Incyte Announces First Patient Treated in Phase 3 Clinical Trial of Pemigatinib as a First-Line Therapy for Cholangiocarcinoma

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WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 4, 2019-- Incyte (Nasdaq:INCY) today announced that the first patient has been treated in FIGHT-302, an open-label Phase 3 study evaluating pemigatinib (INCB54828), its selective fibroblast growth factor receptor (FGFR) inhibitor, compared to gemcitabine with cisplatin chemotherapy, the current standard of care, as a first-line therapy for patients with metastatic or surgically unresectable cholangiocarcinoma (bile duct cancer) and activating FGFR2 rearrangements.

“We are pleased to initiate FIGHT-302 – the first Phase 3 study of pemigatinib – which we hope will add to the growing body of evidence demonstrating its potential as a safe and effective treatment for patients with cholangiocarcinoma with known FGFR2 rearrangements, a rare and potentially life-threatening form of cancer,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “Most patients that present with cholangiocarcinoma, like those patients to be enrolled in the FIGHT-302 study, have an advanced form of the disease that cannot be surgically removed, and the majority do not respond to the current standard of care, demonstrating the significant need for new treatment options.”

Cholangiocarcinoma is a cancer that arises from the cells within the bile ducts. It is often diagnosed late (stages III and IV) and the prognosis is poor. It is most common in those over 70 years old and is more common in men than women. FGFR2 fusion genes are drivers of the disease – occurring almost exclusively in patients with intrahepatic cholangiocarcinoma (iCCA), a subset of the disease. The incidence of cholangiocarcinoma with FGFR2 rearrangements is increasing and is currently estimated at 2,000-3,000 patients in the U.S., Europe and Japan.

About FIGHT and FIGHT-302

The FIGHT (**FI**broblast **G**rowth factor receptor in oncology and **H**ematology **T**rials) clinical trial program includes several ongoing studies investigating the safety and efficacy of pemigatinib monotherapy across several FGFR-driven malignancies. Currently, the program is comprised of the recently initiated FIGHT-302 study, and three Phase 2 studies: 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; FIGHT-203 in patients with myeloproliferative neoplasms with activating FGFR1 translocations; and FIGHT-207 in patients with previously-treated, locally-advanced/metastatic or surgically unresectable solid tumor malignancies harboring activating FGFR mutations or translocations, irrespective of tumor type.

FIGHT-302 (NCT03656536) is an open-label, randomized, active-controlled Phase 3 trial evaluating the safety and efficacyof pemigatinib (INCB54828), Incyte’s selective oral fibroblast growth factor receptor (FGFR) inhibitor compared to the current standard of care – gemcitabine plus cisplatin chemotherapy – as a first-line treatment for adult (age ≥ 18 years) patients with metastatic or surgically unresectable cholangiocarcinoma with a known FGFR receptor 2 (FGFR2) rearrangements.

The study will enroll approximately 432 participants 1:1 into one of two treatment groups – Group A will receive pemigatinib (13.5 mg once daily [QD]) administered as continuous therapy schedule (a cycle is three weeks), and Group B will receive gemcitabine (1000 mg/m^2) plus cisplatin (25 mg/m^2) administered on Days 1 and 8 of every three-week cycle for up to eight cycles.

The primary endpoint of FIGHT-302 is progression free survival (PFS) across both groups, assessed by independent review per RECIST v1.1. Secondary endpoints include overall response rate (ORR), overall survival (OS), duration of response (DOR), disease control rate (DCR), safety and quality of life impact.

FIGHT-302 is currently recruiting participants; for more information about the study, please visit https://clinicaltrials.gov/ct2/show/NCT03656536.

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. The U.S. Food and Drug Administration (FDA) has granted pemigatinib Breakthrough Therapy designation for the second-line treatment of cholangiocarcinoma. The FDA’s Breakthrough Therapy designation is designed to expedite the development and review of drugs for serious conditions that have shown encouraging early clinical results and may demonstrate substantial improvements over available medicines.

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 Company’s ongoing clinical development program for pemigatinib and its potential in treating cholangiocarcinoma, and the enrollment, design, timing and results of the

FIGHT-302 study, 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 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; the Company's dependence on its relationships with its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; greater than expected expenses; expenses relating to litigation or strategic activities; 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 ending March 31, 2019. The Company disclaims any intent or obligation to update these forward-looking statements.

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