Incyte Announces Positive Updated Results from Phase 2 Trial of Pemigatinib in Patients with Previously Treated, Advanced Cholangiocarcinoma

September 27, 2019

- *Data presented at ESMO support the planned submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for pemigatinib before the end of 2019*
- *Investor conference call and webcast scheduled for today, September 27, at 5:00 p.m. CEST (11:00 a.m. EDT)*

WILMINGTON, Del.--(BUSINESS WIRE)--Sep. 27, 2019-- Sixth paragraph, fourth sentence of release should read: Serous retinal detachment was observed in 4 percent of patients (Grade ≥3, 1 percent) with none of the cases resulting in clinical sequelae. (instead of Serious retinal detachment was observed in 4 percent of patients (Grade ≥3, 1 percent) with none of the cases resulting in clinical sequelae.)

The corrected release reads:

INCYTE ANNOUNCES POSITIVE UPDATED RESULTS FROM PHASE 2 TRIAL OF PEMIGATINIB IN PATIENTS WITH PREVIOUSLY TREATED, ADVANCED CHOLANGIOCARCINOMA

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Incyte (Nasdaq:INCY) announces updated results, including the final result for the primary endpoint, from its Phase 2 FIGHT-202 trial evaluating pemigatinib, a selective fibroblast growth factor receptor (FGFR) inhibitor, as a treatment for patients with previously treated, locally advanced or metastatic cholangiocarcinoma. In patients harboring FGFR2 fusions or rearrangements (Cohort A), pemigatinib monotherapy resulted in an overall response rate (ORR) of 36 percent (primary endpoint), and median progression free survival (PFS) of 6.9 months (secondary endpoint) with a median follow-up of 15 months. Pemigatinib was generally well tolerated.

These results are being presented at the European Society for Medical Oncology (ESMO) 2019 Congress in Barcelona, Spain during a late-breaking oral session today, September 27, from 3:00 p.m. CEST to 3:15 p.m. CEST (9:00 a.m. EDT to 9:15 a.m. EDT) in Madrid Auditorium (Hall 2); Abstract #LBA40.

“We are excited to share updated data for pemigatinib, which may provide a promising and targeted treatment approach for patients with cholangiocarcinoma harboring FGFR2 fusions or rearrangements,” said Peter Langmuir, M.D., Group Vice President, Targeted Therapeutics, Incyte. “Patients with advanced cholangiocarcinoma face a poor prognosis, and currently there is no standard of care beyond first-line chemotherapy. We are committed to advancing pemigatinib, a potent and selective therapy targeting a key driver of this disease, and plan to submit the New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) shortly.”

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.[1,2] The incidence of cholangiocarcinoma varies regionally and ranges between 0.3 – 3.4 per 100,000 in North America and Europe.[1] FGFR2 fusions or rearrangements occur almost exclusively in iCCA, where they are observed in 10-16 percent of patients.[3-5]

Key Findings from FIGHT-202

Updated data presented today at ESMO show that in patients with previously treated, locally advanced or metastatic cholangiocarcinoma with FGFR2 fusions or rearrangements (Cohort A, n=107), pemigatinib monotherapy resulted in a confirmed overall response rate (ORR) of 36 percent based on an independent central radiographic review, including 3 patients with a complete response (CR) and 35 patients with a partial response (PR). In these patients, the disease control rate (DCR) was 82 percent, median duration of response (DOR) was 7.5 months, and median progression free survival (PFS) was 6.9 months. Preliminary overall survival (OS) data were encouraging (median: 21.1 months) and follow-up will continue as these data are not yet mature.

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

	Cohort A FGFR2 Fusions or Rearrangements	Cohort B Other FGF/FGFR Genetic Alterations	Cohort C No FGF/FGFR Genetic Alterations
	(N=107)	(N=20)	(N=18)
ORR, % (95% CI)	36 (27-45)	0	0
Best OR, n (%)	3 CR (3)	0	0
	35 PR (33)	0	0
	50 SD (47)	8 SD (40)	4 SD (22)
Median DOR, Months (95% CI)	7.5 (5.7-14.5)	-	-
DCR, % (95% CI)	82 (74-89)	40 (19-64)	22 (6-48)
Median PFS, Months (95% CI)	6.9 (6.2-9.6)	2.1 (1.2-4.9)	1.7 (1.3-1.8)
Median OS, Months (95% CI)	21.1 (14.8-NE)	6.7 (2.1-10.6)	4.0 (2.3-6.5)

NE: not evaluable

Note: One patient did not have confirmed FGF/FGFR status by central laboratory and was included in the safety analysis but was not assigned to any cohort for efficacy.

The safety analysis, including 146 patients, showed that pemigatinib was generally well tolerated. Grade 1 or 2 hyperphosphatemia, the most common treatment-emergent adverse event (TEAE; 60 percent), was managed with a low phosphate diet, phosphate binders and diuretics, or dose reduction or interruption. The most common Grade ≥3 TEAE was hypophosphatemia (12 percent); none of the cases was considered clinically significant or serious and none led to dose reduction or discontinuation. Serous retinal detachment was observed in 4 percent of patients (Grade ≥3, 1 percent) with none of the cases resulting in clinical sequelae.

“Patients with cholangiocarcinoma face a significant challenge as they cope with a life-threatening condition that is often diagnosed once it has progressed into late stages,” said Arndt Vogel, M.D., Senior Consultant and Professor at Hannover Medical School. “As a physician, I am encouraged to see the data from the FIGHT-202 study, which demonstrate the potential that pemigatinib has to become an important and much needed targeted treatment option for this patient population.”

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. The U.S. Food and Drug Administration (FDA) has granted pemigatinib Breakthrough Therapy designation for the treatment of previously treated, advanced/metastatic or unresectable FGFR2 translocated 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.

Conference Call Information

Incyte will host an investor conference call and webcast at 11:00 a.m. EDT (5:00 p.m. CEST) today, September 27, 2019—the call and webcast can be accessed via the Events and Presentations tab of the Investor section of www.incyte.com and it will be available for replay for 30 days.

To access the conference call, please dial 877-407-3042 for domestic callers or +1 201-389-0864 for international callers. When prompted, provide the conference identification number, 13694537.

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 presentation of data from the Company's ongoing clinical development program for pemigatinib, the potential of such program, whether and when the Company will submit an NDA to the U.S. FDA for pemigatinib, and whether and when pemigatinib will become an effective and approved treatment for patients with cholangiocarcinoma harboring FGFR2 fusions or rearrangements, 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, 2019. The Company disclaims any intent or obligation to update these forward-looking statements.

References

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. Graham RP, et al. Hum Pathol. 2014;45:1630–1638.
4. Farshidfar F, et al. Cell Rep. 2017;18(11):2780–2794.
5. Ross JS et al. The Oncologist. 2014;19:235–242.

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