News Release

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Janssen Initiates First-of-its-Kind Clinical Study to Bridge Critical Gaps in Care for People of Color with Moderate to Severe Plaque Psoriasis

The only large-scale prospective study in dermatology designed to generate key disease insights among Black, Hispanic, Asian, Indigenous and other people of color

Study reinforces Janssen's commitments to inclusive clinical research and addressing health inequities

HORSHAM, PENNSYLVANIA, March 22, 2022 – Psoriasis (PsO) can take a physical, psychological, and emotional toll on the more than 8 million Americans living with the disease; and for people of color, there are additional challenges due to limited medical research and education, as well as underrepresentation in clinical studies.[1,2,3] This has led to a lack of data and barriers to optimal care for diverse patient populations.[2] PsO may also present with less noticeable skin reddening on darker skin tones, which can make it harder for healthcare providers to identify and lead to misdiagnoses in people of color. To help address these health inequities, the Janssen Pharmaceutical Companies of Johnson & Johnson today announced the initiation of VISIBLE,

a first-of-its-kind, large-scale prospective clinical study dedicated to people of color living with moderate to severe plaque and/or scalp PsO.

VISIBLE will further evaluate the efficacy and safety of TREMFYA® (guselkumab) in people of color to generate additional data and provide valuable information about disease burden and the psoriatic disease patient journey in this population. TREMFYA has a well-established safety and efficacy profile across a broad patient population of adults with moderate to severe PsO. However, there is still a pressing need for more data in people of color,[4] given that over the course of about 20 years, the majority of Phase 3 PsO clinical trials (across topical, oral, and biologic therapies) have enrolled predominantly white participants (86 percent).[2] The VISIBLE study is guided by the company's strong commitment to bioethics[a] and designed to help promote more diverse, equitable and inclusive clinical research in PsO through new approaches to enrollment and retention, broader community engagement and new data components.

"There are racial and ethnic variations in the prevalence, quality of life impact, and clinical presentation of psoriasis. Limited research data, gaps in medical education, and access barriers to advanced treatments may also contribute to healthcare disparities in populations with skin of color, so it is imperative that we have more diverse representation in clinical studies," said Andrew Alexis, M.D., M.P.H., professor of clinical dermatology and vice-chair for diversity and inclusion at Weill Cornell Medicine in New York and lead study investigator.[b] "By collecting additional safety, efficacy, biomarker, and disease progression data that are specific to people of color, we can put more information in the hands of healthcare professionals and their patients so that, together, they can make the best treatment decisions."

Biologics are a class of prescription treatments that block specific parts of the immune system responsible for inflammation and causing plaque PsO and its symptoms when overactive in the body.[5] For more than 20 years, biologics

have been increasingly used to treat patients with autoimmune diseases, and these medications have been particularly effective in helping patients living with more severe forms of disease.[5] The VISIBLE study findings, along with other industry efforts to address education and research gaps in dermatology, will help foster a greater understanding of how biologic treatment may help improve health outcomes in people of color living with moderate to severe plaque and/or scalp PsO.

In line with its commitment to expanding inclusive clinical research, Janssen is partnering with community health centers, retail clinics, and local and national organizations to support communities in raising disease awareness and reducing potential obstacles to clinical study enrollment. Because PsO presents differently in people of color,[6,7] the company is also offering training support for study investigators and taking a unique approach to confirm diagnosis. These efforts aim to help address issues that have led to low screening and recruitment of people of color. The VISIBLE study will also generate a collection of clinical photos across varying skin tones that will help advance patient and healthcare provider education on how psoriatic disease presents in people of color.

"We are proud to be working to set a new standard where diversity in clinical studies is both expected and necessary to relentlessly advance care for all patients who carry the burden of disease as we continue to confront underrepresentation in clinical research," said David Jimenez, President, Janssen Immunology, Janssen Biotech, Inc. "Janssen is committed to supporting providers in their efforts to connect with their patients on a more personal level, better meet individual patient needs, and ensure optimal care that helps alleviate inequities in their healthcare."

The VISIBLE study is one of the many ways in which Janssen, as a part of Johnson & Johnson's Our Race to Health Equity (ORTHE) commitment, is working to ensure that skin color is not a determinant of access to care,

quality of care, or health outcomes. For more information about the study, please visit https://clinicaltrials.gov/.

Editor's Note:

a. Janssen is conducting this research in accordance with the company's Ethical Code for the Conduct of Research and Development and Position on Bioethics.
b. Dr. Andrew Alexis is a paid consultant for Janssen. He has not been compensated for any media work.

About Psoriasis (PsO)

PsO is an immune-mediated disease resulting in an overproduction of skin cells, which causes raised, red, scaly plaques that may be itchy or painful.[8] It is estimated that more than 8 million Americans and more than 125 million people worldwide live with the disease.[3] Nearly one-quarter of all people with PsO have cases that are considered moderate to severe.[3] Living with PsO can be a challenge and impact life beyond a person's physical health, including emotional health, relationships, and handling the stressors of life.[2] Data on the clinical presentation of PsO amongst people of color are scarce, and there have been no large-scale prospective studies to date that evaluate the use of biologics exclusively in patients from diverse racial and ethnic backgrounds.[2] People of color often are misdiagnosed or experience a delay in diagnosis, and they are less likely to receive treatment with more advanced and effective therapies, which can have negative effects on their physical health and quality of life.[6,9]

About VISIBLE (NCT05272150)

VISIBLE is a randomized Phase 3b multicenter, randomized, double-blind, placebo-controlled study examining the efficacy and safety of guselkumab administered by subcutaneous injection in participants with moderate to severe plaque PsO and/or moderate to severe scalp PsO who self-identify as non-white. The study will evaluate approximately 200 participants from the

U.S. and Canada who will be treated and followed for approximately two years.

About TREMFYA® (guselkumab)

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 moderate to severe plaque PsO and active psoriatic arthritis (PsA).[10] 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 may benefit from taking 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 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 and Janssen Biotech, Inc. are 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 development of TREMFYA® (guselkumab). 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, Janssen Biotech, Inc., 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 Janssen Research & Development, LLC, Janssen Biotech, Inc., 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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