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Incyte Japan Announces Approval of Zynyz® (retifanlimab) for the First-Line Treatment of Advanced Anal Cancer

December 22, 2025

TOKYO--(BUSINESS WIRE)--Dec. 22, 2025-- Incyte Biosciences Japan G.K. today announced the Japan Ministry of Health, Labour and Welfare (MHLW) approval of Zynyz® (retifanlimab) in combination with carboplatin and paclitaxel (platinum-based chemotherapy) for the first-line treatment of advanced squamous cell carcinoma of the anal canal (SCAC).

"Today's approval marks a significant milestone for patients with advanced anal cancer in Japan – the MHLW's approval of Zynyz as the first and only first-line treatment for SCAC," said Yasuyuki Ishida, General Manager, Incyte Biosciences Japan G.K. "By offering combination therapy with chemotherapy, Zynyz provides a vital new path forward for patients facing this challenging disease, addressing a significant unmet need in cancer care for patients with SCAC and their families."

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

Results from POD1UM-303/InterAACT2 (NCT04472429) published in [The Lancet](#) showed a statistically significant 37% reduction in the risk of progression or death ($P=0.0006$).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 No new safety concerns were identified. Serious adverse reactions occurred in 47% of patients receiving Zynyz in combination with chemotherapy.¹ The most frequent serious adverse reactions ($\geq 2\%$ of patients) were sepsis, pulmonary embolism, diarrhea and vomiting.¹

SCAC accounts for approximately 16% to 24% of anal canal cancer cases in Japan, with adenocarcinomas comprising about 70%.² The overall incidence rate for anal canal in Japan is approximately 0.26 to 0.41 per 100,000 persons.²

This is the first regulatory approval for Zynyz in Japan, and the second regulatory approval for Zynyz in advanced SCAC. In May 2025, the U.S. Food and Drug Administration (FDA) approved Zynyz in combination with carboplatin and paclitaxel (platinum-based chemotherapy) for the first-line treatment of adult patients with inoperable locally recurrent or metastatic SCAC.

Incyte has also submitted a Type II variation Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for retifanlimab in advanced SCAC.

About Squamous Cell Carcinoma of the Anal Canal (SCAC)

Worldwide, SCAC is the most common type of anal cancer, making up 85% of cases.³ It is a rare disease for which the incidence increases approximately 3% per year.^{4,5,6,7} About 90% of cases are associated with human papillomavirus (HPV) infection—the number one risk factor for anal cancer.⁷ HIV is an important amplifier of anal cancer, as people with HIV are 25 to 35 times more likely to develop it.^{8,9} 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.¹⁰

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, including a registration-directed trial evaluating retifanlimab in combination with platinum-based chemotherapy for patients with non-small cell lung cancer.

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).

Zynyz is also indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) in the U.S. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Zynyz is marketed by Incyte in the United States. 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.

Important Safety

Please refer to the Zynyz package insert for precautions concerning indications, dosage and administration, and safety information in Japan, [Japan Pharmaceuticals and Medical Devices Agency](#).

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.

Incyte Biosciences Japan G.K. is a wholly owned subsidiary of Incyte. For more information on Incyte in Japan, visit www.incyte.jp.

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 whether and when Zynzyg might provide a successful treatment option for patients with SCAC, 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 MHLW, 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-Q for the quarter ended September 30, 2025. Incyte disclaims any intent or obligation to update these forward-looking statements.

¹ Rao S, Samalin-Scalzi E, Evesque L, et al. 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* 2025;405(10495):2144-52.

² Yamada K, Saiki Y, Komori K, et al. Characteristics of anal canal cancer in Japan. *Cancer Med* 2022;11:2735-2743.

³ Symer MM, Yeo HL. Recent advances in the management of anal cancer. *F1000Research* 2018;7:F1000 Faculty Rev-1572.

⁴ Islami F, Ferlay J, Lortet-Tieulent J, et al. International trends in anal cancer incidence rates. *Int J Epidemiol* 2017;46:924-938.

⁵ Giuliano AR, Nyitray AG, Kreimer AR, et al. 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* 2015;136:2752-2760.

⁶ Morris V, Eng C. Strengthening the immunotherapy paradigm in anal cancer. *J Gastrointest Oncol* 2016;7:721-726.

⁷ 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 November, 2025.

⁸ Wang CJ, Sparano J, Palefsky JM. Human immunodeficiency virus/AIDS, human papillomavirus, and anal cancer. *Surg Oncol Clin N Am* 2017;26:17-31.

⁹ NCCN clinical practice guidelines in oncology: cancer in people with HIV. Version 1.2021. 2021.

¹⁰ Anal Cancer Foundation. Anal cancer: signs, symptoms, causes & treatment. Available at: <https://www.analcancerfoundation.org/what-is-anal-cancer/>. Accessed November 2025.

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