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NEWS RELEASE

Johnson & Johnson announces ICOTYDE® (icotrokinra) delivers significant improvement in psoriatic arthritis disease activity among biologic-naive patients with once-daily targeted oral peptide

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- Late-breaking data from Phase 3 investigational study presented at the American College of Rheumatology Convergence show 58% of ICOTYDE-treated patients achieved an ACR20 response and 29% achieved an ACR50 response at Week 16
- ICOTYDE is a first-in-class IL-23R targeted oral peptide, demonstrating significant joint and skin improvements and a favorable safety profile in a once-daily pill

NEW BRUNSWICK, N.J., Nov. 7, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced positive results from a Phase 3 study investigating ICOTYDE® (icotrokinra) in biologic-naïve adults with active psoriatic arthritis (PsA).[a,b] ICOTYDE is the first and only targeted oral peptide that precisely blocks the IL-23 receptor.[1] ICOTYDE met the primary endpoint, with 58% of patients achieving an American College of Rheumatology 20 (ACR20) response compared with 41% receiving placebo at Week 16.[2] Safety findings were consistent with the established safety profile of ICOTYDE, with no new safety signals identified. These results are being presented as a late-breaking poster at the American College of Rheumatology (ACR) Convergence 2026.

Psoriatic arthritis is a chronic, immune-mediated inflammatory disease that can affect both the joints and skin.[3,4] Nearly 30 percent of people with plaque psoriasis also develop psoriatic arthritis.[5,6] It can cause pain, stiffness and swelling in and around the joints, along with the skin lesions associated with plaque psoriasis.[7] Because inflammation can lead to progressive disease, there remains a need for treatment approaches that address the multiple ways psoriatic arthritis can affect patients. In clinical studies, ACR response is a composite measure whereby ACR20 represents ≥20% improvement in tender joint count, swollen joint count and other

measures of disease activity. ACR50 and ACR70 use the same framework but represent ≥50% and ≥70% improvement, respectively.

"The significant joint responses observed in this study show the exciting potential for ICOTYDE, a targeted oral peptide therapy, to open an entirely new chapter in treating psoriatic arthritis with an oral option," said Joseph F. Merola, MD MMSc, Rheumatologist, Dermatologist, President of the Psoriasis and Psoriatic Arthritis Multicenter Advancement Network, Co-President of the Group for Research in Psoriasis and Psoriatic Arthritis and President of the Rheumatologic Dermatology Society.[d] "Effective management of psoriatic arthritis requires addressing both joint and skin disease, and patients continue to need treatment options that can provide meaningful improvement across both."

ICOTYDE demonstrated joint and skin improvements through Week 24[2]

The Phase 3 ICONIC-PsA 1 study met its primary endpoint, with a significantly higher proportion of patients receiving ICOTYDE 200 mg achieving an American College of Rheumatology 20 (ACR20)[c] response compared with placebo (58% vs. 41%) at Week 16. Numerically higher proportions of patients receiving ICOTYDE also achieved ACR50 (29% vs. 16%) and ACR70 (13% vs. 5%). Among patients with qualifying skin involvement, 57% receiving ICOTYDE achieved clear or almost clear skin (Investigator's Global Assessment [IGA] 0/1)[e], compared with 14% receiving placebo (nominal $p<0.001$), while 37% achieved a Psoriasis Area and Severity Index (PASI)[f] score of 90 compared with 6% receiving placebo (nominal $p<0.001$).

Response rates with ICOTYDE 200 mg continued to increase numerically through Week 24, with 69% of patients achieving ACR20, 40% achieving ACR50, and 18% achieving ACR70. Among patients with qualifying baseline skin involvement (BSA)[g], 64% achieved clear or almost clear skin (IGA 0/1) and 56% achieved PASI 90. Safety data through Week 24 were consistent with the established safety profile of ICOTYDE, with no new safety signals identified.

"Many people living with psoriatic arthritis are still searching for treatments that can effectively address the full burden of their disease," said David M. Lee, M.D., Ph.D., Global Immunology Therapeutic Area Head, Johnson & Johnson. "These new findings underscore the potential of ICOTYDE to meaningfully improve outcomes in psoriatic arthritis and add to the growing body of evidence across psoriatic disease."

Editor's notes:

a. ICONIC-PsA 1 is an investigational Phase 3, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of once-daily oral icotrokinra in biologic-naïve adults with active psoriatic arthritis. At Week 16, participants in the placebo group who were still on study treatment crossed over to receive ICOTYDE.

b. ICOTYDE is not approved for the treatment of active PsA.
c. American College of Rheumatology 20/50/70 (ACR20/50/70) response is defined as at least a 20%/50%/70% improvement in both tender and swollen joint counts and at least a 20%/50%/70% improvement in three of five other measures of disease activity.[8]
d. Dr. Joseph Merola is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.
e. 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.[9]
f. 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.[10]
g. Patients with a baseline plaque psoriasis body surface area (BSA) ≥3% and IGA score ≥2.

