Progression-Free Survival Data from ECHO-202 Trial of Incyte's Epacadostat in Combination with KEYTRUDA® (pembrolizumab) Underscore Durability of Response in Patients with Advanced Melanoma

September 9, 2017

Updated Data to be Presented at ESMO 2017 Congress

WILMINGTON, Del.--(BUSINESS WIRE)--Sep. 9, 2017-- Incyte Corporation (Nasdaq:INCY) today announced updated data from the ongoing Phase 1/2 ECHO-202 trial (KEYNOTE-037) evaluating epacadostat, Incyte's selective IDO1 enzyme inhibitor, in combination with KEYTRUDA ® (pembrolizumab), an anti-PD-1 therapy marketed by Merck & Co., Inc., Kenilworth, NJ USA (known as MSD outside the United States and Canada), in patients with advanced melanoma. Among all patients with advanced melanoma, including treatment-naïve and treatment-experienced, data showed an overall response rate (ORR) of 56 percent (n=35/63) in patients treated with the combination of epacadostat and KEYTRUDA; median progression-free survival (PFS) was 12.4 months, with PFS rates of 65 percent at six months, 52 percent at 12 months, and 49 percent at 18 months. Results were generally consistent across dosing schedules of epacadostat combined with KEYTRUDA, including epacadostat 100 mg BID, the epacadostat dose being studied in the Phase 3 ECHO-301 trial.

These results will be presented at the European Society for Medical Oncology (ESMO) 2017 Congress in Madrid, Spain, in an oral presentation on Saturday, September 9 from 3-3:15 pm CEST (Location: Madrid Auditorium) (Abstract #1214O).

"The updated results of the ECHO-202 trial support earlier published findings, and continue to suggest that the novel immunotherapy combination of epacadostat plus KEYTRUDA has the potential to offer a favorable efficacy and safety profile for the treatment of patients with advanced melanoma," said Omid Hamid, M.D., Chief of Translational Research and Immuno-Oncology and Director of Melanoma Therapeutics, The Angeles Clinic and Research Institute, Los Angeles, California. "Data have shown that combination immunotherapy can offer higher response rates and improved progression-free survival. These results show that this combination has demonstrated increased and durable response rates and improved progression-free survival, compared to what we would expect from KEYTRUDA alone, without sacrificing safety."

Key Findings from the ECHO-202 (KEYNOTE-037) Melanoma Cohort

Data at ESMO (as of June 9, 2017) show an ORR of 56 percent among all patients with advanced melanoma treated with the combination of epacadostat and KEYTRUDA, with a complete response (CR) in nine patients (14%); partial response (PR) in 26 patients (41%); and stable disease (SD) in 10 patients (16%). Data also show a disease control rate (DCR) of 71 percent (n=45/63). Of the 35 responses to treatment, 30 were ongoing at the time of analysis; the median duration of response was 45 weeks (range: 1+ to 121+).

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

	All Patients (N=65)	**Treatment-Naïve** (all epacadostat doses) (N=54)	**Treatment-Naïve** (epacadostat 100 mg BID) (N=39)
Per-protocol evaluable n (%)[1]	n=63	n=53	n=38
ORR	35 (56)	29 (55)	22 (58)
	9 CR (14) 26 PR (41) 10 SD (16)	7 CR (13) 22 PR (42) 9 SD (17)	3 CR (8) 19 PR (50) 6 SD (16)
DCR	45 (71)	38 (72)	28 (74)
	18 PD or death (29) 2 not evaluable[2]	15 PD or death (28) 1 not evaluable[2]	10 PD or death (26) 1 not evaluable[2]
DoR	30/35 responses ongoing Duration of response: <1+ to 121+ weeks 4/5 patients completing study treatment maintained ongoing response at last follow-up	25/29 responses ongoing Duration of response: <1+ to 121+ weeks 3/4 patients completing study treatment maintained ongoing response at last follow-up	20/22 responses ongoing Duration of response: <1+ to 81+ weeks 1/1 patient completing study treatment maintained ongoing response at last follow-up
Median PFS, months (90% CI)	12.4 (6.2, 23.8)	22.8 (6.2, 23.8)	Not yet reached (4.2, NR)
PFS rate, % (90% CI)	6-month: 65 (54, 74) 12-month: 52 (40, 63) 18-month:	6-month: 65 (53, 75) 12-month: 52 (38, 64) 18-month:	6-month: 64 (49, 76) 12-month: 55 (39, 69) 18-month:

	49 (37, 60)	52 (38, 64)	55 (39, 69)

1. ≥1 post-baseline scan, or discontinuation or death before first post-baseline scan

2. Scan data not documented in the clinical trial database at time of data cutoff

The most common (≥10 percent) all grade treatment-related adverse events (TRAEs) were rash (46 percent), fatigue (43 percent), pruritus (29 percent), and arthralgia (17 percent). Grade ≥3 TRAEs were observed in 20 percent of patients; the most common were increased lipase (6 percent) and rash (5 percent). Four patients (6 percent) discontinued for TRAEs. No treatment-related deaths occurred. The safety profile was consistent with previously reported Phase 1 findings, as well as the Phase 1/2 safety results in other tumor cohorts and pooled safety data from this study. In general, the safety profile of the combination was also consistent with KEYTRUDA (pembrolizumab) monotherapy.

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.

Incyte Conference Call Information

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.

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 Statement of Incyte Corporation

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding whether the combination of epacadostat plus KEYTRUDA will offer a safe and effective treatment for patients with advanced melanoma and the phase 3 trial of epacadostat in combination with KEYTRUDA for the treatment of melanoma, 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.

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