Incyte Announces Positive Topline Results From Two Phase 3 Clinical Trials of Povorcitinib in Patients With Hidradenitis Suppurativa

March 17, 2025

- *Statistically significant results for primary endpoints in both STOP-HS1 and STOP-HS2 Phase 3 studies for both doses tested*

- *Favorable safety profile, with no safety concerns*

- *Data will support planned regulatory submission for povorcitinib in hidradenitis suppurativa (HS) worldwide*

- *Incyte to hold an analyst and investor call on Monday, March 17, 2025 from 8:00-9:00 a.m. ET*

WILMINGTON, Del.--(BUSINESS WIRE)--Mar. 17, 2025-- Incyte (Nasdaq: INCY) today announced positive topline results from its pivotal Phase 3 STOP-HS clinical trial program evaluating the safety and efficacy of povorcitinib (INCB054707), an oral small-molecule JAK1 inhibitor, in adult patients (≥18 years) with moderate to severe hidradenitis suppurativa (HS).

Both the STOP-HS1 and STOP-HS2 studies met their primary endpoint at both tested doses (45 mg and 75 mg). A significantly higher proportion of patients treated with povorcitinib once daily (QD) versus placebo achieved Hidradenitis Suppurativa Clinical Response (HiSCR), a ≥50% reduction from baseline in the total abscess and inflammatory nodule count (AN count), with no increase from baseline in abscess or draining tunnel count. The percentage of povorcitinib treated patients achieving HiSCR50 compared to placebo at Week 12 was:

STOP-HS1:	45 mg: 40.2% vs. 29.7% [*P*=0.024]
	75 mg: 40.6% vs 29.7% [*P*=0.022]
STOP-HS2:	45 mg: 42.3% vs. 28.6% [*P*=0.004]
	75 mg: 42.3% vs. 28.6% [*P*=0.003]

Within a predefined subgroup of patients previously exposed to biologics, povorcitinib demonstrated greater differential efficacy (HiSCR50) when compared to placebo (nominal *P*-values):

STOP-HS1:	45 mg: 34.2% vs. 21.9% [*P*=0.096]
	75 mg: 37.8% vs. 21.9% [*P*=0.037]
STOP-HS2:	45 mg: 45.0% vs. 19.5% [*P*=0.001]
	75 mg: 40.0% vs. 19.5% [*P*=0.005]

In addition, at Week 12, patients treated with povorcitinib achieved deep levels of clinical response with a greater proportion achieving HiSCR75, reduction in flares, ≥3-point decrease in the Skin Pain Numeric Rating Scale (NRS) score and Skin Pain NRS30. Furthermore, povorcitinib demonstrated rapid onset of response, including rapid skin pain reduction.

The overall safety profile of povorcitinib is consistent with previous data. No new safety signals were observed and both doses were well tolerated.

"Hidradenitis suppurativa is a challenging and debilitating condition without a cure. Given the limitations of current HS treatments and its impact on patients' daily lives, there is a critical need for new, well tolerated and effective therapies that provide a rapid reduction in the signs and symptoms of HS, in particular, pain," said Steven Stein, M.D., Chief Medical Officer, Incyte. "The positive Phase 3 data highlights the potential of povorcitinib as an effective oral treatment option for people living with HS."

These data support the planned regulatory submission of povorcitinib for the treatment of HS worldwide. Additionally, data from both STOP-HS studies will be submitted for presentation at upcoming scientific meetings.

About STOP-HS
The STOP-HS clinical trial program includes two Phase 3 studies, STOP-HS1 (NCT05620823) and STOP-HS2 (NCT05620836), evaluating the efficacy and safety of povorcitinib (INCB54707) in adult patients with moderate to severe HS. Both studies include a 12-week double-blind, placebo-controlled treatment period, followed by a 42-week extension period and 30-day safety follow-up.

The studies have each enrolled approximately 600 patients (age ≥18 years) diagnosed with moderate to severe HS for at least three months prior to the screening visit and meet certain criteria: total AN count of ≥5, lesions in at least two distinct anatomical areas, and have a documented history of inadequate response to at least a three-month course of at least one conventional systemic therapy (oral antibiotic or biologic drug) for HS, or have demonstrated intolerance to, or have a contraindication to, such conventional systemic therapies.

