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NEWS RELEASE

Icotrokinra results show 75% of adolescents with plaque psoriasis achieved completely clear skin and demonstrate favorable safety profile in a once daily pill

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ICONIC-LEAD is the first ever Phase 3 registrational study in moderate-to-severe plaque psoriasis to assess safety and efficacy of a systemic therapy in adolescents and adults simultaneously

84% of adolescents with moderate-to-severe plaque psoriasis treated with investigational icotrokinra achieved clear or almost clear skin (IGA 0/1) at Week 16

SPRING HOUSE, Pa., April 10, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new icotrokinra (JNJ-2113) data from a subgroup analysis of ICONIC-LEAD[a], the first ever Phase 3 registrational study in moderate-to-severe plaque psoriasis (PsO) to assess efficacy and safety of a systemic therapy in adolescents and adults simultaneously. These data, presented at the 2025 World Congress of Pediatric Dermatology (WCPD) Annual Meeting, show adolescents treated with once daily icotrokinra achieved higher rates of clear or almost clear skin at Week 16 compared to patients receiving placebo with no new safety signals identified.[1] Icotrokinra is a first-in-class investigational targeted oral peptide that selectively blocks the IL-23 receptor and is being studied in adults and adolescents 12 years of age and older with moderate-to-severe plaque PsO.

In the study, 84.1% of adolescent patients treated with once daily icotrokinra achieved an Investigator's Global Assessment (IGA)[b] score of 0/1 (clear or almost clear skin) and 70.5% achieved a Psoriasis Area and Severity Index (PASI)[c] 90 response, compared to 27.3% and 13.6% receiving placebo, respectively, at Week 16.[1]

Response rates continued to improve through Week 24 where 86.4% of adolescents achieved IGA 0/1 (clear or

almost clear skin) and 88.6% achieved PASI 90.[1] Further, at Week 24, 75% of adolescents achieved IGA 0 (completely clear skin) and 63.6% achieved PASI 100.[1]

"Data from the Phase 3 ICONIC LEAD subgroup analysis demonstrate impressive efficacy rates, showing the promise of this novel therapeutic option in the treatment of adolescents with moderate-to-severe plaque psoriasis who've often not yet received an advanced therapy," said Lawrence Eichenfield, M.D., Chief of Pediatric and Adolescent Dermatology at Rady Children's Hospital-San Diego, and Professor of Pediatrics and Medicine (Dermatology), at the University of California, San Diego (UCSD) School of Medicine, ICONIC-LEAD presenter.[d] "Young patients with plaque psoriasis face unique challenges due to the visible and uncomfortable nature of the disease, making effective treatment options that align with their needs and preferences all the more important."

Icotrokinra demonstrated a favorable safety profile. At Week 16, 50% of adolescents treated with icotrokinra experienced ≥1 adverse event (AE), compared to 73% of adolescents receiving placebo, with no new safety signals identified.[1]

"Adolescents living with moderate to severe plaque psoriasis shouldn't have to wait for effective treatments options that have the potential to deliver completely clear skin, which is the driving force for studying this younger population as part of the pivotal ICONIC program," said Liza O'Dowd, Vice President, Immunodermatology Disease Area Lead, Johnson & Johnson Innovative Medicine. "These data underscore the promise of next-generation therapies and the potential for icotrokinra to offer adolescents with moderate-to-severe plaque psoriasis the unique combination of a favorable safety profile and complete skin clearance in a once-daily pill."

Editor's notes:

a. ICONIC-LEAD is a Phase 3 randomized controlled trial (RCT) evaluating the efficacy and safety of icotrokinra compared with placebo in 684 participants (icotrokinra=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.

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.[2]

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.[3] PASI 90 corresponds to an improvement of >=90% in PASI score from baseline.[3]

d. Dr. Lawrence Eichenfield is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

About the ICONIC Clinical Development Program

The pivotal Phase 3 ICONIC clinical development program of icotrokinra (JNJ-2113) in adult and adolescent individuals with moderate-to-severe plaque PsO was initiated with two studies in Q4 2023 – ICONIC-LEAD and ICONIC-TOTAL – pursuant to the license and collaboration agreement between Protagonist Therapeutics, Inc. and Janssen Biotech, Inc., a Johnson & Johson company.[4]

ICONIC-LEAD (**NCT06095115**) is a randomized controlled trial (RCT) to evaluate the efficacy and safety of icotrokinra 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.[5]

ICONIC-TOTAL (**NCT06095102**) is a RCT to evaluate the efficacy and safety of icotrokinra 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]

Other Phase 3 studies in the development program include ICONIC-ADVANCE 1 (**NCT06143878**) and ICONIC-ADVANCE 2 (**NCT06220604**), which are evaluating the efficacy and safety of icotrokinra compared with both placebo and deucravacitinib in adults with moderate-to-severe plaque PsO.[7,8] ICONIC-ASCEND will evaluate the efficacy and safety of icotrokinra compared with placebo and ustekinumab in participants with moderate-to-severe plaque psoriasis. ICONIC-PsA 1 (**NCT06878404**) and ICONIC-PsA 2 (**NCT06807424**) will evaluate the efficacy and safety of icotrokinra compared to placebo in participants with active psoriatic arthritis. will evaluate the efficacy and safety of icotrokinra compared to placebo in participants with active psoriatic arthritis.

