

New Johnson & Johnson ICOTYDE® (icotrokinra) long-term data demonstrate robust 2-year results in the treatment of adults and adolescents with plaque psoriasis

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- Phase 3 data presented at Fall Clinical Dermatology show high, sustained response rates in adults and adolescents, with nearly three-quarters achieving clear or almost clear skin at two years and a continued favorable safety profile

SPRING HOUSE, Pa., Oct. 9, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new two-year results from the Phase 3 ICONIC-LEAD^a study evaluating ICOTYDE® (icotrokinra), the first and only targeted oral peptide that precisely blocks the IL-23 receptor¹, in adults and pediatric patients 12 years of age and older (adolescents) with moderate-to-severe plaque psoriasis.

These data, presented at Fall Clinical Dermatology (FCD) 2026, demonstrated consistently high levels of skin clearance and patient-reported symptom improvement at Week 112, with no new safety signals identified.²

"As plaque psoriasis is a chronic lifelong disease, durable results are essential in therapy selection. With two-year data that show long-term skin clearance and a consistent safety profile, ICOTYDE is transforming how we think about plaque psoriasis treatment," said Mark Lebwohl, M.D., Professor and Chair Emeritus, Department of Dermatology, Icahn School of Medicine at Mount Sinai and ICONIC-LEAD study investigator. ^b "I'm excited to have this practice-changing targeted oral peptide as a first-line systemic therapy for both my adult and adolescent patients."

ICOTYDE clinical data highlights²

- High levels of skin clearance were observed at Week 112, with $\geq 72\%$ of ICOTYDE-treated patients achieving a Psoriasis Area and Severity Index score (PASI)^c of 90 and $\geq 70\%$ achieving clear or almost clear skin (Investigator's Global Assessment [IGA]^d 0/1) from Week 64 through Week 112.
- Complete skin clearance was sustained from Week 64 through Week 112, with $\geq 44\%$ of ICOTYDE-treated patients achieving PASI 100 and $\geq 46\%$ achieving IGA 0 (clear skin).
- Clinically meaningful improvement in itch was sustained in 78% of patients from Week 64 to Week 112.
- Among PASI 90 responders who were withdrawn from ICOTYDE at Week 24, 85% regained PASI 90 response within 24 weeks of retreatment.
- Safety findings through Week 112 remained consistent with the established safety profile of ICOTYDE, with no new safety signals identified.

"These long-term results affirm that ICOTYDE, as the first and only targeted oral peptide, represents a groundbreaking shift in the treatment of plaque psoriasis," said David M. Lee, M.D., Ph.D., Global Immunology Therapeutic Area Head, Johnson & Johnson. "Due to the chronic nature of the disease, long-term management is key, and ICOTYDE is delivering on the promise of transformational innovation to meet the needs of patients."

Editor's notes:

a. ICONIC-LEAD is a Phase 3 RCT evaluating the efficacy and safety of ICOTYDE compared with placebo in 684 participants (ICOTYDE=456; placebo=228) 12 years of age or older with moderate-to-severe plaque PsO, with the higher efficacy bar of PASI 90 and IGA score of 0/1 with at least a 2-grade improvement as co-primary endpoints. ICONIC-LEAD enrolled 66 adolescent patients. Drug withdrawal and retreatment responses were also captured among PASI 75 or IGA 0/1 responders at Week 24.

b. Dr. Lebwohl is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

c. The Psoriasis Area and Severity Index (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 100 corresponds to an improvement of 100% in PASI score from baseline.³

d. The Investigator's Global Assessment (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.⁴

About the ICONIC clinical development program

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

- ICONIC-LEAD (NCT06095115) is a 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.⁵

- 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.⁶
- 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.^{7,8}

Additional studies underway include: ICONIC-PsA 1 (**NCT06878404**) and ICONIC-PsA 2 (**NCT06807424**) in active psoriatic arthritis; ICONIC-ASCEND (**NCT06934226**) in moderate-to-severe plaque psoriasis; ICONIC-UC (**NCT071196748**) in moderately to severely active ulcerative colitis; and ICONIC-CD (**NCT7196722**) in moderately to severely active Crohn's disease.^{9,10,11,12,13}

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.¹⁴ It is estimated that 8 million Americans and more than 125 million people worldwide live with the disease.¹⁵ Nearly one-quarter of all people with plaque PsO have cases that are considered moderate-to-severe.¹⁵ 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.¹⁶ 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.¹⁷ 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.¹⁸

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.^{1,19,20} ICOTYDE binds to the IL-23 receptor with single-digit picomolar affinity and demonstrated potent, precise inhibition of IL-23 signaling in human T cells.²¹ Clinical significance of these findings is unknown.

