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MEDIA UPDATE • MEDIA UPDATE • MEDIA UPDATE

Novartis investigational lung cancer therapy capmatinib (INC280) granted FDA Breakthrough Therapy Designation for patients with MET-mutated advanced non-small cell lung cancer

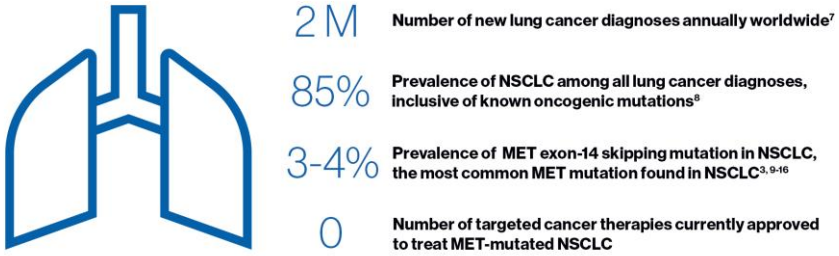
- *Currently, there are no targeted therapies approved to treat MET exon14 skipping-mutated non-small cell lung cancer (NSCLC), a particularly aggressive form of the disease*
- *Breakthrough Therapy Designation (BTD) now covers treatment-naïve and patients previously treated with platinum-based chemotherapy*
- *Regulatory filing for capmatinib in the U.S. is anticipated in Q4 2019*

Basel, September 6, 2019 – "We are pleased to announce that the U.S. Food and Drug Administration granted Breakthrough Therapy Designation to capmatinib (INC280) as a first-line treatment for patients with metastatic MET exon14 skipping-mutated non-small cell lung cancer (NSCLC)," said John Tsai, MD, Head of Global Drug Development and Chief Medical Officer, Novartis.

Recent research concludes that the cMET gene is an oncogenic driver[1,2], and the investigational lung cancer therapy capmatinib has been shown to be a highly potent and selective MET inhibitor. The MET mutation is seen in an estimated 3% - 4% of all patients with NSCLC[3]. These patients are generally older and often have a poor prognosis that can limit lung cancer treatment options[4-6]. "As we continue to reimagine medicine and place a renewed focus on the development of innovative lung cancer treatments, we look forward to working with the FDA and global health authorities to bring capmatinib to patients who currently have no available targeted therapy options," continued Dr. Tsai.

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. The FDA granted Breakthrough Therapy Designation for capmatinib based on positive primary results from the GEOMETRY mono-1 study presented at the 2019 meeting of American Society of Clinical Oncology. Please click link for complete study results [http://bit.ly/2L7L3ta]

Capmatinib (INC280) is an investigational, oral, highly potent and selective MET inhibitor 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.



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