Incyte to Present Late-Breaking Phase 3 Results for Retifanlimab (Zynyz®) and Initial Data from Phase 1 CDK2 Inhibitor Program at the European Society of Medical Oncology (ESMO) Congress 2024

August 21, 2024

- Presidential Symposium to feature Phase 3 retifanlimab (Zynyz®) results in squamous cell anal carcinoma (SCAC); filing of supplemental Biologics License Application (sBLA) in SCAC planned by year end 2024

- Mini oral presentation to highlight initial Phase 1 data from potential first-in-class CDK2 inhibitor program in patients with CCNE1 ovarian and other advanced cancers

- Incyte to host an in-person analyst and investor event to review key data at ESMO, including new results from a later CDK2 data cut-off, on Saturday, September 14, 2024, from 1:00-2:30 p.m. ET (7:00-8:30 p.m. CEST)

WILMINGTON, Del.--(BUSINESS WIRE)--Aug. 21, 2024-- Incyte (Nasdaq: INCY) today announced that the Company will present key data from its oncology portfolio at the upcoming European Society of Medical Oncology (ESMO) Congress 2024, to be held September 13-17 in Barcelona and virtually.

"The data at ESMO underscore the progress across our oncology portfolio and the potential to impact patients where additional treatment options are needed. Notably, a Presidential Symposium will feature new, pivotal results from the Phase 3 POD1UM-303/InterAACT2 study of retifanlimab (Zynyz®) for the treatment of squamous cell anal carcinoma (SCAC). The POD1UM-303 data will support the supplemental Biologics License Application (sBLA) filing for retifanlimab in SCAC planned by year end 2024," said Pablo Cagnoni M.D., President, Head of Research and Development, Incyte. "We will also present new data on INCB123667, a potential first-in-class CDK2 inhibitor, which we believe has the potential to enhance outcomes and serve as a foundational treatment for platinum-resistant ovarian and other cancers."

Details on the abstracts accepted for presentation at ESMO include:

Presidential Symposium

Retifanlimab (PD-1)
POD1UM-303/InterAACT2: Phase 3 Study of Retifanlimab With Carboplatin-Paclitaxel (C-P) in Patients (Pts) With Inoperable Locally Recurrent or Metastatic Squamous Cell Carcinoma of the Anal Canal (SCAC) Not Previously Treated With Systemic Chemotherapy
Presidential Symposium I: Practice-changing trials. Presentation Number: LBA2. Presentation Time: 10:50-11:02 a.m. ET (4:50-5:02 p.m. CET), September 14, 2024

Mini Oral Session

INCB123667
Safety and Tolerability of INCB123667, a Selective CDK2 Inhibitor, in Patients (Pts) With Advanced Solid Tumors: A Phase 1 Study
Mini oral session: Developmental therapeutics. Presentation Number: 617MO. Presentation Time: 9:35 – 9:40 a.m. ET (3:35-3:40 p.m. CET), September 14, 2024

Conference Call and Webcast
Incyte will host an in-person analyst and investor event on Saturday, September 14, 2024, from 1:00-2:30 p.m. ET (7:00-8:30 p.m. CEST) to discuss key data presentations at ESMO including data from the POD1UM-303 Presidential Symposia and its CDK2 inhibitor program. The CDK2 data presentation will include new results from a later data cut-off, as well as the data included in the ESMO accepted abstract and mini-oral presentation. The event will be webcasted and can be accessed via the Events and Presentations tab of the Investor section of Incyte.com and it will be available for replay for 90 days.

Conference call details will be provided on the Investor section of Incyte.com.

Abstracts will be available to registered attendees on the ESMO Virtual Congress platform beginning on September 9, 2024. All accepted abstracts will be published in the ESMO Congress 2024 Abstract Book, a supplement to the official ESMO journal, *Annals of Oncology*.

More information regarding the 2024 ESMO Congress can be found at https://www.esmo.org/meeting-calendar/esmo-congress-2024.

About Retifanlimab (Zynyz®)
Retifanlimab (Zynyz®), is an intravenous PD-1 inhibitor indicated in the U.S. for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC). 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 U.S. In 2017, Incyte entered into an exclusive collaboration and license agreement with MacroGenics, Inc. for global rights to retifanlimab.

Zynyz is a trademark of Incyte.

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. 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 the presentation of data from Incyte's clinical development pipeline, the potential for retifanlimab and INCB123667 to positively impact patients and plans to submit an sBLA for retifanlimab in SCAC by year end 2024, contain predictions, estimates, and other forward-looking statements.

These forward-looking statements are based on our 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 and the ability to enroll subjects in accordance with planned schedules; determinations made by the FDA and regulatory agencies outside of the United States; the efficacy or safety of our products; the acceptance of our products in the marketplace; market competition; unexpected variations in the demand for our products and the products of our collaboration partners; the effects of announced or unexpected price regulation or limitations on reimbursement or coverage for our products; sales, marketing, manufacturing, and distribution requirements, including our ability to successfully commercialize and build commercial infrastructure for newly approved products and any additional new products that become approved; 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 June 30, 2024. We disclaim any intent or obligation to update these forward-looking statements.

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