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NEWS RELEASE

# Icotrokinra delivered an industry-leading combination of significant skin clearance with demonstrated tolerability in a once daily pill in Phase 3 topline results

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Icotrokinra (JNJ-2113), a first-in-class investigational targeted oral peptide that selectively blocks the IL-23 receptor, met its co-primary endpoints in patients with moderate to severe plaque psoriasis

74% of patients achieved clear or almost clear skin (IGA 0/1) at week 24

Comprehensive results are being prepared for presentation at upcoming medical congresses

SPRING HOUSE, Pa., Nov. 18, 2024 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced positive topline results from **ICONIC-LEAD**[a], a pivotal Phase 3 investigational study of icotrokinra (JNJ-2113), the first targeted oral peptide that selectively blocks the IL-23 receptor, in adults and adolescents 12 years of age and older with moderate to severe plaque psoriasis (PsO). The Phase 3 study met its co-primary endpoints of Psoriasis Area and Severity Index (PASI) 90[b] and Investigator's Global Assessment (IGA) of 0/1[c] response at week 16 and response rates continued to improve through week 24.[1]

Once daily icotrokinra showed significant skin clearance versus placebo in adults and adolescents with moderate to severe plaque psoriasis. At week 16, nearly two-thirds (64.7%) of patients treated with icotrokinra achieved IGA scores of 0/1 (clear or almost clear skin), and 49.6% achieved PASI 90, compared to 8.3% and 4.4% on placebo, respectively.[1] Further increases in response rates continued to be observed at week 24, with 74.1% of patients treated with icotrokinra achieving IGA scores of 0/1, and 64.9% achieving PASI 90.[1] Safety data was found to be consistent with the Phase 2 FRONTIER 1 and 2 studies. A similar proportion of patients experienced adverse events

(AEs) between icotrokinra and placebo, with 49.3% and 49.1% of participants experiencing a treatment emergent adverse event (TEAE) at week 16.[1,2,3]

Furthermore, positive topline results from the Phase 3 **ICONIC-TOTAL**[d] study showed once daily icotrokinra met the primary endpoint of IGA of 0/1 at week 16 compared to placebo.[4] Comprehensive results from ICONIC-LEAD and ICONIC-TOTAL are being prepared for presentation at upcoming medical congresses and will be shared with health authorities in planned submissions.

"We are excited to see impressive Phase 3 results with once-daily icotrokinra treatment aligned with our Phase 2 study of this first-in-class targeted oral peptide that selectively blocks the IL-23 receptor," said Liza O'Dowd, Vice President, Immunodermatology Disease Area Lead, Johnson & Johnson Innovative Medicine. "The majority of people living with moderate to severe plaque psoriasis are eligible for, but are still not receiving, advanced therapies. Icotrokinra has the potential to offer once-daily oral therapy that could help address the needs and preferences of people living with plaque psoriasis."

Other studies in the Phase 3 ICONIC clinical development program are ongoing, including **ICONIC-ADVANCE 1** and **ICONIC-ADVANCE 2**, which will evaluate the safety and efficacy of icotrokinra compared with both placebo and deucravacitinib in moderate to severe plaque PsO. The Phase 3 ICONIC-PsA program which will investigate icotrokinra in psoriatic arthritis will be initiated in the beginning of 2025.

## Editor's notes:

a. ICONIC-LEAD is a randomized controlled trial (RCT) to evaluate the safety and efficacy of icotrokinra compared with placebo in participants 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 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]

c. The IGA is a five-point scale with a severity ranging from 0 to 4, where 0 indicates clear, 1 is minimal, 2 is mild, 3 is moderate, and 4 indicates severe disease.[6]

d. ICONIC-TOTAL 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.

## 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.[7]

ICONIC-LEAD (**NCT06095115**) is a randomized controlled trial (RCT) to evaluate the safety and efficacy 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.[8]

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.[9]

Other Phase 3 studies in the development program include ICONIC-ADVANCE 1 (**NCT06143878**) and ICONIC-ADVANCE 2 (**NCT06220604**), which evaluate the safety and efficacy of icotrokinra compared with both placebo and deucravacitinib in adults with moderate to severe plaque PsO.[10]

## 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 eight 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.[12] 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.[13] Plaques can appear anywhere on the body, although they most often appear on the scalp, knees, elbows, and torso.[13] 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.[13,15]

## About Icotrokinra (JNJ-77242113, JNJ-2113)

Investigational icotrokinra is the first targeted oral peptide designed to selectively block the IL-23 receptor,[3] which underpins the inflammatory response in moderate to severe plaque PsO and other IL-23-mediated diseases.[16,17] 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.[18] The license and collaboration agreement established

between Protagonist Therapeutics, Inc. and Janssen Biotech, Inc., in 2017 enabled the companies to work together to discover and develop next-generation compounds that ultimately led to icotrokinra.[19] 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.[20,21,22]

## 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 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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] Data on file.

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