Incyte Announces New Positive 54-Week Late-Breaking Data for Povorcitinib in Hidradenitis Suppurativa at the 2026 American Academy of Dermatology (AAD) Annual Meeting

March 28, 2026

- Phase 3 data from the STOP-HS program demonstrate povorcitinib's substantial and durable clinical efficacy through Week 54 in patients with moderate to severe hidradenitis suppurativa (HS).
- Through Week 54, clinically meaningful and durable responses were observed across all groups in both STOP-HS1 and STOP-HS2, with up to 71.4% of patients achieving HiSCR50. Improvements in clinical responses across high stringent thresholds were observed, with up to 57% of participants achieving HiSCR75 and up to 29% of participants achieving HiSCR100.
- Povorcitinib treatment led to consistent reductions across key inflammatory lesion types, with full resolution (ANdT=0) achieved in up to 20% of patients. Additionally, clinically meaningful improvements in quality-of-life measures, including skin pain and fatigue, were observed at Week 54.
- The overall safety profile of povorcitinib through 54 weeks is consistent with previously reported data, and both doses were well tolerated.

WILMINGTON, Del.--(BUSINESS WIRE)--Mar. 28, 2026-- Incyte (Nasdaq:INCY) today announced 54-week 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). The late-breaking oral presentation of these data is taking place at the 2026 American Academy of Dermatology (AAD) Annual Meeting, being held March 27-31, 2026, in Denver (Session: S034 – Late-Breaking Research: Session 2. Saturday, March 28, 2026, 1:00-4:00 p.m. MT).

"The 54-week results from the STOP-HS program deliver compelling, long-term evidence supporting the potential of povorcitinib for patients with moderate to severe HS," said Pablo J. Cagnoni, M.D., President and Global Head of Research and Development, Incyte. "Across both studies, povorcitinib demonstrated substantial and durable improvements over time in key measures of treatment success and meaningful clinical benefit with a manageable safety profile, underscoring its promise to help transform the HS treatment landscape as the first oral option. We look forward to advancing our regulatory applications in the U.S. and Europe."

As previously reported, both STOP-HS1 and STOP-HS2 met the primary endpoint of Hidradenitis Suppurativa Clinical Response (HiSCR50, ≥50% reduction from baseline in the total abscess and inflammatory nodule count [AN count] without an increase in abscess or draining tunnel count relative to baseline), versus placebo at Week 12, at both doses (45 mg and 75 mg).

After Week 12, study participants entered the 42-week extension period. Participants receiving 45 mg or 75 mg of povorcitinib in the double-blind period continued to receive the same dose, while participants who received placebo were reassigned 1:1 to receive povorcitinib 45 mg or 75 mg.

Through Week 54, clinically meaningful and durable responses were observed across all groups in both STOP-HS1 and STOP-HS2, with up to 71.4% of patients achieving HiSCR50. Improvements in clinical responses across high stringent thresholds were observed, with up to 57% of participants achieving HiSCR75 and up to 29% of participants achieving HiSCR100.

Across both trials, povorcitinib treatment led to consistent reductions across all three key inflammatory lesion types—abscesses (A), inflammatory nodules (N) and draining tunnels (dT). Full clearance of inflammatory lesions (ANdT=0) was achieved by 16.1-20.2% of patients at Week 54. Reductions in dT counts were observed with both doses (75 mg, up to −62.0%; 45 mg, up to −57.7%), as well as reduction in inflammatory nodule counts (75 mg, up to −63.2%; 45 mg, up to −57.0%) and abscess counts (75 mg, up to −63.7%; 45 mg, up to −62.9%).

Additionally, at Week 54, a high proportion of participants across both doses achieved clinically meaningful improvements in skin pain (40.5-46.8%), fatigue (49.0-58.0%) and skin condition-related (59.4-64.7%) and HS-specific (33.7-40.2%) quality of life (QoL).

