Johnson&Johnson

NEWS RELEASE

U.S. FDA approves TREMFYA® (guselkumab) for the treatment of pediatric plaque psoriasis and active psoriatic arthritis, marking a first and only approval for an IL-23 inhibitor

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TREMFYA® is now approved for pediatric patients living with moderate to severe plaque psoriasis, who are candidates for systemic therapy or phototherapy, and active psoriatic arthritis in children six years and older, weighing at least 40 kg

Approval was based on PROTOSTAR study, which showed pediatric patients receiving TREMFYA ® achieved high levels of skin clearance vs. placebo at Week 16

HORSHAM, Pa., Sept. 29, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced that the U.S. Food and Drug Administration (FDA) has approved TREMFYA® (guselkumab) for the treatment of children six years and older who also weigh at least 40 kg with moderate to severe plaque psoriasis (PsO), who are candidates for systemic therapy or phototherapy, or active psoriatic arthritis (PsA). This milestone makes TREMFYA® the first and only IL-23 inhibitor approved for these pediatric indications and builds on the initial FDA approvals in adults living with moderate to severe plaque PsO in 2017 and active PsA in 2020.

These approvals for TREMFYA® offer important new treatment options for the roughly 20,000 children under 10 diagnosed with plaque PsO annually and the approximately 14,000 children impacted by PsA.[1,2,3] One-third of PsO cases begin in childhood and the inflamed, scaly plaques caused by the chronic disease may be itchy or painful and can be highly stressful for children, leading to a potential long-term impact on those affected.[4] Active PsA accounts for approximately five percent of the juvenile idiopathic arthritis population and is characterized by chronic joint inflammation, swelling and PsO, potentially impacting a child's physical ability and overall wellbeing.[5]

"Despite advancements in the treatment of pediatric plaque psoriasis and active psoriatic arthritis, there continues to be a significant gap in available therapies for these debilitating immune-mediated diseases that impact a child's physical and emotional wellbeing during critical years," said Vimal Hasmukh Prajapati, M.D., Clinical Associate Professor, University of Calgary, Councilor for the International Psoriasis Council, as well as Co-Founder and Co-Director of the Skin Health & Wellness Centre, Dermatology Research Institute, and Dermphi Centre, and study investigator. "The approval of TREMFYA offers physicians, as well as parents and care partners, an established treatment option with proven safety and demonstrated efficacy that can significantly improve the signs and symptoms in children living with these diseases."

The plaque PsO approval was based on results from the Phase 3 PROTOSTAR study in pediatric patients with moderate to severe plaque PsO and supportive data from the Phase 3 VOYAGE 1 and 2 studies in adult patients with moderate to severe plaque PsO. In the PROTOSTAR study, the co-primary endpoints of Psoriasis Area Severity Index (PASI) 90 and Investigator's Global Assessment (IGA) score of 0/1 were achieved at Week 16. Approximately 56% of patients receiving TREMFYA® achieved PASI 90, compared to 16% of patients receiving placebo ($p<0.01$). At Week 16, 66% of patients receiving TREMFYA® compared to 16% of patients receiving placebo ($p<0.001$) achieved high levels of skin clearance (IGA score of 0/1). Nearly 40% of pediatric patients receiving TREMFYA® achieved complete clearance (IGA 0) at Week 16 compared to 4% on placebo ($p<0.01$).[6]

Approval of the active PsA indication was supported by evidence from pharmacokinetic extrapolation analyses from TREMFYA® PsO and PsA studies, including VOYAGE 1 and 2, DISCOVER 1 and 2 and PROTOSTAR. Findings from these analyses corroborate the efficacy and safety data from adults with PsO and PsA and children with moderate to severe plaque PsO to children with active PsA.

"Every child deserves to feel comfortable in their own skin and to be active without the limitations of joint pain, stiffness and swelling," said Brandee Pappalardo, PhD, MPH, Vice President, Medical Affairs, Dermatology & Rheumatology, Johnson & Johnson Innovative Medicine. "The approval of the first and only pediatric indications for an IL-23 inhibitor marks an important step forward not only for children, but also for the parents and care partners who support them every day. We remain committed to advancing research that demonstrates the long-term safety and efficacy of TREMFYA and to exploring its full potential for adult and pediatric patients."

For the treatment of pediatric plaque PsO and PsA, TREMFYA® is administered as a subcutaneous injection at Week 0, Week 4 and then every 8 weeks thereafter. The recommended dosage for moderate to severe pediatric plaque PsO and active PsA in these patients is 100 mg administered by subcutaneous injection using a 1 mL prefilled syringe.