ICOTYDE is currently approved in the U.S. for the treatment of moderate-to-severe plaque PsO 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. Patients on ICOTYDE take one pill, once daily upon waking with water on an empty stomach, at least

30 minutes prior to eating.²²

ICOTYDE is also approved in Europe, Japan and China for the treatment of adults and adolescents with psoriasis.

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.^{23,24, 25}

ICOTYDE is also being studied in active psoriatic arthritis, moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease.^{9,10,11,12,13}

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?

- 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:

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| <ul style="list-style-type: none">• fever, sweat, or chills• cough• shortness of breath• blood in your mucus (phlegm)• muscle aches | <ul style="list-style-type: none">• 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 |
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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:

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| <ul style="list-style-type: none">• headache• nausea• cough | <ul style="list-style-type: none">• fungal infection• tiredness |
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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, 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.

REFERENCES

¹ Bissonnette R, et al. Data presentation. A phase 2, randomized, placebo-controlled, dose-ranging study of oral JNJ-77242113 for the treatment of moderate-to-severe plaque psoriasis: FRONTIER 1. Presented at WCD 2023, July 3-8.

² Bissonnette R, et al. Data presentation. Durability of Clinical Response, Participant-Reported Outcomes, and Safety Through 2 Years With Icotrokinra in Adults and Adolescents With Moderate-to-Severe Plaque Psoriasis: Results From the Phase 3, ICONIC-LEAD Study. Presented at the Fall Clinical Dermatology Conference 2026. Poster presentation. October 2026.

³ Thompson Jr, D. How the Psoriasis Area and Severity Index works. Everyday Health. Available at: <https://www.everydayhealth.com/psoriasis/living-with/how-the-pasi-index-works>. Accessed October 2026.

⁴ Langley RG, Feldman SR, Nyrady J, van de Kerkhof P, Papavassilis C. The 5-point Investigator's Global Assessment (IGA) Scale: A modified tool for evaluating plaque psoriasis severity in clinical trials. *J Dermatolog Treat*. 2015 Feb;26(1):23-31. doi: 10.3109/09546634.2013.865009. Epub 2013 Dec 20. PMID: 24354461. Accessed October 2026.

⁵ Clinicaltrials.gov. A study of JNJ-2113 in adolescent and adult participants with moderate-to-severe plaque psoriasis (ICONIC-LEAD). Identifier NCT06095115. <https://classic.clinicaltrials.gov/ct2/show/NCT06095115>. Accessed October 2026.

⁶ Clinicaltrials.gov. A study of JNJ-2113 for the treatment of participants with plaque psoriasis involving special areas (scalp, genital, and/or palms of the hands and the soles of the feet) (ICONIC-TOTAL). Identifier NCT06095102. <https://classic.clinicaltrials.gov/ct2/show/NCT06095102>. Accessed October 2026.

⁷ Clinicaltrials.gov. A Study of JNJ-77242113 for the Treatment of Participants With Moderate-to-severe Plaque Psoriasis. Identifier NCT06143878. <https://clinicaltrials.gov/study/NCT06143878?term=jnj-77242113&rank=10>. Accessed October 2026.

⁸ Clinicaltrials.gov. A Study of JNJ-77242113 for the Treatment of Participants With Moderate-to-severe Plaque Psoriasis (ICONIC-ADVANCE 2). Identifier NCT06220604. <https://clinicaltrials.gov/study/NCT06220604>. Accessed

October 2026.

⁹ Clinicaltrials.gov. A Study to Evaluate the Efficacy and Safety of JNJ-77242113 (Icotrokinra) in Biologic-naïve Participants With Active Psoriatic Arthritis (ICONIC-PsA 1). Identifier NCT06878404.

<https://clinicaltrials.gov/study/NCT06878404>. Accessed October 2026.

