Incyte Announces Positive Interim Data from Phase 2 Trial of Pemigatinib, Its Selective FGFR Inhibitor, in Patients with Cholangiocarcinoma

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- *Updated results presented at ESMO support planned submission of NDA in U.S. in 2019*

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 21, 2018-- Incyte Corporation (Nasdaq:INCY) announces updated data from its ongoing Phase 2 FIGHT-202 trial evaluating pemigatinib (INCB54828), its selective fibroblast growth factor receptor (FGFR) inhibitor, in patients with advanced/metastatic or surgically unresectable cholangiocarcinoma (bile duct cancer) who failed at least one previous treatment. In patients with FGFR2 translocations who were followed for at least eight months, interim study results demonstrated an overall response rate (ORR) of 40 percent, the primary endpoint, and a median progression free survival (PFS) of 9.2 months, a key secondary endpoint.

These results are being presented at the European Society for Medical Oncology (ESMO) 2018 Congress in Munich, Germany in a poster presentation on Sunday, October 21 from 12:45 p.m. CEST to 1:45 p.m. CEST (6:45 a.m. ET to 7:45 a.m. ET). (Location: Hall A3 – Poster Area Networking Hub; Abstract #756P)

"We are pleased to share updated interim results from our ongoing FIGHT-202 trial at ESMO, which underscore the potential of pemigatinib as an effective new treatment option for patients with advanced cholangiocarcinoma who have FGFR2 translocations," said Steven Stein, M.D., Chief Medical Officer, Incyte. "If the full data set warrant it, we look forward to submitting our new drug application to the FDA in 2019, seeking approval of pemigatinib as a first-in-class selective FGFR inhibitor to treat patients with advanced cholangiocarcinoma, a devastating disease."

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 – and are found in up to 20 percent of iCCA patients. The incidence of cholangiocarcinoma with FGFR2 translocation is increasing and is currently estimated at 2,500-3,000 patients in the U.S., Europe and Japan.

Key Findings from FIGHT-202

Updated, longer-term follow-up data from the interim analysis presented today at ESMO (data cut as of July 24, 2018) show that in patients with advanced/metastatic or surgically unresectable iCCA with FGFR2 translocations treated with pemigatinib who had at least eight months of follow up (Cohort A, n=47), the combined overall response rate (ORR) was 40 percent, including 19 (40 percent) patients with confirmed partial responses and 21 (45 percent) patients with stable disease (SD). The combined disease control rate (DCR) was 85 percent (40/47). Additionally, median progression free survival (PFS) was 9.2 months and median overall survival (OS) was 15.8 months.

FIGHT-202 Overall Response Rates (ORR), Disease Control Rates (DCR), Durability of Response (DOR), Progression-Free Survival (PFS) and Overall Survival (OS) by Patient Cohort

	Cohort A FGFR2 Translocations (N=47)	**Cohort B Other FGF/FGFR Genetic Alterations** (N=22)	**Cohort C No FGF/FGFR Genetic Alterations** (N=18)
ORR, % (95% CI)	40 (26.4-55.7)	0 (0.0-15.4)	0 (0.0-18.5)
Best OR, n (%)	0 CR (0.0) 19 PR (40) 21 SD (45)	0 CR (0.0) 0 PR (0.0) 10 SD (46)	0 CR (0.0) 0 PR (0.0) 4 SD (22)
Median DOR, Months (95% CI)	NE (6.93-NE) Median (range) duration of response has not been reached	NE (NE-NE) Median (range) duration of response has not been reached	NE (NE-NE) Median (range) duration of response has not been reached
DCR, % (95% CI)	85 (71.7-93.8)	46 (24.4-67.8)	22 (6.4-47.6)
Median PFS, Months (95% CI)	9.2 (6.44-NE)	2.1 (1.18-6.80)	1.68 (1.38-1.84)
Median OS, Months (95% CI)	15.8	6.8	4.0

NE = not evaluable, upper limit was not reached

Pemigatinib was well-tolerated. The most common treatment-emergent adverse events (TEAEs) were hyperphosphatemia (61 percent), alopecia (42 percent), diarrhea (39 percent), decreased appetite (37 percent) and fatigue (36 percent). Grade ≥3 TEAEs (observed >5 percent of patients) were hypophosphatemia (14 percent), hyponatremia (8 percent), abdominal pain (7 percent) and arthralgia (7 percent). Five patients had TEAEs with a fatal

outcome, none of which were related to study treatment.

“I am extremely encouraged by the interim results of the FIGHT-202 study, which demonstrated meaningful clinical activity and promising preliminary progression-free survival estimates, and, as a practicing clinician, I am excited about the potential of pemigatinib to provide a new treatment option for my patients suffering from the life-threatening nature of advanced cholangiocarcinoma,” said Antoine Hollebecque, M.D., Institut de Cancérologie Gustave Roussy, Villejuif, France.

About FIGHT-202

The FIGHT-202 open-label, multicenter study (NCT02924376) is evaluating the safety and efficacy of pemigatinib (INCB54828), Incyte’s investigational, selective, potent, oral fibroblast growth factor receptor (FGFR) inhibitor in adult (age ≥ 18 years) patients with advanced/metastatic or surgically unresectable cholangiocarcinoma with known fibroblast growth factor (FGF)/FGFR alterations and who have failed at least one previous treatment.

Patients were enrolled into one of three cohorts – Cohort A (FGFR2 translocations), Cohort B (other FGF/FGFR genetic alterations [GA]) or Cohort C (no FGF/FGFR GAs). All patients received 13.5 mg pemigatinib orally once daily (QD) on a 21-day cycle (two weeks on/one week off) until radiological disease progression or unacceptable toxicity.

The primary endpoint of FIGHT-202 is overall response rate (ORR) in Cohort A, assessed by independent review per RECIST v1.1. Secondary endpoints include ORR in Cohorts B, C and A plus B, progression free survival (PFS), overall survival (OS), duration of response (DOR), disease control rate (DCR) and safety.

The FIGHT-202 study is fully recruited outside of Japan, and updated data are expected to be presented in the second half of 2019. For more information about FIGHT-202, visit https://clinicaltrials.gov/ct2/show/NCT02924376.

About FIGHT

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. FIGHT-302, a randomized Phase 3 trial in newly-diagnosed patients with cholangiocarcinoma and activating FGFR2 translocations, is expected to be initiated before the end of 2018 (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.

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, the Company’s plans to file an NDA for pemigatinib and the expected timing of such filing, whether further data will support the interim results, and plans for commencing FIGHT-302 before the end of 2018, 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 ended June 30, 2018. The Company disclaims any intent or obligation to update these forward-looking statements.

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