# Incyte Announces Outcome of FDA Oncologic Drugs Advisory Committee (ODAC) Meeting Reviewing Retifanlimab as a Treatment for Patients with Squamous Cell Carcinoma of the Anal Canal (SCAC)

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WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced the outcome of a meeting of the Oncologic Drugs Advisory Committee (ODAC) of the U.S. Food and Drug Administration (FDA), which reviewed the Biologics License Application (BLA) for retifanlimab, an intravenous PD-1 inhibitor, as a potential treatment for adult patients with locally advanced or metastatic squamous cell carcinoma of the anal canal (SCAC) who have progressed on, or who are intolerant of, platinum-based chemotherapy. The Committee voted 13-4 that a regulatory decision on retifanlimab for the treatment of advanced or metastatic SCAC should be deferred until further data are available from clinical trial POD1UM-303, a confirmatory trial in platinum-naïve advanced SCAC that is currently underway.

The ODAC provides the FDA with independent opinions and recommendations from outside experts on marketed and investigational medicines for use in the treatment of cancer. The FDA considers the advice of the ODAC in its review but is not bound to follow its recommendations.

“While we are disappointed by the outcome of today’s ODAC vote, we will continue to work closely with the FDA as it completes its review of the BLA for retifanlimab,” said Lance Leopold, M.D., Group Vice President, Immuno-Oncology Clinical Development, Incyte. “Patients with advanced SCAC who have progressed after first-line platinum-based chemotherapy currently have no FDA-approved treatments available to them and face an extremely poor prognosis. We continue to believe that retifanlimab can provide an additional, much-needed option for these patients based on the favorable benefit/risk shown in our trial.”

The BLA for retifanlimab is based on data from the Phase 2 POD1UM-202 trial evaluating retifanlimab in 94 previously treated patients with locally advanced or metastatic SCAC who have progressed on, or are intolerant of, platinum-based chemotherapy. The FDA previously granted retifanlimab Orphan Drug Designation for the treatment of anal cancer, along with Priority Review, and set the Prescription Drug User Fee Act (PDUFA) target action date for retifanlimab as July 25, 2021.

SCAC is almost always associated with human papillomavirus (HPV) and HIV infections and accounts for nearly 3% of digestive system cancers.[1] Patients with metastatic SCAC have a poor 5-year survival, and there are no FDA-approved treatments for patients who have progressed after first-line chemotherapy.[2]

**About POD1UM-202**

POD1UM-202 (NCT03597295) is an open-label, single-arm, multicenter, Phase 2 study evaluating retifanlimab in 94 patients with locally advanced or metastatic squamous cell carcinoma of the anal canal (SCAC) who have progressed on, or were ineligible for or intolerant of, platinum-based chemotherapy. Retifanlimab 500mg is administered as an intravenous infusion every 4 weeks for up to 2 years.

The primary endpoint was overall response rate (ORR) as determined by independent central review using RECIST v1.1. Secondary endpoints included duration of response (DOR), disease control rate (DCR), progression-free survival (PFS) and overall survival (OS); safety and pharmacokinetics.

For more information about the study, please visit https://clinicaltrials.gov/ct2/show/NCT03597295.

**About POD1UM**

The POD1UM (PD1 Clinical Program in Multiple Malignancies) clinical trial program for retifanlimab includes Phase 1, 2 and 3 studies for patients with solid tumors both as monotherapy and in combination with Incyte’s early development portfolio. Additional indications in late-stage development include platinum-naïve squamous cell carcinoma of the anal canal (SCAC), microsatellite instability-high endometrial cancer, Merkel cell carcinoma and non-small cell lung cancer.

**About Retifanlimab**

Retifanlimab (formerly INCMGA0012), an investigational intravenous PD-1 inhibitor, is currently under evaluation in Phase 1, 2 and 3 studies for patients with solid tumors both as monotherapy and in combination with Incyte’s early development portfolio. Additional indications in late-stage development include platinum-naïve squamous cell carcinoma of the anal canal (SCAC), microsatellite instability-high endometrial cancer, Merkel cell carcinoma and non-small cell lung cancer.

Retifanlimab has been granted Orphan Drug Designation by the U.S. Food and Drug Administration for the treatment of anal cancer. A Marketing Authorization Application for retifanlimab is also under review by the European Medicines Agency.

In 2017, Incyte entered into an exclusive collaboration and license agreement with MacroGenics, Inc. for global rights to retifanlimab. In 2019, Incyte and Zai Lab announced a collaboration and license agreement for the development and commercialization of retifanlimab in Greater China.

**About Incyte**

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

**Forward Looking Statements**

Except for the historical information set forth herein, the matters set forth in this press release, including statements about whether or when the FDA may approve retifanlimab for the treatment of patients with squamous cell carcinoma of the anal canal (SCAC), the potential of retifanlimab to treat patients with SCAC, the retifanlimab development program generally, and the safety and efficacy of retifanlimab in patients with SCAC, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on the Company'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; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain, other third-party providers and development and discovery operations; determinations made by the FDA; the efficacy or safety of the Company's products; the acceptance of the Company's products in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its annual report for the year ended December 31, 2020, and the quarterly report on Form 10-Q for the quarter ended March 31, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

[1] Ghosn M, et.al. Anal cancer treatment: current status and future perspectives. *World J Gastroenterol* 2015;21:2294-2302.
[2] Eng C, et al. The role of systemic chemotherapy and multidisciplinary management in improving the overall survival of patients with metastatic squamous cell carcinoma of the anal canal. *Oncotarget* 2014;5:11133-11142.

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