Incyte and Foundation Medicine Announce Agreement to Develop Companion Diagnostic for Pemigatinib (INCB54828), a Selective FGFR Inhibitor, in Patients with Cholangiocarcinoma

September 11, 2018

WILMINGTON, Del. & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 11, 2018-- Incyte Corporation (NASDAQ:INCY) and Foundation Medicine, Inc., today announced that the companies have entered into an agreement for the development, regulatory support and commercialization of companion diagnostics (CDx), with an initial focus on CDx development for pemigatinib (INCB54828), Incyte's selective FGFR1/2/3 inhibitor, in patients with cholangiocarcinoma. The initial CDx, which will include detection of activating FGFR2 translocations, is expected to be incorporated into FoundationOne®CDx, Foundation Medicine's FDA-approved comprehensive genomic profiling (CGP) assay and broad CDx platform.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20180911005165/en/

"There is an urgent need for a novel, biomarker-based, targeted therapeutic approach for patients with cholangiocarcinoma. The initial goal of this collaboration is to develop a companion diagnostic to enable testing at diagnosis of stage IV disease, with the aim of helping to reduce morbidity and mortality, and we are very pleased to be working with Foundation Medicine as we seek to improve outcomes for these patients," said Steven Stein, M.D., Chief Medical Officer, Incyte. "Incyte is evaluating pemigatinib in patients with cholangiocarcinoma as part of the FIGHT clinical development program; initial data have been accepted for presentation at the European Society of Medical Oncology meeting in Munich this October."

"We're committed to helping our biopharma partners bring biomarker-driven therapies to cancer patients. Partnerships with innovative biopharma companies, such as Incyte, who leverage our FDA-approved platform to help accelerate companion diagnostics development, are essential to achieving this mission," said Melanie Nallicheri, Chief Business Officer and Head of Biopharma at Foundation Medicine. "We're proud to partner with Incyte to advance development of a potential new

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precision oncology treatment option for cholangiocarcinoma."

About FGFR and Pemigatinib (INCB54828)

Fibroblast growth factor receptors (FGFRs) play an important role in tumor cell proliferation and survival, migration and angiogenesis (the formation of new blood vessels). Activating mutations, translocations and gene amplifications in FGFRs are closely correlated with the development of various cancers.

Pemigatinib is a potent, selective, oral inhibitor of FGFR isoforms 1, 2 and 3 which, in preclinical studies, has demonstrated selective pharmacologic activity against cancer cells with FGFR alterations. Phase 2 studies investigating the safety and efficacy of pemigatinib monotherapy across several FGFR-driven malignancies are ongoing—the FIGHT (FIbroblast Growth factor receptor in oncology and Hematology Trials) clinical trial program currently comprises FIGHT-201 in patients with metastatic or surgically unresectable bladder cancer, including with activating FGFR3 alterations; FIGHT-202 in patients with metastatic or surgically unresectable cholangiocarcinoma who have failed previous therapy, including with activating FGFR2 translocations; and FIGHT-203 in patients with myeloproliferative neoplasms with activating FGFR1 translocations.

About FoundationOne®CDx

FoundationOne®CDx is a next generation, sequencing based *in vitro* diagnostic device for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens.

FoundationOne CDx is intended as a companion diagnostic to identify patients who may benefit from treatment with certain targeted therapies in accordance with their approved therapeutic product labeling. Additionally, FoundationOne CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms.

For a full list of targeted therapies for which FoundationOne CDx is indicated as a companion diagnostic, please visit http://www.foundationmedicine.com/genomic-testing/foundation-one-cdx.

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.

Follow @Incyte on Twitter at https://twitter.com/Incyte.

About Foundation Medicine

Foundation Medicine is a molecular information company dedicated to a transformation in cancer care in which treatment is informed by a deep understanding of the genomic changes that contribute to each patient's unique cancer. The company offers a full suite of comprehensive genomic profiling tests to identify the molecular alterations in a patient's cancer and match them with relevant targeted therapies, immunotherapies and clinical trials. Foundation Medicine's molecular information platform aims to improve day-to-day care for patients by serving the needs of clinicians, academic researchers and drug developers to help advance the science of molecular medicine in cancer.

For more information, please visit http://www.FoundationMedicine.com or follow Foundation Medicine on Twitter (@FoundationATCG).

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Forward-Looking Statement of Incyte Corporation

Except for the historical information set forth herein, the matters set forth in this release contain predictions, estimates and other forward-looking statements, including without limitation statements regarding a collaboration between Incyte and Foundation Medicine, whether the companion diagnostic will enable testing at diagnosis of stage IV cholangiocarcinoma or help reduce morbidity and mortality, and the expected timing to report data from Incyte's INCB54828 study. 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: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by the FDA; Incyte's dependence on its relationships with its collaboration partners; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended June 30, 2018. Incyte disclaims any intent or obligation to update these forward-looking statements.

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