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MEDIA UPDATE

Novartis receives European Commission approval for Tabrecta® for the treatment of METex14 skipping advanced non-small cell lung cancer

- *Tabrecta® (capmatinib) provides a new targeted therapy option for previously-treated patients in Europe who are living with advanced non-small cell lung cancer (NSCLC) harboring alterations leading to MET exon 14 (METex14) skipping*

- *Approval based on the Phase II GEOMETRY mono-1 trial, which showed an overall response rate (ORR) of 51.6% in a cohort evaluating primarily second-line patients and 44% in all previously-treated patients with advanced NSCLC harboring alterations leading to METex14 skipping*[1]

- *Tabrecta is the number one prescribed targeted therapy for advanced NSCLC with alterations leading to METex14 skipping globally*[2]

Basel, June 22, 2022 — Novartis announced today that the European Commission (EC) approved Tabrecta® (capmatinib) 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.

“Patients with METex14 skipping alterations typically have a more advanced form of lung cancer that is often associated with a poor prognosis and limited response to standard therapy, including immunotherapy,” said Juergen Wolf, MD, from the Center for Integrated Oncology, University Hospital Cologne, Germany, and lead investigator of the GEOMETRY mono-1 trial. “With the approval of Tabrecta in Europe, supported by advances in biomarker testing that can help doctors direct treatment more precisely, patients with this specific genomic profile have a new targeted treatment option that can lead to improved outcomes.”

The approval is based on results from the Phase II GEOMETRY mono-1 trial that demonstrated positive overall response rates (ORR) among adult patients with advanced NSCLC whose tumors had alterations leading to METex14 skipping[1]. 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 pain[1].

“As the leading cause of cancer-related deaths worldwide, lung cancer can be a devastating diagnosis for patients and their families,” said Marie-France Tschudin, President, Innovative Medicines International & Chief Commercial Officer, Novartis. “With this new targeted therapy that treats a specific mutation driving cancer growth, we are delivering a much-needed treatment option and bringing hope to patients with this challenging disease.”

In the European Union, there are an estimated 291,000 patients with locally advanced or metastatic NSCLC[2]. METex14 skipping, a recognized oncogenic driver, occurs in approximately 3-4% of NSCLC cases[3,4].

About Tabrecta (capmatinib)
Tabrecta (capmatinib) is approved in several countries including the EU, US, Switzerland and Japan. It is the number one prescribed targeted therapy for patients with advanced NSCLC with alterations leading to METex14 skipping globally[5].

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.

Novartis and lung cancer
The needs in lung cancer are urgent and significant. Each year, more than 2 million people are newly diagnosed globally, and lung cancer remains the number one cause of cancer-related death worldwide[6]. There are two main types of lung cancer—small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC). NSCLC accounts for approximately 85% of lung cancer diagnoses[7].

Novartis is making bold investments in advancing the science to drive treatment and make an impact for patients around the world. The company is committed to working with the scientific and medical communities to reimagine the treatment of lung cancer and pursue advances in medicine that could extend the survival of people living with lung cancer.

With one of the most diverse lung cancer development programs in the industry, Novartis is developing therapies that block cancer growth; learning more about ways to activate the body’s immune system; increasing understanding of the relationship between unregulated inflammation and tumor growth and recurrence; and exploring the potential for advanced nuclear medicine to fight the disease. Through these programs, Novartis aims to redefine possibilities in lung cancer and pursue a trajectory to make lung cancer history.

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About Novartis
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