Incyte Announces Acceptance and Priority Review of NDA for Capmatinib for Advanced Non-Small Cell Lung Cancer

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- *The U.S. Food and Drug Administration (FDA) Priority Review for capmatinib is based on Phase 2 data in first-line and previously treated patients with MET exon 14 skipping (METex14) mutated advanced non-small cell lung cancer (NSCLC)*[1]
- *Novartis has exclusive worldwide development and commercialization rights to capmatinib*

WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 11, 2020-- Incyte (Nasdaq:INCY) today announced that the U.S. Food and Drug Administration (FDA) has accepted and granted Priority Review to the New Drug Application (NDA) for capmatinib, an investigational, selective MET inhibitor, as a treatment for first-line and previously treated patients with locally advanced or metastatic MET exon 14 skipping (METex14) mutated non-small cell lung cancer (NSCLC). If approved, capmatinib will be the first therapy to specifically target METex14 mutated advanced lung cancer, a type of lung cancer with a particularly poor prognosis[2,3].

There are currently no approved therapies that specifically target METex14 mutated advanced NSCLC. NSCLC accounts for approximately 85% of lung cancer diagnoses[4]. METex14 mutations occur in 3-4% of newly-diagnosed advanced NSCLC cases[5] and is a recognized oncogenic driver[6,7].

“Patients with METex14 mutated advanced NSCLC, an aggressive form of the disease, often face a poor prognosis due to lack of available treatment options,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “We are pleased the FDA has accepted the NDA for capmatinib for Priority Review – a critical step toward providing the first METex14 mutation targeted therapy to this subset of lung cancer patients.”

The FDA grants Priority Review to medicines that may offer a major advance in treatment where none currently exists. This designation shortens the FDA review period following the acceptance of the NDA to six months compared to 10 months for Standard Review. Capmatinib was previously granted Breakthrough Therapy designation by the FDA.

The NDA submission for capmatinib was supported by results from the Novartis-sponsored GEOMETRY *mono*-1 Phase 2 study, which demonstrated overall response rates of 67.9% (95% CI, 47.6 - 84.1)[1] and 40.6% (95% CI, 28.9–53.1)[1] among treatment-naïve and previously treated patients, respectively, based on the Blinded Independent Review Committee (BIRC) assessment per RECIST v1.1. The study also demonstrated that capmatinib provided durable responses among all patients: median duration of response was 11.14 months (95% CI, 5.55 - NE) in treatment-naïve patients and 9.72 months (95% CI, 5.55 - 12.98) in previously treated patients[1].

All results were based on independent assessment by the BIRC, and all tumor CT scans were evaluated in parallel by two radiologists to confirm the response[1]. The most common treatment-related adverse events (AE) (≥ 10% all grades) across all cohorts (N=334), were peripheral edema (42%), nausea (33%), creatinine increase (20%), vomiting (19%), fatigue (14%), decreased appetite (13%) and diarrhea (11%). The majority of the AEs were grades 1/2[1].

About GEOMETRY *mono*-1

The Novartis-sponsored GEOMETRY *mono*-1 trial is an international, prospective, multi-cohort, non-randomized, open-label Phase 2 study to evaluate the efficacy and safety of single-agent capmatinib in adult patients with EGFR wildtype, ALK-negative rearrangement, advanced NSCLC harboring a MET amplification and/or mutation. Patients with locally advanced or metastatic NSCLC harboring a MET exon-14 skipping mutation (centrally confirmed) were assigned to Cohorts 4 (previously treated patients) or 5B (treatment-naïve), regardless of MET amplification/gene copy number and received 400 mg capmatinib tablets orally twice daily. The primary endpoint was ORR based on BIRC assessment per RECIST v1.1. The key secondary endpoint was DOR by BIRC.

About Capmatinib

Capmatinib (INC280) is an investigational, oral and selective MET inhibitor discovered by Incyte and licensed to Novartis in 2009. Under the terms of the Agreement, Incyte granted Novartis exclusive worldwide development and commercialization rights to capmatinib and certain back-up compounds in all indications. If capmatinib is successfully developed by Novartis, Incyte may become eligible for over $500 million in future milestones as well as royalties of between 12 and 14 percent on global sales by Novartis.

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 the ongoing clinical development program for capmatinib and its potential in treating NSCLC, whether and when the FDA might approve capmatinib in the U.S., and whether and when Incyte may receive milestone payments or royalties from Novartis relating to capmatinib, 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 September 30, 2019. The Company disclaims any intent or obligation to update these forward-looking statements.

References

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Source: Incyte Corporation

Media
Catalina Loveman +1 302 498 6171
cloveman@incyte.com

Investors
Michael Booth, DPhil +1 302 498 5914
mbooth@incyte.com