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ASIA EDITION

FDA Approves Novartis Lung Cancer Drug, Tabrecta

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MET inhibitor Tabrecta™ for metastatic non-small cell lung cancer with METex14 is the first and only therapy approved by the FDA

Novartis announced on 6 May 2020 that the US Food and Drug Administration (FDA) approved Tabrecta™ (capmatinib, formerly INC280), an oral MET inhibitor for 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 a confirmatory trial(s).

This approval fills a long-recognized and urgent need among METex14 patients who have not had a treatment option approved to specifically target the driver of their lung cancer. Tabrecta is approved for first-line and previously treated patients, regardless of prior treatment type, and is expected to be available to patients in the coming days.

The FDA also approved FoundationOne®CDx as the companion diagnostic for Tabrecta, to aid in detecting mutations that lead to MET exon 14 skipping in tumor tissue.

“Non-small cell lung cancer is a complex disease, with many different possible mutations that may encourage the cancer’s growth,” said Juergen Wolf, MD, from the Center for Integrated Oncology, University Hospital Cologne and lead investigator of the GEOMETRY study. “MET exon 14 skipping is a known oncogenic driver. With today’s decision by the FDA, we can now test for and treat this challenging form of lung cancer with a targeted therapy, offering new hope for patients with NSCLC harboring this type of mutation.”

Novartis was previously granted Breakthrough Therapy Designation for capmatinib. According to FDA guidelines, treatments that receive Breakthrough Therapy Designation must target a serious or life-threatening disease and demonstrate a substantial improvement over existing therapies on one or more significant preliminary research endpoints.

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