About the ICONIC clinical development program

Phase 3 studies investigating ICOTYDE in active psoriatic arthritis include:

- ICONIC-PsA 1 (NCT06878404) is a RCT to evaluate the efficacy and safety of ICOTYDE compared to placebo for the treatment of biologic-naïve participants with active PsA.[11]
- ICONIC-PsA 2 (NCT06807424) is a RCT to evaluate the efficacy and safety of ICOTYDE compared to placebo for the treatment of biologic-experienced and biologic-naïve participants with active PsA.[12]

Pivotal Phase 3 studies in moderate-to-severe plaque psoriasis include:

- 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.[13]
- 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).[14]
- 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.[15,16]

Additional studies underway include: ICONIC-UC (**NCT071196748**) in moderately to severely active ulcerative colitis; and ICONIC-CD (**NCT7196722**) in moderately to severely active Crohn's disease.[17,18,19]

About psoriatic arthritis

Psoriatic arthritis (PsA) is a chronic, immune-mediated, inflammatory disease characterized by peripheral joint

inflammation, enthesitis (pain where the bone, tendon and ligament meet), dactylitis (a type of inflammation in the fingers and toes that can result in a swollen, sausage-like appearance), axial disease and the skin lesions associated with plaque psoriasis (PsO).[20,3,4] The disease causes pain, stiffness and swelling in and around the joints; it commonly appears between the ages of 30 and 50, but can develop at any age.[21] Nearly half of patients with PsA experience moderate fatigue and about one-third suffer from severe fatigue as measured by the modified fatigue severity scale.[22] In patients with PsA, comorbidities such as obesity, cardiovascular disease, anxiety and depression are often present.[23] Studies show up to 30% of people with plaque PsO also develop PsA.[5,6]

About ICOTYDE® (icotrokinra)

ICOTYDE® (icotrokinra) is the only targeted oral peptide designed to precisely block the IL-23 receptor, which underpins the inflammatory response in moderate-to-severe plaque PsO.[1,24,25] 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.[26] 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.[27]

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.[28,29,30]

ICOTYDE is also being studied in active psoriatic arthritis, moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease.[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:

- 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.

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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] Mitsumasa K, et al. Data presentation. Icotrokinra, a Targeted Oral Peptide, in Biologic-Naïve Participants With Active Psoriatic Arthritis: Results Through Week 24 of a Phase 3, Randomized, DoubleBlind, Placebo-Controlled Study. Late-breaking research presentation (Abstract #LB12) at the American College of Rheumatology (ACR) Convergence 2026. November 2026.
[3] Belasco J., Wei N. Psoriatic Arthritis: What is Happening at the Joint? Rheumatol Ther. 2019 Sep;6(3):305-315. Available at: **https://pubmed.ncbi.nlm.nih.gov/31102105/**. Accessed November 2026.
[4] Gower, T. Enthesitis and PsA. Arthritis Foundation. Available at: **https://www.arthritis.org/health-wellness/about-arthritis/related-conditions/physical-effects/enthe**. Accessed November 2026.
[5] National Psoriasis Foundation. Are You at Risk for Psoriatic Arthritis? **https://www.psoriasis.org/risk-for-psoriatic-arthritis/**
[6] Arthritis Foundation. 11 Things to Know About Psoriatic Arthritis. **https://www.arthritis.org/diseases/more-about/11-things-to-know-about-psoriatic-arthritis**
[7] National Psoriasis Foundation. About Psoriatic Arthritis. Available at: **https://www.psoriasis.org/about-psoriatic-arthritis/**. Accessed November

2026.
[8] Ogdie, A., Coates, L. C., & Mease, P. (2020). Measuring outcomes in psoriatic arthritis. Arthritis Care & Research, 72(S10), 82–109. **https://doi.org/10.1002/acr.24242**. Accessed November 2026.
[9] Langley RG, Feldman SR, Nyirady 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 November 2026.
[10] 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 November 2026.
[11] 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 November 2026.
[12] Clinicaltrials.gov. 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 November 2026.
[13] 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 November 2026.
[14] 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 November 2026.
[15] 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 November 2026.
[16] Clinicaltrials.gov. A Study of JNJ-77242113 for the Treatment of Participants With Moderate-to-severe Plaque Psoriasis (ICONIC-ADVANCE 2). Identifier NCT06220604. Accessed November 2026.
[17] 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 November 2026.
[18] 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 November 2026.
[19] 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 November 2026.
[20] Donvito T., CreakyJoints: What Is Dactylitis? The 'Sausage Finger' Swelling You Should Know About. Accessed November 2026.
[21] National Psoriasis Foundation. About Psoriatic Arthritis. Available at: **https://www.psoriasis.org/about-psoriatic-arthritis/**. Accessed November 2026.
[22] Husted J.A., et al. Occurrence and correlates of fatigue in psoriatic arthritis. Ann Rheum Dis, 2008:68(10), 1553–1558. Available at: **https://doi.org/10.1136/ard.2008.098202**. Accessed November 2026.
[23] Haddad A., Zisman D. Comorbidities in Patients with Psoriatic Arthritis. Rambam Maimonides Med J 2017 Jan 30;8(1):e0004. Available at: **https://doi.org/10.5041/RMMJ.10279**. Accessed November 2026.
[24] 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. Accessed November 2026.
[25] Tang C, et al. Interleukin-23: as a drug target for autoimmune inflammatory diseases. Immunology. 2012 Feb; 135(2): 112–124. Accessed November 2026.
[26] 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.
[27] ICOTYDE® prescribing information.
[28] 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 November 2026.
[29] 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 November 2026.
[30] 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 November 2026.

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