Incyte Announces the Validation by the European Medicines Agency of its Marketing Authorization Application for Pemigatinib in Patients with Cholangiocarcinoma

January 7, 2020

WILMINGTON, Del.--(BUSINESS WIRE)--Jan. 7, 2020-- Incyte (Nasdaq:INCY) today announced the validation of the Company's Marketing Authorization Application (MAA) for pemigatinib for the treatment of adults with 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 European Medicines Agency's (EMA) validation of the MAA confirms that the submission is sufficiently complete to begin the formal review process.

"The EMA's validation of Incyte's Marketing Authorization Application opens the review process as we seek to bring the first targeted therapy to Europe for patients with cholangiocarcinoma," said Peter Langmuir, M.D., Group Vice President, Targeted Therapeutics, Incyte. "The need for new therapies for cholangiocarcinoma was also recently recognized by the U.S. Food and Drug Administration's acceptance, for Priority Review, of our New Drug Application for pemigatinib this past November. We are looking forward to continuing to work with regulatory authorities to bring this novel targeted therapy to eligible patients around the world."

The MAA application is based on data from the FIGHT-202 study evaluating pemigatinib as a treatment for patients with previously treated, locally advanced or metastatic cholangiocarcinoma.[1]

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 poor.[2,3] The incidence of cholangiocarcinoma varies regionally, but ranges between 0.4 – 1.8 per 100,000 in Europe.[4] FGFR2 fusions or rearrangements occur almost exclusively in iCCA, where they are observed in 10-16 percent of patients.[5-7]

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 in Cohorts B, A plus B, and C; 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 (**FI**broblast **G**rowth factor receptor in oncology and **H**ematology **T**rials) 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-205 is a Phase 2 study investigating pemigatinib plus pembrolizumab combination therapy and pemigatinib monotherapy in patients with previously untreated, metastatic or unresectable bladder cancer harboring FGFR3 mutations or fusions/rearrangements who are not eligible to receive cisplatin. FIGHT-302 is a recently initiated 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, the US or elsewhere for the treatment of, and whether or when pemigatinib might provide a treatment option for, patients with previously treated, locally advanced or metastatic cholangiocarcinoma with FGFR2 fusions or rearrangements, 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 the EMA; 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, 2019. The Company disclaims any intent or obligation to update these forward-looking statements.

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[1] Vogel A, et al. FIGHT-202: A Phase 2 Study of Pemigatinib in Patients with Previously Treated Locally Advanced or Metastatic Cholangiocarcinoma. Proffered paper #2550. European Society for Medical Oncology. 2019.

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

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Source: Incyte Corporation

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