

Johnson & Johnson announces new ICOTYDE® (icotrokinra) data in difficult-to-treat plaque psoriasis with proven durability through 2-years, affirming its use as a powerful first line systemic therapy

2026-10-02

- Revolutionary IL-23R targeted oral peptide delivers sustained skin clearance and a favorable safety profile in patients with psoriasis affecting sensitive, highly visible areas of the body
- 60% of patients with scalp psoriasis and 89% with genital psoriasis achieved site-specific complete skin clearance at Week 112

SPRING HOUSE, Pa., Oct. 2, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new two-year data from the Phase 3 ICONIC-TOTAL^a study demonstrating the positive impact of ICOTYDE® (icotrokinra) on high-impact plaque psoriasis (PsO) sites. ICOTYDE is 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).

The late-breaking results, shared as an oral presentation at the European Academy of Dermatology and Venereology (EADV) Congress 2026, evaluated adults and adolescents with at least moderate high-impact site involvement. Through Week 112, ICOTYDE demonstrated sustained skin clearance.²

"People with plaque psoriasis that affect high-impact sites deal with severe functional disability and intense daily pain. Even when these affected areas cover a small percentage of the body, they often do not respond to topical creams, limit activity, and degrade mental health due to unrelenting symptoms," said Richard B. Warren, M.D., Ph.D., Professor of Dermatology, University of Manchester.^b "These robust two-year data validate that ICOTYDE provides enduring skin clearance with a favorable safety profile, making it a pivotal advancement in plaque psoriasis treatment."

ICOTYDE clinical data highlights²

- Among patients treated with ICOTYDE, rates of clear or almost clear skin (Investigator's Global Assessment [IGA] 0/1)^c increased from 57% at Week 16 to 67% at Week 24 and 70% at Week 112.
- At Week 112, high rates of site-specific complete skin clearance were reported among ICOTYDE-treated patients:
 - 60% of patients with scalp psoriasis achieved a scalp-specific Investigator's Global Assessment (ss-IGA)^d score of 0;
 - 89% of patients with genital psoriasis achieved a Physician's Global Assessment of Genitalia (sPGA-G)^e score of 0;
 - 63% of patients with psoriasis affecting the hands and/or feet achieved a hand and/or foot Physician's Global Assessment (hf-PGA)^f score of 0.
 - Nail psoriasis improved over time, with mean percentage improvement in modified Nail Psoriasis Severity Index (mNAPSI)^g increasing from 33% at Week 16 to 62% at Week 52 to 71% at Week 112.
- Safety findings through Week 112 remained consistent with the established safety profile of ICOTYDE, with no new safety signals identified.²

"Availability of long-term data are vital for informing the treatment of plaque psoriasis including particularly challenging areas of the body where conventional treatments may fall short," said David M. Lee, M.D., Ph.D., Global Immunology Therapeutic Area Head, Johnson & Johnson. "These two-year ICOTYDE results empower physicians to treat high-impact sites, knowing that data support sustained clinical outcomes for patients."

Editor's notes:

a. ICONIC-TOTAL evaluates the efficacy and safety of ICOTYDE compared with placebo in participants with at least moderate scalp, genital, and/or hand/foot PsO with once daily ICOTYDE or placebo, with placebo-to-ICOTYDE transition at Week 16.

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

c. 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.³

d. The scalp-specific Investigator's Global Assessment (ss-IGA) is a five-point scale where scalp lesions are assessed in terms of clinical signs of redness, thickness, and scaliness on a severity score ranging from 0 to

4, where 0 indicates absence of disease, 1 is very mild, 2 is mild, 3 is moderate and 4 indicates severe disease.

e. The Physician's Global Assessment of Genitalia (sPGA-G) is a six-point scale used to evaluate the severity of genital psoriasis at a given time point ranging from 0 to 5, where 0 indicates clear, 1 is minimal, 2 is mild, 3 is moderate, 4 is severe and 5 indicates very severe disease.⁴

f. The Physician's Global Assessment of Psoriasis on the Hands and/or Feet (hf-PGA) assesses the severity of hand and foot psoriasis using a 5-point scale to score the plaques on the hands and feet as: clear (0), almost clear (1), mild (2), moderate (3) and severe (4).⁵

g. The modified Nail Psoriasis Severity Index (mNAPSI) is a composite score used to assess the severity of nail psoriasis based on features of the nail matrix and nail bed, with scores ranging from 0 to 13 per fingernail, where 0 indicates no nail psoriasis and higher scores indicate greater disease severity.

