Incyte Announces the European Commission Approval of Zynyz® (retifanlimab) for the First-Line Treatment of Advanced Squamous Cell Carcinoma of the Anal Canal (SCAC)

March 6, 2026

-Zynyz® (retifanlimab) in combination with carboplatin and paclitaxel (platinum-based chemotherapy) is the first systemic treatment for adult patients with advanced SCAC in Europe

- The EC approval is based on results of the POD1UM-303 study which showed that adult patients with advanced SCAC achieved significantly improved progression-free survival with Zynyz in combination with carboplatin and paclitaxel as a first-line treatment compared to chemotherapy alone.[1]

WILMINGTON, Del.--(BUSINESS WIRE)--Mar. 6, 2026-- Incyte (Nasdaq:INCY) today announced that the European Commission (EC) has approved Zynyz® (retifanlimab) in combination with carboplatin and paclitaxel (platinum-based chemotherapy) for the first-line treatment of adult patients with metastatic or with inoperable locally recurrent squamous cell carcinoma of the anal canal (SCAC).

“The EC approval of Zynyz marks an important step forward for patients with advanced SCAC, a rare cancer for which meaningful treatment advances have not occurred in several decades,” said Bill Meury, President and Chief Executive Officer, Incyte. “As the first PD-1 immunotherapy approved in Europe in combination with platinum-based chemotherapy in the first-line setting, Zynyz helps expand the standard-of-care options available to clinicians and underscores our commitment to delivering innovative medicines that can have an impact for patients.”

The EC decision follows the January 2026 positive opinion received from the European Medicines Agency’s Committee for Medicinal Products for Human Use (CHMP). This marks the second indication in Europe for Zynyz, which was previously approved by the EC as a monotherapy for the first-line treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma.

This approval is based on data from the Phase 3 POD1UM-303/InterAACT2 trial (NCT04472429) evaluating Zynyz or placebo in combination with platinum-based chemotherapy (carboplatin and paclitaxel) in adult patients with metastatic or inoperable locally recurrent SCAC not previously treated with systemic chemotherapy.[1]

Results from the trial, also published in *The Lancet*, demonstrated a statistically significant 37% reduction in the risk of progression or death (*P*=0.0006).[1] Patients in the Zynyz and chemotherapy combination group achieved a median progression-free survival (PFS) of 9.3 months compared to 7.4 months for patients in the placebo combination group.[1] Clinically meaningful improvement was also demonstrated for all secondary efficacy endpoints, including the key secondary endpoint of overall survival. No new safety signals were identified, and the safety profile was representative of other combinations with PD-1 inhibitors and chemotherapy. Serious adverse reactions occurred in 47% of patients receiving Zynyz in combination with chemotherapy.[1] The most frequent serious adverse reactions (≥ 2% of patients) were sepsis, pulmonary embolism, diarrhea and vomiting.[1]

“For patients with metastatic or inoperable locally recurrent SCAC, first-line care has historically relied on chemotherapy alone, despite the clear need for better outcomes,” said Sheela Rao, M.D., Consultant Medical Oncologist, The Royal Marsden National Health Service Foundation Trust and Lead Investigator for POD1UM-303. “The approval of Zynyz in combination with carboplatin and paclitaxel is a significant clinical milestone that brings an immunotherapy-based regimen into earlier treatment and offers clinicians in Europe an important new option for patients.”

About Squamous Cell Carcinoma of the Anal Canal (SCAC)

Worldwide, SCAC is the most common type of anal cancer, making up 85% of cases.[2] It is a rare disease for which the incidence increases approximately 3% per year, with an estimated prevalence at around 1 or 2 cases per 100,000 people.[3,4,5,6] About 90% of cases are associated with human papillomavirus (HPV) infection—the number one risk factor for anal cancer.[5] HIV is an important amplifier of anal cancer, as people with HIV are 25 to 35 times more likely to develop it.[7,8] Anal cancer shares many of the same symptoms as non-cancerous conditions, such as hemorrhoids —including pain, itching, a lump or mass and changes in bowel movements—and as a result can go undetected leading to the majority of patients presenting with locally advanced disease.[9]

About POD1UM

The POD1UM (PD1 Clinical Program in Multiple Malignancies) clinical trial program for retifanlimab includes POD1UM-303, POD1UM-202 and several other Phase 1, 2 and 3 studies for patients with solid tumors.

For more information about the study, please visit https://clinicaltrials.gov/study/NCT04472429.

About Zynyz® (retifanlimab)

Zynyz® (retifanlimab) is a humanized monoclonal antibody targeting programmed death receptor-1 (PD-1), indicated in combination with carboplatin and paclitaxel (platinum-based chemotherapy) for the first-line treatment of adult patients with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC) in the U.S and Japan and as a single agent for the treatment of adult patients with locally recurrent or metastatic SCAC with disease progression or intolerance to platinum-based chemotherapy in the U.S.

Zynyz is also indicated as monotherapy for the first-line treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) in the U.S., EU, Canada and Switzerland.

Zynyz is marketed by Incyte in the U.S. In 2017, Incyte entered into an exclusive collaboration and license agreement with MacroGenics, Inc. for

global rights to retifanlimab.

Zynyz is a registered trademark of Incyte.

For more information, see the Zynyz SmPC.

About Incyte

A global biopharmaceutical company on a mission to *Solve On,* Incyte follows 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 Hematology, Oncology and Inflammation and 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.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the potential for retifanlimab, in combination with platinum-based chemotherapy, to become a new treatment option for the treatment of adults with locally recurrent or with metastatic SCAC with disease progression on or intolerance to platinum-based chemotherapy, contain predictions, estimates, and other forward-looking statements.

These forward-looking statements are based on Incyte's current expectations and are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: determinations made by the EC 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 on Form 10-K for the year ended December 31, 2025. Incyte disclaims any intent or obligation to update these forward-looking statements.

[1] Retifanlimab with carboplatin and paclitaxel for locally recurrent or metastatic squamous cell carcinoma of the anal canal (POD1UM-303/InterAACT-2): a global, phase 3 randomised controlled trial
Rao, Sheela et al. The Lancet, Volume 405, Issue 10495, 2144 – 2152 Link to source (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(25)00631-2/fulltext)

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