



News Release

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Janssen Presents Study Results Showing Clinical Efficacy for TREMFYA® (guselkumab) and Long-Term Safety for STELARA® (ustekinumab) for Patients Living with Inflammatory Bowel Disease at Digestive Disease Week® 2022

New data show proportions of patients treated with TREMFYA who achieved clinical-biomarker response ranged from 47.5-66.7 percent across dose groups in the Phase 2 GALAXI 1 study

Other data presented demonstrate the long-term safety profile of STELARA® (ustekinumab) in bio-naïve and bio-failure patients living with inflammatory bowel disease

SPRING HOUSE, PENNSYLVANIA, May 24, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data from the Phase 2 GALAXI 1 clinical trial of TREMFYA® (guselkumab) in adult patients with moderately to severely active Crohn’s disease (CD), and from three separate long-term pooled analyses of adult patients with ulcerative colitis (UC) and CD treated with STELARA® (ustekinumab).^{1,2,3,4} These data are being presented as oral and poster

presentations and are among 29 Janssen abstracts presented during the Digestive Disease Week® (DDW) meeting taking place in person and virtually in San Diego, California on May 21-24, 2022.

The GALAXI 1 data showed study participants with an inadequate response or intolerance to conventional therapies and/or biologics treated with TREMFYA achieved high levels of clinical-biomarker response^a (47.5-66.7 percent), endoscopic response^b (44.3-46 percent), and clinical remission^c with C-reactive protein (CRP) ≤ 3 mg/L or fecal calprotectin ≤ 250 μ g/g (39.3-66.7 percent) at 48 weeks across dose groups.¹ TREMFYA is not approved to treat adult patients with CD or UC in the U.S.

The STELARA pooled analyses of long-term safety data in bio-naïve and bio-failure CD/UC patients treated with STELARA demonstrated a favorable safety profile consistent with analyses in the overall inflammatory bowel disease (IBD) population and the established safety profile across approved indications.^{2,3} In addition, a STELARA pooled safety analysis from 13 total studies across all approved indications (including data up to one year in psoriatic arthritis [PsA], two in UC, and five in CD and plaque psoriasis [PsO]), showed no increased incidence (adjusted for duration of follow up) of malignancy with STELARA treatment compared to placebo.⁴

“These new data from the GALAXI 1 study are encouraging as we continue to investigate long-term treatment solutions to address the unmet needs for our patients who live with the burden of moderately to severely active Crohn’s disease,” said GALAXI 1 presenting study author Remo Panaccione, M.D., Professor of Medicine and Director of the Inflammatory Bowel Disease Unit at the University of Calgary, Alberta, Canada.^d “The clinical-biomarker response and endoscopic response data from the Phase 2 GALAXI 1 clinical trial build upon the study’s clinical remission outcomes and give us insight into the potential that TREMFYA may provide sustained remission.”

New GALAXI week 48 analyses (oral presentation #888) show:¹

- **Clinical-biomarker response:^a** The proportions of patients treated with TREMFYA across dose groups^e (n=185) who achieved clinical-biomarker response at week 48 ranged from 47.5-66.7 percent.^{f,g}
- **Endoscopic response:^b** The proportions of patients treated with TREMFYA achieving endoscopic response ranged from 44.3-46 percent across dose groups^e (n=185) at week 48.^f
- **Clinical remission and achieving CRP or fecal calprotectin normalization:^c** The proportions of patients treated with TREMFYA achieving clinical remission and CRP ≤ 3 mg/L or fecal calprotectin ≤ 250 $\mu\text{g/g}$ ranged from 39.3-66.7 percent across dose groups (n=185).^{e,f,h}
- **Safety:** Safety results were consistent with the known safety profile of TREMFYA in approved indications.

Janssen previously announced [48-week clinical remission and corticosteroid-free clinical remission results](#) from the GALAXI 1 Phase 2 study.⁵ Phase 3 clinical trials evaluating TREMFYA for the treatment of moderately to severely active CD are ongoing and actively enrolling participants. Learn more through the [Janssen Global Trial Finder](#).

STELARA long-term pooled safety analyses showed:

- **Safety profile similar to placebo in bio-naïve patients:** In a pooled long-term safety analysis of four Phase 2/3 IBD studies, 771 bio-naïve patientsⁱ received STELARA with 1511 patient-years of follow up and 425 bio-naïve patients received placebo with 376 patient-years of follow up.³ Event rates adjusted per 100 patient-years for adverse events (AEs), serious AEs, infections, serious infections, major adverse cardiac events (MACE), and malignancies were similar between STELARA and placebo through up to one year.³ Rates per 100 patient-years (adjusted for duration of follow up) for AEs, serious AEs, infections, serious infections, and MACE were similar and/or numerically lower for STELARA versus placebo through up to five years in

bio-naïve patients with CD and up to two years in bio-naïve patients with UC (Poster #Tu1440).³

