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NEWS RELEASE

New SPECTREM study findings reveal TREMFYA® (guselkumab) effectively clears overlooked and undertreated plaque psoriasis

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First-of-its-kind Phase 3b study shows TREMFYA® achieved statistical significance across all primary and secondary endpoints in low body surface area psoriasis with special site involvement

Johnson & Johnson launches library of clinical images from Phase 3b VISIBLE study to enhance clinical decision making for people across all skin tones living with moderate to severe plaque psoriasis

LAS VEGAS, Oct. 25, 2024 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) announced today that treatment with TREMFYA® (guselkumab) resulted in clear or almost clear skin in the majority of adults with low body surface area (BSA) moderate plaque psoriasis (PsO) with special site involvement who had failed topical treatment. Sensitive or highly visible areas affected by PsO, including the scalp, face, skin folds and genitals, are considered "special sites" and can have significant impact on patients' daily lives, yet systemic treatment is infrequently provided and this group of patients remains largely undertreated.[1] Data from the Phase 3b SPECTREM study, the first prospective, large-scale, randomized-controlled, double-blind clinical study to measure skin clearance and other treatment outcomes in low BSA moderate PsO with involvement across four special sites (scalp, face, skin folds and genitals) and previous topical treatment failure, were presented today at the 2024 Fall Clinical Dermatology Conference.

"People who have special site plaque psoriasis with lesions that cover a smaller total area of their body are often only prescribed topical treatments and not considered candidates for advanced therapies, as treatment decisions are often driven by body surface area coverage and not symptomatic burden," said Linda Stein Gold, MD, Director of Dermatology Clinical Research at Henry Ford Health, and SPECTREM investigator. "Results of the SPECTREM study could represent a new approach to care for patients with low body surface area psoriasis, as the majority of

patients treated with TREMFYA achieved clear or almost clear skin."

SPECTREM Week 16 Results Show High Levels of Skin Clearance

A significantly greater proportion of patients who received TREMFYA® achieved the primary endpoint of an Investigator's Global Assessment (IGA) score of cleared (0) or minimal disease (1) compared to those who received placebo (74.2% versus 12.4%, respectively; p<0.001). These results were comparable irrespective of baseline BSA.

Results Demonstrate High Levels of Skin Clearance in Patients with Special Site Involvement[2,3,4]

- Significant clearance (defined as site-specific IGA 0/1 response) versus placebo at Week 16: scalp (75.0% versus 14.5%), face (87.8% versus 28.6%), intertriginous (86.5% versus 28.8%) and genital (78.0% versus 37.5%) (all comparisons p<0.001).
- Complete clearance of each special site was consistently achieved in the majority of patients who received TREMFYA® versus placebo: scalp (60.3% versus 9.3%), face (75.7% versus 23.9%), intertriginous (76.6% versus 24.2%) and genital (72.7% versus 32.7%).

Statistically significant improvements were also achieved across all major secondary endpoints, including:

- 52.9% achieved a Psoriasis Area Severity Index (PASI) 90 response compared to 6.2% of participants who received placebo (p<0.001).
- The average patient saw over 80% improvement from baseline for both BSA and PASI compared to those who received placebo (80.6% versus 6.1% and 82.6% versus 13.7%, respectively; p<0.001).

Participants Report Improved Quality of Life Impact After Three Doses of TREMFYA®[5]

- A greater proportion of TREMFYA®-treated patients achieved:
  - Dermatology Life Quality Index (DLQI) scores of 0/1 compared to patients receiving placebo (48.9% versus 3.5%).
  - A 4-point greater improvement from baseline in Psoriasis Symptoms and Signs Diary (PSSD) itch compared to placebo (62.7% versus 12.5%).

The overall safety in the SPECTREM study was consistent with the established TREMFYA® safety profile.

TREMFYA® Clearance Photo Library Debuts

Beginning today, healthcare providers will have access to the **TREMFYA® Clearance Photo Library**, an expansive, longitudinal library of before and after treatment photographs from **the Phase 3b VISIBLE study**. The online resource enables patient images to be filtered based on clinical characteristics, such as disease severity, areas of

involvement, and clearance outcomes across all skin tones.

Currently, only 4-19% of images in dermatology textbooks show PsO on darker skin tones, which makes it challenging to recognize the disease in patients with skin of color.[6] People of color living with plaque and scalp PsO also face challenges such as misdiagnosis and delayed diagnosis at much higher rates than white individuals with PsO.[7] The TREMFYA® Clearance Photo Library will continue to be updated with additional images from ongoing and future studies that address underrepresented PsO patient types, with the goal of setting a new standard for inclusion in medical research.

"The results from this study are aligned with our commitment to elevate the standard of care for the millions of adults impacted by moderate-to-severe plaque psoriasis, many of whom are currently overlooked and undertreated," said Brandee Pappalardo, PhD, MPH, Vice President of Dermatology and Rheumatology Medical Affairs, Immunology, Johnson & Johnson Innovative Medicine. "The positive SPECTREM data and TREMFYA Clearance Photo Library both reinforce the significance of TREMFYA as the only biologic treatment to demonstrate robust and clinically significant data across a broad range of patients, including those with low body surface area or special site plaque psoriasis, as well as patients of color."

Editor's Notes:

a. TREMFYA® is a biologic therapy approved for adult patients with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light), for the treatment of adult patients with active psoriatic arthritis (PsA), and for adults with moderately to severely active ulcerative colitis.

b. Dr. Stein Gold is a paid consultant for Johnson & Johnson. She has not been compensated for any media work.