¹⁰ A Study to Evaluate the Efficacy and Safety of Icotrokinra (JNJ-77242113) in Biologic-experienced Participants With Active Psoriatic Arthritis (ICONIC-PsA 2). Identifier NCT06807424. <https://clinicaltrials.gov/study/NCT06807424>. Accessed October 2026.

¹¹ Clinicaltrials.gov. A Study to Assess Efficacy and Safety of JNJ-77242113 Compared to Placebo and Ustekinumab in Participants With Moderate-to-severe Plaque Psoriasis (ICONIC-ASCEND). Identifier NCT06934226. <https://clinicaltrials.gov/study/NCT06934226>. Accessed October 2026.

¹² Clinicaltrials.gov. A Protocol of Icotrokinra Therapy in Adult and Adolescent Participants With Moderately to Severely Active Ulcerative Colitis (ICONIC-UC). Identifier NCT07196748. <https://clinicaltrials.gov/study/NCT07196748>. Accessed October 2026.

¹³ Clinicaltrials.gov. A Study of Icotrokinra in Participants With Moderately to Severely Active Crohn's Disease (ICONIC-CD). Identifier NCT07196722. <https://clinicaltrials.gov/study/NCT07196722>. Accessed October 2026.

¹⁴ National Psoriasis Foundation. About Psoriasis. Available at: <https://www.psoriasis.org/about-psoriasis>. Accessed October 2026.

¹⁵ National Psoriasis Foundation. Psoriasis Statistics. Available at: <https://www.psoriasis.org/content/statistics>. Accessed October 2026..

¹⁶ National Psoriasis Foundation. Plaque Psoriasis. Available at: <https://www.psoriasis.org/plaque/>. Accessed October 2026.

¹⁷ National Psoriasis Foundation. Life with Psoriasis. Available at: <https://www.psoriasis.org/life-with-psoriasis/>. Accessed October 2026.

¹⁸ National Psoriasis Foundation. High Impact Sites. Available at: <https://www.psoriasis.org/high-impact-sites/>. Accessed October 2026.

¹⁹ Razawy W, et al. The role of IL-23 receptor signaling in inflammation-mediated erosive autoimmune arthritis and bone remodeling. *Eur J Immunol*. 2018 Feb; 48(2): 220–229.

²⁰ Tang C, et al. Interleukin-23: as a drug target for autoimmune inflammatory diseases. *Immunology*. 2012 Feb; 135(2): 112–124.

²¹ Pinter A, et al. Data Presentation. JNJ-77242113 Treatment Induces a Strong Systemic Pharmacodynamic Response Versus Placebo in Serum Samples of Patients with Plaque Psoriasis: Results from the Phase 2, FRONTIER 1 Study. Presented at EADV 2023, October 11-14.

²² ICOTYDE® prescribing information.

²³ Protagonist Therapeutics. Press release. Protagonist Therapeutics announces amendment of agreement with Janssen Biotech for the continued development and commercialization of IL-23 antagonists. Available at: <https://www.prnewswire.com/news-releases/protagonist-therapeutics-announces-amendment-of-agreement-with->

janssen-biotech-for-the-continued-development-and-commercialization-of-il-23-antagonists-301343621.html. Accessed October 2026.

²⁴ Protagonist Therapeutics. Press release. Protagonist Reports positive results from Phase 1 and pre-clinical studies of oral Interleukin-23 receptor antagonist JNJ-2113. Available at: <https://www.prnewswire.com/news-releases/protagonist-reports-positive-results-from-phase-1-and-pre-clinical-studies-of-oral-interleukin-23-receptor-antagonist-jnj-2113-301823039.html>. Accessed October 2026.

²⁵ Protagonist Therapeutics. Press release. Protagonist Therapeutics announces positive topline results for Phase 2b FRONTIER 1 clinical trial of oral IL-23 receptor antagonist JNJ-2113 (PN-235) in psoriasis. Available at: <https://www.prnewswire.com/news-releases/protagonist-therapeutics-announces-positive-topline-results-for-phase-2b-frontier-1-clinical-trial-of-oral-il-23-receptor-antagonist-jnj-2113-pn-235-in-psoriasis-301764181.html>. Accessed October 2026.

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