



## **News Release**

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## **New Analyses Suggest Favorable Results for STELARA® (ustekinumab) When Used as a First-Line Therapy for Bio-Naïve Patients with Moderately to Severely Active Crohn's Disease and Ulcerative Colitis**

*STELARA when used as a first-line therapy was associated with longer time in clinical remission or clinical response, including the postponing of surgery, among adult patients with moderately to severely active ulcerative colitis compared with usage as a second- or third-line therapy in a modelled analysis*

*Bio-naïve patients with moderately to severely active Crohn's disease started on STELARA showed higher rates of persistence at one year compared to adalimumab in a retrospective real-world evidence study*

**SPRING HOUSE, PENNSYLVANIA, October 25, 2021** – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced data from two new analyses of STELARA® (ustekinumab) for the treatment of adults with moderately to severely active Crohn's disease (CD) and ulcerative colitis (UC).<sup>1,2</sup> In a modelled analysis<sup>a</sup> focused on treatment sequencing using data from randomized controlled trials, network meta-analysis and literature, results showed patient time spent in clinical remission or response was highest when STELARA was used as a

first-line advanced therapy for bio-naïve patients with moderately to severely active UC relative to outcomes associated with second- or third-line use (P0540).<sup>1</sup> Additionally, in a separate real-world claims analysis, a greater proportion of bio-naïve patients who started biologic therapy with STELARA (n=948) for moderately to severely active CD showed persistence at 12 months versus adalimumab (n=4,143) (P0525).<sup>2</sup> These data are among 16 abstracts, including one oral presentation, presented at the 2021 American College of Gastroenterology Annual Scientific Meeting, which is taking place October 22-27 in Las Vegas, Nevada.<sup>1,2</sup>

“Data emerging from these analyses inform physicians with additional evidence to support STELARA as a first-line option for patients with moderately to severely active Crohn’s disease and ulcerative colitis,” said Christopher Gasink, M.D., Head of Immunology Medical Affairs, Gastroenterology, Janssen Scientific Affairs, LLC. “Many patients living with inflammatory bowel disease can cycle through different therapies as a result of loss or lack of treatment response. Studies like these are important in helping guide physicians to select an appropriate therapeutic option for their patients in a first-line setting.”

**“Identifying the Optimal Treatment Sequence for STELARA in Treatment Algorithms for Advanced Therapies in UC (P0540)” Results Suggested:**

Initiating STELARA as a first-line advanced therapy for UC in a hybrid decision tree model resulted in more favorable patient outcomes in terms of increased amount of time spent in remission or response and the postponing of surgery compared with second-line and third-line use.<sup>1</sup>

- When used first-line, STELARA-treated patients in the cohort model spent on average:
  - 8.5 months (71 percent of the time) in remission or response over one year.<sup>1</sup>
  - 23.1 months (64 percent of the time) in remission or response over three years.<sup>1</sup>
  - 32.2 months (54 percent of the time) in remission or response over five years.<sup>1</sup>

- When STELARA was used in the second-line setting, patients spent on average:
  - 7.9 months (66 percent of the time) in remission or response over one year.<sup>1</sup>
  - 14.5 months (40 percent of the time) in remission or response over three years.<sup>1</sup>
  - 17.5 months (29 percent of the time) in remission or response over five years.<sup>1</sup>
- Modelled use of STELARA in the first- versus second-line reduced time affected by active UC by 0.6, 8.3, and 13.8 months over one, three, and five years, respectively. When compared to third-line, first-line use of STELARA suggested even greater reductions at the one-year (0.9 months), three-year (9 months), and five-year (14.5 months) timepoints.<sup>1</sup>
- Future research is required to generate long-term clinical data to confirm these results.<sup>1</sup>

**“Treatment Persistence Among Bio-Naïve Patients with CD Initiated on STELARA or adalimumab (P0525)” Results Suggested:**

A higher proportion of bio-naïve patients selected from the IQVIA PharMetrics® Plus claims database who started on STELARA (n=948) were persistent on therapy at 12 months, including persistent and corticosteroid-free and persistent and on monotherapy versus patients who started on adalimumab (n=4,143).<sup>2</sup> Specifically, patients in the STELARA versus adalimumab cohort showed:

