Johnson&Johnson

NEWS RELEASE

Johnson & Johnson seeks U.S. FDA approval for first pediatric indications for TREMFYA® (guselkumab)

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Applications filed for TREMFYA® to treat children with moderate to severe plaque psoriasis and active juvenile psoriatic arthritis

SPRING HOUSE, Pa., Dec. 2, 2024 /PRNewswire/ -- Johnson & Johnson today announced the submission of two supplemental Biologics License Applications (sBLAs) to the U.S. Food and Drug Administration (FDA) seeking approval of TREMFYA® (guselkumab) for the treatment of children 6 years and older with moderate-to-severe plaque psoriasis (PsO) and children 5 years of age and older with active juvenile psoriatic arthritis (jPsA).[a]

The PsO submission is based on data from the Phase 3 PROTOSTAR study in pediatric patients with moderate to severe plaque PsO and bridging pharmacokinetic (PK) data from the Phase 3 VOYAGE 1 and 2 studies in adult patients with moderate to severe plaque PsO. The jPsA submission is based on PK extrapolation analyses from adult PsA studies (DISCOVER 1 and 2) and TREMFYA efficacy and safety data from the PROTOSTAR study.[b]

"This milestone underscores our commitment to transform the standard of care for patients of all ages and builds on our expertise and legacy in IL-23 and immune-mediated diseases," said Liza O'Dowd, M.D., Vice President, Immunodermatology Disease Area Leader, Johnson & Johnson Innovative Medicine. "There is a critical gap in the treatment of children and adolescents with these skin and joint conditions, where debilitating symptoms can present challenges related to physical appearance and ability to function. At Johnson & Johnson, we are working to address this gap by investigating the efficacy and well-characterized safety profile of TREMFYA for pediatric patients."

TREMFYA® is the first approved 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 immune-mediated diseases such as plaque PsO and PsA.

Editor's Notes:

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a. TREMFYA® is not currently approved to treat moderate to severe pediatric plaque psoriasis or active juvenile psoriatic arthritis (jPsA).

b. Data extrapolation is the process of estimating future trends or effects based on previous observations. With limited pediatric patients available for clinical trial inclusion, researchers can extrapolate data from adult patient trials to determine the potential efficacy and tolerability of a treatment for the pediatric population.

ABOUT PEDIATRIC PLAQUE PSORIASIS

Plaque psoriasis (PsO) is an immune-mediated disease resulting in overproduction of skin cells, which causes inflamed, scaly plaques that may be itchy or painful.[1] Almost one-third of PsO cases begin in childhood, with

roughly 20,000 children under 10 diagnosed with psoriasis each year.[1] Having visible skin disease can be highly stressful for children and adolescents and can have a long-term impact on those affected.[2]

ABOUT JUVENILE PSORIATIC ARTHRITIS

Juvenile psoriatic arthritis (jPsA) is a form of juvenile idiopathic arthritis (JIA) characterized by chronic joint inflammation, swelling and psoriasis. Juvenile PsA is relatively rare, accounting for approximately 5% of the JIA population. In many cases, the skin manifestations start before the arthritis.[3]

ABOUT THE PHASE 3 PROTOSTAR STUDY (**NCT03451851**)

PROTOSTAR is a Phase 3, multicenter, randomized, placebo- and active comparator-controlled study evaluating the efficacy, safety, and pharmacokinetics of subcutaneously administered TREMFYA® for the treatment of chronic plaque psoriasis in pediatric patients six years of age and older. Co-primary endpoints of the study were Investigator's Global Assessment (IGA) 0/1 and PASI 75 at Week 16.[4]

ABOUT THE PHASE 3 VOYAGE STUDIES (**NCT02207231** and **NCT02207244**)

VOYAGE 1 and 2 were Phase 3 randomized, double-blind, placebo- and active comparator-controlled studies designed to evaluate the efficacy and safety of TREMFYA® compared with placebo and adalimumab in adults with moderate to severe plaque PsO. The co-primary endpoints of the studies were the proportions of patients receiving TREMFYA® versus patients receiving placebo achieving Investigator's Global Assessment (IGA) 0/1 (clear/almost clear skin) and PASI 90 at week 16.[5,6]

