Johnson&Johnson

NEWS RELEASE

FDA approval of ICOTYDE™ (icotrokinra) ushers in new era for first-line systemic treatment of plaque psoriasis with a targeted oral peptide

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Johnson & Johnson introduces the first and only IL-23R targeted oral peptide that delivers complete skin clearance and favorable safety profile in a once-daily pill

ICOTYDE offers an innovative new option for patients with moderate-to-severe plaque psoriasis to address patients cycling on topical therapies in need of systemic treatment

SPRING HOUSE, Pa., March 18, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) announced today that the U.S. Food and Drug Administration (FDA) has approved ICOTYDE™ (icotrokinra), an interleukin-23 (IL-23) receptor antagonist for the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40 kg who are candidates for systemic therapy or phototherapy.[1] ICOTYDE is the first and only targeted oral peptide that precisely blocks the IL-23 receptor.[2]

"ICOTYDE delivers something unique in psoriasis treatment – combining skin clearance with a favorable safety profile in a once–daily pill, making it an easy addition to a patient's routine," said Linda Stein Gold, M.D., Director of Dermatology Clinical Research at Henry Ford Health.[a] "With new guidance from the International Psoriasis Council that clarifies when to move beyond cycling on topical treatments to systemic therapy, an innovative option like ICOTYDE is a potential game–changer for many adult and adolescent patients."

Experience the interactive multimedia news release here: **https://www.multivu.com/johnson-johnson/9378651-en-icotyde-icotrokinra-fda-approval-first-line-systemic-treatment-plaque-psoriasis**

Clinical evidence summary

ICOTYDE met all primary efficacy endpoints and demonstrated a favorable safety profile across four Phase 3 studies including 2,500 patients. The approval is based on an unprecedented body of evidence from the ICONIC clinical development program, which simultaneously evaluated ICOTYDE in adults and adolescents, high impact sites such as scalp and genital PsO, and in duplicate head-to-head trials versus an active comparator. In the head-to-head superiority studies, approximately 70% of patients achieved clear or almost clear skin (IGA 0/1) and 55% of patients achieved a Psoriasis Area and Severity Index (PASI) 90 response at Week 16.[3,b,c] Rates of adverse reactions for ICOTYDE treated patients were within 1.1% of placebo through Week 16 and no new safety signals were identified through Week 52.[4]

"With the FDA approval of ICOTYDE, Johnson & Johnson is setting a new standard for the treatment of moderate-to-severe plaque psoriasis," said Jennifer Taubert, Executive Vice President, Worldwide Chairman, Innovative Medicine, Johnson & Johnson. "We're proud to bring this game-changing innovation to the market, marking a transformative shift in plaque psoriasis management that empowers patients and clinicians to reach their treatment goals."

Unmet need in moderate-to-severe plaque psoriasis

Psoriasis affects more than 8 million Americans, impacting physical comfort and quality of life, especially when lesions are on visible or sensitive areas.[5] For many with moderate-to-severe disease, targeted systemic treatments are key. This aligns with International Psoriasis Council guidance to transition to systemic therapy if two cycles of topical medications applied for four weeks fail to bring meaningful improvement.[6]

"Finding the right treatment can take time, during which people with psoriatic disease should be considering multiple factors from efficacy to safety to how the treatment fits into their everyday life," said Leah M. Howard, J.D., President and CEO of the National Psoriasis Foundation.[d] "The approval of a novel systemic therapy changes the conversation about treatment options for our community."

"The approval of ICOTYDE represents a pivotal moment for people with plaque psoriasis," said John Reed, M.D., Ph.D., Executive Vice President, R&D, Innovative Medicine, Johnson & Johnson. "At Johnson & Johnson, we are harnessing our scientific expertise to transform cutting-edge science into meaningful solutions for patients. ICOTYDE is a fundamentally different treatment with the potential to redefine what physicians and patients can expect from psoriasis treatment."

Access and support in the U.S.

Johnson & Johnson is committed to helping patients access our treatments. Once a patient and their doctor have

decided that ICOTYDE is right for the patient, ICOTYDE withMe provides a simple, comprehensive patient support program offering patients free resources and dedicated support, including cost support options, a dedicated Nurse Guide[e] and educational resources, regardless of insurance type.

Editor's notes:

a. Dr. Stein Gold is a paid consultant for Johnson & Johnson. She has not been compensated for any media work.
b. 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.[7]
c. The PASI score grades the amount of surface area on each body region that is covered by psoriasis plaques and the severity of plaques for their redness, thickness and scaliness. PASI 90 corresponds to an improvement of >=90% in PASI score from baseline.[8]
d. Leah Howard has not been compensated for any media work.
e. Nurse Guides do not provide medical advice.

About the ICONIC Clinical Development Program

The pivotal Phase 3 ICONIC clinical development program includes five Phase 3 studies of ICOTYDE in patients 12 and older with moderate-to-severe plaque PsO.