- 50 percent higher rate of persistence on biologic (hazard ratio [HR] 1.50; 95% confidence interval [CI]: 1.29-1.74).<sup>2</sup>
- 17 percent higher rate of persistence and being corticosteroid-free (HR: 1.17; 95% CI: 1.04-1.31).<sup>2</sup>
- 47 percent higher rate of persistence on monotherapy (HR: 1.47; 95% CI: 1.30-1.65).<sup>2</sup>

“These analyses in ulcerative colitis and Crohn’s disease expand the body of data

for STELARA and give us insight into treatment sequencing and persistence rates, which are important when assessing biologic therapy options for patients. The data are informative because patients with inflammatory bowel disease can demonstrate a short-term clinical response and improvement with therapy and then lose response,” said Jan Wehkamp, M.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. “Janssen is committed to conducting analyses that provide additional insight when treating patients with inflammatory bowel disease.”

**Editor’s Note:**

- a. A hybrid model with decision tree for induction and a Markov cohort model for maintenance was developed to assess clinical efficacy of STELARA therapy when used 1st, 2nd, or 3rd line. Transition probabilities for remission, response and surgery were derived from randomized controlled trials, network meta-analysis, and the literature. Full details are available in the poster.<sup>1</sup>

**About (P0540): Identifying the Optimal Treatment Sequence for STELARA in Treatment Algorithms for Advanced Therapies in UC<sup>1</sup>**

In the hybrid model described in the editor’s note, the treatment basket for first- and second-line UC was represented by infliximab (33 percent), adalimumab (33 percent), and vedolizumab (33 percent), and third-line treatment was comprised of vedolizumab (50 percent) and tofacitinib (50 percent). Patients moved to next line of treatment upon loss of response, and those failing the first three lines of advanced therapy moved to conventional treatment (e.g., aminosalicylates and/or immunosuppressants, corticosteroids). The model estimated time spent in remission, response, active UC (Mayo score 6-12), surgery, as well as occurrences of death over one, three and five years. Transition probabilities for remission, response and surgery were derived from randomized controlled trials, network meta-analysis, and the literature. These are modelled results based on input assumptions largely from clinical trials and a network meta-analysis.

**About (P0525): Treatment Persistence Among Bio-Naïve Patients with CD Initiated on STELARA or adalimumab<sup>2</sup>**

Bio-naïve adults with CD initiated on STELARA or adalimumab between September 23, 2016 and August 1, 2019 were selected from a de-identified health insurance claims data from the IQVIA PharMetrics® Plus. Bio-naïve patients were defined as patients with no medical or pharmacy claim for biologics indicated for CD during the baseline period (12 months before the initiation of the index agent). Baseline characteristics were balanced in weighted STELARA (n=948) and adalimumab (n=4,143) cohorts using inverse probability of treatment weights. Persistence on index agent was defined as absence of gaps >120 days (STELARA) or >60 days (adalimumab) between days of therapy supply. Composite endpoints of being persistent on index biologic and corticosteroid-free (<14 days of supply after day 90 post-index) and persistent and on monotherapy (no immunomodulators or non-index biologics) were assessed. All endpoints were estimated at 12 months post-index using weighted Kaplan-Meier and Cox's proportional hazards model analyses. Analyses of claims database depend on correct diagnosis, procedure, and drug codes, and misclassification may have occurred. All patients are assumed to have moderate to severe disease since they started biologic treatment.

### **Modeling and Real-World Data Limitations**

Modeling and real-world data have the potential to supplement randomized controlled trial data by providing additional information about how a medicine performs across all available Phase 2 and 3 clinical trials and in routine clinical practice. There are limitations, however, and these data cannot be used as stand-alone evidence to validate the efficacy or safety of a treatment.

### **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.<sup>3</sup> 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.<sup>4</sup> It is the result of an abnormal response by the body's immune system.<sup>4</sup> Symptoms vary, but may include loose and more urgent bowel

movements, persistent diarrhea, abdominal pain, bloody stool, loss of appetite, weight loss, and fatigue.<sup>5</sup>

### **About Crohn's Disease (CD)**

CD is one of the two main forms of inflammatory bowel disease, which affects an estimated three million Americans.<sup>6</sup> 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.<sup>7</sup> Symptoms of CD can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever.<sup>8</sup> There is currently no cure for CD.<sup>9</sup>

### **About STELARA® (ustekinumab)<sup>10</sup>**

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 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®.

