Incyte Announces Positive 52-Week Data from Phase 2b Study Evaluating Povorcitinib (INCB54707) in Patients with Extensive Nonsegmental Vitiligo

October 11, 2023

- Longer-term use of povorcitinib resulted in further improvement in total body and facial repigmentation

- Results were presented in a late-breaking news session at the European Academy of Dermatology and Venereology (EADV) Congress 2023

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 11, 2023-- Incyte (Nasdaq:INCY) today announced new 52-week 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. Results showed that treatment with oral povorcitinib was associated with substantial total body and facial repigmentation across all treatment groups at Week 52. These data were presented today in a late-breaking oral presentation (Abstract #6749 Session: D1T01.1A – Late-Breaking News) at the European Academy of Dermatology and Venereology (EADV) Congress 2023, held from October 11-14 in Berlin.

Specifically, these results, which build on the previously announced data, showed:

- Mean percentage total body depigmentation improvement from baseline as measured by the Total Vitiligo Area Scoring Index (T-VASI) at Week 52 for povorcitinib 15-to-75 mg, 45 mg, 75 mg and placebo-to-75 mg were 40.7%, 42.7%, 41.3% and 18.1%, respectively.
- Mean percentage facial depigmentation improvement from baseline as measured by the facial Vitiligo Area Scoring Index (F-VASI) at Week 52 for povorcitinib 15-to-75 mg, 45 mg, 75 mg and placebo-to-75 mg were 63.6%, 63.8%, 64.4% and 54.8%, respectively.

“These 52-week results further support earlier data and reinforce the efficacy profile and potential of povorcitinib as an oral treatment for patients with extensive nonsegmental vitiligo,” said Kurt Brown, M.D., Vice President and Povorcitinib Global Program Head, Incyte. “At Incyte, we are deeply committed to addressing unmet needs in the vitiligo community and understanding how this disease can affect patients’ lives. Today’s data highlight exciting progress as we work to bring new potential treatment options to patients living with this immune-mediated skin condition.”

Key secondary endpoint findings include:

- More on-treatment patients achieved ≥50% reduction from baseline in T-VASI (T-VASI50) at Week 52 compared to initial findings at Week 24 (povorcitinib 15-to-75 mg arm, 45.2%; 45 mg arm, 37.0%; 75 mg arm, 37.9%; placebo-to-75 mg arm, 15.2%).
- More on-treatment patients achieved ≥50% and ≥75% reduction from baseline in F-VASI (F-VASI50 and F-VASI75, respectively) at Week 52 compared to initial findings at Week 24 (povorcitinib 15-to-75 mg arm, 71.0% and 48.4%; 45 mg arm, 77.8% and 55.6%; 75 mg arm, 69.0% and 58.6%; placebo-to-75 mg arm, 63.6% and 45.5%, respectively).
- Povorcitinib was well tolerated at all doses. Treatment-emergent adverse events (TEAEs) of any grade occurred in 89.2% of 83 patients who received 45 mg or 75 mg doses throughout the study period; the most common were COVID-19 (36.1%), blood creatine phosphokinase increased (13.3%), acne (12.0%), fatigue (10.8%) and headache (9.6%).
- Among the 32 patients who completed the follow-up period through Week 76, total body and facial repigmentation was maintained, which suggests durability of response following treatment discontinuation. Sample size during post-treatment was small, limiting interpretation, and findings need to be confirmed in a larger population.

“Vitiligo often has a significant impact on patients’ lives, and there is a need for new treatment options that can offer solutions to people with extensive disease who desire repigmentation,” said Khaled Ezzedine, M.D., Ph.D., Professor, Department of Dermatology, Henri Mondor Hospital and EpiDermE, Université Paris. “Today’s results provide an encouraging update in support of a potential oral option to treat extensive nonsegmental vitiligo. It is exciting to see continued progress in this space that, until recently, had limited options for patients.”

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].

More information regarding the EADV Congress 2023 can be found at https://eadvcongress2023.org/.

About the Phase 2b Study (NCT04818346)

The Phase 2b randomized, double-blind, placebo-controlled, dose ranging study evaluated 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 was a 24-week follow-up period.

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

Additional endpoints included the percentage of patients achieving ≥50% reduction from baseline in facial Vitiligo Area Scoring Index (F-VASI; F-VASI50), ≥75% reduction from baseline in F-VASI (F-VASI75) 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/study/NCT04818346.

About Povorcitinib (INCB54707)

Povorcitinib (INCB54707) is an oral small-molecule JAK1 inhibitor currently in Phase 2 clinical trials for vitiligo, hidradenitis suppurativa (HS), prurigo nodularis, chronic spontaneous urticaria and asthma. 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, hidradenitis suppurativa, 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, if so, whether it will provide a successful treatment option for patients with vitiligo, and Incyte's dermatology program generally 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; determinations made by the FDA, EMA and other regulatory authorities; the efficacy or safety of Incyte's products; the acceptance of Incyte's 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 and its quarterly report on Form 10-Q for the quarter ended June 30, 2023. 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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