Johnson&Johnson

NEWS RELEASE

Icotrokinra results show significant skin clearance in patients with difficult-to-treat scalp and genital psoriasis

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66% of patients with scalp psoriasis and 77% with genital psoriasis treated with investigational icotrokinra achieved site-specific clear or almost clear skin at Week 16

Icotrokinra continues to demonstrate a standout combination of significant skin clearance (IGA 0/1) and a favorable safety profile in a once daily pill

SPRING HOUSE, Pa., May 9, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new data from the Phase 3 ICONIC-TOTAL[a] study investigating icotrokinra (JNJ-2113), the first-in-class investigational targeted oral peptide that selectively blocks the IL-23 receptor. The study evaluated adults and adolescents 12 years of age and older with body surface area as low as 1% and at least moderate plaque psoriasis (PsO) affecting high-impact skin sites.

Data presented at the 2025 Society for Investigative Dermatology (SID) Annual Meeting show 57% of patients treated with once daily icotrokinra achieved the study's primary endpoint with an Investigator's Global Assessment (IGA)[b] score of 0/1 (clear or almost clear skin) and a ≥2-grade improvement from baseline at Week 16 compared to 6% of patients receiving placebo (P<0.001).[1]

Icotrokinra demonstrated high rates of skin clearance in patients with scalp psoriasis as 66% achieved a scalp-specific Investigator's Global Assessment (ss-IGA)[c] score of 0/1 compared to 11% receiving placebo (P<0.001) at Week 16. At the same time point, among patients with genital psoriasis, 77% treated with icotrokinra achieved a static Physician's Global Assessment of Genitalia (sPGA-G)[d] score of 0/1 compared to 21% receiving placebo

(P<0.001).[i] In the smaller subset of patients with hand/foot psoriasis, treatment with icotrokinra showed a numerically higher rate of skin clearance at Week 16 with 42% achieving a hand and/or foot Physician's Global Assessment (hf-PGA)[e] score of 0/1 compared to 26% receiving placebo.

"While plaque psoriasis can appear in any location on the body, most high-impact skin sites affect areas critical for mobility, personal care, and intimacy, and can be very challenging to treat effectively. Notably, almost 80% of psoriasis patients experience scalp involvement," said Melinda Gooderham, MSc, MD, FRCPC, SKiN Centre for Dermatology, Queen's University, and Probity Medical Research, Peterborough, ON, Canada and ICONIC-TOTAL study investigator.[f] "Results from the ICONIC-TOTAL study demonstrate impressive rates of skin clearance in these difficult-to-treat areas and show the potential for treatment with icotrokinra to offer patients a novel therapeutic option that aligns with their treatment needs and preferences."

Icotrokinra demonstrated a favorable safety profile. A similar proportion of patients experienced adverse events (50% and 42%) and serious adverse events (0.5% and 1.9%) in icotrokinra and placebo respectively through Week 16, with no new safety signals identified.[1]

"When plaque psoriasis affects sensitive areas of the body, patients often experience unique challenges that can have a profound impact on their daily lives," said Liza O'Dowd, MD, Vice President, Immunodermatology Disease Area Lead, Johnson & Johnson Innovative Medicine. "These new findings build upon the impressive scalp psoriasis results seen in ICONIC-LEAD and strengthen the breadth of data demonstrating the potential for icotrokinra to shift the treatment paradigm in moderate-to-severe plaque psoriasis, by offering a combination of skin clearance and favorable safety in a once daily pill."

Editor's notes:

a. ICONIC-TOTAL is a Phase 3 randomized controlled trial (RCT) evaluating the efficacy and safety of icotrokinra compared with placebo for the treatment of plaque PsO in 311 participants (icotrokinra=208; placebo=103) 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.

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 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.

d. The 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.[3]

e. 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).[4]

f. Dr. Melinda Gooderham is a paid consultant for Johnson & Johnson. She 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.[5]

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.[6]

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.[7]

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.[8,9] 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.[10,11]

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.[12] It is estimated that 8 million Americans and more than 125 million people worldwide live with the disease.[13] Nearly one-quarter of all people with plaque PsO have cases that

are considered moderate to severe.[14] On Caucasian skin, plaques typically appear as raised, red patches covered with a silvery white buildup of dead skin cells or scale.[14] On skin of color, the plaques may appear darker and thicker and more of a purple, gray or dark brown color.[15] Plaques can appear anywhere on the body, although they most often appear on the scalp, knees, elbows, and torso.[15] 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.[15] 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.[15,16]

About Icotrokinra (JNJ-77242113, JNJ-2113)

Investigational icotrokinra is the first targeted oral peptide designed to selectively block the IL-23 receptor,[17] which underpins the inflammatory response in moderate-to-severe plaque PsO, ulcerative colitis and offers potential in other IL-23-mediated diseases.[18,19] 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.[20] 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.[21]

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.[22,23,24]

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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Janssen Research & Development, LLC and Janssen Biotech, Inc. are Johnson & Johnson companies.

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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