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NEWS RELEASE

Johnson & Johnson seeks first icotrokinra U.S. FDA approval aiming to revolutionize treatment paradigm for adults and adolescents with plaque psoriasis

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Icotrokinra is a first-in-class investigational targeted oral peptide that selectively blocks the IL-23 receptor

Filing based on unprecedented data package that met all primary endpoints across four Phase 3 studies, including head-to-head superiority comparisons versus deucravacitinib and evaluation of difficult to treat skin sites

Submission underscores potential to shift the treatment paradigm for moderate-to-severe plaque psoriasis patients with the standout combination of complete skin clearance, a favorable safety profile, and simplicity of a once daily pill

SPRING HOUSE, Pa., July 21, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking the first approval of icotrokinra, a first-in-class investigational targeted oral peptide that selectively blocks the IL-23 receptor for the treatment of adults and pediatric patients 12 years of age and older with moderate to severe plaque psoriasis (PsO). Icotrokinra is uniquely designed to block the IL-23 receptor, which underpins the inflammatory response in plaque PsO and offers potential in other IL-23-mediated diseases.[1,2,3]

The application included data from four pivotal Phase 3 studies conducted as part of the ICONIC clinical development program, including ICONIC-LEAD[a], ICONIC-TOTAL[b] and ICONIC-ADVANCE 1 & ICONIC-ADVANCE 2[c]. Treatment with icotrokinra met all primary and co-primary endpoints across the development program among adults and pediatric patients 12 years of age and older with moderate-to-severe plaque PsO, demonstrating significant skin clearance and a favorable safety profile in a once-daily pill. Results from the ICONIC-ADVANCE 1 & 2

studies show icotrokinra achieved co-primary endpoints and showed superiority to deucravacitinib in moderate-to-severe plaque PsO. Across all studies, pooled safety data showed a similar proportion of patients experienced adverse events (AEs) between icotrokinra (49.1%) and placebo (51.9%) groups, with no new safety signals identified to date.[4,5,6,7,8]

"The rapid patient enrollment across our ICONIC clinical program underscores the unmet need for an advanced plaque psoriasis treatment that meaningfully addresses their needs and preferences," said Liza O'Dowd, MD, Vice President, Immunodermatology and Respiratory Disease Area Lead, Johnson & Johnson Innovative Medicine. "Given the breadth and depth of our studies, along with the robust clinical results reported to date, we are confident that icotrokinra has the potential to transform how physicians and patients think about plaque psoriasis care, establishing a new standard in the treatment of this immune-mediated disease."

Data submitted to the FDA as part of the NDA include:

- Results from the Phase 3 ICONIC-LEAD study, **presented** as a late-breaking abstract at the 2025 American Academy of Dermatology (AAD) Annual Meeting, that showed icotrokinra successfully met the co-primary endpoints of Investigator's Global Assessment (IGA)[d] score of 0/1 (clear or almost clear skin) and Psoriasis Area and Severity Index (PASI)[e] 90 compared to placebo at Week 16.[4]
- A subgroup analysis of ICONIC-LEAD, **presented** at the 2025 World Congress of Pediatric Dermatology (WCPD), which demonstrated pediatric patients 12 years of age and older 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.[5]
- Data from the Phase 3 ICONIC-TOTAL study, **presented** at the 2025 Society for Investigative Dermatology (SID) Annual Meeting, that highlighted the potential of icotrokinra in patients with difficult-to-treat scalp and genital psoriasis.[6]
- **Results** from the Phase 3 ICONIC-ADVANCE 1 & ICONIC-ADVANCE 2 studies, that further reinforced the overall efficacy profile met 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.[7,8] Comprehensive results are being prepared for presentation at a future medical meeting.
- Long-term data from the ICONIC development program, including at least 52-weeks of treatment for ICONIC-LEAD and ICONIC-TOTAL, and results from a randomized withdrawal analysis evaluating the durability of response, are being prepared for presentation at a future medical meeting.

Johnson & Johnson has also initiated the Phase 3 ICONIC-ASCEND[f] 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.[9]

Editor's notes:

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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. ICONIC-TOTAL is a Phase 3 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.
c. 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.
d. 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.[10]
e. 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.[11] PASI 90 corresponds to an improvement of >=90% in PASI score from baseline.[11]
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.[9]

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.[12]

ICONIC-LEAD (**NCT06095115**) is a 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.[13]

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.[14]

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.[15,16] 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.[17,18]

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.[19] It is estimated that 8 million Americans and more than 125 million people worldwide live with the disease.[20] Nearly one-quarter of all people with plaque PsO have cases that are considered moderate-to-severe.[20] Plaques typically appear as raised patches with a silvery white buildup of dead skin cells or scales. Plaques may appear red in lighter skin or more of a purple, gray or dark brown color in patients with darker skin tones. Plaques can appear anywhere on the body, although they most often appear on the scalp, knees, elbows, and torso.[21] 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.[22] 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.[22,23]

About Icotrokinra (JNJ-77242113, JNJ-2113)

Investigational icotrokinra is the first targeted oral peptide designed to selectively block the IL-23 receptor,[1] which underpins the inflammatory response in moderate-to-severe plaque PsO, ulcerative colitis and offers potential in other IL-23-mediated diseases.[2,3] 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.[24] 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.[25]

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.[26,27,28]

Icotrokinra is being studied in the pivotal Phase 3 ICONIC clinical development program in moderate-to-severe plaque psoriasis, including ICONIC-ASCEND; the ICONIC-PSA 1 and ICONIC-PSA 2 studies in active psoriatic arthritis; and the Phase 2b ANTHEM-UC study in moderately to severely active ulcerative colitis.

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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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 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. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

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