastroenterology Annual Scientific Meeting 2018

PHILADELPHIA, PENNSYLVANIA, October 9, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data showing treatment with a single intravenous (IV) dose of STELARA® (ustekinumab) induces clinical remission and response in adults with moderate to severe ulcerative colitis (UC) who previously experienced an inadequate response or were intolerant to conventional or biologic therapies. The findings will be presented today at 2:00 pm EDT as part of the Late Breaking Abstract Plenary at the American College of Gastroenterology (ACG) Scientific Meeting 2018.

Results from the induction phase of the Phase 3 UNIFI study show that treatment with a single IV dose of STELARA induced clinical remission in a significantly greater proportion of UC patients at week 8, compared with placebo, at both doses studied. Major secondary endpoints including the proportion of patients in clinical response, endoscopic healing, as well as improvement in health-related quality of life, were also

significantly higher at week 8 among patients receiving STELARA compared with patients receiving placebo. About 50 percent of study participants are considered biologic refractory, and 17 percent have a history of inadequate response or intolerance to an anti-TNF and/or Entyvio* (vedolizumab).

"Ulcerative colitis is a complex immune disease, and more than half of UC patients have not experienced remission with currently available conventional or biologic treatment options," said lead investigator Bruce E. Sands, MD, Dr. Burrill B. Crohn Professor of Medicine and Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at the Icahn School of Medicine at Mount Sinai. "The significant rates of remission observed through the 8-week induction, coupled with a safety profile that is well-documented through years of research and use in other immune diseases, demonstrate the potential for ustekinumab as an effective treatment for UC."

Patients participating in the Phase 3 UNIFI study were randomized 1:1:1 at week 0 and received a single IV dose of placebo, STELARA 130 mg, or STELARA ~6 mg/kg (weight tiered dosing: patients weighing less than or equal to 55 kg received 260 mg; patients weighing more than 55 kg and less than or equal to 85 kg received 390 mg; and patients weighing more than 85 kg received 520 mg). At week 8, patients (n=961) were evaluated for clinical remission, endoscopic healing, clinical response, change from baseline in the IBDQ score, and mucosal healing (an endpoint that includes both endoscopic healing and histologic healing).

At week 8:

- 15.6 percent of patients receiving STELARA 130 mg and 15.5 percent of patients receiving STELARA ~6 mg/kg achieved clinical remission compared with 5.3 percent of patients receiving placebo ($p < 0.001$). Remission was defined as a Mayo score ≤2 points, with no individual subscore >1.

- 26.3 percent of patients receiving STELARA 130 mg and 27 percent of patients receiving STELARA ~6 mg/kg experienced endoscopic healing compared with 13.8 percent of patient receiving placebo ($p<0.001$). Endoscopic healing was

defined as a Mayo endoscopy subscore of 0 (normal mucosa or inactive disease) or 1 (mild disease activity).

- 51.3 percent and 61.8 percent of patients receiving STELARA 130 mg and STELARA ~6 mg/kg achieved clinical response compared with 31.3 percent of patients receiving placebo ($p < 0.001$). Clinical response was defined as a decrease from baseline in the Mayo score by ≥30% and ≥3 points, with either a decrease from baseline in the rectal bleeding subscore ≥1 or a rectal bleeding subscore of 0 or 1.

- 20.3 percent and 18.4 percent of patients receiving STELARA 130 mg and STELARA ~6 mg/kg achieved mucosal healing compared with 8.9 percent of patients receiving placebo ($p < 0.001$). Mucosal healing is defined as combined endoscopic healing (Mayo endoscopy subscore of 0 or 1) and histologic healing (defined as 0-<5% neutrophils in epithelium, no crypt destruction, and no erosions or ulcerations or granulations).

In addition, both doses of STELARA resulted in statistically significant improvements in the Inflammatory Bowel Disease Questionnaire (IBDQ), a health-related quality of life measure for patients with IBD, as well as markers of inflammation, including C-reactive protein (CRP), fecal lactoferrin and calprotectin.

Through week 8, adverse events (AEs), serious AEs and infections (including serious infections) were reported in similar proportions across STELARA and placebo treatment groups. No malignancies, opportunistic infections or tuberculosis were reported through week 8. One death from an esophageal varices hemorrhage was reported for a patient with no known history of cirrhosis or portal hypertension in the ~6mg/kg dose group prior to week 8.

"STELARA is the first biologic approved for any indication that targets interleukin (IL)-12 and IL-23 cytokines, which are believed to play a role in immune-mediated diseases, like ulcerative colitis," said Philippe Szapary, MD, MSCE, Vice President, Clinical Development, Janssen Research & Development, LLC. "These induction data from the

Phase 3 UNIFI study underscore the potential for this pathway in the treatment of UC, which may lead to a new effective and safe treatment option for UC patients in the future."

In addition to the UNIFI study data, Janssen is also presenting results from the IM-UNITI open label long-term extension (LTE) for STELARA in the treatment of adults with moderate to severe Crohn's disease, including an oral presentation on long-term efficacy of STELARA with and without concomitant immunosuppressants through 2 years. A poster demonstrating the long-term efficacy and safety of STELARA through 3 years of treatment will also be presented.

About the UNIFI Trial

UNIFI is a Phase 3 protocol designed to evaluate the safety and efficacy of STELARA induction and maintenance dosing for the treatment of moderate to severe ulcerative colitis in adults 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 or vedolizumab) therapies. Both the induction and maintenance studies are randomized, double-blind, placebo-controlled, parallel group, multi-center studies The Induction study was of at least 8 weeks duration for each participant. Participants achieving clinical response in the Induction study were eligible for the Maintenance study. The Maintenance study was 44 weeks duration. The primary endpoint of the induction study is clinical remission at week 8 and the primary endpoint for the maintenance study is clinical remission at week 44 among responders to a single IV STELARA infusion.

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

About Ulcerative Colitis

More than five million people worldwide are living with Crohn's disease and ulcerative colitis—collectively known as IBD. Ulcerative colitis, or UC, affects nearly 907,000 people in the United States, with approximately 38,000 new cases diagnosed each year.[1] UC is a chronic disease of the large intestine, also known as the colon, in which

the lining of the colon becomes inflamed and develops tiny open sores, or ulcers, that produce pus and mucous. It is the result of an abnormal response by your body's immune system. Symptoms vary but may include loose and more urgent bowel movements, persistent diarrhea, abdominal pain, bloody stool, loss of appetite, weight loss and fatigue.[2]

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 and can be used alone or in combination with methotrexate (MTX); 3) adult patients (18 years and older) with moderately to severely active Crohn's disease who have failed or were intolerant to immunomodulators or corticosteroids; or failed or were intolerant to anti-TNF therapies who have already taken other medicine that did not work well enough or they could not tolerate it.

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.
- 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: 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, including the 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 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 http://www.janssen.com/. Follow us at http://www.twitter.com/JanssenGlobal. Janssen Research & Development, LLC is 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 new study data on 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 31, 2017, 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. 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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*Entyvio is a registered trademark of Millennium Pharmaceuticals, Inc.

1. World IBD Day. Home. Available at http://www.worldibdday.org/index.html. Accessed September 11, 2018.
2. Crohn's & Colitis Foundation of America. What is Ulcerative Colitis? Available at http://www.crohnscolitisfoundation.org/what-are-crohns-and-colitis/what-is-ulcerative-colitis/. Accessed September 11, 2018.