News Release

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New Phase 3b Interim Data from STARDUST Study Show Two-Thirds of Patients with Moderately to Severely Active Crohn's Disease Achieved Clinical Remission After Two Doses of STELARA® (ustekinumab)

First Study to Explore a Treat-to-Target Strategy in Crohn's Disease Using Endoscopy to Guide Dose Adjustment

First Study to Evaluate Intestinal Ultrasound Monitoring in an Interventional Setting

VIENNA, AUSTRIA, February 14, 2020 - The Janssen Pharmaceutical Companies of Johnson & Johnson today announced interim data from the Phase 3b STARDUST study. At week 16, 79 percent of patients with moderately to severely active Crohn's disease (CD) achieved clinical response[1] and 67 percent were in clinical remission[2] after receiving one ~6 mg/kg intravenous (IV) dose followed by one 90 mg subcutaneous (SC) dose of STELARA® (ustekinumab), open label.[3] Intestinal ultrasound (IUS) responses were assessed and were detected as early as week 4.[4] Week 16 data (digital oral presentation, or DOP 13) and IUS response data (DOP

10) from STARDUST are being presented as digital oral presentations at the 15th Congress of the European Crohn's & Colitis Organization (ECCO).[3,4]

The primary endpoint of the 48-week STARDUST study is comparative endoscopic response[5] among adult patients with CD receiving STELARA maintenance therapy. At week 16, patients who achieved a ≥70 point decrease in Crohn's Disease Activity Index score[6] (CDAI70 responders) were randomized into treat-to-target or routine standard of care treatment groups at a 1:1 ratio.[7]

Of the 220 CDAI70 responders randomized to the treat-to-target arm, 37 percent achieved endoscopic response at week 16.[3] Endoscopy at week 16 was measured only in the treat-to-target group.[7] Treat-to-target is a proactive treatment strategy where frequently monitored outcomes, like endoscopic response, biomarkers and clinical symptoms, guide use of the medication.[8] STARDUST is the first study of a treat-to-target strategy in CD using endoscopic response to guide treatment.

"Crohn's disease patients may respond to treatment while continuing to experience internal inflammation that can cause irreversible damage. These patients may benefit from a more proactive, robust treatment approach and less invasive monitoring methods," said Professor Silvio Danese[i], Head of the Inflammatory Bowel Diseases Centre at Humanitas Research Hospital, Milan, Italy and principal investigator. "I am encouraged by these data, that demonstrate the potential clinical utility of the noninvasive IUS method in helping guide treatment of CD and look forward to forthcoming data that may help us better understand the possible benefits of a treat-to-target strategy."

IUS is a complementary method of assessing CD activity, based upon measuring transmural bowel features, like thickness of the bowel wall and presence of hypervascularization.[9] STARDUST is the first study to use IUS for monitoring CD patients in an interventional setting. Future studies need to confirm whether early IUS response at week 4 is predictive of longer-term (i.e., week 16 and up to week 48) clinical and endoscopic outcomes for CD patients.

The STARDUST week 16 interim analysis includes 500 participants with moderately to severely active CD receiving an IV induction dose of STELARA ~6 mg/kg, followed by a STELARA 90 mg SC injection at week 8.[3] In the interim analysis, patient response was assessed up to week 16. Participants were either naïve to prior biologics or had previously been exposed to no more than one biologic medicine. At week 16, the safety profile for STELARA in STARDUST was consistent with the established safety profile observed in Phase 3 inflammatory bowel disease (IBD) clinical trials, as well as that seen in other indications.[10,11]

"STARDUST represents a significant milestone in our commitment to helping Crohn's disease patients and the physicians who treat them," said Jan Wehkamp, M.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. "The data from this study may provide us with key clinical insights which may inform future treatment strategies."

Janssen is presenting a total of 23 abstracts at this year's ECCO congress. STELARA is currently approved for the treatment of adults with moderately to severely active Crohn's disease in the U.S., Canada, the European Union (EU) and Japan.

