Incyte Announces Data from Phase 2b Study Evaluating Povorcitinib (INCB54707) in Patients with Extensive Nonsegmental Vitiligo

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- Patients treated with povorcitinib experienced improvements in total body and facial repigmentation; investigational therapy was well tolerated

- Results were featured as an oral presentation in a late-breaking abstract session at the 2023 American Academy of Dermatology (AAD) Annual Meeting

WILMINGTON, Del.--(BUSINESS WIRE)--Mar. 18, 2023-- Incyte (Nasdaq:INCY) today announced new data from a Phase 2b clinical trial evaluating the safety and efficacy of povorcitinib (INCB54707), an investigational oral JAK1 inhibitor, in adult patients with extensive nonsegmental vitiligo. These data were presented today in a late-breaking oral presentation (Session: S042 – Late-Breaking Research: Session 2) at the 2023 American Academy of Dermatology (AAD) Annual Meeting, held from March 17-21 in New Orleans.

Results from the study demonstrate that treatment with oral povorcitinib was associated with substantial total body repigmentation in patients with extensive nonsegmental vitiligo, as measured by total Vitiligo Area Scoring Index (T-VASI) scores. Specifically, the study met its primary endpoint and patients receiving povorcitinib experienced statistically superior improvements in T-VASI at Week 24 compared to placebo (povorcitinib 15 mg, –19.1%; 45 mg, –17.8%; 75 mg, –15.7% vs. placebo, +2.3%; least squares mean [LSM] difference, P<0.01). Additionally, more patients who received povorcitinib achieved the key secondary endpoint of T-VASI50 (≥50% reduction from baseline in the T-VASI) at Week 24 (10.5%, 15 mg arm; 15.2%, 45 mg arm; 5.6%, 75 mg arm vs. 3.0%, placebo arm) and continued to improve during an open-label extension period through Week 36 of treatment (28.6%, povorcitinib 15 → 75 mg arm; 17.2%, 45 mg arm; 15.2%, 75 mg arm; and 3.0%, placebo → 75 mg arm), following dose adjustment.

“Vitiligo is a chronic, immune-mediated disease which, until recently, had limited treatment options available to patients. We are proud to have brought to market the first and only U.S. Food and Drug Administration (FDA) approved pharmacologic therapy for vitiligo, and continue to develop additional treatments for patients with vitiligo,” said Kurt Brown, M.D., Global Program Head, Povorcitinib, and Associate Vice President, Drug Development, Inflammation & Autoimmunity, Incyte. “These data suggest the potential of povorcitinib as an oral treatment for patients with extensive nonsegmental vitiligo and its potential versatility across multiple autoimmune and inflammatory conditions, including hidradenitis suppurativa for which we recently announced 52-week Phase 2 results.”

Additional key findings from the study include:

- Treatment with povorcitinib also resulted in facial repigmentation in patients with extensive nonsegmental vitiligo, as measured by facial Vitiligo Area Scoring Index (F-VASI) scores. At Week 24, patients receiving povorcitinib experienced statistically superior improvements in F-VASI compared to placebo (15 mg, –27.7%; 45 mg, –36.4%; 75 mg, –29.4% vs. placebo, –5.1%; LSM difference, P<0.01).
    - At Week 24, 18.4% (15 mg), 45.5% (45 mg) and 27.8% (75 mg) of patients treated with povorcitinib achieved ≥50% reduction from baseline in F-VASI (F-VASI50) compared to 9.1% in the placebo group.
    - Additionally at Week 24, 13.2% (15 mg), 18.2% (45 mg) and 13.9% (75 mg) of patients treated with povorcitinib achieved ≥75% reduction from baseline in F-VASI (F-VASI75) compared to 3.0% in the placebo group.
- Continued improvement of total body and facial repigmentation with povorcitinib was seen through 36 weeks of treatment.
    - At Week 36, T-VASI/F-VASI scores were –30.3%/–38.4% (povorcitinib 15 → 75 mg arm), –28.4%/–51.1% (45 mg arm), –28.8%/–54.3% (75 mg arm) and –5.3%/–26.1% (placebo → 75 mg arm).

Povorcitinib was generally well tolerated. The most common treatment-emergent adverse events (TEAEs) during the 24-week placebo-controlled period (n=126) were COVID-19 (16.7%), headache (10.3%), fatigue (9.5%), blood creatine phosphokinase increased (7.9%), and acne (7.1%). No serious TEAEs were considered related to povorcitinib treatment. Additionally, no new safety signals were observed after Week 24.

