New Data for Epacadostat in Combination with KEYTRUDA® (pembrolizumab) Demonstrate Durable Responses in Patients with Advanced Melanoma

August 30, 2017

Updated Phase 1 and new Phase 2 data from the ECHO-202 trial to be highlighted as an oral presentation at ESMO 2017 Congress

WILMINGTON, Del.--(BUSINESS WIRE)--Aug. 30, 2017-- Incyte Corporation (Nasdaq:INCY) today announced that the European Society for Medical Oncology (ESMO) has published an abstract (#1214O) containing new and updated data from the ongoing Phase 1/2 ECHO-202 trial evaluating epacadostat, Incyte's selective IDO1 enzyme inhibitor, in combination with the anti-PD-1 KEYTRUDA ® (pembrolizumab), marketed by Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada), in patients with advanced melanoma.

"We are encouraged by these additional data from our ECHO-202 trial, which demonstrate robust and durable responses in patients with advanced melanoma treated with the combination of epacadostat and KEYTRUDA," said Steven Stein, M.D., Chief Medical Officer, Incyte. "These results further underscore the potential of this novel immunotherapy combination, and we look forward to reporting more detailed results from this study at ESMO next month."

Key Findings from the ECHO-202 Advanced Melanoma Cohort

Results of efficacy evaluable patients (N=54) as of February 27, 2017 include:

ECHO-202 Overall Response Rates (ORR), Disease Control Rates (DCR) and Durability of Response (DoR) in Advanced Melanoma

n/N (%)	All Patients	Treatment-Naïve Advanced Melanoma Patients	Treatment-Naïve Advanced Melanoma Patients (epacadostat 100 mg BID)
ORR	30/54 (56)	25/45 (56)	18/30 (60)
	8 CR (15) 22 PR (41)	6 CR (13) 19 PR (42)	2 CR (7) 16 PR (53)
DCR	42/54 (78)	35/45 (78)	Not yet reported
DoR	28/30 responses ongoing Median (range) duration of response: 287.5+ (1+ to 763+) days		

Across all efficacy-evaluable advanced melanoma patients, median progression-free survival (PFS) was 12.4 months, with PFS rates of 70 percent, 54 percent, and 50 percent at 6 months, 12 months, and 18 months respectively. In patients who were treatment-naïve for advanced disease, median PFS has not been reached, with landmark PFS rates of 68 percent, 52 percent, and 52 percent at 6 months, 12 months, and 18 months respectively.

Epacadostat in combination with KEYTRUDA was well-tolerated. The most common (≥15 percent) all grade treatment-related adverse events (TRAEs) were fatigue (39 percent), rash (33 percent), pruritus (27 percent), and arthralgia (16 percent). Grade ≥3 TRAEs were observed in 17 percent of patients; the most common were increased lipase (n=4), rash (n=3), and increased amylase (n=2). Three patients discontinued for TRAEs. No treatment-related deaths occurred.

The abstract was made available today on the ESMO Congress website at http://esmo.org/Conferences/ESMO-2017-Congress.

Updated data from ECHO-202 will be highlighted in an oral presentation on Saturday, 9 September 2017 from 15:00 – 15:15 CET at the ESMO 2017 Congress in Madrid, Spain. Following the presentation, Incyte will host an investor conference call and webcast at 17:00 CET (11:00 a.m. ET) on 9 September 2017—the call and webcast 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 enzyme inhibitor, in combination with KEYTRUDA. 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 + KEYTRUDA 2 mg/kg IV Q3W and epacadostat 300 mg BID + KEYTRUDA 200 mg IV Q3W) and Phase 1 dose expansion (epacadostat 50, 100, and 300 mg BID + KEYTRUDA 200 mg IV Q3W) portions of the trial. For more information about ECHO-202, visit https://clinicaltrials.gov/ct2/show/NCT02178722.

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 are evaluating epacadostat in combination with PD-1 and PD-L1 inhibitors 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 investigating KEYTRUDA in combination with epacadostat or placebo for the treatment of patients with unresectable or metastatic melanoma, is also ongoing and fully recruited. For more information about the ECHO clinical trial program, visit www.ECHOClinicalTrials.com.

About Epacadostat (INCB024360)

The immunosuppressive effects of indoleamine 2,3-dioxygenase 1 (IDO1) enzyme activity on the tumor microenvironment help cancer cells evade immunosurveillance. Epacadostat is an investigational, highly potent and selective oral inhibitor of the IDO1 enzyme. In single-arm studies, the combination of epacadostat and immune checkpoint inhibitors has shown proof-of-concept in patients with unresectable or metastatic melanoma, non-small cell lung cancer, renal cell carcinoma, squamous cell carcinoma of the head and neck and bladder cancer. In these studies, epacadostat combined with the CTLA-4 inhibitor ipilimumab or the PD-1 inhibitors KEYTRUDA or nivolumab improved response rates compared with studies of the immune checkpoint inhibitors alone.

Conference Call Information

To access the conference call on Saturday 9 September 2017, please dial 877-407-3042 for domestic callers or +1-201-389-0864 for international callers. When prompted, provide the conference identification number, 13667084.

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, 13667084.

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 of updated ECHO-202 data at ESMO, whether epacadostat and KEYTRUDA may be an effective and safe treatment for advanced melanoma patients, and expectations for presentation of data from the ECHO-301 trial, 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 30, 2017. Incyte disclaims any intent or obligation to update these forward-looking statements.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. KEYTRUDA is marketed by Merck (known as MSD outside the United States and Canada).

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