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Incyte Announces Positive CHMP Opinion for Zynyz® (retifanlimab) for First-Line Treatment of Advanced Squamous Cell Carcinoma of the Anal Canal (SCAC)

January 30, 2026

- *Pending the European Commission decision, Zynyz® (retifanlimab) in combination with carboplatin and paclitaxel (platinum-based chemotherapy) will be the first PD-1 immunotherapy treatment for patients with advanced squamous cell carcinoma of the anal canal (SCAC) in Europe*
- *Globally, the prevalence of SCAC is estimated at around 1 or 2 cases per 100,000 people, with a higher incidence in women than in men^{1,2,3}*
- *The Committee for Medicinal Products for Human Use (CHMP) positive opinion is based on data from the Phase 3 POD1UM-303/InterAACT2 trial which showed patients with advanced SCAC achieved significantly improved progression-free survival with Zynyz in combination with carboplatin and paclitaxel as a first-line treatment⁴*

MORGES, Switzerland--(BUSINESS WIRE)--Jan. 30, 2026-- Incyte (Nasdaq:INCY) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending the approval of 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).

"Today's positive CHMP opinion is an important step towards addressing the urgent need for new treatment options for patients in Europe with advanced SCAC, a disease which has seen limited innovation for decades," said Lee Heeson, Executive Vice President and Head of Incyte International. "If approved, Zynyz in combination with platinum-based chemotherapy has the potential to become a new standard-of-care for patients living with this rare and difficult-to-treat cancer."

The positive CHMP opinion was based on data from the Phase 3 POD1UM-303/InterAACT2 trial evaluating Zynyz in combination with (platinum-based chemotherapy) in adult patients with metastatic or inoperable locally recurrent SCAC not previously treated with systemic chemotherapy.⁵

Results from POD1UM-303/InterAACT2 (NCT04472429) published in [The Lancet](#) showed a statistically significant 37% reduction in the risk of progression or death ($P=0.0006$).⁴ Patients in the Zynyz and (platinum-based 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.⁴ No new safety signals were identified. Serious adverse reactions occurred in 47% of patients receiving Zynyz in combination with chemotherapy.⁴ The most frequent serious adverse reactions ($\geq 2\%$ of patients) were sepsis, pulmonary embolism, diarrhoea and vomiting.⁴

SCAC is the most common type of anal cancer, accounting for approximately 85% of all anal cancer cases.⁶ Globally, the prevalence of SCAC is estimated at around 1 or 2 cases per 100,000 people, with a higher incidence in women than in men.^{1,2,3}

The CHMP opinion is now being reviewed by the European Commission, which has the authority to grant approval for all centrally authorized products in the EU.

About Squamous Cell Carcinoma of the Anal Canal (SCAC)

Worldwide, SCAC is the most common type of anal cancer, making up 85% of cases.⁶ It is a rare disease for which the incidence increases approximately 3% per year.^{7,8,9,10} About 90% of cases are associated with human papillomavirus (HPV) infection—the number one risk factor for anal cancer.¹⁰ HIV is an important amplifier of anal cancer, as people with HIV are 25 to 35 times more likely to develop it.^{11,12} 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.¹³

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 & 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 whether and when Zynyz might provide a successful treatment option or become the standard-of-care for patients in Europe with advanced SCAC, 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: 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 European Commission, the U.S. FDA and other regulatory authorities; the efficacy or safety of Incyte's 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 Incyte's reports filed with the Securities and Exchange Commission, including its annual report on Form 10-K and its report on Form 10-Q for the quarter ended September 30, 2025. Incyte disclaims any intent or obligation to update these forward-looking statements.

¹ National Cancer Institute. Cancer stat facts: anal cancer. Available at: <https://seer.cancer.gov/statfacts/html/anus.html>. Accessed January 2026

² Mignozzi S., Santucci C., Malvezzi M., et al. (2024) Global trends in anal cancer incidence and mortality. *Eur J Cancer Prev*, 33:77-86. Link to source (<https://pubmed.ncbi.nlm.nih.gov/38047709/>)

³ English K.J. (2024) Anal carcinoma - exploring the epidemiology, risk factors, pathophysiology, diagnosis, and treatment. *World J Exp Med*, 14:98525. Link to source (<https://pubmed.ncbi.nlm.nih.gov/39312693/>)

⁴ Rao S., Samalin-Scalzi E., Evesque L., et al. (2025) 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. *Lancet*, 405(10495):2144-52. Link to source ([https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(25\)00631-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(25)00631-2/fulltext))

⁵ Clinical [Trials.Gov](#). Carboplatin-paclitaxel with retifanlimab or placebo in participants with locally advanced or metastatic squamous cell anal carcinoma (POD1UM-303/InterAACT 2). Available at: <https://clinicaltrials.gov/study/NCT04472429>. Accessed January 2026

⁶ Symer M.M., Yeo H.L. (2018) Recent advances in the management of anal cancer. *F1000Research*, 7:F1000 Faculty Rev-1572. Link to source (<https://pubmed.ncbi.nlm.nih.gov/30345012/>)

⁷ Islami F., Ferlay J., Lortet-Tieulent J., et al. (2017) International trends in anal cancer incidence rates. *Int J Epidemiol*, 46:924-938. Link to source (<https://pubmed.ncbi.nlm.nih.gov/27789668/>)

⁸ Giuliano A.R., Nyitray A.G., Kreimer A.R., et al. (2015) EUROGIN 2014 roadmap: differences in human papillomavirus infection natural history, transmission and human papillomavirus-related cancer incidence by gender and anatomic site of infection. *Int J Cancer*, 136:2752-2760. Link to source (<https://pubmed.ncbi.nlm.nih.gov/25043222/>)

⁹ Morris V., Eng C. (2016) Strengthening the immunotherapy paradigm in anal cancer. Available at: https://c.peerview.com/live/programs/150210387-1/downloads/PVI_slides_SCAC-SF25.pdf?ProjectNumber=150210387_1. Accessed January 2026

¹⁰ U.S. Centers for Disease Control and Prevention. Cancers linked with HPV each year. Available at: <https://www.cdc.gov/cancer/hpv/cases.html>. Accessed January 2026

¹¹ Wang C.C.J., Sparano J., Palefsky J.M. (2017) Human immunodeficiency virus/AIDS, human papillomavirus, and anal cancer. *Surg Oncol Clin N Am*, 26:17-31. Link to source (<https://pubmed.ncbi.nlm.nih.gov/27889034/>)

¹² NCCN clinical practice guidelines in oncology: cancer in people with HIV. Version 1.2021. 2021

¹³ Anal Cancer Foundation. Anal cancer: signs, symptoms, causes & treatment. Available at: <https://www.analcancerfoundation.org/what-is-anal-cancer/>. Accessed January 2026

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