



First Data from Combination of Epacadostat with Opdivo® (nivolumab) Will Be Highlighted at ASCO 2017

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Combination is well-tolerated and demonstrates promising clinical outcomes in multiple advanced solid tumors

WILMINGTON, Del.--(BUSINESS WIRE)--May 17, 2017-- Incyte Corporation (Nasdaq:INCY) today announced that the American Society of Clinical Oncology (ASCO) has published Phase 1/2 data from the ongoing ECHO-204 trial evaluating the safety and efficacy of epacadostat, Incyte's selective IDO1 enzyme inhibitor, in combination with Opdivo® (nivolumab), Bristol-Myers Squibb's PD-1 immune checkpoint inhibitor. Efficacy data in patients with squamous cell carcinoma of the head and neck (SCCHN), melanoma (MEL), ovarian cancer (OVC), and colorectal cancer (CRC), as well as overall safety data will be highlighted in an oral presentation at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago, Illinois from June 2-6, 2017.

"These first Phase 1/2 data from our ECHO-204 trial evaluating epacadostat plus nivolumab in multiple solid tumors add to our knowledge of the therapeutic potential of IDO1 enzyme inhibition when combined with PD-1 blockade," said Steven Stein, M.D., Chief Medical Officer, Incyte. "These results show that the combination was well-tolerated across patients studied and demonstrates promising clinical responses, particularly in melanoma and SCCHN. We look forward to sharing updated data from these cohorts at ASCO next month, and to progressing our clinical development program for this combination into pivotal studies."

ECHO-204 Abstract Highlights

ECHO-204 evaluated the safety and efficacy of the epacadostat and nivolumab combination in 241 patients (data cut-off as of October 29, 2016). In 30 patients with MEL treated with nivolumab plus epacadostat at 100 mg or 300 mg, the combined disease control rate (DCR; defined as complete response + partial response + stable disease) was 73 percent (22/30). In patients with SCCHN treated with nivolumab plus epacadostat 300 mg, the preliminary DCR was 70 percent (16/23). Response rates based on updated data will be presented at the ASCO Annual Meeting.

In Phase 1 (dose escalation), 36 patients were enrolled and no dose-limiting toxicities were observed. Among the 205 patients enrolled in Phase 2, the most frequent treatment-related adverse events (TRAEs) (≥15 percent) in patients receiving epacadostat 100 mg BID (70/205) and 300 mg BID (135/205) were rash (33 percent and 22 percent, respectively), fatigue (26 percent and 31 percent), and nausea (24 percent and 19 percent). Rash was the most common ≥3 TRAE (10 percent and 12 percent). TRAEs led to discontinuation in 7 percent (100 mg) and 13 percent (300 mg) of patients. There were no treatment-related deaths.

This ECHO-204 abstract (#3003) was made available today on the ASCO website at www.asco.org.

About ECHO-204

The ECHO-204 study (NCT02327078) is a Phase 1/2 study evaluating the safety and efficacy of epacadostat, Incyte's selective IDO1 inhibitor, in combination with nivolumab in subjects with select advanced solid tumors and lymphomas, including melanoma (MEL), non-small cell lung cancer (NSCLC), colorectal cancer (CRC), head and neck squamous cell carcinoma (SCCHN), ovarian cancer, and B cell non-Hodgkin lymphoma (NHL) or Hodgkin lymphoma (HL). Patients previously treated with anti-PD-1 or anti-CTLA-4 therapies were excluded from this trial. Enrollment for the Phase 2 (epacadostat 100 or 300 mg BID + nivolumab 240 Q2W) tumor-specific cohorts is ongoing. For more information about ECHO-204, visit <https://clinicaltrials.gov/ct2/show/NCT02327078>.

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. 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-204 study, whether and when epacadostat in combination with nivolumab will continue to show

promising clinical responses or progress into pivotal trials, 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.

Opdivo is a registered trademark of Bristol-Myers Squibb. Bristol-Myers Squibb holds development and commercial rights to *Opdivo* globally except for in the Ono Pharmaceutical territories of Japan, South Korea and Taiwan.



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