"Vitiligo is a chronic autoimmune condition that can be difficult to manage, particularly for patients with extensive disease that manifests across a significant portion of their body,” said Amit G. Pandya, M.D., Staff Dermatologist, Department of Dermatology, Palo Alto Foundation Medical Group and Adjunct Professor, Department of Dermatology, University of Texas Southwestern Medical Center. “As vitiligo can impact patients in different ways, I am encouraged by the continued focus on expanding medical treatment options, and I believe these data highlight the potential of this investigational oral treatment for patients with extensive nonsegmental vitiligo.”

More information regarding the 2023 AAD Annual Meeting can be found at https://www.aad.org/member/meetings-education/am23.

About Vitiligo

Vitiligo is a chronic autoimmune disease characterized by depigmentation of skin that results from the loss of pigment-producing cells known as melanocytes. Overactivity of the JAK signaling pathway is believed to drive inflammation involved in the pathogenesis and progression of vitiligo. In the United States, more than 1.5 million people are diagnosed with vitiligo[1]. The overall prevalence of the condition is estimated to be approximately 2-3 million[2], with the majority of patients (approximately 85%) suffering from nonsegmental vitiligo[3]. Vitiligo can occur at any age, although many patients with vitiligo will experience initial onset before the age of 30[4].

About the Phase 2b Study (NCT04818346)

The Phase 2b randomized, double-blind, placebo-controlled, dose ranging study is evaluating the efficacy and safety of povorcitinib (formerly INCB54707) in adult patients with extensive nonsegmental vitiligo.

The study enrolled 171 patients (age 18 to 75 years) diagnosed with nonsegmental vitiligo affecting ≥8% of their body surface area and randomized them 1:1:1:1 to receive once-daily (QD) povorcitinib 15 mg (n=43), 45 mg (n=41), 75 mg (n=42), or placebo (n=42) for 24 weeks during the placebo-controlled period. Of the 171 randomized patients, 168 patients were treated as part of the 24-week placebo-controlled period. During the 28-week extension period (n=138), patients originally randomized to receive povorcitinib 45 mg QD continued with the same dose (n=32). Patients originally randomized to receive povorcitinib 15 mg QD, 75 mg QD or placebo each received 75 mg povorcitinib QD for the duration of the 28-week extension period (n=37, 34 and 35, respectively). Following the extension period is a 24-week follow-up period.

The primary endpoint is the percentage change from baseline in total body Vitiligo Area Scoring Index (T-VASI) at Week 24. The key secondary endpoint is the percentage of patients achieving T-VASI50 (≥50% reduction from baseline in the T-VASI) at Week 24.

Additional endpoints include the percentage of patients achieving F-VASI50 (≥50% reduction from baseline in facial Vitiligo Area Scoring Index [F-VASI]), F-VASI75 (≥75% reduction from baseline in F-VASI) and T-VASI50 at each visit. Safety of povorcitinib was assessed by the frequency and severity of treatment-emergent adverse events (TEAEs).

For more information about this Phase 2b study, please visit: https://clinicaltrials.gov/ct2/show/NCT04818346.

About Povorcitinib (INCB54707)

Povorcitinib (INCB54707) is an oral small-molecule JAK1 inhibitor currently in Phase 2 clinical trials for vitiligo, hidradenitis suppurativa (HS) and prurigo nodularis. Phase 3 studies in HS 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, lichen planus, lichen sclerosus and prurigo nodularis.

To learn more, visit the Dermatology section of Incyte.com.

About Incyte

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @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 Incyte's current expectations and 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; the effects of the COVID-19 pandemic and measures to address the pandemic on Incyte and its partners' clinical trials, supply chain, other third-party providers and development and discovery operations; determinations made by the U.S. FDA and other regulatory authorities outside of the United States; the efficacy or safety of Incyte and its partners' products; the acceptance of Incyte and its partners' products in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its annual report for the year ended December 31, 2022. Incyte disclaims any intent or obligation to update these forward-looking statements.

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[1] Bergqvist C, Ezzedine K. Vitiligo: A Review. *Dermatology*. 2020;236:571-592.

[2] Gandhi K, et al. Prevalence of vitiligo among adults in the United States. *JAMA Dermatol*. 2022;158(1):43-50.

[3] Ezzedine K, et al. Seminar: Vitiligo. *Lancet*. 2015;386:74–84.

[4] Frisoli M, et al. Vitiligo: mechanisms of pathogenesis and treatment. *Annu. Rev. Immunol*. 2020;38(1):621-648.

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