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

June 29, 2020

- The approval of Tabrecta in Japan follows U.S. FDA approval earlier this year

- Tabrecta is the third Incyte-discovered molecule to be approved by the MHLW

- Novartis has exclusive worldwide development and commercialization rights to Tabrecta

WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 29, 2020-- Incyte (Nasdaq: INCY) today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) approved Tabrecta™ (capmatinib) for MET exon 14 skipping (METex14) mutation-positive advanced and/or recurrent unresectable non-small cell lung cancer (NSCLC). Tabrecta is approved for first-line and previously treated patients, regardless of prior treatment type.

Tabrecta is the third Incyte-discovered medicine to receive approval in Japan. Novartis has exclusive worldwide development and commercialization rights to Tabrecta. Approval of Tabrecta in Japan triggers a $20 million milestone payment to Incyte, and Incyte is also eligible to receive 12-14% royalties on global net sales of Tabrecta by Novartis.

“We are grateful for the efforts of Novartis Pharma K.K. and MHLW and are delighted that this important, targeted treatment option will now become available to patients in Japan diagnosed with METex14 NSCLC,” said Lothar Finke, M.D., Ph.D., Group Vice President, Head of Development and General Manager, Asia, Incyte. “This approval highlights the strength of the Incyte in-house discovery program, and our commitment to finding solutions for serious medical needs.”

The approval of Tabrecta is based on results 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.

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.

For more information on Incyte Biosciences Japan G.K., please visit Incyte.jp.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding 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 March 31, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.

Disclaimer

The drug information contained herein is intended for the disclosure of Incyte corporate information and is not intended to advertise or promote any medicinal product, including those under development.

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