Health Canada approves PrTabrecta®: Targeted cancer therapy for locally advanced unresectable or metastatic non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition (MET) exon 14 skipping alterations

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- Newest treatment for lung cancer reinforces Novartis commitment to developing innovative therapies that improve outcomes for Canadians affected by advanced lung cancer

Dorval, Quebec, June 8, 2022 – Novartis Pharmaceuticals Canada Inc. (Novartis) is pleased to announce that Health Canada has granted a Notice of Compliance with conditions (NOC/c) for Tabrecta® (capmatinib tablets) for the treatment of adult patients with locally advanced unresectable or metastatic non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition (*MET*) exon 14 skipping alterations. Efficacy and safety results of Tabrecta® were based on the pivotal phase 2, single-arm study A2201 (GEOMETRY mono-1) conducted in adult patients with treatment-naive or previously treated, locally advanced (Stage IIIB) or metastatic (Stage IV) NSCLC with *MET* dysregulation, with overall response rate and duration of response as primary and key secondary endpoints, respectively. Documentation of the presence of a *MET* exon 14 (METex14) alteration based on a validated test is required prior to treatment with Tabrecta®.[2]

“Lung cancer patients diagnosed with non-small cell lung cancer can have limited treatment options available to them,” said Dr. Barbara Melosky, UBC Clinical Professor. “The approval of Tabrecta® is welcome news for lung cancer patients, and fills a treatment gap for this population. Furthermore, this innovation demonstrates how having a better understanding of a tumour’s genetic makeup can offer new avenues for treatment and hope for better outcomes.”

In 2022, 30,000 Canadians will be diagnosed with lung and bronchus cancer, with 20,700 Canadians dying from these diseases. This represents 24 per cent of all cancer deaths in 2022.[5] NSCLC is the most common type of lung cancer, making up around 80 to 85 per cent of all lung cancer cases.[5] Patients with metastatic (un-operable) NSCLC, with *MET*ex14 alterations often have a poorer prognosis, as the cancer may have advanced to other parts of the body.[6]

Tabrecta® works as an inhibitor of the *MET* receptor tyrosine kinase. *MET* receptor tyrosine kinase is involved in all stages of cancer cell growth, survival, migration and metastasis. This *MET* inhibitor works towards controlling the growth of cancer cells, showing anti-tumour activity in NSCLC in both preclinical and clinical trials. Treatment with Tabrecta® resulted in antitumor activity in patients with advanced NSCLC with a *MET* ex14 skipping alteration, particularly in those not treated previously, as well as a tolerable and predictable safety profile.[9]

“We welcome the approval of a new treatment option for lung cancer, a serious disease affecting thousands of Canadians every year,” said Shem Singh, Executive Director, Lung Cancer Canada. “Patients who have been diagnosed with this type of cancer in the past often have had limited options available to them in their

treatment journey. Knowing more about the molecular makeup of the tumour, and what mutation is driving the cancer, along with newer treatment options like Tabrecta®, will enable healthcare teams to better support patients in their treatment journey."

The conditional approval of Tabrecta® is based on results from the pivotal GEOMETRY mono-1 Phase II multi-center, non-randomized, open-label, multi-cohort study. The study primary endpoint was overall response rate (ORR) by Blinded Independent Review Committee (BIRC) per RECIST v1.1. Key secondary endpoint was duration of response (DOR) by BIRC.

"Novartis is proud that Tabrecta® has been approved as an additional option for Canadians living with lung cancer," said Andrea Marazzi, Country President, Novartis Pharmaceuticals Canada Inc., "The approval reinforces our commitment to innovative therapies and improving the outcomes for those living with lung cancer for the future."

About Tabrecta®

Tabrecta® (capmatinib tablets) is a tyrosine 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.

About GEOMETRY mono-1

GEO*MET*RY mono-1 is a Phase II multi-center, non-randomized, open-label, multi-cohort study evaluating capmatinib in adult patients with *MET*ex14-mutated or MET-amplified advanced NSCLC across 6 cohorts. Patients (> 18 yrs) with ECOG PS 0-1, ALK and EGFR wild-type, and stage IIIB/IV NSCLC were eligible. Primary endpoint was overall response rate (ORR) by Blinded Independent Review Committee (BIRC) per RECIST v1.1. Key secondary endpoint was duration of response (DOR) by BIRC. The trial evaluated 160 adult patients with metastatic NSCLC harboring mutations that lead to METex14 (centrally confirmed) who were treatment-naive (Cohort 5b, n=28, and Cohort 7, n=32) and those who had previously received 1 or 2 lines of therapy for their advanced disease (expansion Cohort 6, n=31, and Cohort 4, n=69) ,and received capmatinib tablets 400 mg orally twice daily.

About Novartis Pharmaceuticals Canada Inc.

Novartis Pharmaceuticals Canada Inc., a leader in the healthcare field, is committed to the discovery, development and marketing of innovative products to improve the well-being of all Canadians. Over the last five years, our average annual research and development investment in Canada was $47 million. Located in Dorval, Quebec, Novartis Pharmaceuticals Canada Inc. employs approximately 1,000 people in Canada and is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. For further information, please consult https://www.novartis.com/ca-en/.

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 more than 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 110,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com/.

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