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NEWS RELEASE

Icotrokinra results show potential to set a new standard of treatment in plaque psoriasis

2025-03-08

Standout combination of complete skin clearance and favorable safety profile in a once daily pill could shift treatment paradigm

Nearly half of patients with moderate-to-severe plaque psoriasis (PsO) treated with investigational icotrokinra achieved completely clear skin (IGA 0) at Week 24 in Phase 3 ICONIC-LEAD

Topline results from Phase 3 ICONIC-ADVANCE 1&2 studies show icotrokinra achieved co-primary endpoints and showed superiority to deucravacitinib in moderate-to-severe plaque PsO

These results pave the way to initiate the first-ever head-to-head study seeking to demonstrate the superiority of a pill versus injectable biologic in moderate-to-severe plaque PsO

SPRING HOUSE, Pa., March 8, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new icotrokinra (JNJ-2113) data from its comprehensive Phase 3 clinical program and the start of the first-ever head-to-head study in plaque psoriasis (PsO) seeking to demonstrate the superiority of an oral pill, icotrokinra, compared to an injectable biologic, ustekinumab. 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.

Data from the Phase 3 ICONIC-LEAD[a] study, presented as a late-breaking abstract at the 2025 American Academy of Dermatology (AAD) Annual Meeting, show once daily icotrokinra demonstrated significant skin clearance and a favorable safety profile in adults and adolescents 12 years of age and older with moderate-to-severe plaque PsO.[1]

In the ICONIC-LEAD study, nearly two-thirds (65%) of patients treated with once daily icotrokinra achieved an Investigator's Global Assessment (IGA)[b] score of 0/1 (clear or almost clear skin) and 50% achieved a Psoriasis Area and Severity Index (PASI)[c] 90 response, compared to 8% and 4% receiving placebo, respectively (P<0.001 for both endpoints) at Week 16.[1] Continued skin clearance improvement was reported at Week 24 with 74% of patients treated with icotrokinra achieving IGA 0/1 and 65% achieving PASI 90. At Week 24, nearly half of patients treated with icotrokinra achieved completely clear skin – 46% reached IGA 0 and 40% reached PASI 100.[1] Similar proportions of patients experienced adverse events (AEs) between icotrokinra (49%) and placebo groups (49%), with no new safety signals identified.[1]

Results from a subgroup analysis of the ICONIC-LEAD study evaluating icotrokinra in the adolescent population will be presented at a forthcoming medical meeting.

"People living with moderate-to-severe plaque psoriasis are seeking options that balance efficacy, safety and ease of use," said Robert Bissonnette, M.D., Chairman at Innovaderm Research, Montreal, Canada and ICONIC-LEAD study investigator.[d] "These study results are promising, and show the potential for treatment with icotrokinra to offer patients the unique combination of complete skin clearance and a favorable safety profile in a once daily pill."

Additionally, topline results show that the Phase 3 ICONIC-ADVANCE 1&2[e] studies met their co-primary endpoints of IGA 0/1 and PASI 90 versus placebo at Week 16. Icotrokinra also met all key secondary endpoints at Weeks 16 and 24 that measured superiority to deucravacitinib in patients with moderate-to-severe plaque PsO.[2,3] Based on the positive outcomes of the ADVANCE studies, Johnson & Johnson is initiating the Phase 3 ICONIC-ASCEND[g] study, the first-ever head-to-head study seeking to demonstrate the superiority of an oral pill, icotrokinra, compared to an injectable biologic, ustekinumab representing an important step forward in psoriasis research.

"The robust results seen to date underscore the potential for icotrokinra to shift treatment expectations in moderate-to-severe plaque psoriasis," said Liza O'Dowd, Vice President, Immunodermatology Disease Area Lead, Johnson & Johnson Innovative Medicine. "As part of our ongoing commitment to pioneer innovations for patients, we are proud to advance this first-in-class investigational targeted oral peptide that selectively blocks the IL-23 receptor, which shows promise as a potential first-line systemic therapy for the treatment of plaque psoriasis."

For further details and the full list of data being presented at the 2025 AAD Annual Meeting, visit **https://innovativemedicine.jnj.com/focus-areas/immunology/immudermatology-newsroom**.

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.[4]

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.[5] PASI 90 corresponds to an improvement of >=90% in PASI score from baseline.[5]

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

e. ICONIC- ADVANCE 1 & 2 are Phase 3 RCTs evaluating the efficacy and safety of icotrokinra compared with placebo and deucravacitinib in participants with moderate-to-severe plaque PsO with PASI 90 and IGA score of 0/1 with at least a 2-grade improvement as co-primary endpoints.

f. ICONIC-ASCEND is a Phase 3 RCT and the first-ever head-to-head study seeking to demonstrate the superiority of an oral pill, icotrokinra, compared to an injectable biologic, ustekinumab in moderate-to-severe plaque PsO.

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.[6]

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.[7]

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.[8]

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.[9,10] 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 2 (**NCT06807424**) 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.[11] It is estimated that 8 million Americans and more than 125 million people worldwide live with the disease.[12] 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.[13] 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.[14] 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.[12,15]

About Icotrokinra (JNJ-77242113, JNJ-2113)

Investigational icotrokinra is the first targeted oral peptide designed to selectively block the IL-23 receptor,[16] which underpins the inflammatory response in moderate-to-severe plaque psoriasis (PsO), ulcerative colitis (UC) and offers potential in other IL-23-mediated diseases.[17,18] 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.[19] 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.[20]

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.[21,22,23]

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

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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.

[1] Bissonnette, R et al. Icotrokinra, a Targeted Oral Peptide That Selectively Blocks the Interleukin-23–Receptor, for the Treatment of Moderate-to-Severe Plaque Psoriasis: Results Through Week 24 of the Phase 3, Randomized, Double-blind, Placebo-Controlled ICONIC-LEAD Trial. Late-breaking research presentation (Abstract #66708) at the American Academy of Dermatology (AAD) 2024 Annual Meeting. March 2025.

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[3] Data on file.

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