Additional Phase 1 Data from ECHO-202 Reinforce Durability of Response in Patients with Treatment-naive Advanced or Metastatic Melanoma Treated with Epacadostat in Combination with Keytruda® (pembrolizumab)

October 7, 2016

Updated data published at ESMO to be discussed on Incyte investor conference call and webcast today, 7 October, at 14:00 CET / 8:00 a.m. ET

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 7, 2016-- Incyte Corporation (Nasdaq:INCY) today announced that updated data from the Phase I portion of the ECHO-202 trial evaluating the safety and efficacy of epacadostat, Incyte's selective IDO1 enzyme inhibitor, in combination with pembrolizumab (Keytruda®)*, Merck's anti-PD-1 therapy, have been published as a poster at the European Society for Medical Oncology (ESMO) Annual Congress 2016 in Copenhagen, Denmark.

Further to the previously published abstract, today's updated data show that among patients with treatment-naïve advanced melanoma (n=19), the combination of epacadostat plus pembrolizumab resulted in progression-free survival (PFS) rates of 74 percent and 57 percent at 6 months and 12 months, respectively. Median PFS has not been reached. The updated data also show an increase in the complete response (CR) rate to 26 percent. The objective response rate (ORR) and disease control rate (DCR) remained consistent with the previously published abstract data, at 58 percent and 74 percent, respectively. All responses are confirmed and ongoing (median follow-up among responders 56 plus [range of 46 to 90 plus] weeks).

"We are excited to share further data with additional follow-up from the Phase 1 portion of the ECHO-202 study," said Steven Stein, M.D., Incyte's Chief Medical Officer. "The durable responses seen in patients with treatment-naïve advanced or metastatic melanoma reaffirm the activity of this immunotherapy combination, and we look forward to the read-out of ECHO-301, the ongoing, pivotal Phase 3 trial."

Epacadostat in combination with pembrolizumab was well tolerated in the Phase 1 population (n=62). The most common (≥15%) all grade treatment-related AEs (TRAEs) were fatigue, rash, pruritus, arthralgia, diarrhea and nausea. Grade ≥3 TRAEs were observed in 19 percent of patients; the most common were rash (8%) and increased lipase (5%). Five patients (8%) discontinued treatment due to TRAEs.

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