"HS and its associated symptoms can disrupt a person's routine and interfere with their daily lives," said Dr. Martina Porter, Assistant Professor of Dermatology at Harvard Medical School and Vice Chair for Research and Academics, Department of Dermatology at Beth Israel Deaconess Medical Center and STOP-HS study investigator. "The Phase 3 STOP-HS program not only demonstrated substantial clinical efficacy across key measures of disease activity, but also improved patient-reported symptoms, including skin pain and fatigue. Povorcitinib is an oral medication that targets the immune system in a different manner than the currently approved injectable treatments for HS, and these findings underscore the potential for povorcitinib to become a meaningful treatment option for people living with HS."

The overall safety profile of povorcitinib over 54 weeks was consistent with previously reported 24-week data, and both doses were well tolerated. Through Week 54, treatment-emergent adverse events (TEAEs) were similar across doses and studies, occurring in 76.2% to 83.4% of patients. The most frequent TEAEs across both studies and doses were acne, nasopharyngitis and upper respiratory tract infections with most events reported as mild or moderate. The incidence of serious TEAEs were low (3.7% to 6.4%) and similar across studies. Grade ≥3 TEAEs were 5.4% to 8.0%. TEAEs leading to discontinuation were low and similar between doses and studies (6.1% to 9.4%).

Rates of adverse events of special interest (AESI) including herpes zoster, serious infections, opportunistic infections, malignancies and other embolic

or thromboembolic events, were low (≤2.3%) for both studies. One event of MACE was reported and deemed unrelated to study drug by the Company. The number of major adverse cardiovascular and DVT/PE events observed through Week 54 was low (n=4) and consistent with published rates that have been reported in HS patients.

The STOP-HS data supported the submission of a New Drug Application (NDA) and Marketing Authorization Application (MAA) for povorcitinib as a treatment for HS which are under review by the U.S. Food and Drug Administration and European Medicines Agency, respectively.

More information regarding the 2026 AAD Annual Meeting can be found at: https://www.aad.org/member/meetings-education/am26.

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 double-blind extension period. Eligible participants either continued treatment in the STOP-HS LTE study (NCT06212999) or concluded treatment and entered a 30-day safety follow-up period.

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 who meet certain criteria: total AN count of ≥5, lesions in at least two distinct anatomical areas and 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 a demonstrated intolerance or 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 at least 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 over 12 weeks, the proportion of patients with a >3-point decrease in the Skin Pain NRS score at Week 12, 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, among those with a baseline score of ≥3. 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, https://clinicaltrials.gov/study/NCT05620836, and https://clinicaltrials.gov/study/NCT06212999.

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 being investigated in Phase 3 clinical trials for moderate to severe HS (STOP-HS1, STOP-HS2, STOP- HS LTE), nonsegmental vitiligo (STOP-V1, STOP-V2) and prurigo nodularis (PN; STOP-PN1, STOP-PN2), as well as a Phase 2 trial for moderate to severe asthma. The New Drug Application (NDA) and Marketing Authorization Application (MAA) for povorcitinib as a potential treatment for patients with moderate to severe HS is under review by the U.S. Food and Drug Administration and European Medicines Agency, respectively. Topline Phase 3 data for povorcitinib in vitiligo and PN are anticipated in mid-2026 and Q4 2026, respectively.

About Incyte®

Incyte is redefining what's possible in biopharmaceutical innovation. Through deep scientific expertise and a relentless focus on patients, we have built an established portfolio of first-in-class medicines and an extensive pipeline of next-generation medicines across our key franchises: Hematology, Oncology and Inflammation and Autoimmunity.

To learn more, visit Incyte.com and Investor.Incyte.com. Follow us on social media: LinkedIn, X and Instagram.

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 and promise offered by povorcitinib, including its ability to transform treatment or become a meaningful oral option for patients with HS, the continuation, completion or success of any clinical development of povorcitinib for the treatment of hidradenitis suppurativa, nonsegmental vitiligo, prurigo nodularis or asthma, expectations regarding 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 risks and uncertainties regarding research and development of products and product candidates, the sufficiency of clinical trial data 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 and the timing thereof, the efficacy or safety of Incyte's assets and 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 U.S. Securities and Exchange Commission, including its annual report on form 10-K for the year ended December 31, 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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