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Incyte Announces European Commission Approval of Tabrecta® (capmatinib) for METex14 Skipping Advanced Non-Small Cell Lung Cancer

WILMINGTON, Del. – June 22, 2022 – The European Commission (EC) has approved Tabrecta® (capmatinib), a MET kinase inhibitor discovered by Incyte, as a monotherapy for the treatment of adults with advanced non-small cell lung cancer (NSCLC) harboring alterations leading to mesenchymal-epithelial-transition factor gene (MET) exon 14 (METex14) skipping who require systemic therapy following prior treatment with immunotherapy and/or platinum-based chemotherapy.

The approval follows a positive opinion issued in April by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and is applicable to all 27 European Union member states plus Iceland, Norway and Liechtenstein.

The approval is based on results from the Phase 2 GEOMETRY mono-1 trial that demonstrated positive overall response rates (ORR) among adult patients with advanced NSCLC whose tumors had alterations leading to METex14 skipping¹. In the study, among 31 patients who received Tabrecta as second- (n=30) or later-line (n=1) therapy in the METex14 skipping pretreated population, a confirmed ORR of 51.6% (95% CI, 33.1-69.8) was achieved, and the ORR across all 100 previously-treated patients, which included patients who received one or more prior lines of systemic therapy, was 44.0% (95% CI, 34.1-54.3)¹. The most common treatment-related adverse events (AEs) (incidence ≥20%) were peripheral oedema, nausea, fatigue, increased blood creatinine, vomiting, dyspnea, decreased appetite and back pain¹.

In the European Union, there are an estimated 291,000 patients with locally advanced or metastatic NSCLC². METex14 skipping, a recognized oncogenic driver, occurs in approximately 3-4% of NSCLC cases^{3,4}.

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.

About Tabrecta® (capmatinib)

Tabrecta is approved in several countries including the U.S., Japan and Switzerland. It is the number one prescribed targeted therapy for patients with advanced NSCLC with alterations leading to METex14 skipping globally⁵.

Tabrecta is a kinase inhibitor that targets MET. Tabrecta was discovered by Incyte and licensed to Novartis in 2009. Under the agreement, Incyte granted Novartis worldwide exclusive development and commercialization rights to capmatinib and certain back-up compounds in all indications.

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](https://twitter.com/Incyte).

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding whether and when Tavegyl might provide a successful treatment for patients with advanced non-small cell lung cancer (NSCLC), generally contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on Incyte'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 and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID-19 pandemic and measures to address the pandemic on clinical trials, supply chain and other third-party providers and development and discovery operations; Incyte's dependence on its relationships with its collaboration partners; determinations made by the European Commission and other regulatory authorities; the efficacy or safety of Incyte's products and the products of Incyte's collaboration partners; the acceptance of Incyte's products and the products of Incyte'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 Incyte's reports filed with the Securities and Exchange Commission, including its annual report and its quarterly report on Form 10-Q for the quarter ended March 31, 2022. Incyte disclaims any intent or obligation to update these forward-looking statements.

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¹ Tavegyl (capmatinib) Summary of Product Characteristics. 2022.

² Data on file.

³ Sadiq AA, Salgia R. MET as a possible target for non-small-cell lung cancer. *J Clin Oncol.* 2013;31:1089.

⁴ Salgia R. MET in lung cancer: biomarker selection based on scientific rationale. *Mol Cancer Ther.* 2017;16(4):555-565.

⁵ Data on file.