### **STELARA® (USTEKINUMAB) 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<sup>®</sup>, 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<sup>®</sup> and watch you closely for signs and symptoms of TB during treatment with STELARA<sup>®</sup>.
- If your doctor feels that you are at risk for TB, you may be treated for TB before and during treatment with STELARA<sup>®</sup>.

You should not start taking STELARA<sup>®</sup> if you have any kind of infection unless your doctor says it is okay.

**Before starting STELARA<sup>®</sup>, 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<sup>®</sup>, call your doctor right away** if you have any symptoms of an infection (see above). STELARA<sup>®</sup> 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<sup>®</sup> 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

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### **About REMICADE® (infliximab)<sup>11</sup>**

REMICADE was the first anti-TNF-alpha treatment approved in the United States in August 1998 and the first TNF inhibitor to be approved in three different therapeutic areas: gastroenterology, rheumatology, and dermatology. REMICADE has demonstrated broad clinical utility with indications in Crohn's disease, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, ulcerative colitis, pediatric Crohn's disease and psoriasis. The safety and efficacy of REMICADE have been well established in clinical trials over the past 17 years and through commercial experience with more than 2.7 million patients treated worldwide.

In the U.S., REMICADE is approved for the following indications:

#### **Crohn's Disease:**

- Can reduce signs and symptoms and induce and maintain remission in adult

patients with moderately to severely active Crohn's disease who haven't responded well to other therapies.

**Pediatric Crohn's Disease:**

- Can reduce signs and symptoms and induce and maintain remission in children (ages 6-17) with moderately to severely active Crohn's disease who haven't responded well to other therapies.

**Ulcerative Colitis:**

- Can reduce signs and symptoms, induce and maintain remission, promote intestinal healing, and reduce or stop the need for steroids in adult patients with moderately to severely active ulcerative colitis who haven't responded well to other therapies.

**Pediatric Ulcerative Colitis:**

- Can reduce signs and symptoms and induce and maintain remission in children (ages 6-17) with moderately to severely active ulcerative colitis who haven't responded well to other therapies.

**Rheumatoid Arthritis:**

- Can reduce signs and symptoms, help stop further joint damage, and improve physical function in adult patients with moderately to severely active rheumatoid arthritis, in combination with methotrexate.

**Ankylosing Spondylitis:**

- Can reduce signs and symptoms in adult patients with active ankylosing spondylitis.

**Psoriatic Arthritis:**

- Can reduce signs and symptoms of active arthritis, help stop further joint damage, and improve physical function in adult patients with psoriatic arthritis.

**Plaque Psoriasis:**

- Approved for the treatment of adult patients with chronic severe (extensive and/or disabling) plaque psoriasis under the care of a physician who will determine if REMICADE® is appropriate considering other available therapies.

Janssen Biotech, Inc. discovered and developed REMICADE and markets the product in the United States. The Janssen Pharmaceutical Companies market REMICADE in Canada, Central and South America, the Middle East, Africa and Asia Pacific.

In Japan, Indonesia, and Taiwan, Janssen Biotech, Inc. licenses distribution rights to REMICADE to Mitsubishi Tanabe Pharma Corporation.

In Europe, Russia and Turkey, Janssen Biotech, Inc. licenses distribution rights to REMICADE to Schering-Plough (Ireland) Company, a subsidiary of Merck & Co, Inc.

### **REMICADE® (INFLIXIMAB) IMPORTANT SAFETY INFORMATION**

Only your doctor can recommend a course of treatment after checking your health condition. REMICADE® (infliximab) can cause serious side effects such as lowering your ability to fight infections. **Some patients, especially those 65 years and older, have had serious infections which include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body or caused infections in certain areas (such as skin). Some of these infections have been fatal. Your doctor should monitor you closely for signs and symptoms of TB during treatment with REMICADE®.**

**Unusual cancers have been reported in children and teenage patients taking tumor necrosis factor (TNF) blocker medicines. Hepatosplenic T-cell lymphoma, a rare form of fatal lymphoma, has occurred mostly in male teenagers or young men with Crohn's disease or ulcerative colitis who were taking REMICADE® and azathioprine or 6-mercaptopurine.** For children and adults taking TNF blockers, including REMICADE®, the chances of getting lymphoma or other cancers may increase. You should discuss any concerns about your health and medical care with your doctor.