- ICONIC-LEAD (**NCT06095115**) is a randomized clinical trial (RCT) to evaluate the efficacy and safety of ICOTYDE compared with placebo in participants with moderate-to-severe plaque PsO, with PASI 90 and IGA score of 0 or 1 with at least a 2-grade improvement as co-primary endpoints.[9]
- ICONIC-TOTAL (**NCT06095102**) is a RCT to evaluate the efficacy and safety of ICOTYDE compared with placebo for the treatment of PsO in participants with at least moderate severity affecting special areas (e.g., scalp, genital, and/or hands and feet) with overall IGA score of 0 or 1 with at least a 2-grade improvement as the primary endpoint.[10]
- ICONIC-ADVANCE 1 (**NCT06143878**) and ICONIC-ADVANCE 2 (**NCT06220604**) are RCTs to evaluate the efficacy and safety of ICOTYDE compared with both placebo and deucravacitinib in adults with moderate-to-severe plaque PsO.[11,12]
- ICONIC-ASCEND (**NCT06934226**) is a RCT to evaluate the efficacy and safety of ICOTYDE compared with placebo and ustekinumab in participants with moderate-to-severe plaque psoriasis.[13]

Additional studies underway in other disease areas include: ICONIC-PsA 1 (**NCT06878404**) and ICONIC-PsA 2 (**NCT06807424**) in active psoriatic arthritis; ICONIC-UC (**NCT071196748**) in moderately-to-severely active ulcerative colitis; and ICONIC-CD (**NCT7196722**) in moderately-to-severely active Crohn's disease.[14,15,16,17]

About Plaque Psoriasis

Plaque psoriasis (PsO) is a chronic immune-mediated disease resulting in overproduction of skin cells, which causes inflamed, scaly plaques that may be itchy or painful.[18] It is estimated that 8 million Americans and more than 125 million people worldwide live with the disease.[19] Nearly one-quarter of all people with plaque PsO have cases that are considered moderate-to-severe.[19] Plaques typically appear as raised patches with a silvery white buildup of dead skin cells or scales. Plaques may appear red in lighter skin or more of a purple, gray or dark brown color in patients with darker skin tones. Plaques can appear anywhere on the body, although they most often appear on the scalp, knees, elbows, and torso.[20] 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.[21] Psoriasis on highly visible areas of the body or sensitive skin, such as the scalp, hands, feet, and genitals, can have an increased negative impact on quality of life.[17,22]

About ICOTYDE™ (icotrokinra)

ICOTYDE (icotrokinra) is the first and only targeted oral peptide designed to precisely block the IL-23 receptor, which underpins the inflammatory response in moderate-to-severe plaque PsO.[2,23,24] ICOTYDE binds to the IL-23 receptor with high affinity and demonstrated potent, inhibition of IL-23 signaling in human T cells.[25] Clinical significance of these findings is unknown.

ICOTYDE is currently approved in the U.S. for the treatment of adults, and pediatric patients 12 years of age and older who weigh at least 40 kg, with moderate-to-severe plaque PsO who are candidates for systemic therapy or phototherapy. Patients on ICOTYDE take one pill, once a day with water upon waking, 30 minutes prior to eating food.[1]

ICOTYDE was jointly discovered and is being developed pursuant to the license and collaboration agreement between Protagonist and Johnson & Johnson. Johnson & Johnson retains exclusive worldwide rights to develop ICOTYDE in Phase 2 clinical trials and beyond, and to commercialize compounds derived from the research conducted pursuant to the agreement against a broad range of indications.[26,27,28]

ICOTYDE is also being studied in active psoriatic arthritis, moderately-to-severely active ulcerative colitis and moderately-to-severely active Crohn's disease.[15,16,17,18]

For more information visit: **www.icotyde.com**.

ICOTYDE™ INDICATION AND IMPORTANT SAFETY INFORMATION

WHAT IS ICOTYDE™ (icotrokinra)?

ICOTYDE 200 mg is a prescription medicine used to treat moderate to severe plaque psoriasis in adults and children 12 years of age and older who weigh at least 88 pounds (40 kg), who may benefit from taking injections or medicines by mouth (systemic therapy) or treatment using ultraviolet or UV light (phototherapy).

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ICOTYDE?
ICOTYDE may cause serious side effects, including:

- Infections. Medicines that interact with the immune system, such as ICOTYDE, may lower your ability to fight infections and may increase your risk of infections. Your healthcare provider may check you for infections and tuberculosis (TB) before starting treatment and may treat you for TB before you begin treatment with ICOTYDE 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 ICOTYDE.

Tell your healthcare provider right away if you have any infection or have symptoms of an infection, including:

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

Before taking ICOTYDE, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection that does not go away or that keeps coming back.
- have tuberculosis (TB) or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). Avoid receiving live vaccines during treatment with ICOTYDE.
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if ICOTYDE can harm your unborn baby. Pregnancy Safety Study. There is a pregnancy safety study for women who take ICOTYDE during pregnancy. The purpose of this study is to collect information about the health of you and your baby. If you are pregnant or become pregnant during treatment with ICOTYDE, you can report your pregnancy by calling 1-800-526-7736 or visiting **www.ICOTYDE.com.**

- are breastfeeding or plan to breastfeed. It is not known if ICOTYDE passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with ICOTYDE.

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 ICOTYDE?

ICOTYDE may cause serious side effects. See "What is the most important information I should know about ICOTYDE?"

The most common side effects of ICOTYDE include:

- headache
- nausea
- cough
- fungal infection
- tiredness

These are not all the possible side effects of ICOTYDE. Call your doctor for medical advice about side effects. 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.

How should I take ICOTYDE?

- Take ICOTYDE exactly as your healthcare provider tells you to take it.
- Take ICOTYDE 1 time a day when you wake up on an empty stomach with water. Wait at least 30 minutes after taking ICOTYDE before eating food.
- If you have difficulty swallowing tablets, ICOTYDE can be dispersed in water. For more information, please read the Medication Guide.
- If you miss a dose of ICOTYDE, take the dose as soon as you remember and go back to your regular schedule the next day.

Please read the full **Prescribing Information,** including **Medication Guide**, for ICOTYDE and discuss any questions that you have with your doctor.

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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 **www.innovativemedicine.jnj.com**. Follow us at @JNJInnovMed.

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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 ICOTYDE™ (icotrokinra). 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: 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 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** 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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