News Release

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New Analysis Presented by Janssen at United European Gastroenterology Week (UEGW) Demonstrates Long-Term Safety Profile for STELARA® (ustekinumab) in Older Patients Across Approved Indications

First examination of safety events in the 60 and over sub-population across STELARA indications, including inflammatory bowel disease where relatively little biologics safety data exists, are generally consistent with placebo

Janssen presents 13 abstracts, including four oral presentations and two late breakers

SPRING HOUSE, PENNSYLVANIA, October 4, 2021 – Today, the Janssen Pharmaceutical Companies of Johnson & Johnson announced a new analysis of STELARA® (ustekinumab) pooled safety data from 13 clinical studies across approved indications, showing rates of key safety events among adults 60 years and older treated with STELARA for up to five years[a] were similar to rates observed with placebo during the control phase of these trials.[1,b] Approved indications included adults with moderately to severely active Crohn's disease (CD), moderately to severely active ulcerative colitis (UC), moderate to severe plaque psoriasis (PsO) and active psoriatic arthritis (PsA) (Oral Presentation OP198).[1]

These data represent an important patient population as patients 60 years old and older are at a higher risk of disease and therapy-associated morbidity, which can result in disease management challenges.[1]

"Little has been intentionally explored about the safety profile of biologics in patients aged 60 and older with inflammatory bowel disease, as this population is often limited in number in clinical trials," said Professor Subrata Ghosh, Chair and Head of Department of Medicine, University College Cork, Ireland and lead study investigator of the pooled safety analysis.[c] "This analysis arms physicians with data to consider when treating older patients with STELARA given the safety profile observed across all approved indications."

Pooled Safety (Oral Presentation OP198) data show:[1]

Data from 13 Phase 2 and 3 studies, including six studies in CD/UC and seven studies in PsO/PsA for STELARA, were pooled. Of patients 60 years old or older with moderate to severe CD or UC, 214 received STELARA, the equivalent of 311 patient years (PYs) of follow up, and 120 received placebo, the equivalent of 97 PYs. Across additional approved indications, 811 received STELARA (1,590 PYs) and 272 received placebo (143 PYs). Number of events across pooled indications per 100 PYs were as follows:

- Overall rates for adverse events (AEs) per 100 PYs were no greater for STELARA (269.12) than placebo (455.9).
- Overall rates for infections per 100 PYs were similar between STELARA (75.49) and placebo (86.44).
- Rates of serious AEs (STELARA: 19.88; placebo: 27.19) and serious infections (STELARA: 3.33; placebo: 3.49) were similar between STELARA and placebo treatment groups.
- No increased risk of malignancy with STELARA was observed based on a comparison of observed versus expected malignancies.
- Overall, the safety profile of STELARA-treated patients 60 years old and older from the long-term pooled safety dataset across approved indications did not demonstrate higher rates on STELARA versus placebo.

"Continuing to follow occurrences of safety events in older adults who are treated with our therapies is valuable information that can help physicians evaluate treatment options for their patients," said Jan Wehkamp, M.D., Ph.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. "These data build on the body of evidence for the safety profile of STELARA and underscore our commitment to developing meaningful therapies for people of all ages who are living with an untreated or undertreated immune-mediated disease."

These data are among 13 total abstracts, including three other oral presentations (OP122, OP153, OP199), two posters of week 12 data for TREMFYA® (guselkumab) in the treatment of adults with moderately to severely active CD from the GALAXI study (P0402, P0403), and two late breakers Janssen is presenting at UEGW. TREMFYA is not currently approved for the treatment of CD in the United States.[2] Late-breaking presentations are:

- The Pharmacokinetics and Immunogenicity of Ustekinumab and Adalimumab in Patients with Moderate to Severe Crohn's Disease: Results from the SEAVUE Study (LB15)
- Clinical and Endoscopic Outcomes with Ustekinumab in Patients with Crohn's Disease: Results from the Long-Term Extension Period of the STARDUST Trial (LB14)

Editor's Notes:

a. Mean patient follow-up was 102 weeks.
b. This analysis compares a shorter follow-up duration on placebo (often due to per-protocol crossover of placebo patients) to the much longer periods of time (including follow-up) that patients receive STELARA during the same studies, including long-term extensions of up to five years.
c. Dr. Subrata Ghosh is a paid consultant for Janssen. He has not been compensated for any media work.

