Povofortay® (povorcitinib) Approved in Europe as the First Once-Daily Oral Treatment for Adults with Moderate to Severe Hidradenitis Suppurativa

November 16, 2026

European Commission approval based on data from Phase 3 STOP-HS1 and STOP-HS2, which showed that Povofortay® (povorcitinib) met the primary endpoint at Week 12 and delivered clinically meaningful, durable responses through Week 54 and was well tolerated [1,2]

WILMINGTON, Del.--(BUSINESS WIRE)--Nov. 16, 2026-- Incyte (Nasdaq:INCY) today announced that the European Commission (EC) has approved Povofortay® (povorcitinib) 45 mg and 75 mg for the treatment of eligible adults with moderate to severe hidradenitis suppurativa (HS).

“The European Commission approval of Povofortay marks an important milestone for Incyte, advancing a key growth driver for our business and bringing a new treatment option to people living with HS, a chronic and often debilitating disease,” [2,3] said Bill Meury, Chief Executive Officer, Incyte. "As the first and only once-daily oral treatment approved in the European Union for eligible adults with moderate to severe HS, Povofortay gives physicians an important new option for their patients.”

The approval is based on results from the pivotal STOP-HS1 (NCT05620823) and STOP-HS2 (NCT05620836) trials evaluating the safety and efficacy of Povofortay in patients with moderate to severe HS.[2]

Data from the Phase 3 STOP-HS program demonstrated Povofortay’s clinically meaningful and durable efficacy. Both studies 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 studied doses (45 mg and 75 mg) in the overall intent-to-treat (ITT) population. Consistent efficacy was observed in the post-anti-TNF population, which is reflected in the EU indication, with a greater proportion of patients achieving HiSCR50 at Week 12 compared with placebo. 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. 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).

The overall safety profile of Povofortay over 54 weeks was consistent with previously reported data; both doses were well tolerated, with no new or unexpected safety signals. 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.[2]

“HS is a challenging disease to manage, and many patients struggle with the significant burden that affects many aspects of their lives,” said Professor Dr. Falk Bechara, Ruhr University Bochum, Germany. “For clinicians, treatment goals need to go beyond controlling disease activity and also focus on what matters most to patients – genuine improvement in their daily life. This approval gives healthcare professionals and patients an important new option to consider when treating adults with moderate to severe HS, one that could help close the gap that exists in effectively managing this complex disease.”

The U.S. Food and Drug Administration is currently reviewing Incyte’s New Drug Application (NDA) for povorcitinib as a treatment for moderate to severe HS. The application is supported by results from the STOP-HS1 and STOP-HS2 studies, with U.S. approval and launch anticipated in the first quarter of 2027.

About Hidradenitis Suppurativa
Hidradenitis suppurativa (HS) is a chronic inflammatory skin condition characterized by painful nodules, abscesses and draining tunnels that can lead to irreversible tissue destruction and scarring. Given the debilitating nature of the condition, it can have a profoundly negative effect on patients’ quality of life.[2,4] Overactivity of the JAK/STAT signaling pathway is believed to drive inflammation involved in the pathogenesis and progression of HS.[3] HS affects approximately 1% of the global population.[4]

About Povofortay® (povorcitinib)
Povofortay (povorcitinib) is an oral small-molecule JAK1 selective inhibitor approved in Europe as a treatment for active moderate to severe hidradenitis suppurativa (HS) in adults who have responded inadequately to, or who are intolerant or contraindicated to, an anti-tumor necrosis factor (TNF) therapy.

A New Drug Application (NDA) for povorcitinib in adults with moderate to severe HS is under review by the U.S. Food and Drug Administration.

Incyte has worldwide rights for the development and commercialization of Povofortay.

Povofortay is a registered trademark of Incyte.

For more information, see the Povofortay SmPC.

About Incyte®
Incyte is redefining what is 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 portfolio of next-generation potential 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.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding Povofortay's potential contribution to Incyte's future growth; Povofortay's potential to become an important new treatment option for patients with HS and help address unmet needs in the treatment of HS; the potential for regulatory approval of povorcitinib in the U.S.; the timing of any such approval and commercial launch, including the potential for U.S. approval and launch in the first quarter of 2027; the potential commercial availability and success of Povofortay; the further development of povorcitinib in additional indications; and Incyte's aspirations and goals as set forth under the heading "About Incyte."

Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including the sufficiency of clinical trial data to meet applicable regulatory standards or warrant continued development; actions of regulatory agencies, which may affect the timing and scope of marketing approval; the efficacy or safety of Incyte's products; Incyte's ability to achieve commercial success for its marketed products and product candidates, if approved; Incyte's ability to obtain and maintain protection of intellectual property for its products and technology; Incyte's reliance on third parties and partners; the acceptance of Incyte's products in the marketplace; market competition, sales, marketing, manufacturing and distribution requirements; greater than expected expenses, including expenses relating to litigation or strategic activities; and those risks and uncertainties discussed in greater detail 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, and its quarterly report on Form 10-Q for the quarter ended September 30, 2026. Incyte disclaims any intent or obligation to update these forward-looking statements.

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1 European Medicines Agency. Povofortay (povorcitinib). Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/povofortay. Accessed October 6, 2026.

2 Porter ML, Martorell A, Sayed CJ, Bechara FG, Lev-Tov H, Hsiao JL, et al. Povorcitinib for hidradenitis suppurativa: The randomized, double-blind, placebo-controlled STOP-HS1 and STOP-HS2 Phase 3 trials. *Nat Med*. Published online 2026. doi:10.1038/s41591-026-04534-z.

3 Jemec GBE, Villumsen B, van Straalen KR, van der Zee HH, Valiukevičienė S, Tzellos T, et al. European S2k guidelines for hidradenitis suppurativa/acne inversa Part 1. Epidemiology, diagnosis and clinical assessment. *J Eur Acad Dermatol Venereol*. 2026; 00: 1–20. https://doi.org/10.1111/jdv.70638.

4 Bouazzi D, Nielsen SM, Hagan PG, et al. Prevalence of hidradenitis suppurativa: A meta-analysis of Global Hidradenitis Suppurativa Atlas studies. *JAMA Dermatol*. 2025;161(10):1022-1028. https://doi.org/10.1001/jamadermatol.2025.2373

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