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Incyte Presents New Late-Breaking Data from Phase 2 Study Evaluating Povorcitinib in Patients with Prurigo Nodularis

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- *Randomized Phase 2 study met its primary and secondary endpoints following 16 weeks of treatment across all dosing groups, reinforcing povorcitinib's potential role in treating prurigo nodularis (PN)*
- *Results presented as a late-breaking oral presentation at the American Academy of Dermatology (AAD) Annual Meeting marks Incyte's first presentation of data in PN*

WILMINGTON, Del.--(BUSINESS WIRE)--Mar. 10, 2024-- Incyte (Nasdaq:INCY) today announced results from a Phase 2 study evaluating the efficacy and safety of povorcitinib (INCB54707), an oral JAK1 inhibitor, in adult patients with prurigo nodularis (PN). These data were presented as a late-breaking oral presentation (Session: S050 – Late-Breaking Research: Session 2) at the American Academy of Dermatology (AAD) Annual Meeting, held from March 8-12, 2024, in San Diego.

The study met its primary endpoint with a ≥ 4 -point improvement in itch Numerical Rating Scale (NRS4) score achieved by significantly more patients who received povorcitinib across all dosing groups (36.1% [P<0.01], 44.4% [P<0.001], 54.1% [P<0.0001] for 15, 45, 75 mg, respectively) than those who received placebo (8.1%) at Week 16. Median times to itch NRS4 were 58, 35 and 17 days for patients who received 15, 45 and 75 mg of povorcitinib, respectively, and was not estimable for the placebo arm.

"PN is a condition that can cause itchy bumps on the skin called nodules, which appear after excessive scratching. Despite the severity of the disease and the significant impact it can have on a patient's day-to-day life, there remains a significant need for effective treatments," said Kurt Brown, M.D., Vice President and povorcitinib Global Program Head, Incyte. "These Phase 2 results, particularly the demonstrated improvement in itch resolution after just four weeks of treatment, are promising for patients around the world living with this disease. We are excited to be expanding research on povorcitinib into this new potential indication."

The secondary endpoints of the study were also met. At Week 16, 13.9%, 30.6% and 48.6% of patients who received 15, 45 and 75 mg of povorcitinib, respectively, achieved an Investigator's Global Assessment Treatment Success (IGA-TS) score of 0 or 1 with a ≥ 2 -grade improvement from baseline, versus 5.4% of patients who received placebo. Further, 8.3%, 22.2% and 35.1% of patients who received 15, 45 and 75 mg of povorcitinib, respectively, achieved both itch NRS4 and IGA-TS at Week 16, versus 2.5% of patients who received placebo.

Povorcitinib was generally well-tolerated, and the safety profile was consistent with previously reported data. The most common treatment-emergent adverse events (TEAEs) among patients who received povorcitinib were headache (11.1%), fatigue (9.3%) and nasopharyngitis (7.4%). Grade ≥ 3 TEAEs and serious TEAEs occurred in four (3.7%) and nine (8.3%) povorcitinib-treated patients, respectively, and discontinuations due to AEs were infrequent (povorcitinib, n=5 [4.6%]; placebo, n=1 [2.7%]).

"PN can often be difficult to treat due to the uncontrollable itching and scratching, which can multiply the nodules that appear on a patient's skin," said Dr. Martin Metz, Professor of Dermatology and Allergy, Charité. "Breaking the itch-scratch cycle is imperative when treating patients with PN, and I'm encouraged by these results illustrating improvement in itch and also skin clearance by Week 16 which shows promise for povorcitinib as a potential novel treatment option for these patients."

More information regarding the AAD Annual Meeting 2024 can be found at <https://www.aad.org/member/meetings-education/am24>.