ABOUT THE PHASE 3 DISCOVER STUDIES (**NCT03162796** and **NCT03158285**)

DISCOVER-1 was a Phase 3, multicenter, randomized, double-blind study evaluating the efficacy and safety of TREMFYA® administered by subcutaneous injection in participants with active PsA, including those previously treated with one to two tumor necrosis factor inhibitors (TNFi). The primary endpoint was response of ACR20 at week 24.[7] DISCOVER-2 was a Phase 3, multicenter, randomized, double-blind study evaluating the efficacy and safety of TREMFYA® administered by subcutaneous injection in biologic-naïve patients with active PsA. The primary endpoint was response of ACR20 at week 24.[8]

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 a prescription medicine approved in the U.S. to treat:

- adults with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light).
- adults with active psoriatic arthritis.
- adults with moderately to severely active ulcerative colitis.[9]

TREMFYA® is approved 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 adults with active psoriatic arthritis.

Johnson & Johnson maintains exclusive worldwide marketing rights to TREMFYA®. For more information, visit: **www.tremfya.com**.

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
- 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. 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. Learn more at **https://www.jnj.com/** or at **https://www.innovativemedicine.jnj.com/**. Follow us at **@JNJInnovMed**. Janssen Research & Development, LLC and Janssen Biotech, Inc. are Johnson & Johnson companies.

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®. 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. 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 December 31, 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. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

[1] National Psoriasis Foundation. About psoriasis. Available at: https://www.psoriasis.org/children-with-psoriasis/. Accessed October 2024.

[2] Bronckers IM, Paller AS, van Geel MJ, van de Kerkhof PC, Seyger MM. Psoriasis in Children and Adolescents: Diagnosis, Management and Comorbidities. Paediatr Drugs. 2015 Oct;17(5):373-84. doi: 10.1007/s40272-015-0137-1.

[3] Brunello, Francesco et al. New Insights on Juvenile Psoriatic Arthritis. Frontiers in pediatrics. 2022. Available at: **https://pmc.ncbi.nlm.nih.gov/articles/PMC9199423/#:~:text=Juvenile%20psoriatic%20arthritis%20(JPsA)%20is,Idiopathic%20Arthritis%20(JIA)%20population** Accessed October 2024.

[4] **ClinicalTrials.gov**.A Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Subcutaneously Administered Guselkumab for the Treatment of Chronic Plaque Psoriasis in Pediatric Participants (PROTOSTAR). Identifier: NCT03451851. Available at: **https://clinicaltrials.gov/study/NCT03451851**

[5] **Clinicaltrials.gov**. A Study of Guselkumab in the Treatment of Participants With Moderate to Severe Plaque-Type Psoriasis (VOYAGE 1). Identifier NCT02207231. **https://www.clinicaltrials.gov/ct2/show/NCT02207231**. Accessed October 2024.

[6] **Clinicaltrials.gov**. A Study of Guselkumab in the Treatment of Participants With Moderate to Severe Plaque-Type Psoriasis With Randomized Withdrawal and Retreatment (VOYAGE 2). Identifier NCT02207244. **https://www.clinicaltrials.gov/ct2/show/NCT02207244**. Accessed October 2024.

[7] **ClinicalTrials.gov**. A Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Participants With Active Psoriatic Arthritis Including Those Previously Treated With Biologic Anti-Tumor Necrosis Factor (TNF) Alpha Agent(s) (DISCOVER 1). Identifier: NCT03162796. Available at: **https://clinicaltrials.gov/ct2/show/NCT03162796**. Accessed October 2024.

[8] ClinicalTrials.gov. A Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Participants With Active Psoriatic Arthritis. Identifier: NCT03158285. Available at: **https://clinicaltrials.gov/ct2/show/NCT03158285**. Accessed October 2024.

[9] TREMFYA® Prescribing Information. Available at: **https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf**. Accessed October 2024.

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