New Data for Presentation at ASCO 2017 Reinforce Clinical Profile of Epacadostat in Combination with Keytruda® (pembrolizumab)

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Incyte's IDO1 enzyme inhibitor in combination with Merck's anti-PD-1 therapy is well-tolerated and demonstrates durable clinical responses across multiple solid tumors

WILMINGTON, Del.--(BUSINESS WIRE)--May 17, 2017-- Incyte Corporation (Nasdaq:INCY) today announced the publication of new data from the ongoing ECHO-202 trial, evaluating epacadostat, Incyte's selective IDO1 enzyme inhibitor, in combination with Keytruda ® (pembrolizumab), Merck's anti-PD-1 therapy. Abstracts published online by the American Society of Clinical Oncology (ASCO) in advance of its annual meeting in Chicago, Illinois, June 2-6, 2017 include ECHO-202 Phase 1/2 efficacy and safety data from the following cohorts: non-small cell lung cancer (NSCLC), renal cell carcinoma (RCC), bladder cancer, squamous cell carcinoma of the head and neck (SCCHN), triple-negative breast cancer (TNBC), and ovarian cancer (OVC). Pooled Phase 2 safety data across cohorts were also released today.

"We are very pleased to share these new data for epacadostat in combination with pembrolizumab. The combination is well-tolerated and preliminary efficacy outcomes for these cohorts demonstrate encouraging clinical activity, both within and across tumor types, which compares favorably to contemporary data in the second-line setting. These data, including updated data which will be presented at ASCO next month, supported the recently-announced progression of the epacadostat and pembrolizumab combination into pivotal trials in NSCLC, RCC, bladder cancer and SCCHN," said Steven Stein, M.D., Chief Medical Officer, Incyte.

ECHO-202 abstract data for the tumor types entering Phase 3 (data cut as of October 29, 2016) include:

n/N (%)	NSCLC			UC		SCCHN			RCC		
	All pts	0-2 prior lines of therapy for advanced disease		All pts	Prior Lines of Treatment	All pts	Prior Lines of Treatment		All pts	Prior Lines of Treatment	
	Total	TPS ≥50%	TPS <50%	Total	0-1	Total	1-2	≥3	Total	0-1	≥2
ORR	14/40 (35)	3/7 (43)	6/17 (35)	13/37 (35)	10/27 (37)	11/36 (31)	10/29 (34)	1/7 (14)	9/30 (30)	9/19 (47)	0/11 (0)
	all PR	all PR	all PR	all PR	all PR	2 CR, 9 PR	2 CR, 8 PR	1 PR	1 CR, 8 PR	1 CR, 8 PR	-
DCR	24/40 (60)	4/7 (57)	9/17 (53)	21/37 (57)	17/27 (63)	21/36 (58)	18/29 (62)	3/7 (43)	15/30 (50)	11/19 (58)	4/11 (36)
DoR	12/14 responses ongoing range 1+ - 519 days			12/13 responses ongoing range 1+ - 652+ days		9/11 responses ongoing range 1+ - 563+ days			9/9 responses ongoing range 1+ - 372+ days		

In a pooled analysis evaluating 244 patients in the ECHO-202 Phase 2 safety population (abstract #3012), treatment-related adverse events (TRAEs) that occurred in ≥5 percent of patients, included fatigue (23 percent); rash (16 percent); diarrhea and nausea (7 percent each); increased alanine aminotransferase, increased aspartate aminotransferase, and pruritus (6 percent each); and pyrexia (5 percent). A total of 37 patients (15 percent) experienced Grade ≥3 TRAEs; the most common of which were increased lipase (asymptomatic) and rash (3 percent each). TRAEs led to discontinuation of treatment in 3 percent of study patients.

These abstracts, including data for TNBC and OVC (abstract #1103), were made available today on the ASCO website at www.asco.org.

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. 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 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 investigating KEYTRUDA in combination with epacadostat or placebo for the treatment of patients with unresectable or metastatic melanoma, is also underway. For more information about the ECHO clinical trial program, visit www.ECHOClinicalTrials.com.

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 regulates the tumor immune microenvironment, thereby restoring 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.

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 planned pivotal trials of epacadostat in combination with pembrolizumab, 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 March 31, 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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