Incyte Announces New 24-Week Phase 3 Data from the STOP-HS Clinical Trial Program of Povorcitinib in Hidradenitis Suppurativa at EADV 2025

September 17, 2025

- *Across both STOP-HS1 and STOP-HS2, povorcitinib treatment resulted in continued clinically meaningful and statistically significant improvements for patients with active moderate to severe hidradenitis suppurativa (HS) through Week 24*
- *At Week 24, nearly 60% of efficacy-evaluable patients among both povorcitinib treatment groups achieved HiSCR50*
- *Additionally, patients treated with povorcitinib achieved HiSCR75 (31.0%-40.3%), HiSCR90 (13.8%-27.7%) and HiSCR100 (9.2%-21.3%) through Week 24*
- *Povorcitinib-treated patients also achieved greater improvements in skin pain by the first visit (Week 3) through Week 24 with 62%-70% achieving mild or no pain at Week 24*

WILMINGTON, Del.--(BUSINESS WIRE)--Sep. 17, 2025-- Incyte (Nasdaq:INCY) today announced new 24-week interim data evaluating the safety and efficacy of povorcitinib (INCB54707), an oral small-molecule highly-selective JAK1 inhibitor, from the pivotal Phase 3 STOP-HS clinical trial program in adult patients (≥18 years) with moderate to severe hidradenitis suppurativa (HS). These data will support the planned regulatory submissions for povorcitinib in HS in Europe and the United States in 2025 and early 2026, respectively.

The presentation will take place today at 2:45 p.m. CEST during a late-breaking oral presentation (Session: Late Breaking News; Presentation ID D1T01.1C) at the European Association of Dermatology and Venereology (EADV) 2025 Congress.

“HS remains a challenging and often debilitating condition and many patients are in need of new, well-tolerated and effective therapies that address prominent signs and symptoms of the disease, including inflammatory lesions and pain,” said Pablo J. Cagnoni, M.D., President and Head of Research and Development, Incyte. “We are pleased to share these late-breaking data with the dermatology community, including health care providers and people with HS. The STOP-HS abstract will provide additional detail on povorcitinib as an oral treatment option for HS and its ability to rapidly improve symptoms, with continued clinical responses seen through 24 weeks.”

As previously reported, both STOP-HS1 and STOP-HS2 studies met their primary endpoint at each tested dose (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) at Week 12, with no increase from baseline in abscess or draining tunnel count. In addition, at Week 12, more patients treated with povorcitinib compared to placebo, achieved HiSCR75 (a ≥75% reduction from baseline in the total AN count at Week 12), ≥3-point decrease in the Skin Pain Numeric Rating Scale (NRS) score, and Skin Pain NRS30; additionally, fewer patients experienced a flare by Week 12.

New data at Week 24 show nearly 60% of efficacy-evaluable patients among the povorcitinib 45 mg and 75 mg treatment groups achieved HiSCR50. The percentage of povorcitinib treated patients achieving HiSCR50 compared to placebo at Week 12 and 24 was:

STOP-HS1:	12-week 45 mg: 40.2% vs. 29.7% [*P*=0.024]
	24-week 45 mg: 52.9%-64.0%
	12-week 75 mg: 40.6% vs. 29.7% [*P*=0.0214]
	24-week 75 mg: 50.0%-62.7%
STOP-HS2:	12-week 45 mg: 42.3% vs. 28.6% [*P*=0.0035]
	24-week 45 mg: 57.1%-58.0%
	12-week 75 mg: 42.3% vs. 28.6% [*P*=0.0033]
	24-week 75 mg: 56.3%-58.5%

Additionally, across STOP-HS1 and STOP-HS2, povorcitinib treatment in both dosing groups resulted in continued improvements at Week 24 in endpoints associated with higher thresholds of response: HiSCR75 was achieved by 31.0%-40.3%, HiSCR90 by 13.8%-27.7% and HiSCR100 by 9.2%-21.3% of patients treated with povorcitinib. Those treated with povorcitinib also achieved greater improvements in skin pain, reducing pain by the first visit (Week 3) through Week 24. Further, 62%-70% of povorcitinib-randomized patients achieved skin pain scores of mild or no pain at Week 24.

In both studies, participants receiving povorcitinib 45 mg and 75 mg achieved dt100 (a 100% decrease in draining tunnels from baseline, among those with ≥1 draining tunnel at baseline): 34.6% and 41.6% at Week 12 and 39.0% and 50.6% at Week 24, respectively.

The overall safety profile of povorcitinib is consistent with previous data and both doses were well tolerated. Treatment-emergent adverse events (TEAEs) for patients who transitioned from placebo to povorcitinib (at Week 12) were 42.4%-54.3%, and 70.2%-78.7% for patients initially randomized to povorcitinib through Week 24. Serious adverse events, and adverse events of special interest (AESI) were observed in 2.9%-4.8% and 0%-1.4% of patients. No MACE or deaths occurred during this period.

“HS is a complex and often misunderstood condition that can profoundly affect patients’ daily lives,” said Dr. Martina Porter, STOP-HS study investigator, Assistant Professor of Dermatology at Harvard Medical School and Vice Chair for Research and Academics, Department of Dermatology at Beth Israel Deaconess Medical Center. “Data from the STOP-HS clinical trial program highlight the potential of povorcitinib to address key signs and symptoms for those living with HS, and it is encouraging to see advancements in potential new, effective treatment options for this patient community.”

More information regarding the 2025 EADV Congress can be found at: https://eadv.org/congress/scientific-programme/.

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.

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.[1,2] Over-activity of the JAK/STAT signaling pathway is believed to drive inflammation involved in the pathogenesis and progression of HS.[3] More than 150,000 patients in the U.S. are estimated to have moderate to severe HS.[3] Given the debilitating nature of the condition, it can have a profoundly negative effect on patients' quality of life. [4]

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).

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 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, the potential offered by povorcitinib, planned regulatory submissions for povorcitinib and whether or when povorcitinib will be approved or commercially available for use in 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; determinations made by the FDA, EMA, and other regulatory authorities; 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 our reports filed with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K and our quarterly report on Form 10-K for the quarter ended June 30, 2025. Incyte disclaims any intent or obligation to update these forward-looking statements.

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[1] McCarthy, S. (2025) Hidradenitis suppurativa. *Annu Rev Med.* 76(1):69-80. Link to source (https://pubmed.ncbi.nlm.nih.gov/39869430/)

[2] Kirby J.S., 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. *J Am Acad Dermatol*. 90(3):521-529. Link to source (https://pubmed.ncbi.nlm.nih.gov/37871805/)

[3] Maronese C.A., et al. (2024) Biologics for Hidradenitis suppurativa: evolution of the treatment paradigm. *Expert Rev Clin Immunol*. 20(5), 525-545. Link to source (https://pubmed.ncbi.nlm.nih.gov/38130204/)

[4] McMillan K. (2014) Hidradenitis suppurativa: number of diagnosed patients, demographic characteristics, and treatment patterns in the United States. *Am J Epidemiol*. 179(12):1477-83. Link to source (https://pubmed.ncbi.nlm.nih.gov/24812161/)

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