Incyte Announces Acceptance and Priority Review of BLA for Retifanlimab as a Potential Treatment for Patients with Squamous Cell Carcinoma of the Anal Canal (SCAC)

January 22, 2021

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review its 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 BLA submission is 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 are intolerant of, standard platinum-based chemotherapy. The trial enrolled 94 patients, including several with well-controlled human immunodeficiency virus (HIV) infection. The study, which was recently presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020, resulted in an objective response rate (ORR) of 14% for retifanlimab monotherapy as determined by independent central review (ICR) using RECIST v1.1. Responses were observed regardless of PD-L1 status, presence of liver metastases, age or HIV+ status and were durable (median 9.5 months). Treatment-related adverse events ≥Grade 3 occurred in 11.7% of patients. Immune-related adverse events ≥Grade 3 occurred in 6.4% of patients. The most common adverse reactions (incidence ≥ 20%) were fatigue and diarrhea.

“Patients with SCAC who have progressed after first-line chemotherapy treatment currently have no approved treatments available, and we are encouraged that the FDA’s acceptance of this BLA for Priority Review brings us one step closer to addressing this historically neglected, yet important, tumor,” said Lance Leopold, M.D., Group Vice President, Immuno-Oncology Clinical Development, Incyte. “Despite SCAC being a rare disease, its incidence is increasing and its impact is profound. We look forward to working with the FDA to potentially fill an unmet need and advance progress in SCAC for patients.”

Retifanlimab has been granted Orphan Drug Designation by the FDA for the treatment of anal cancer, along with Priority Review. The FDA grants Priority Review to medicines that may offer a major advance in treatment where none currently exists. This designation shortens the review period by four months as compared to Standard Review. The Prescription Drug User Fee Act (PDUFA) target action date for retifanlimab is July 25, 2021.

SCAC is associated with human papillomavirus (HPV) and HIV infections and accounts for almost 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]

POD1UM-303/InterAACT 2 (NCT04472429), a Phase 3 trial of retifanlimab in combination with carboplatin and paclitaxel in patients with inoperable locally recurrent or metastatic SCAC, is now open and recruiting patients.

About POD1UM-202

POD1UM-202 (NCT03597295) is an open-label, single-arm, multicenter, Phase 2 study evaluating retifanlimab in patients with squamous cell carcinoma of the anal canal (SCAC) who have progressed on, or who are intolerant of, platinum-based chemotherapy. Retifanlimab 500 mg is administered intravenously every 4 weeks.

The primary endpoint is objective response rate (ORR) as determined by independent central review using RECIST v1.1. Secondary endpoints include additional measures of clinical benefit – 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 POD1UM-202, POD1UM-303 and several other Phase 1, 2 and 3 studies for patients with solid tumors including squamous cell carcinoma of the anal canal (SCAC), microsatellite instability-high endometrial cancer, Merkel cell carcinoma and non-small cell lung cancer, among others.

About Retifanlimab

Retifanlimab (formerly INCMGA0012), an investigational intravenous anti-PD1 antibody, 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 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 provide a meaningful treatment for patients with SCAC, the retifanlimab development program, 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; 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; greater than expected expenses; expenses relating to litigation or strategic activities; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended September 30, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.

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[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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