

Novartis announces FDA approval of MET inhibitor Tabrecta™ for metastatic non-small cell lung cancer with METex14

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- Tabrecta (capmatinib, formerly INC280) is the first and only therapy approved by the FDA to specifically target metastatic NSCLC with a mutation that leads to MET exon 14 skipping (METex14)(1)
- 4,000-5,000 patients are diagnosed with METex14 metastatic NSCLC each year in the US and may face poor prognosis due to presence of the mutation(2-3)
- Tabrecta demonstrated an overall response rate of 68% and 41% in treatment-naïve and previously treated METex14 patients, respectively(1)
- FDA approval reinforces the company's bold vision to deliver innovative treatment approaches for patients living with lung cancer

EAST HANOVER, N.J., May 6, 2020 /PRNewswire/ -- Novartis announced today 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 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 cancer³. 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.

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-naïve (n=28) and previously treated

patients (n=69), respectively, based on the Blinded Independent Review Committee (BIRC) assessment per RECIST v1.1¹. In patients taking Tavegra, the study also demonstrated a median duration of response of 12.6 months (95% CI, 5.5–25.3) in treatment-naïve patients (19 responders) and 9.7 months (95% CI, 5.5-13.0) in previously treated patients (28 responders)¹. The most common treatment-related adverse events (AEs) (incidence ≥20%) are peripheral edema, nausea, fatigue, vomiting, dyspnea, and decreased appetite¹.

"Today, and especially during these difficult times, we are incredibly proud that Tavegra is the first treatment approved by the FDA specifically to treat patients diagnosed with this aggressive NSCLC associated with METex14," said Susanne Schaffert, PhD, President, Novartis Oncology. "In our quest to reimagine medicine, we have worked tirelessly over the past decades to advance the understanding and treatment of NSCLC, striving to make a difference in patients' lives, one mutation at a time. We thank all the physicians, patients and families involved in the Tavegra clinical trials, and we remain committed to advancing innovative solutions for the patients we work to serve."

NSCLC accounts for approximately 85% of the 2 million new lung cancer diagnoses each year worldwide, including about 228,000 in the United States⁴⁻⁵. Nearly 70% of NSCLC patients have a genomic mutation⁶. METex14, a recognized oncogenic driver, occurs in approximately 3%-4% of newly diagnosed metastatic NSCLC cases (about 4,000 – 5,000 patients in the US annually)^{7-9, 2}.

"With NSCLC, understanding whether a mutation is driving the cancer is critical, and it's important for doctors and patients to use comprehensive biomarker testing at the time of diagnosis or progression to check for mutations like those that cause METex14," said Andrea Ferris, President and CEO of LUNgevity. "Knowing more about the molecular makeup of their tumor will help patients and their healthcare teams make informed treatment-related decisions from the start."

Novartis is committed to providing patients with access to medicines, as well as resources and support to address a range of needs. The Novartis Oncology Patient Support Program is available to help guide eligible patients through the various aspects of getting started on treatment, from providing educational information to helping them understand their insurance coverage and identify potential financial assistance options. Patients or providers can call 800-282-7630 or visit [Patient.NovartisOncology.com](https://www.novartis.com/patient) or [HCP.Novartis.com/Access](https://www.novartis.com/hcp) to learn more about eligibility and to enroll.

Full prescribing information for Tavegra can be found at <https://www.novartis.us/sites/www.novartis.us/files/tavegra.pdf>

About Tavegra (capmatinib)

Tavegra (capmatinib) is a kinase inhibitor that targets MET. Tavegra 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.

About GEOMETRY mono-1

GEOMETRY mono-1 is a Phase II multi-center, non-randomized, open-label, multi-cohort study in adult patients with EGFR wild-type, metastatic NSCLC as measured by ORR.

The trial evaluated 97 adult patients with metastatic NSCLC harboring mutations that lead to METex14 (centrally confirmed) who were assigned to Cohorts 4 (n=69, previously treated patients) or 5b (n=28, treatment-naïve), and received capmatinib tablets 400 mg orally twice daily.

The major efficacy outcome is ORR based on BIRC assessment per RECIST v1.1. An additional efficacy

outcome is duration of response by BIRC.