The primary endpoint for both studies is the proportion of patients who achieve HiSCR50, defined as at least a 50% reduction from baseline in the total AN count at Week 12, with no increase from baseline in abscess or draining tunnel count. Key secondary endpoints include the proportion of patients achieving a 75% reduction in AN count with no increase from baseline in abscess or draining tunnel count (HiSCR75) at Week 12, the proportion of patients experiencing at least one flare-up over 12 weeks, the proportion of patients with a ≥3-point decrease in the Skin Pain NRS score among those with a baseline score of ≥3, and the proportion of patients achieving a 30% reduction and at least 1-unit reduction from baseline in Skin Pain NRS at Week 12. The studies also evaluate the frequency and severity of adverse events during the study.

For more information on the STOP HS studies, please visit https://clinicaltrials.gov/study/NCT05620823 and https://clinicaltrials.gov/study/NCT05620836.

Incyte Conference Call and Webcast

Incyte will hold a conference call and webcast today at 8:00 a.m. ET. To access the conference call, please dial 877-407-3042 for domestic callers or +1 201-389-0864 for international callers. When prompted, provide the conference identification number: 13752265. If you are unable to participate, a replay of the conference call will be available for 30 days. The replay dial-in number for the United States is 877-660-6853 and the dial-in number for international callers is +1 201-612-7415. To access the replay, you will need the conference identification number: 13752265.

The conference call will also be webcast live and can be accessed at investor.incyte.com.

About Hidradenitis Suppurativa
Hidradenitis suppurativa (HS) is a chronic inflammatory skin condition characterized by painful nodules and abscesses that can lead to irreversible tissue destruction and scarring.[i,ii] Over-activity of the JAK/STAT signaling pathway is believed to drive inflammation involved in the pathogenesis and progression of HS.[iii] More than 150,000 patients in the U.S. are estimated to have moderate to severe HS.[iv] Given the debilitating nature of the condition, it can have a profoundly negative effect on patients' quality of life. [v]

About Povorcitinib
Povorcitinib (INCB54707) is an oral small-molecule JAK1 selective inhibitor currently in Phase 3 clinical trials for HS, vitiligo and prurigo nodularis (PN), as well as Phase 2 trials for asthma and chronic spontaneous urticaria (CSU).

Incyte Forward-Looking Statements
Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the regulatory submissions for povorcitinib worldwide; the submission of STOP-HS data for presentation at upcoming scientific meetings; the potential of povorcitinib to be an effective and well-tolerated treatment option for HS patients; and further clinical studies of povorcitinib, 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 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 for the year ended December 31, 2024. Incyte disclaims any intent or obligation to update these forward-looking statements.

1 National Center for Advancing Translational Science Genetic and Rare Diseases Information Center. Hidradenitis suppurativa. https://rarediseases.info.nih.gov/diseases/6658/hidradenitis-suppurativa. Accessed February 7, 2024.
2 Kirby, JS et al. (2024). Efficacy and safety of the oral Janus kinase 1 inhibitor povorcitinib (INCB054707) in patients with hidradenitis suppurativa in a phase 2, randomized, double-blind, dose-ranging, placebo-controlled study. Journal of the American Academy of Dermatology, Volume 90, Issue 3, 521-529.
3 Maronese, CA et al (2024). Biologics for Hidradenitis suppurativa: evolution of the treatment paradigm. Expert Review of Clinical Immunology, Volume 20, Issue 5, 525-545.
4 McMillan, K. Hidradenitis suppurativa: number of diagnosed patients, demographic characteristics, and treatment patterns in the United States. Am J Epidemiol. 2014 Jun 15;179(12):1477-83. doi: 10.1093/aje/kwu078. Epub 2014 May 8.
5 Sabat, R et al (2025). Hidradenitis suppurativa. The Lancet, Volume 405, Issue 10476, 420-438.

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