- **Safety profile similar to placebo in bio-failure patients:** In a pooled long-term safety analysis of five Phase 2/3 IBD studies, 1596 bio-failure^j patients with 1970 patient-years of follow up received STELARA and 847 bio-failure patients with 473 patient-years of follow up received placebo.² Event rates per 100 patient-years (adjusted for duration of follow up) for AEs, serious AEs, infections, serious infections, MACE, and malignancies were similar between STELARA and placebo through up to five years in bio-failure patients with CD and up to two years in bio-failure patients with UC.² The safety profile of STELARA was consistent with the established safety profile in IBD and across approved indications (Poster #Tu1438).²
- **Malignancy risk comparable to placebo:** In an analysis of pooled long-term safety data from 13 studies across approved indications, including CD and UC, in 2501 placebo-treated patients with 1244 patient-years of follow up and 6710 STELARA-treated patients with 13807 patient-years of follow up, STELARA showed no increased incidence (adjusted for duration of follow up) of malignancy compared to placebo through up to five years of STELARA follow up.⁴ Comparisons between the number of malignancies observed for patients treated with STELARA compared to expected malignancies based on the National Institutes of Health Surveillance, Epidemiology, and End Results database (SEER),^{6,k} which does not include nonmelanoma skin cancer (NMSC) and cervical cancer in situ, resulted in a standard incidence ratio (SIR)^l of 0.85 (95 percent confidence intervals:^m 0.65, 1.09) for STELARA across approved indications, suggesting no increased malignancy risk with STELARA treatment. (Oral presentation #14).⁴

“These data provide validation and underscore our commitment to continuing to innovate for patients with disease where considerable need remains,” said Jan Wehkamp, M.D., Ph.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. “Drawing from a two-decade legacy of immunology innovation, we continue to generate new evidence for STELARA and are

investing deeply in our pipeline to usher in a new era of treatment, leveraging the continued research of pathway science aiming to establish TREMFYA as a trusted therapeutic option for healthcare professionals and people who are living with inflammatory bowel disease.”

Editor’s Notes:

- a. Clinical-biomarker response is defined as clinical response and ≥ 50 percent reduction from baseline in CRP or fecal calprotectin.¹
- b. Endoscopic response is defined as ≥ 50 percent improvement from baseline in Simple Endoscopic Score for Crohn’s Disease (SES-CD) or SES-CD ≤ 2 . SES-CD score at week 48 was based on all observed segments scored at week 48. Subjects who had insufficient data to calculate the total SES-CD score at week 48 were considered not to be in endoscopic response.¹
- c. Clinical remission is defined as a Crohn’s Disease Activity Index (CDAI) score of < 150 .¹
- d. Dr. Panaccione is a paid consultant for Janssen. He has not been compensated for any media work.
- e. The GALAXI 1 48-week analyses report the results of 248 patients randomized to TREMFYA or STELARA: patients receiving TREMFYA 200 mg intravenous (IV) were shifted to TREMFYA 100 mg subcutaneous (SC) dose every eight weeks (q8w); patients receiving TREMFYA at 600 or 1200 mg IV changed to TREMFYA 200 mg SC every four weeks (q4w).¹ Please see the ‘About GALAXI 1’ section below for further details regarding dose and study design.
- f. Patients who had a prohibited change in concomitant CD medication, a CD-related surgery, or discontinued study agent due to lack of efficacy, or an AE of worsening CD prior to the designated analysis timepoint were considered not to be in clinical remission, clinical response, clinical-biomarker response, endoscopic response, or clinical remission and CRP concentration ≤ 3 mg/L or fecal calprotectin concentration ≤ 250 $\mu\text{g/g}$ from that timepoint onwards. Patients who had discontinued the study agent due to any other reasons prior to the designated analysis timepoint had their observed data used, if

available, to determine responder and non-responder status from that timepoint onwards.¹

- g. Patients who had a missing CDAI score or who were missing both CRP and fecal calprotectin values at the designated analysis timepoint were considered not to be in clinical-biomarker response at that timepoint.¹
- h. Patients who had missing CDAI score or who were missing both CRP and fecal calprotectin values at the designated analysis timepoint were considered not to be in clinical remission and CRP concentration ≤ 3 mg/L or fecal calprotectin concentration ≤ 250 $\mu\text{g/g}$ at that timepoint.¹
- i. All patients who received ≥ 1 dose of STELARA and were never treated with a biologic were included in the analysis.³
- j. All patients who received ≥ 1 dose of STELARA and were identified as having a history of prior biologic failure were included in the analysis.²
- k. The expected number of patients with malignancies is based on the SEER Database (year 2016), adjusted for age, gender, and race. Only patients with race belonging to White, Black or African American, Asian, American Indian/Alaska Native, Native Hawaiian, or other Pacific Islander were included since SEER only contains incidence rates for these populations.⁷
- l. Standard incidence ratio is the observed number of patients with malignancy divided by the expected number of patients with malignancy.⁸
- m. Confidence intervals are based on an exact method assuming that the observed number of events follows a Poisson distribution.⁴

About GALAXI 1 (NCT03466411; EudraCT 2017-002195-13)^{9,10}

GALAXI 1 is a double-blind, placebo-controlled, active-reference arm, global, multicenter, treat-through, Phase 2 dose-ranging study evaluating the efficacy and safety of TREMFYA in adult participants with moderately to severely active CD with inadequate response/intolerance to conventional therapies (corticosteroids, immunosuppressives) and/or biologics (tumor necrosis factor [TNF] antagonists, vedolizumab).