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.⁶
- 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.⁷
- 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.^{8,9}

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.^{10,11,12,13,14}

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.¹⁵ It is estimated that 8 million Americans and more than 125 million people worldwide live with the disease.¹⁶ Nearly one-quarter of all people with plaque PsO have cases that are considered moderate-to-severe.¹⁶ 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.¹⁷ 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.¹⁸ 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.¹⁹

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.^{1,20,21} 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.²² 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 before eating.²³

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.^{24, 25, 26}

ICOTYDE is also being studied in active psoriatic arthritis, moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease.^{10,11,12,13,14}

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:

-
- | | |
|---|--|
| <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 |
|---|--|

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:

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

cp-564097v2

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.

Janssen Biotech, Inc. is a Johnson & Johnson company.

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 Richard B, et al. Data presentation. Long-term Durability and Safety of the Targeted Oral Peptide Icotrokinra for High-Impact Site Psoriasis: 2-year Findings From the ICONIC-TOTAL Randomized Controlled Trial. Late-breaking research presentation (Abstract #LB-245) at the European Academy of Dermatology and Venereology Congress. September 2026.
- ³ Langley RG, Feldman SR, Niyirady 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.
- ⁴ Merola JF, Bleakman AP, Gottlieb AB, et al. The Static Physician's Global Assessment of Genitalia: a clinical outcome measure for the severity of genital psoriasis. *J Drugs Dermatol*. 2017;16(8):793-799
- ⁵ Goldblum O, et al. Validation of the physician's global assessment of psoriasis of the hands and/or feet as a clinical endpoint. *J Am Acad Dermatol*. 2013;68(4)Supplement1:AB218.
- ⁶ 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.
- ⁷ 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.
- ⁸ 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.
- ⁹ Clinicaltrials.gov. A Study of JNJ-77242113 for the Treatment of Participants With Moderate-to-severe Plaque Psoriasis (ICONIC-ADVANCE 2). Identifier NCT06220604.
- ¹⁰ 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.
- ¹¹ 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.
- ¹² 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.
- ¹³ 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.
- ¹⁴ 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.
- ¹⁵ National Psoriasis Foundation. About Psoriasis. Available at: <https://www.psoriasis.org/about-psoriasis>. Accessed October 2026.
- ¹⁶ National Psoriasis Foundation. Psoriasis Statistics. Available at: <https://www.psoriasis.org/content/statistics>. Accessed October 2026..
- ¹⁷ National Psoriasis Foundation. Plaque Psoriasis. Available at: <https://www.psoriasis.org/plaque/>. Accessed October 2026.
- ¹⁸ National Psoriasis Foundation. Life with Psoriasis. Available at: <https://www.psoriasis.org/life-with-psoriasis/>. Accessed October 2026..
- ¹⁹ National Psoriasis Foundation. High Impact Sites. Available at: <https://www.psoriasis.org/high-impact-sites/>. Accessed October 2026..
- ²⁰ 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.
- ²¹ Tang C, et al. Interleukin-23: as a drug target for autoimmune inflammatory diseases. *Immunology*. 2012 Feb; 135(2): 112-124.
- ²² 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.
- ²³ ICOTYDE® prescribing information.
- ²⁴ 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.
- ²⁵ 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.
- ²⁶ 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.

Media contact:
Meg Farina
mfarina@its.jnj.com

Investor contact:
Jessica Margevich
investor-relations@its.jnj.com

View original content to download multimedia:<https://www.prnewswire.com/news-releases/johnson--johnson-announces-new-icotyde-icotrokinra-data-in-difficult-to-treat-plaque-psoriasis-with-proven-durability-through-2-years-affirming-its-use-as-a-powerful-first-line-systemic-therapy-302896648.html>

SOURCE Johnson & Johnson