**It is not known if REMICADE® is safe and effective in children under 6 years of age.**

**What should I tell my doctor before I take REMICADE®?**

**You should let your doctor know if you have or ever had any of the**

**following:**

- Tuberculosis (TB) or have been near someone who has TB. Your doctor will check you for TB with a skin test. If you have latent (inactive) TB, you will begin TB treatment before you start REMICADE®.
- Lived in a region where certain fungal infections like histoplasmosis or coccidioidomycosis are common.
- Infections that keep coming back, have diabetes or an immune system problem.
- Any type of cancer or a risk factor for developing cancer, for example, chronic obstructive pulmonary disease (COPD) or had phototherapy for psoriasis.
- Heart failure or any heart condition. Many people with heart failure should not take REMICADE®.
- Hepatitis B virus (HBV) infection or think you may be a carrier of HBV. Your doctor will test you for HBV.
- Nervous system disorders (like multiple sclerosis or Guillain-Barré syndrome).

**Also tell your doctor if you:**

- Use the medicines Kineret® (anakinra), Orencia® (abatacept) or Actemra® (tocilizumab) or other medicines called biologics used to treat the same problems as REMICADE®.
- Are pregnant, plan to become pregnant, are breast-feeding or plan to breastfeed, or have a baby and were using REMICADE® during your pregnancy. Tell your baby's doctor about your REMICADE® use. If your baby receives a live vaccine within 6 months after birth, your baby may develop infections with serious complications that can lead to death.
- Recently received or are scheduled to receive a vaccine. Adults and children

taking REMICADE® should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer) while taking REMICADE®.

### **What should I watch for and talk to my doctor about before or while taking REMICADE®?**

The following serious (sometimes fatal) side effects have been reported in people taking REMICADE®.

You should tell your doctor right away if you have any of the signs listed below:

- **Serious infections (like TB, blood infections, pneumonia)**—fever, tiredness, cough, flu-like symptoms, or warm, red or painful skin or any open sores. REMICADE® can make you more likely to get an infection or make any infection that you have worse.
- **Reactivation of HBV**—feeling unwell, poor appetite, tiredness, fever, skin rash and/or joint pain.
- **Lymphoma, or any other cancers in adults and children.**
- **Skin cancer**—any changes in or growths on your skin.
- **Cervical cancer**—your doctor may recommend that you be regularly screened. Some women with rheumatoid arthritis, particularly those over 60, have developed cervical cancer.
- **Heart failure**—new or worsening symptoms, such as shortness of breath, swelling of ankles or feet, or sudden weight gain.
- **Other heart problems within 24 hours of infusion, including heart attack, low blood flow to the heart, or abnormal heart rhythm**—chest discomfort or pain, arm pain, stomach pain, shortness of breath, anxiety, lightheadedness, dizziness, fainting, sweating, nausea, vomiting, fluttering or pounding in your chest, and/or a fast or a slow heartbeat.
- **Liver injury**—jaundice (yellow skin and eyes), dark brown urine, pain on the

right side of your stomach area, fever, or severe tiredness.

- **Blood problems**—fever that doesn't go away, bruising, bleeding or severe paleness.
- **Nervous system disorders**—changes in your vision, numbness or tingling in any part of your body, seizures, or weakness in your arms or legs.
- **Stroke within 24 hours of infusion**—numbness or weakness of the face, arm or leg, especially on one side of the body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking; dizziness; loss of balance or coordination; or a sudden, severe headache.
- **Allergic reactions during or after infusion**—hives, difficulty breathing, chest pain, high or low blood pressure, and fever or chills.
- **Delayed allergic reactions (3 to 12 days after infusion)**—fever, rash, headache, sore throat, muscle or joint pain, swelling of the face and hands, or difficulty swallowing.
- **Lupus-like syndrome**—chest discomfort or pain that does not go away, shortness of breath, joint pain, rash on the cheeks or arms that gets worse in the sun.
- **Psoriasis**—new or worsening psoriasis such as red scaly patches or raised bumps on the skin that are filled with pus.

**The more common side effects of REMICADE® include** respiratory infections (such as sinus infections and sore throat), headache, coughing and stomach pain.

**Please read the full [Prescribing Information](#) and [Medication Guide](#) for REMICADE® 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](http://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](http://www.janssen.com). Follow us at [www.twitter.com/JanssenGlobal](https://www.twitter.com/JanssenGlobal).

Janssen Research & Development, LLC and Janssen Scientific Affairs, LLC are each 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 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, 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 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](http://www.sec.gov), [www.jnj.com](http://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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