Updated Phase 1 Data Reinforce the Clinical Profile of Epacadostat in Combination with Keytruda® (Pembrolizumab)

September 28, 2016

Incyte's IDO1 inhibitor in combination with Merck's anti-PD-1 therapy is well-tolerated and demonstrates durable clinical response in patients with treatment-naïve advanced melanoma

WILMINGTON, Del.--(BUSINESS WIRE)--Sep. 28, 2016-- Incyte Corporation (Nasdaq: INCY) today announced that the European Society for Medical Oncology (ESMO) has published an abstract (#1110PD) containing updated data from the Phase 1 portion of the ECHO-202 trial evaluating the safety and efficacy of epacadostat, Incyte's selective IDO1 enzyme inhibitor, in combination with Keytruda ® (pembrolizumab), Merck's anti-PD-1 therapy. These data will be highlighted in a poster discussion on Monday, 10 October 2016 from 11:00-12:00 CET at the ESMO Annual Congress 2016 in Copenhagen, Denmark.

In patients with treatment-naïve advanced melanoma (n=19), updated data show a disease control rate (DCR) of 74 percent and an overall response rate (ORR) of 58 percent. All responses are confirmed and ongoing (median follow-up 42 weeks); median progression-free survival (PFS) has not been reached.

"We are very pleased that after extended treatment and longer follow-up, these updated Phase 1 data for epacadostat in combination with pembrolizumab demonstrate robust, durable clinical activity in patients with treatment-naïve advanced melanoma and reinforce the promise of IDO1 inhibition in combination with an anti-PD-1 therapy as an important component of immunotherapy," said Steven Stein, M.D., Incyte's Chief Medical Officer.

Epacadostat in combination with pembrolizumab was well-tolerated. The most common (≥15%) all grade treatment-related adverse events (TRAEs) were fatigue, rash, arthralgia, pruritus, diarrhea and nausea. Grade ≥3 TRAEs were observed in 18% of patients; the most common were rash (8%) and increased lipase (3%).

The ECHO-202 abstract was made available today on the ESMO Congress website at http://esmo.org/Conferences/ESMO-2016-Congress.

The ECHO-202 poster is expected to be made available to attendees at the ESMO Congress on Friday, 7 October 2016, at which time the ECHO-202 poster will be made available via the Events and Presentations tab of the Investor section of www.incyte.com. Incyte will also host an investor conference call and webcast at 14:00 CET (8:00 a.m. ET) on 7 October 2016 which can be accessed via the Events and Presentations tab of the Investor section of www.incyte.com.

About ECHO-202 (KEYNOTE-037)

The ECHO-202 study (NCT02178722) is evaluating the safety and efficacy of epacadostat, Incyte's selective IDO1 inhibitor, in combination with pembrolizumab. Patients previously treated with anti-PD-1 or anti-CTLA-4 therapies were excluded from this trial. Enrollment is complete for the Phase 1 dose escalation (epacadostat 25, 50, 100 mg BID + pembrolizumab 2 mg/kg IV Q3W and epacadostat 300 mg BID + pembrolizumab 200 mg IV Q3W) and Phase 1 dose expansion (epacadostat 50, 100, and 300 mg BID + pembrolizumab 200 mg IV Q3W) portions of the trial. Enrollment in the Phase 2 tumor-specific cohorts is ongoing.

About ECHO

The ECHO clinical trial program was established to investigate the efficacy and safety of epacadostat as a core component of combination therapy in oncology. Ongoing Phase 1 and Phase 2 studies evaluating epacadostat in combination with PD-1 and PD-L1 inhibitors collectively plan to enroll over 900 patients in a broad range of solid tumor types, as well as hematological malignancies. ECHO-301 (NCT02752074), a Phase 3 randomized, double-blind, placebo-controlled study evaluating pembrolizumab in combination with epacadostat or placebo as first-line treatment for patients with advanced or metastatic melanoma, is also underway. ECHO-301 was initiated in June 2016 and initial data from this study are expected to be available in 2018.

About Epacadostat (INCB024360)

Indoleamine 2,3-dioxygenase 1 (IDO1) is a key immunosuppressive enzyme that modulates the anti-tumor immune response by promoting regulatory T cell generation and blocking effector T cell activation, thereby facilitating tumor growth by allowing cancer cells to avoid immune surveillance. Epacadostat is a first-in-class, highly potent and selective oral inhibitor of the IDO1 enzyme that reverses tumor-associated immune suppression and restores effective anti-tumor immune responses. In single-arm studies, the combination of epacadostat and immune checkpoint inhibitors has shown proof-of-concept in patients with unresectable or metastatic melanoma. In these studies, epacadostat combined with the CTLA-4 inhibitor ipilimumab or the PD-1 inhibitor pembrolizumab improved response rates compared with studies of the immune checkpoint inhibitors alone.

Conference Call Information

To access the conference call, please dial 877-407-9221 for domestic callers or +1-201-689-8597 for international callers. When prompted, provide the conference identification number, 13644034.

If you are unable to participate, a replay of the conference call will be available for 30 days. The replay dial-in number for the United States is 877-660-6853 and the dial-in number for international callers is +1-201-612-7415. To access the replay you will need the conference identification number, 13644034.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company's website at www.incyte.com.

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Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the presentation and discussion of data regarding the Company's ECHO-202 study and the expected timetable for availability of initial data from its ECHO-301 study, 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 and the risks related to the efficacy or safety of the Company's development pipeline, the results of further research and development, the high degree of risk and uncertainty associated with drug development, clinical trials and regulatory approval processes, other market or economic factors and competitive and technological advances; 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 June, 2016. Incyte disclaims any intent or obligation to update these forward-looking statements.

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