Results from an Ongoing Phase I/II Trial of Oral INCB7839 Presented at ASCO

June 6, 2010

Data suggest that treatment with INCB7839 in combination with trastuzumab provides improved clinical responses in a subset of metastaticbreast cancer patients with p95HER2

WILMINGTON, Del., Jun 06, 2010 (BUSINESS WIRE) --Incyte Corporation (Nasdaq:INCY) announced today additional positive results from an ongoing Phase I/II clinical trial for its selective oral sheddase inhibitor, INCB7839, involving 66 patients with HER2-positive metastatic breast cancer during a poster session at the American Society of Clinical Oncology (ASCO) meeting in Chicago, IL, June 4 to June 8, 2010.

INCB7839 has been shown to markedly reduce the cleavage of the EGFR family member HER2 thereby inhibiting the release of the HER2 extracellular domain (ECD) and the generation of a constitutively active kinase in the remaining truncated HER2 protein (p95HER2). Data previously published by other groups have shown that these breast cancer patients, characterized as p95HER2-positive, tend to be resistant to chemotherapy and trastuzumab-based therapies and have poor clinical outcomes as compared to patients with full-length HER2, characterized as p95HER2-negative patients (Scaltriti et al 2007).

In contrast to outcomes reported for p95HER-positive patients in the published literature, results from this study suggest that, when treated with a combination of INCB7839 and trastuzumab, the subset of patients with p95HER2-positive metastatic cancer showed clinical benefit in terms of overall response rate (ORR) and progression-free survival (PFS) when compared to the p95HER2-negative patients.

"Biomarker and clinical results from this ongoing trial support our hypothesis that treatment with INCB7839 has the potential to inhibit HER2 cleavage and prevent the formation of the truncated, constitutively active kinase p95HER2. This activity, which is expected to restore and improve treatment with trastuzumab, may lead to improved therapeutic outcomes in p95HER2-positive breast cancer patients," stated Victor Sandor, Vice President, Global Oncology Drug Development at Incyte.

Study INCB7839-202

Study INCB7839-202 was initiated as a single-arm, dose-escalation trial of INCB7839 plus trastuzumab in women with HER2-positive metastatic breast cancer, naïve to chemotherapy. Three doses of INCB7839 were studied (100 mg, 200 mg, 300 mg BID) with an expansion group at the 300 mg dose. Trastuzumab was administered on a Q3 week schedule. Pharmacokinetics, plasma HER2 ECD levels and p95HER2 expression in primary tumor tissue were assessed in addition to clinical response and safety. The study was expanded to evaluate the addition of docetaxel to the INCB7839-plus-trastuzumab treatment regimen.

Thus far, 66 HER2-positive breast cancer patients have been enrolled in the study. Key findings include:

- Treatment with INCB7839 results in a dose-dependent reduction in plasma HER2 ECD.
- ORR was 41% versus 12% based on an intent-to-treat analysis (ITT) and the median PFS was 178 days versus 94 days for the p95HER2-positive and p95HER2-negative patients, respectively. This contrasts with the results of prior published studies conducted in the absence of INCB7839 where the ORR was lower and the PFS was shorter in p95HER2-positive patients.
- INCB7839 has been generally well-tolerated. Apart from thrombotic events, observed in 17% of patients, the frequency of adverse events and serious adverse events observed is similar to what is expected with trastuzumab alone.
- Of the 66 patients, 20 patients were enrolled in a group that received docetaxel in addition to the INCB7839-plus-trastuzumab regimen. Preliminary data, irrespective of p95HER2 status, demonstrate that the ORR in this group was 50% (N=20) and 59% (N=17), based on ITT and per protocol analyses, respectively.
- The combination of INCB7839 with trastuzumab and docetaxel has also been generally well tolerated.

A copy of the poster, *Clinical Benefit Of INCB7839, A Potent And Selective ADAM Inhibitor, In Combination With Trastuzumab In Metastatic HER2+ Breast Cancer Patients*, can be accessed at: http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NDg3NDZ8Q2hpbGRJRD0tMXxUeXBlPTM=&t=1

About Incyte

Incyte Corporation is a Wilmington, Delaware-based drug discovery and development company focused on developing proprietary small molecule drugs for oncology and inflammation. Incyte's most advanced compound, INCB18424, is in Phase III development for myelofibrosis. For additional information on Incyte, visit the Company's web site at www.incyte.com.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements with respect to data from the ongoing Phase I/II trial of oral INCB7839 suggesting that treatment with INCB7839 in combination with trastuzumab provides improved clinical responses in a subset of p95HER2-positive patients with metastatic breast cancer, results from this study suggesting that the subset of patients with p95HER2-positive metastatic cancer showed clinical benefit in terms of overall response rate and progression-free survival when compared to the p95HER2-negative patients, results from this study supporting Incyte's hypothesis that treatment with INCB7839 has the potential to inhibit HER2

cleavage and prevent the formation of the truncated, constitutively active kinase p95HER2 and Incyte's expectations that this activity may restore and improve treatment with trastuzumab and may lead to improved therapeutic outcomes in p95HER2-positive breast cancer patients, are all 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 subject to risks and uncertainties that may cause actual results to differ materially, including the high degree of risk and uncertainty associated with drug development and clinical trials, unanticipated developments in and risks related to the efficacy or safety of INCB7839 in clinical trials, the results of further research and development, risks related to the timing of and patient enrollment in clinical trials, 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, 2010. Incyte disclaims any intent or obligation to update these forward-looking statements.

SOURCE: Incyte Corporation

Incyte Corporation
Pamela M. Murphy
Vice President, Investor Relations/Corporate Communications
302-498-6944