Incyte Announces Pivotal GEOMETRY mono-1 Study Results of Capmatinib (Tabrecta™) in Patients with METex14 Metastatic Non-Small Cell Lung Cancer Published in NEJM

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—Tabrecta is the first and only therapy approved by the FDA to specifically target 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)-- Incyte (Nasdaq: INCY) today announced that data from the Novartis pivotal Phase 2 GEOMETRY mono-1 study demonstrating that treatment with Tabrecta™ (capmatinib) resulted in positive overall response rates (ORR) with durable responses among adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to skipping of MET exon 14 (METex14) have been published in *The New England Journal of Medicine*.[1]

MET, a receptor tyrosine kinase coded by the *MET* gene, normally plays an important role in cell signaling, proliferation and survival.[2] Many cancers are associated with abnormal signaling through the MET receptor pathway, caused by multiple mechanisms including point mutations, insertions/deletions that lead to skipping of exon 14.[2] Results from the GEOMETRY mono-1 study describe METex14 as an important biomarker for physicians to consider when selecting metastatic NSCLC treatment options; and emphasize the importance of broad molecular testing for NSCLC patients.

“The GEOMETRY mono-1 study results published in *The New England Journal of Medicine* further highlight the clinical benefit that Tabrecta can provide to patients with metastatic METex14 NSCLC,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “Having a therapy that targets a recognized oncogenic driver offers a much-needed treatment option for patients living with this aggressive form of lung cancer and we are proud that the world-class discovery program at Incyte contributed to the fulfillment of this unmet medical need.”

Published data from the GEOMETRY mono-1 study demonstrate that in the METex14 population (n=97), the ORR as confirmed by the Blinded Independent Radiology Committee (BIRC) was 68% (95% CI, 48-84) among treatment-naïve patients (n=28) and 41% (95% CI, 29-53) among previously treated patients (n=69).[1] In patients with METex14 who responded to treatment with Tabrecta, the study also demonstrated a median duration of response of 12.6 months (95% CI, 5.6-not estimable) in treatment-naive patients (19 responders) and 9.7 months (95% CI, 5.6-13.0) in previously treated patients (28 responders).[1]

Thirteen of 14 patients with METex14 had brain metastases at baseline (3 treatment-naïve and 10 previously treated patients) and were considered evaluable by the BIRC.[1] In a post-hoc analysis, 7 intracranial responses were observed, including 4 complete responses.[1]

The most common treatment-related adverse events (incidence ≥20%) were peripheral edema (43%), nausea (34%), increased blood creatinine (18%) and vomiting (19%). The majority of AEs were grades 1 or 2.[1]

NSCLC accounts for approximately 85% of lung cancer diagnoses.[3] METex14 occurs in 3-4% of newly-diagnosed metastatic NSCLC cases[4] and is a recognized oncogenic driver.[2,5] Tabrecta is the first and only therapy approved by the FDA to specifically target metastatic NSCLC with a mutation the leads to METex14.

Novartis has exclusive worldwide development and commercialization rights to Tabrecta. Incyte is eligible for a total of over $500 million in milestones as well as royalties of between 12-14% on global net sales by Novartis.

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

About Tabrecta

Tabrecta (capmatinib) 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 a total of over $500 million in milestones as well as royalties of between 12-14% on global net 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 clinical benefit of Tabrecta, and milestone payments or royalties Incyte may receive from Novartis relating to Tabrecta, 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, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.

References

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3. American Cancer Society. About Lung Cancer. Available at https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/what-is-non-small-cell-lung-cancer.html. Accessed September 1, 2020.
4. Salgia R. MET in Lung Cancer: Biomarker Selection Based on Scientific Rationale. *Mol Cancer Ther.* 2017;16(4):555-565.
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