Participants were randomized equally into five treatment arms, including treatment with TREMFYA dosed at 200, 600, or 1200 mg IV at weeks 0, 4 and 8, respectively; or treatment with the reference product, STELARA, dosed at ~6 mg/kg IV at week 0 and then dosed at 90 mg SC at week 8; or IV placebo. The study was not powered to evaluate differences between treatment groups after the primary endpoint at week 12.

The primary endpoint of the Phase 2 GALAXI 1 study is change from baseline in CDAI scores at week 12.¹¹ All three induction doses of TREMFYA significantly improved CDAI scores from baseline as compared to placebo, with placebo-subtracted Least Squares Mean reductions of 124.2 ($p < 0.001$), 102.7 ($p < 0.001$), and 108.7 ($p < 0.001$) for the 200 mg IV, 600 mg IV, and 1200 mg IV groups, respectively. Additional key outcomes evaluated at week 12 include clinical remission (CDAI < 150), clinical response (decrease from baseline in CDAI ≥ 100 or CDAI < 150), PRO-2 remission (abdominal pain mean daily score ≤ 1 and mean daily stool frequency score ≤ 3 and no worsening from baseline), clinical-biomarker response (clinical response and ≥ 50 percent reduction from baseline in CRP or fecal calprotectin), endoscopic response (≥ 50 percent improvement from baseline in the SES-CD or SES-CD ≤ 2), and safety in participants treated with TREMFYA compared with placebo.¹¹ Participants may receive treatment through five years.

The 48-week analyses report the results of the 248 patients randomized to TREMFYA or STELARA.¹² After completing 12 weeks of IV induction therapy, patients transitioned to their long-term maintenance treatments as follows: patients receiving TREMFYA 200 mg IV were shifted to TREMFYA 100 mg SC dose q8w; patients receiving TREMFYA dosed at 600 mg IV or 1200 mg IV changed to TREMFYA 200 mg SC q4w; patients receiving STELARA continued with a 90 mg SC dose q8w; in addition to the 248 randomized patients, placebo non-responders began STELARA IV followed by STELARA SC q8w; and placebo responders continued on a placebo SC q4w.¹²

About DDW

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and virtual meeting from May 21-24, 2022. The meeting showcases more than 5000 abstracts and hundreds of lectures on the latest advances in GI research, medicine, and technology. More information can be found at www.ddw.org.

About Crohn's Disease

CD is one of the two main forms of IBD, which affects an estimated three million Americans.¹³ 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.¹⁴ Symptoms of CD can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss and fever.¹⁵ There is currently no cure for CD.¹⁶

About Ulcerative Colitis

In the United States, about one million people are affected by UC.¹⁷ 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.¹⁸ It is the result of an abnormal response by the body's immune system.¹⁸ Symptoms vary, but may include loose and more urgent bowel movements, persistent diarrhea, abdominal pain, bloody stool, loss of appetite, weight loss and fatigue.¹⁹

About TREMFYA® (guselkumab)²⁰

Developed by Janssen, TREMFYA is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of interleukin (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 moderate to severe plaque PsO and active PsA. TREMFYA is approved in the U.S., Canada, Japan, and a number of other countries 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.

About STELARA® (ustekinumab)²¹

STELARA is a fully human monoclonal antibody and is the first biologic treatment to selectively inhibit the IL-12 and IL-23 pathways. Janssen commercializes STELARA in the U.S., EU, and in countries around the world. STELARA is approved in the U.S. for the treatment of: 1) adults and children six years and older with moderate to severe plaque PsO who are candidates for phototherapy or systemic therapy; 2) adult patients (18 years or older) with active PsA, used alone or in combination with methotrexate (MTX); 3) adult patients (18 years and older) with moderately to severely active CD; 4) adult patients (18 years and older) with moderately to severely active UC.

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

IMPORTANT SAFETY INFORMATION

STELARA® (ustekinumab) 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 or have any open cuts.
- 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). These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications. 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.

Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is a rare condition that affects the brain and can cause death. The cause of PRES is not known. If PRES 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 PRES.
- 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, bronchitis, diarrhea, stomach pain, 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 click to 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](tel: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 & Retina; 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 TREMFYA® (guselkumab) and STELARA® (ustekinumab) product development. 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 2, 2022, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other 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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