About Crohn's Disease (CD)

CD is one of the two main forms of inflammatory bowel disease, which affects an estimated three million Americans.[3] 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.[4] Symptoms of CD can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss and fever.[5] There is currently no cure for CD.[6]

About Ulcerative Colitis (UC)

More than five million people worldwide are living with CD and UC—commonly known as inflammatory bowel disease. UC affects nearly 907,000 people in the U.S., with approximately 38,000 new cases diagnosed each year.[7] 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 mucus. It is the result of an abnormal response by the body's immune system.[8] Symptoms vary, but may include loose and more urgent bowel movements, persistent diarrhea, abdominal pain, bloody stool, loss of appetite, weight loss and fatigue.[9]

About STELARA® (ustekinumab)[10]

STELARA® (ustekinumab) is a fully human monoclonal antibody and is the first biologic treatment to selectively inhibit the interleukin (IL)-12 and IL-23 pathways. STELARA is approved in the United States for the treatment of: 1) adults and children six 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.

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 6 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.

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About TREMFYA® (guselkumab)[2]

Developed by Janssen, TREMFYA is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor. IL-23 is an important driver of the pathogenesis of inflammatory diseases such as PsO and PsA.[11]

TREMFYA is approved in the U.S., Canada, Japan, and a number of other countries worldwide for the treatment of adults with moderate to severe plaque PsO who are

candidates for injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light), and for the treatment of adult patients with active PsA. It is also approved in the EU for the treatment of moderate to severe plaque PsO in adults who are candidates for systemic therapy and for the treatment of active PsA in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug therapy.

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

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TREMFYA®?

TREMFYA® is a prescription medicine that may cause serious side effects, including:

- **Serious Allergic Reactions.** Stop using TREMFYA® and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:
  - fainting, dizziness, feeling lightheaded (low blood pressure)
  - swelling of your face, eyelids, lips, mouth, tongue or throat
  - trouble breathing or throat tightness
  - chest tightness
  - skin rash, hives
  - itching

- **Infections.** TREMFYA® may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with TREMFYA® and may treat you for TB before you begin treatment with TREMFYA® if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with TREMFYA®.

  Tell your healthcare provider right away if you have an infection or have symptoms of an infection, including:

  - fever, sweats, or chills
  - muscle aches
  - weight loss
  - cough

- warm, red, or painful skin or sores on your body different from your psoriasis
- diarrhea or stomach pain
- shortness of breath
- blood in your phlegm (mucus)
- burning when you urinate or urinating more often than normal

Do not take TREMFYA® if you have had a serious allergic reaction to guselkumab or any of the ingredients in TREMFYA®.

Before using TREMFYA®, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section **"What is the most important information I should know about TREMFYA®?"**
- have an infection that does not go away or that keeps coming back.
- have TB or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with TREMFYA®.
- are pregnant or plan to become pregnant. It is not known if TREMFYA® can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TREMFYA® passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of TREMFYA®?

TREMFYA® may cause serious side effects. See "What is the most important information I should know about TREMFYA®?"

The most common side effects of TREMFYA® include: upper respiratory infections, headache, injection site reactions, joint pain (arthralgia), diarrhea, stomach flu (gastroenteritis), fungal skin infections, herpes simplex infections, and bronchitis.

These are not all the possible side effects of TREMFYA®. Call your doctor for medical advice about side effects.

Use TREMFYA® exactly as your healthcare provider tells you to use it.

Please read the full Prescribing Information, including Medication Guide for TREMFYA®, and discuss any questions that 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 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.

Janssen Research & Development, LLC is a 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 ongoing and planned development efforts involving STELARA® (ustekinumab) in inflammatory bowel disease. 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 January 3, 2021, 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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