Incyte Presents Final Results from a Phase I Trial of INCB024360, a Novel Oral Immunotherapy, at ASCO

June 1, 2013

- ***Data demonstrate that INCB024360 achieves greater than 90 percent inhibition of IDO1 at generally well-tolerated doses and may represent a new treatment option for advanced malignancies***
- ***Data suggest the potential for INCB024360 to be used as monotherapy or in combination with other cancer agents***

CHICAGO--(BUSINESS WIRE)--Jun. 1, 2013-- Incyte Corporation (Nasdaq: INCY) presented final results today from the Phase I clinical trial for its oral indoleamine dioxygenase-1 (IDO1) inhibitor, INCB024360, at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. IDO1 inhibition may provide a new approach in enhancing the immune system in patients with a variety of solid tumors.

“IDO1 is an enzyme that works to restrain anti-tumor immunity. When IDO1 is activated in cancer patients with a number of tumor types, their prognosis is poor. A compound such as INCB024360, which can significantly inhibit IDO enzyme activity, may remove an important impediment to an anti-tumor immune response at doses that appear to be well-tolerated. IDO inhibition provides another immunotherapeutic approach that may lead to significant advances in the treatment of cancer patients,” stated presenting author Gregory Beatty, MD, PhD, an Assistant Professor in the Department of Medicine, Hematology/Oncology Division, at the Abramson Cancer Center and the Perelman School of Medicine at the University of Pennsylvania in Philadelphia.

The findings of the Phase I study were reported during a discussion session of the poster, *Phase I Study of the Safety, Pharmacokinetics and Pharmacodynamics of the Oral Inhibitor of Indoleamine 2,3-dioxygenase INCB024360 in Patients with Advanced Malignancies.* The Phase I study of INCB024360 is an open-label, single-agent dose-escalation trial in 52 patients with advanced malignancies. Using two independent pharmacodynamic assays, IDO1 inhibition was observed in all patients receiving the compound. Treatment with a number of doses of INCB024360 resulted in greater than 90 percent inhibition of IDO1 activity, which were well tolerated with no maximum tolerated dose established. The most common grade 1 or 2 adverse events were fatigue and gastrointestinal disturbances, and the most common grade 3 or 4 adverse events were abdominal pain, hypokalemia and fatigue.

“Results from this first Phase I study are encouraging. The compound was clearly well-tolerated and led to stable disease for greater than 8 weeks in approximately 30 percent of these highly refractory patients, half of whom had colorectal cancer, which has been refractory to most immune therapy approaches. Additionally, duration of therapy with INCB024360 exceeded duration seen with prior therapies, including two melanoma patients previously treated with ipilimumab. Together, these results suggest that INCB024360 has the potential to be effective as monotherapy but may be particularly useful in combination with other cancer agents since it was so well-tolerated,” stated Lance Leopold, M.D., Vice President of Oncology Drug Development at Incyte. “We look forward to seeing results of the randomized Phase I/II study underway in advanced melanoma in combination with ipilimumab as well as the Phase II trial in patients with ovarian cancer in which INCB024360 is being evaluated as monotherapy.”

The poster can be accessed at: 2013 ASCO - INCB024360 poster

About Indoleamine Dioxygenase-1 (IDO1)

IDO1 is an enzyme that is expressed in tumor cells and in activated immune cells. IDO1 expression dampens the immune response by blocking the maturation of antigen presenting cells, increasing the formation of immune suppressor cells and rendering tumor-specific cytotoxic T lymphocytes functionally inactive. In preclinical models, blocking IDO1 activity can directly influence the ability of tumor-bearing animals to reject tumors in an immune dependent manner, and IDO1 inhibition increases the efficacy of chemotherapeutic agents without increased toxicity. IDO1 is overexpressed by a variety of human tumor types and is chronically activated in many patients with cancer.

IDO1 activation correlates with more extensive disease, and increased expression of IDO1 in tumor cells has been shown to be an independent prognostic factor for reduced survival in patients with cancer. Evidence suggests that the IDO1 pathway is a key regulatory element responsible for induction and maintenance of tumor immune tolerance and that small molecule inhibitors of IDO1 may provide an innovative and tractable method to treat advanced malignancies either alone or in combination with chemotherapeutics or immunotherapy-based strategies.

About INCB024360

INCB024360 is an orally bioavailable small molecule inhibitor of IDO1 that has nanomolar potency in both biochemical and cellular assays, potent activity in enhancing T lymphocyte, dendritic cell and natural killer cell responses in vitro, with a high degree of selectivity. INCB024360 has been shown to be efficacious in mouse models of cancer as a single agent and in combination with cytotoxic and immunotherapy agents, and its ability to reduce tumor growth is dependent on a functional immune system – consistent with its proposed mechanism of action. The Phase I dose-escalation trial demonstrated that INCB024360 results in greater than 90 percent inhibition of IDO1 activity at generally well-tolerated doses.

INCB024360 is currently in Phase I/II development for metastatic melanoma in combination with ipilimumab (www.clinicaltrials.gov Identifier: NCT01604889) and as monotherapy for ovarian cancer (www.clinicaltrials.gov Identifier: NCT01685255).

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of

proprietary small molecule drugs for oncology and inflammation. For additional information on Incyte, please visit the Company's website at www.incyte.com.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including without limitation statements with respect to the potential efficacy, safety and therapeutic value of, and plans for, INCB024360, including that INCB024360 may represent a new treatment option for advanced malignancies and have potential to be used as monotherapy or in combination with other cancer agents, that IDO1 inhibition may provide a new approach in enhancing the immune system in patients with a variety of solid tumors, that a compound such as INCB024360 may remove an important impediment to an anti-tumor immune response at doses that appear to be very well-tolerated, that IDO inhibition provides another immunotherapeutic approach that may lead to significant advances in the treatment of cancer patients, that the Phase I results suggest that INCB024360 has the potential to be effective as monotherapy and may be particularly useful in combination with other cancer agents, that evidence suggests that the IDO1 pathway is a key regulatory element responsible for induction and maintenance of tumor immune tolerance and that small molecule inhibitors of IDO1 may provide an innovative and tractable method to treat advanced malignancies either alone or in combination with chemotherapeutics or immunotherapy-based strategies, contain predictions and estimates and are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995.

These forward-looking statements are based on Incyte’s current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to the efficacy or safety of INCB024360, the results of further research and development, risks that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards, the ability to enroll sufficient numbers of subjects in clinical trials, other market or economic factors and technological advances, unanticipated delays, the ability of Incyte to compete against parties with greater financial or other resources, and other risks detailed from time to time in Incyte's filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2013. Incyte disclaims any intent or obligation to update these forward-looking statements.

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