"The physical and emotional impact of psoriasis and psoriatic arthritis can have children sitting on the sidelines of

life, not attending social events because they are embarrassed of their plaques or their joint pain is too intense," said Leah M. Howard, JD, President and CEO, National Psoriasis Foundation. "The National Psoriasis Foundation welcomes any new treatment option that provides hope for relief from the pain, discomfort and the emotional burden of these conditions."

TREMFYA® is the first and only fully-human, dual-acting monoclonal antibody approved that blocks IL-23 while also binding to CD64, a receptor on cells that produce IL-23. IL-23 is a cytokine secreted by activated monocyte/macrophages and dendritic cells that is known to be a driver of immune-mediated diseases including active PsA, moderate to severe PsO, moderate to severely active ulcerative colitis (UC) and moderately to severely active Crohn's disease (CD). Findings are based on in vitro studies.[7,8,9,10,11]

This approval is another important milestone for patients and is emblematic of Johnson & Johnson's continuous commitment to innovating to improve the lives of people living with chronic immune-mediated diseases. In 2025, Johnson & Johnson received FDA approvals of TREMFYA® (with subcutaneous induction) for the treatment of adults with moderately to severely active **UC** and **CD**, respectively. Additionally, Johnson & Johnson **recently submitted** an application to the FDA to include new evidence in the TREMFYA® label as the only IL-23 inhibitor to demonstrate significant inhibition of joint structural damage in adults living with active psoriatic arthritis.

Editor's Notes:

a. The IGA is a five-point scale with a severity score ranging from 0 to 4, where 0 indicates clear, 1 is minimal, 2 is mild, 3 is moderate and 4 indicates severe disease.
b. Vimal Hasmukh Prajapati is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.
c. For active PsA, TREMFYA® may be administered alone or in combination with a conventional disease-modifying antirheumatic drug (e.g., methotrexate).
d. Leah Howard has not been compensated for any media work.
e. 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.
f. TREMFYA® is not currently approved to treat pediatric moderately to severely active ulcerative colitis or Crohn's disease.

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 PsO 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 90. Safety data through Week 16 showed that 42% of patients receiving guselkumab and 68% of patients receiving placebo reported adverse events (AEs). Common AEs experienced by patients receiving guselkumab included nasopharyngitis, upper respiratory tract infection and COVID-19. No serious or opportunistic infections occurred.[12]

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.[13,14]

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.[15] 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.[16]

ABOUT PEDIATRIC PLAQUE PSORIASIS

Plaque PsO is an immune-mediated disease resulting in overproduction of skin cells, which causes inflamed, scaly plaques that may be itchy or painful. 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.[4]

ABOUT PEDIATRIC PSORIATIC ARTHRITIS

Juvenile psoriatic arthritis (jPsA) is a form of juvenile idiopathic arthritis (JIA) characterized by chronic joint inflammation, swelling and PsO. 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 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 cells 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:

- adult and children 6 years of age and older who also weigh at least 88 pounds (40 kg) with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light).
- adult and children 6 years and older who also weigh at least 88 pounds (40 kg) with active psoriatic arthritis.
- adults with moderately to severely active ulcerative colitis.
- adults with moderately to severely active Crohn's disease.[17]

TREMFYA® is approved in 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.

The legal manufacturer for TREMFYA® is Janssen Biotech, Inc.

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®?

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:

- o fever, sweats, or chills
- o muscle aches
- o weight loss
- o cough
- o warm, red, or painful skin or sores on your body different from your psoriasis
- o diarrhea or stomach pain
- o shortness of breath
- o blood in your phlegm (mucus)
- o burning when you urinate or urinating more often than normal

- Liver problems. With the treatment of Crohn's disease or ulcerative colitis, your healthcare provider will do blood tests to check your liver before and during treatment with TREMFYA®. With the treatment of plaque psoriasis or psoriatic arthritis, your healthcare provider may do blood tests to check your liver before and as necessary during treatment with TREMFYA®. Your healthcare provider may stop treatment with TREMFYA® if you develop liver problems. Tell your healthcare provider right away if you notice any of the following symptoms:

- o unexplained rash
- o vomiting
- o tiredness (fatigue)
- o yellowing of the skin or the whites of your eyes
- o nausea
- o stomach pain (abdominal)
- o loss of appetite
- o dark urine

Do not use 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®. Children should be brought up to date with all vaccines before

starting 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, stomach pain, bronchitis, feeling very tired (fatigue), fever (pyrexia), and skin rash.

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 as 100 mg/mL and 200 mg/2mL for subcutaneous injection and as 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 related to 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 Johnson & Johnson. Risks and uncertainties include, but are not limited to: competition, including technological advances, new products and patents attained by competitors; uncertainty of commercial success for new products; the ability of the company to successfully execute strategic plans; impact of business combinations and divestitures; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; and 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 most recent Annual Report on Form 10-K, 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**, **www.investor.jnj.com** or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

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