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.[9] It is estimated that 8 million Americans and more than 125 million people worldwide live with the disease.[10] Nearly one-quarter of all people with plaque PsO have cases that are considered moderate to severe.[11] On Caucasian skin, plaques typically appear as raised, red patches covered with a silvery white buildup of dead skin cells or scale.[11] On skin of color, the plaques may appear darker and thicker and more of a purple, gray or dark brown color.[12] Plaques can appear anywhere on the body, although they most often appear on the scalp, knees, elbows, and torso.[12] 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.[12] 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.[12,13]

About Icotrokinra (JNJ-77242113, JNJ-2113)

Investigational icotrokinra is the first targeted oral peptide designed to selectively block the IL-23 receptor,[14] which underpins the inflammatory response in moderate-to-severe plaque PsO, ulcerative colitis and offers potential in other IL-23-mediated diseases.[15,16] Icotrokinra binds to the IL-23 receptor with single-digit picomolar affinity and demonstrated potent, selective inhibition of IL-23 signaling in human T cells.[17] The license and collaboration agreement established between Protagonist Therapeutics, Inc. and Janssen Biotech, Inc., a Johnson & Johnson company, in 2017 enabled the companies to work together to discover and develop next-generation compounds that ultimately led to icotrokinra.[18]

Icotrokinra 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 icotrokinra 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.[19,20,21]

Icotrokinra is being studied in the pivotal Phase 3 ICONIC clinical development program in moderate-to-severe plaque psoriasis and active psoriatic arthritis and the Phase 2b ANTHEM-UC study in moderately to severely active ulcerative colitis.

About Johnson & Johnson

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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 icotrokinra (JNJ-2113). 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 Janssen Research & Development, LLC, Janssen Biotech, Inc. and/or 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. None of Janssen Research & Development, LLC, Janssen Biotech, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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[1] Eichenfield, L et al. Efficacy and Safety of Icotrokinra, a Novel Targeted Oral Peptide (IL-23R-inhibitor), in Adolescents With Moderate-to- Severe Plaque Psoriasis: Subgroup Analyses From a Phase 3, Randomized, Double-Blind, Placebo-Controlled Study (ICONIC-LEAD). Presented at the World Congress of Pediatric Dermatology (Abstract #0054). April 2025.
[2] Simpson E, Bissonnette R, Eichenfield LF, et al. The validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD™): The development and reliability testing of a novel clinical outcome measurement instrument for the severity of atopic dermatitis [published online April 25, 2020]. J Am Acad Dermatol. doi: 10.1016/j.jaad.2020.04.104. Accessed April 2025.
[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 April 2025.
[4] Protagonist Therapeutics. Press release. Protagonist announces advancement of JNJ-2113 across multiple indications. Available at: **https://www.accesswire.com/791174/protagonist-announces-advancement-of-jnj-2113-across-multiple-indications**. Accessed April 2025.
[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 April 2025.
[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 April 2025.
[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 April 2025.
[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 April 2025.
[9] National Psoriasis Foundation. About Psoriasis. Available at: **https://www.psoriasis.org/about-psoriasis**. Accessed April 2025.
[10] National Psoriasis Foundation. Psoriasis Statistics. Available at: **https://www.psoriasis.org/content/statistics**. Accessed April 2025.
[11] National Psoriasis Foundation. Plaque Psoriasis. Available at: **https://www.psoriasis.org/plaque/.Accessed** April 2025.
[12] National Psoriasis Foundation. Life with Psoriasis. Available at: **https://www.psoriasis.org/life-with-psoriasis/**. Accessed April 2025.
[13] National Psoriasis Foundation. High Impact Sites. Available at: **https://www.psoriasis.org/high-impact-sites/**. Accessed April 2025.
[14] 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.
[15] 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.
[16] Tang C, et al. Interleukin-23: as a drug target for autoimmune inflammatory diseases. Immunology. 2012 Feb; 135(2): 112–124.
[17] 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.
[18] Johnson & Johnson. Press release. Janssen enters into worldwide exclusive license and collaboration agreement with Protagonist Therapeutics, Inc. for the oral Interlukin-23 receptor antagonist drug candidate for the treatment of Inflammatory Bowel Disease. Available at: **https://www.jnj.com/media-center/press-releases/janssen-enters-into-worldwide-exclusive-license-and-collaboration-agreement-with-protagonist-therapeutics-inc-for-the-oral-interlukin-23-receptor-antagonist-drug-candidate-for-the-treatment-of-inflammatory-bowel-disease**. Accessed April 2025.
[19] 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 April 2025.
[20] 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 April 2025.
[21] 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 April 2025.

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