About the STARDUST Trial

STARDUST is a randomized, international, multi-center, interventional Phase 3b study evaluating the proportion of patients with endoscopic response, defined as a ≥50% reduction from baseline in simple endoscopic score for Crohn's disease (SES-CD) at week 48. STARDUST is evaluating 500 participants receiving an IV induction dose of STELARA 6 mg/kg, followed by a STELARA 90 mg SC injection at week 8. At week 16, patients with a CDAI reduction of ≥70 points (CDAI70) were randomized to treat-to-target or standard of care treatment arms (1:1 ratio) and will be followed through the end of the study (48 weeks). Primary endpoint data are anticipated for presentation later this year.

About Crohn's Disease (CD)

CD is one of the two main forms of IBD, which affect an estimated 3 million Americans.[12] CD is a chronic inflammatory condition of the gastrointestinal tract with no known cause, but the disease is associated with abnormalities of the immune system that could be triggered by a genetic predisposition, diet or other environmental factors. Symptoms of CD can vary but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss and fever. There is currently no cure for CD.[13]

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 Crohn's Disease

Adults with Crohn's disease 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.

cp-113880v1

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.

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Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal. 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 development and potential availability in the US of 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 Research & Development, LLC, and 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. Clinical response is defined as a decrease in Crohn's Disease Activity index (CDAI) score from baseline of ≥100 points, or a CDAI score of <150
2. Clinical remission is defined as a CDAI score of <150.
3. Danese, S., et. Al. Clinical and endoscopic response to ustekinumab in Crohn's Disease: Week 16 interim analysis of the STARDUST trial [Presentation for DOP13] Presented at the 15th Congress of the European Crohn's & Colitis Organization (ECCO) 12-15 February 2020; Vienna, Austria.
4. Kucharzik, T., et. Al. Intestinal ultrasound response and transmural healing after ustekinumab induction in Crohn's Disease: Week 16 interim analysis of the STARDUST trial substudy. [Presentation for DOP10] Presented at the 15th Congress of the European Crohn's & Colitis Organization (ECCO) 12-15 February 2020; Vienna, Austria.
5. Endoscopic response was defined by a 50 percent reduction from baseline in simple endoscopic score (SES-CD).
6. CDAI is a frequently used measure to assess the severity of CD, giving a score from 0–600; a higher score indicates more severe disease activity
7. ClinicalTrials.gov. Study of Treat to Target Versus Routine Care Maintenance Strategies in Crohn's Disease Patients Treated With Ustekinumab (STARDUST). Identifier NCT03107793. Available at: https://clinicaltrials.gov/ct2/show/NCT03107793. Accessed January 2020.
8. Smolen J, *et al*. Treating rheumatoid arthritis to target: 2014 update of the recommendations of an international task. *Ann Rheum Dis* 2015;0:1–13.
9. Fraquelli M *et al*. Impact of intestinal ultrasound on the management of patients with inflammatory bowel disease: how to apply scientific evidence to clinical practice. *Dig Liver Dis* 2020;52:9–18.
10. European Medicines Agency. STELARA Summary of product characteristics. 2020. Available at: https://www.medicines.org.uk/emc/product/7638/smpc. Accessed January 2020.
11. Sandborn WJ, *et al*. Long-term efficacy and safety of ustekinumab for Crohn's disease through the second year of therapy. *Aliment Pharmacol Ther* 2018;48:65–77."
12. Overview of Crohn's Disease. Available at: https://www.crohnscolitisfoundation.org/what-is-crohns-disease/overview. Accessed January 2020.
13. Crohn's and Colitis UK. Crohn's disease. Available at: https://www.crohnscolitisfoundation.org/what-is-crohns-disease/overview. Accessed January 2020.

[i] Professor Danese is a paid consultant for Janssen. He has not been compensated for any media work.