About Prurigo Nodularis

Prurigo nodularis (PN) is a chronic inflammatory skin disease characterized by intense itch and thickened red bumps on the arms, legs and trunk.¹ Due to the result of persistent, intense scratching and rubbing of the skin, PN results in itchy bumps on the skin called "nodules".² PN appears to be more common in older individuals, and the painful bumps and constant itch can have a substantial impact on a patient's sleep and overall quality of life.¹

About the Phase 2 Study (NCT05061693)

This randomized, double-blind, placebo-controlled Phase 2 clinical trial is designed to evaluate the safety and efficacy of povorcitinib (INCB54707) in adult patients with prurigo nodularis (PN), over 16 weeks, followed by a 24-week extension. The study consists of 146 adult patients (age ≥ 18 years) diagnosed with PN who have had inadequate response or are intolerant to prior PN therapy.

The primary outcome measure of the study is proportion of participants achieving ≥ 4 -point improvement in itch Numerical Rating Scale (NRS) score over 16 weeks. The secondary outcome measures include proportion of participants achieving Investigator's Global Assessment Treatment Success (IGA-TS) at Week 16, the proportion of patients achieving both IGA-TS and a ≥ 4 -point improvement from baseline in itch NRS score assessed up to Week 16 and number of participants experiencing treatment-emergent adverse events (TEAEs), assessed up to Week 16.

For more information about the study, please visit <https://classic.clinicaltrials.gov/ct2/show/NCT05061693>.

About Povorcitinib (INCB54707)

Povorcitinib (INCB54707) is an oral small-molecule JAK1 inhibitor currently in Phase 3 clinical trials for hidradenitis suppurativa (HS) and vitiligo. A Phase 3 trial is being planned for prurigo nodularis (PN). Phase 2 studies of povorcitinib in PN, asthma and chronic spontaneous urticaria are also ongoing.

About Incyte Dermatology

Incyte's science-first approach and expertise in immunology has formed the foundation of the company. Today, we are building on this legacy as we discover and develop innovative dermatology treatments to bring solutions to patients in need.

Our research and development efforts in dermatology are initially focused on leveraging our knowledge of the JAK-STAT pathway. We are exploring the potential of JAK inhibition for a number of immune-mediated dermatologic conditions with a high unmet medical need, including atopic dermatitis, vitiligo, hidradenitis suppurativa, lichen planus, lichen sclerosus and prurigo nodularis.

To learn more, visit the [Dermatology section](#) of [Incyte.com](https://www.incyte.com).

About Incyte

A global biopharmaceutical company on a mission to *Solve On.*, Incyte follows the science to find solutions for patients with unmet medical needs. Through the discovery, development and commercialization of proprietary therapeutics, Incyte has established a portfolio of first-in-class medicines for patients and a strong pipeline of products in Oncology and Inflammation & Autoimmunity. Headquartered in Wilmington, Delaware, Incyte has operations in North America, Europe and Asia. For additional information on Incyte, please visit [Incyte.com](https://www.incyte.com) or follow us on social media: [LinkedIn](#), [X](#), [Instagram](#), [Facebook](#), [YouTube](#).

Incyte Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the presentation of data from Incyte's clinical development pipeline, whether or when povorcitinib will be approved or commercially available for use in humans anywhere in the world and Incyte's goal of improving the lives of patients, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on our current expectations and are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; determinations made by the FDA and regulatory agencies outside of the United States; the efficacy or safety of our products; the acceptance of our products in the marketplace; market competition; unexpected variations in the demand for our products and the products of our collaboration partners; the effects of announced or unexpected price regulation or limitations on reimbursement or coverage for our products; sales, marketing, manufacturing, and distribution requirements, including our ability to successfully commercialize and build commercial infrastructure for newly approved products and any additional new products that become approved; and other risks detailed from time to time in our reports filed with the U.S. Securities and Exchange Commission, including our quarterly report on Form 10-Q for the quarter ended December 31, 2023. We disclaim any intent or obligation to update these forward-looking statements.

¹ National Organization for Rare Disorders. Prurigo Nodularis. <https://rarediseases.org/rarediseases/prurigo-nodularis/>. Accessed on February 7, 2024.

² Yale Medicine. Prurigo Nodularis. <https://www.yalemedicine.org/conditions/prurigo-nodularis-overview>. Accessed February 7, 2024.

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