

## MEDIA UPDATE

# Novartis announces MET inhibitor Tabrecta™ approved in Japan for advanced non-small cell lung cancer with METex14




- *Tabrecta demonstrated an overall response rate of 68% and 41% in treatment-naive and previously treated non-small cell lung cancer (NSCLC) patients with MET exon 14 skipping (METex14) respectively*
- *Lung cancer is the most common type of cancer in Japan and approximately 3,000 patients are diagnosed with METex14 metastatic NSCLC, a particularly aggressive form of the disease, in Japan each year<sup>1-2</sup>*
- *Japan follows US approval earlier this year and demonstrates the company's commitment to reimagining medicine for lung cancer patients around the world*

**Basel, June 29, 2020** — Novartis Pharma K.K. (“Novartis Pharma”) today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) approved Tabrecta™ (capmatinib, formerly INC280), an oral MET inhibitor 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.

“With the remarkable overall response rates seen both in treatment-naive and previously treated patients, we are thrilled that MHLW has added Tabrecta as a new treatment option for patients with advanced NSCLC with METex14,” said Brian Gladsden, President of Novartis Oncology Japan. “Today’s approval reinforces the potential benefit this new MET inhibitor can bring to thousands of patients diagnosed in Japan each year and is a positive step in our journey to transform the lives of patients with lung cancer.”

The approval of Tabrecta is based on results from the pivotal GEOMETRY mono-1 Phase II multi-center, non-randomized, open-label, multi-cohort 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.

The companion diagnostic to Tabrecta, FoundationOne®CDx Cancer Genomic Profile, was approved by MHLW on May 25<sup>th</sup> of this year, to aid in detecting mutations that lead to MET exon 14 skipping in tumor tissue.

	Lung cancer is the uncontrolled growth of abnormal cells in one or both lungs. Various mutations have been associated with driving the tumor development of certain types of NSCLC <sup>3</sup> .
70%	Nearly 70% of NSCLC patients have an identifiable genomic mutation <sup>4</sup> .
	In NSCLC, specific oncogenic mutations can cause MET exon 14 skipping (METex14). METex14 can result in overstimulation of the MET pathway <sup>5</sup> .
3%-4%	METex14 can occur in 3%-4% of newly diagnosed metastatic NSCLC cases <sup>6</sup> .
	Many patients with mutations that lead to METex14 are not diagnosed with NSCLC until their disease has progressed to later stages and often have a poor prognosis <sup>7-8</sup> .

### About Tabrecta (capmatinib)

Tabrecta (capmatinib) is a kinase inhibitor that targets MET. Tabrecta was 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. In May 2020, Tabrecta was approved by the US Food and Drug Administration (FDA) for adult patients with metastatic NSCLC whose tumors have a mutation that leads to METex14 as detected by an FDA-approved test. This indication was 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 confirmatory trial(s).

### Disclaimer

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Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this media update as of this date and does not undertake any obligation to update any forward-looking statements contained in this media update as a result of new information, future events or otherwise.

### **About Novartis**

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 145 nationalities work at Novartis around the world. Find out more at <https://www.novartis.us>.

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