About Plaque Psoriasis (PsO)

Plaque PsO is an immune-mediated disease resulting in overproduction of skin cells, which causes inflamed, scaly plaques that may be itchy or painful.[8] It is estimated that eight million Americans and more than 125 million people worldwide live with the disease. Nearly one-quarter of all people with plaque PsO have cases that are considered moderate to severe.[9] Living with plaque PsO can be a challenge and impact life beyond a person's physical health, including emotional health, relationships, and handling the stressors of life.[10]

About SPECTREM (**NCT06039189**)[11]

SPECTREM is a Phase 3b, multicenter, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of TREMFYA® (guselkumab) versus placebo for the treatment of low body surface area (BSA) moderate plaque PsO with special site involvement. Patients (n=338) were randomized approximately 2:1 to receive

TREMFYA® 100 mg subcutaneous injection at Weeks 0 and 4, then every eight weeks (q8w) or placebo at Weeks 0 and 4, followed by crossover to TREMFYA® at Week 16 and q8w. The study was designed to evaluate the efficacy and safety of TREMFYA® in patients with a diagnosis of PsO, BSA 2-15% with at least one plaque outside of special sites, per Investigator's Global Assessment (IGA) 3, and involvement of at least one qualifying special site, including scalp, face, intertriginous, or genital, with at least moderate severity. The primary endpoint of the study is the percentage of patients who achieve an IGA score of cleared (0) or minimal (1) at Week 16; overall lesions are graded for induration, erythema, and scaling. The SPECTREM study is ongoing with an active treatment period from Weeks 16-48 to evaluate final efficacy and from Weeks 16-56 to evaluate final safety.

Through Week 16, 37.8% of patients who received TREMFYA® experienced at least one adverse event (AE), compared to 39.8% who received placebo. Three patients who received TREMFYA® experienced a serious AE, compared to 1 patient who received placebo. There were no discontinuations due to an AE in patients who received TREMFYA®, while 4 patients who received placebo discontinued because of an AE.

The study is evaluating approximately 338 patients from the U.S. and Canada, who will be treated and followed for 56 weeks. SPECTREM enrolled nearly the same number of male and female participants in both the TREMFYA® and placebo treatment groups (51.6% and 48.4% vs. 50.4% and 49.6%), which reflects the similar prevalence of the disease in both men and women.

About VISIBLE (**NCT05272150**)[12]

VISIBLE is a Phase 3b, multicenter, randomized, double-blind, placebo-controlled (Weeks 0-16) trial in adult patients (≥18 years of age) with moderate to severe body and/or scalp PsO. Patients (n=211) were randomized to TREMFYA® 100 mg subcutaneous injection at Weeks 0, 4, and 12, then q8w; placebo at Weeks 0, 4, and 12, followed by crossover to TREMFYA® at Week 16, Week 20, and q8w. The study was designed to evaluate the efficacy and safety of TREMFYA® in skin of color patients (self-identify as non-white) across the entire spectrum of the Fitzpatrick scale (I-VI). The study consisted of 2 cohorts, Cohort A: moderate to severe plaque PsO (IGA ≥3, PASI ≥12, and BSA involvement of ≥10%) and Cohort B: moderate to severe scalp PsO (SSA ≥30%, PSSI ≥12, ss-IGA ≥3, and ≥1 plaque outside the scalp) for at least 6 months before study administration, or central photo review expert confirmed PsO diagnosis, or biopsy confirmed PsO. The VISIBLE study is still ongoing with an active treatment period from Weeks 16-48 and long-term extension through Week 112 where patients continued receiving TREMFYA® q8w.

The study will evaluate approximately 211 participants from the U.S. and Canada who will be treated and followed for approximately two years.

About TREMFYA® (guselkumab)

Developed by Johnson & Johnson, TREMFYA® is the first approved fully-human, dual-acting monoclonal antibody designed to neutralize inflammation at the cellular source by blocking IL-23 and binding to CD64 (a receptor on cell

that produce IL-23). Findings for dual-acting are limited to in vitro studies that demonstrate guselkumab binds to CD64, which is expressed on the surface of IL-23 producing cells in an inflammatory monocyte model. The clinical significance of this finding is not known.

TREMFYA® is approved in the U.S., Europe, Canada, Japan, and a number of other countries for the treatment of adults with moderate to severe plaque psoriasis and for the treatment of adult patients with active psoriatic arthritis. TREMFYA® is also now approved in the U.S. for the treatment of adults with moderately to severely active ulcerative colitis.

Johnson & Johnson maintains exclusive worldwide marketing rights to TREMFYA®.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TREMFYA® (guselkumab)? 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
- diarrhea or stomach pain
- shortness of breath
- blood in your phlegm (mucus)

- warm, red, or painful skin or sores on your body different from your psoriasis
- 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. Pregnancy Registry: If you become pregnant during treatment with TREMFYA®, talk to your healthcare provider about registering in the pregnancy exposure registry for TREMFYA®. You can enroll by visiting **www.mothertobaby.org/ongoing-study/tremfya-guselkumab**, by calling **1-877-311-8972**, or emailing **MotherToBaby@health.ucsd.edu**. The purpose of this registry is to collect information about the safety of TREMFYA® during pregnancy.
- 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: respiratory tract 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**.

Dosage Forms and Strengths: TREMFYA® is available in a 100 mg/mL prefilled syringe and One-Press patient-controlled injector for subcutaneous injection, a 200 mg/2 mL prefilled syringe and prefilled pen (TREMFYA® PEN) for subcutaneous injection, and a 200 mg/20 mL (10 mg/mL) single dose vial for intravenous infusion.

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity.

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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., Janssen Scientific Affairs, LLC 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 1, 2023, 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., Janssen Scientific Affairs, LLC 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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