Incyte Announces FDA Approval of Tabrecta™ (capmatinib) for the Treatment of Patients with Metastatic Non-Small Cell Lung Cancer with METex14

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- Tabrecta is the first and only U.S. Food and Drug Administration (FDA)-approved treatment for adult patients with metastatic non-small cell lung cancer (NSCLC) with a mutation that leads to MET exon 14 skipping (METex14)

- Tabrecta is the fourth molecule discovered by Incyte scientists to be approved by the FDA

- Novartis has exclusive worldwide development and commercialization rights to Tabrecta

WILMINGTON, Del.--(BUSINESS WIRE)--May 6, 2020-- Incyte (Nasdaq:INCY) today announced that the U.S. Food and Drug Administration (FDA) has approved Tabrecta™ (capmatinib) for treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to MET exon 14 skipping (METex14) as detected by an FDA-approved test. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Tabrecta, the first and only treatment approved to specifically target NSCLC with this driver mutation, is approved for first-line and previously treated patients regardless of prior treatment type.

Novartis has exclusive worldwide development and commercialization rights to Tabrecta, and the FDA approval of Tabrecta triggers $70 million in milestone payments from Novartis to Incyte. Incyte is also eligible to receive 12-14 % royalties on net sales of Tabrecta by Novartis.

NSCLC accounts for approximately 85% of lung cancer diagnoses[1]. METex14 occurs in 3-4% of newly-diagnosed metastatic NSCLC cases[2] and is a recognized oncogenic driver[3,4].

“We are pleased that the FDA has approved Tabrecta for patients with METex14 NSCLC,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “Having a therapy that targets the recognized oncogenic driver will provide a much needed treatment option for patients with METex14 NSCLC who currently have limited treatment options. Tabrecta is the fourth Incyte molecule to be approved by the FDA, highlighting our world-class discovery program and commitment to bringing innovative medicines to patients in need.”

The approval of Tabrecta is based on results[5] from the pivotal GEOMETRY mono-1 Study. In the METex14 population (n=97), the confirmed overall response rate was 68% (95% CI, 48-84) and 41% (95% CI, 29-53) among treatment-naive (n=28) and previously treated patients (n=69), respectively, based on the Blinded Independent Review Committee (BIRC) assessment per RECIST v1.1. In patients taking Tabrecta, the study also demonstrated a median duration of response of 12.6 months (95% CI, 5.5–25.3) in treatment-naive patients (19 responders) and 9.7 months (95% CI, 5.5-13.0) in previously treated patients (28 responders). The most common treatment-related adverse events (AEs) (incidence ≥20%) are peripheral edema, nausea, fatigue, vomiting, dyspnea, and decreased appetite.

Capmatinib was previously granted Breakthrough Therapy designation by the FDA, which 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.

Full prescribing information for Tabrecta can be found at: https://www.novartis.us/sites/www.novartis.us/files/tabrecta.pdf.

About GEOMETRY mono-1

The Novartis-sponsored GEOMETRY mono-1 trial is a multi-center, non-randomized, open-label, multi-cohort Phase 2 study to evaluate the efficacy and safety of single-agent capmatinib in adult patients with EGFR wild-type, metastatic NSCLC as measured by ORR.

Patients (n=97) with metastatic NSCLC harboring mutations that lead to METex14 (centrally confirmed) were assigned to Cohorts 4 (n=69, previously treated patients) or 5B (n=28, treatment-naïve), and received 400 mg capmatinib tablets orally twice daily. The major efficacy outcome was ORR based on BIRC assessment per RECIST v1.1. An additional efficacy outcome was DOR by BIRC.

About Tabrecta

Tabrecta (capmatinib; formerly INC280) is a kinase inhibitor that targets MET 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. Incyte is 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, its potential in treating NSCLC 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 March 31, 2019. The Company disclaims any intent or obligation to update these forward-looking statements.

References

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2. Salgia R. MET in Lung Cancer: Biomarker Selection Based on Scientific Rationale. Mol Cancer Ther. 2017;16(4):555-565.
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