

Combination of Epacadostat plus Keytruda® (pembrolizumab) Demonstrates Activity in Clinical Trial of Patients with Advanced Non-Small Cell Lung Cancer (NSCLC)

June 3, 2017

Updated Phase 1/2 data from ECHO-202 investigating the combination of IDO1 enzyme inhibition and anti-PD-1 therapy in patients with advanced NSCLC, regardless of PD-L1 status, presented at 2017 ASCO Annual Meeting

WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 3, 2017-- Incyte Corporation (NASDAQ:INCY) today announced updated data from the advanced non-small cell lung cancer (NSCLC) patient cohort of the ongoing Phase 1/2 ECHO-202 trial, evaluating epacadostat, Incyte's selective IDO1 enzyme inhibitor, in combination with pembrolizumab (Keytruda®), an anti-PD-1 therapy marketed by Merck & Co., Inc., Kenilworth, NJ USA (known as MSD outside the United States and Canada). Data showed an overall response rate (ORR) of 35 percent (n=14/40) among all patients with advanced squamous and non-squamous NSCLC treated with the combination of epacadostat and pembrolizumab, irrespective of PD-L1 status. Findings will be highlighted in a poster discussion at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago on Saturday, June 3, from 3:00 pm to 4:15 p.m. CDT (Location: Hall D2) (Abstracts #9014).

"These updated data suggest that the combination of epacadostat and pembrolizumab has promise for patients with advanced NSCLC, irrespective of PD-L1 status," said ECHO-202 study investigator Tara Gangadhar, M.D., Assistant Professor of Medicine, Perelman School of Medicine at the Hospital of the University of Pennsylvania. "The results show a clinical benefit for patients with advanced lung cancer and establish a strong basis for progressing this novel, investigational immunotherapy combination into pivotal studies for the first-line treatment of these patients."

Key Findings from the ECHO-202 NSCLC Cohort

Data at ASCO (as of February 27, 2017) show an ORR of 35 percent (n=14/40) among all patients with advanced NSCLC treated with the combination of epacadostat and pembrolizumab, with a complete response (CR) in two patients (5%) and partial response (PR) in 12 patients (30%). The data show a disease control rate (DCR) of 63 percent (n=25/40), with 71 percent (n=10/14) of responses ongoing at the time of the data cut-off (duration of response, range: 8.9 to 76.6+ weeks). Responses were observed in patients with high levels of PD-L1 expression [tumor proportion score (TPS) ≥50%], as well as in those patients with lower levels of PD-L1 expression (TPS of less than 50%). All responses were observed in the subgroup of patients with zero to two prior lines of therapy for advanced disease.

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

n/N (%)	All pts	0-2 prior lines of therapy for advanced disease		
	Total	Total	TPS ≥50%*	TPS <50%*
ORR	n=14/40 (35)	n=14/36 (39)	n=3/7 (43)	n=6/18 (33)
	2 CR (5)	2 CR (6)	all PR	
	12 PR (30)	12 PR (33)		5 PR (28)
DCR	n=25/40 (63)	n=23/36 (64)	n=4/7 (57)	n=10/18 (56)
DoR	10/14 responses ongoing			
	Median (range) duration of response: 26.9+ (8.9 to 76.6+) weeks			

*Note: PD-L1 status was not available for 11 of the 36 patients.

Among patients treated with pembrolizumab in combination with epacadostat ≥100 mg twice daily, the ORR was 40 percent (n=14/35).

The most common treatment-related adverse events (TRAEs) for epacadostat plus pembrolizumab included fatigue (28%), arthralgia (17%), nausea (14%), decreased appetite (10%), pruritus (10%), and rash (10%). Grade ≥3 TRAEs that occurred in >1 patient were limited to lipase increased (n=3), fatigue (n=2), and rash (n=2). TRAEs led to discontinuation of treatment in 5 percent of study patients. 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 pembrolizumab monotherapy.

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 (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 + 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 pembrolizumab (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 an investigational, 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 KEYTRUDA 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 Statement of Incyte Corporation

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 ASCO, whether epacadostat and pembrolizumab may be an effective and safe treatment for NSCLC patients, 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., Kenilworth, NJ USA



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