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Incyte Announces Positive CHMP Opinion for Pemigatinib for the Treatment of Adults With Previously Treated, Unresectable Locally Advanced or Metastatic Cholangiocarcinoma With a Fibroblast Growth Factor Receptor 2 (FGFR2) Fusion or Rearrangement

- If approved, pemigatinib will be the first targeted therapy indicated in the EU for this indication

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending the conditional marketing authorization of pemigatinib for the treatment of adults with unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that is relapsed or refractory, after at least one line of systemic therapy.

“The positive CHMP opinion is a crucial milestone for patients with cholangiocarcinoma, who often have very limited treatment options due to the difficulty of identifying patients during the early disease stages,” said Peter Langmuir, M.D., Group Vice President, Oncology Targeted Therapeutics, Incyte. “Following the recent FDA approval of pemigatinib (Pemazyre®), we are delighted to be closer to offering the first targeted therapy in Europe to benefit these patients.”

The CHMP opinion is based on data from the FIGHT-202 study evaluating the safety and efficacy of pemigatinib in adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with documented FGF/FGFR status. The CHMP’s opinion to recommend the use of pemigatinib is now being reviewed by the European Commission, which has the authority to grant marketing authorizations for medicinal products in the European Union (EU). If approved, pemigatinib will be the first targeted treatment in the EU indicated for patients with unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2

(FGFR2) fusion or rearrangement and would be commercialized under the brand name Pemazyre.

Cholangiocarcinoma is a rare cancer that forms in the bile duct. It is classified based on its origin: intrahepatic cholangiocarcinoma (iCCA) occurs in the bile duct inside the liver and extrahepatic cholangiocarcinoma occurs in the bile duct outside the liver. Patients with cholangiocarcinoma are often diagnosed at a late or advanced stage when the prognosis is poor1,2. In Europe, the incidence of cholangiocarcinoma ranges between 6,000 – 8,0003,4. FGFR2 fusions or rearrangements occur almost exclusively in iCCA, where they are observed in 10-16 percent of patients5,6,7.

About FIGHT-202

The FIGHT-202 Phase 2, open-label, multicenter study (NCT02924376) is evaluating the safety and efficacy of pemigatinib – a selective fibroblast growth factor receptor (FGFR) inhibitor – in adult (age ≥ 18 years) patients with previously treated, locally advanced or metastatic cholangiocarcinoma with documented FGF/FGFR status.

Patients were enrolled into one of three cohorts – Cohort A (FGFR2 fusions or rearrangements), Cohort B (other FGF/FGFR genetic alterations) or Cohort C (no FGF/FGFR genetic alterations). 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; progression free survival (PFS), overall survival (OS), duration of response (DOR), disease control rate (DCR) and safety in all cohorts.

For more information about FIGHT-202, visit **https://clinicaltrials.gov/ct2/show/NCT02924376**.

About FIGHT

The FIGHT (FIbroblast Growth factor receptor in oncology and Hematology Trials) clinical trial program includes ongoing Phase 2 and 3 studies investigating safety and efficacy of pemigatinib therapy across several FGFR-driven malignancies. Phase 2 monotherapy studies include FIGHT-202, as well as FIGHT-201 investigating pemigatinib in patients with metastatic or surgically unresectable bladder cancer, including with activating FGFR3 mutations or fusions/rearrangements; FIGHT-203 in patients with myeloproliferative neoplasms with activating FGFR1 fusions/rearrangements; FIGHT-207 in patients with previously treated, locally-advanced/metastatic or surgically unresectable solid tumor malignancies harboring activating FGFR mutations or fusions/rearrangements, irrespective of tumor type.

FIGHT-302 is a Phase 3 study investigating pemigatinib as a first-line treatment for patients with cholangiocarcinoma with FGFR2 fusions or rearrangements.

About FGFR and Pemigatinib

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 fusions, rearrangements, 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 is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit **Incyte.com** and follow **@Incyte**.

Forward Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding whether or when pemigatinib might be approved in the EU for the treatment of, and whether or when pemigatinib might provide a successful treatment option for, patients with unresectable locally advanced or metastatic cholangiocarcinoma, and the FIGHT clinical trial program. 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 European regulatory authorities or other regulatory authorities, including the U.S. 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 September 30, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.

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1 Banales JM, et al. Nat Rev Gastroenterol Hepatol. 2016;13:261–280.

2 Uhlig J, et al. Ann Surg Oncol. 2019;26:1993–2000.

3 Kirstein MM, Vogel A. Visc Med 2016; 32: 395-400.

4 Countries factored include: UK, Germany, France, Spain, Italy, Switzerland, Denmark, Finland, Poland and Austria

5 Graham RP, et al. Hum Pathol. 2014;45:1630–1638.
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