Novartis Commitment to Lung Cancer

Worldwide, lung cancer causes more deaths than colon, breast and prostate cancer combined, and more than 2 million new cases of lung cancer are diagnosed each year⁴. Despite treatment advances, many patients with NSCLC still have a poor prognosis and limited treatment options³. This includes the nearly 70% of NSCLC patients who have a genomic mutation⁶. To determine the most appropriate treatment, medical organizations recommend comprehensive genomic testing for patients with lung cancer as part of their upfront diagnosis⁷.

Novartis Oncology's research has helped transform treatment approaches for patients living with NSCLC. Novartis continues its commitment to the global lung cancer community through ongoing studies, as well as the exploration of investigational compounds in NSCLC, including those that target genetic biomarkers and tumor promoting inflammation.

Indication

TABRECTA™ (capmatinib) tablets is a prescription medicine used to treat adults with a kind of lung cancer called non-small cell lung cancer (NSCLC) that has spread to other parts of the body or cannot be removed by surgery (metastatic), and whose tumors have an abnormal mesenchymal-epithelial transition (MET) gene.

The effectiveness of TABRECTA in these patients is based on a study that measured 2 types of response to treatment (response rate and duration of response). There is no clinical information available to show if patients treated with TABRECTA live longer or if their symptoms improve. There are ongoing studies to find out how TABRECTA works over a longer period of time.

It is not known if TABRECTA is safe and effective in children.

Important Safety Information

TABRECTA may cause serious side effects, such as lung or breathing problems. TABRECTA may cause inflammation of the lungs during treatment that may lead to death. Patients should be advised to contact their health care provider right away if they develop any new or worsening symptoms, including cough, fever, trouble breathing, or shortness of breath.

TABRECTA may cause abnormal blood test results, which may be a sign of liver problems. Patients should be advised that their health care provider will do blood tests to check their liver before starting and during treatment with TABRECTA. Patients should be advised to contact their health care provider right away if they develop any signs and symptoms of liver problems including the skin or the white part of their eyes turning yellow (jaundice), dark or "tea-colored" urine, light-colored stools (bowel movements), confusion, loss of appetite for several days or longer, nausea and vomiting, pain, aching, or tenderness on the right side of the stomach area (abdomen), or weakness or swelling in the stomach area.

The skin may be sensitive to the sun (photosensitivity) during treatment with TABRECTA. Patients should be advised to use sunscreen or wear clothes that cover their skin during treatment with TABRECTA to limit direct sunlight exposure.

For women of reproductive potential, TABRECTA can harm their unborn baby. They should use an effective method of birth control during treatment with TABRECTA and for 1 week after the last dose. Men who have partners who can become pregnant should use effective birth control during treatment with TABRECTA and for 1 week after the last dose.

Before taking TABRECTA, patients should tell their health care provider about all their medical conditions, including if they have or have had lung or breathing problems other than lung cancer, have or have had liver problems, or if they are pregnant or plan to become pregnant, as TABRECTA can harm their unborn babies. Females who are able to become pregnant should have a pregnancy test before they start treatment with TABRECTA and should use effective birth control during treatment and for 1 week after the last dose of TABRECTA. Patients should be advised to talk to their health care provider about birth control choices that might be right for them during this time and to tell their health care provider right away if they become pregnant or think they may be pregnant during treatment with TABRECTA. Males who have female partners who can become pregnant should use effective birth control during treatment and for 1 week after their last dose of TABRECTA.

Patients should tell their health care provider about all the medicines they take or start taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

The most common side effects of TABRECTA include swollen hands, ankles, or feet (peripheral edema); nausea and/or vomiting; tiredness and/or weakness (fatigue, asthenia); shortness of breath (dyspnea); loss of appetite; changes in bowel movements (diarrhea or constipation); cough; pain in the chest; fever (pyrexia); back pain; and decreased weight.

Please see full Prescribing Information for Tabrecta available at <https://www.novartis.us/sites/www.novartis.us/files/tabrecta.pdf>

About Novartis

Located in East Hanover, NJ Novartis Pharmaceuticals Corporation – an affiliate of 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 employs about 15,000 people in the United States. For more information, please visit <http://www.novartis.us>.

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*FoundationOne®CDx is a registered trademark of Foundation Medicine, Inc.

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