



**SOLVE
ON.**

Incyte Provides Regulatory Update on Retifanlimab for the Treatment of Certain Patients with Squamous Cell Carcinoma of the Anal Canal (SCAC)

July 23, 2021

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte Corporation (Nasdaq:INCY) today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding its Biologics License Application (BLA) for retifanlimab, an intravenous PD-1 inhibitor, for the treatment of 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 complete response letter states that the FDA cannot approve the application in its present form. Consistent with the Oncologic Drugs Advisory Committee recommendation on June 24, 2021, the FDA determined that additional data are needed to demonstrate the clinical benefit of retifanlimab for the treatment of patients with advanced or metastatic SCAC. Incyte is reviewing the letter and will discuss next steps with the FDA.

"Patients with SCAC who have progressed after first-line chemotherapy currently do not have approved treatment options," said Hervé Hoppenot, Chief Executive Officer, Incyte. "While we are not surprised with the FDA decision given the ODAC recommendation, we are disappointed. We remain committed to advancing science to find solutions for patients with unmet medical needs, and we will ensure close coordination with the FDA in order to address feedback and determine next steps for the review of retifanlimab."

The BLA submission was based on data from the Phase 2 POD1UM-202 trial evaluating retifanlimab in previously treated patients with locally advanced or metastatic SCAC who have progressed on, or were ineligible for or intolerant of, platinum-based chemotherapy.

About Retifanlimab

Retifanlimab (formerly INCMGA0012), an investigational intravenous PD-1 inhibitor, is currently under evaluation in registration-directed trials as a monotherapy for patients with microsatellite instability-high endometrial cancer, Merkel cell carcinoma and squamous cell carcinoma of the anal canal (SCAC); and in combination with platinum-based chemotherapy for patients with non-small cell lung cancer and SCAC.

Retifanlimab has been granted Orphan Drug Designation by the U.S. Food and Drug Administration for the treatment of anal cancer.

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](https://www.incyte.com) and follow [@Incyte](https://twitter.com/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 Company's dependence on its relationships with its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners 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.



View source version on [businesswire.com](https://www.businesswire.com/news/home/20210723005449/en/): <https://www.businesswire.com/news/home/20210723005449/en/>

Media

Jenifer Antonacci, +1 302 498 7036

jantonacci@incyte.com

Catalina Loveman, +1 302 498 6171

cloveman@incyte.com

Investors

Christine Chiou, +1 302 274 4773

cchiou@incyte.com

Source: Incyte Corporation