# FIRST FDA-APPROVED TARGETED TREATMENT

In mNSCLC with mutations leading to *MET* exon 14 skipping (*MET*ex14)

## TREATMENT-NAIVE PATIENTS (n=28)[1,2]

- **68% overall response rate (ORR)** (95% CI, 48-84; CR, 1 [4%] + PR, 18 [64%])
- **12.6 months median duration of response (mDOR)** (95% CI, 5.5-25.3; n=19)
  - Percentage of patients with responses at ≥12 months was 47%

### OTHER EFFICACY OUTCOMES[2,3]

- **96.4% disease control rate (DCR)** (95% CI, 81.7-99.9)

  DCR was an exploratory efficacy outcome that accounted for CR + PR + SD + non-CR/non-PD, which may reflect the natural history of disease in an individual patient rather than the therapeutic effect of the treatment.
- **12.4 months median progression-free survival (PFS)** (95% CI, 8.21-NE)

  Due to the nonrandomized, noncomparative nature of the study, PFS results are difficult to interpret.

  This indication is approved under accelerated approval based on ORR and DOR. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

## PREVIOUSLY TREATED PATIENTS (n=69)[1,2]

- **41% ORR** (95% CI, 29-53; CR, 0 [0%] + PR, 28 [41%])
- **9.7 months mDOR** (95% CI, 5.5-13.0; n=28)
  - Percentage of patients with responses at ≥12 months was 32%

### OTHER EFFICACY OUTCOMES[2,3]

- **78.3% DCR** (95% CI, 66.7-87.3)

  DCR was an exploratory efficacy outcome that accounted for CR + PR + SD + non-CR/non-PD, which may reflect the natural history of disease in an individual patient rather than the therapeutic effect of the treatment.
- **5.4 months median PFS** (95% CI, 4.17-6.97)

  Due to the nonrandomized, noncomparative nature of the study, PFS results are difficult to interpret.

  This indication is approved under accelerated approval based on ORR and DOR. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

TABRECTA™ (capmatinib) tablets was studied in GEOMETRY mono-1, a multicenter, nonrandomized, open-label, multicohort study of patients with EGFR wild-type, ALK-negative, mNSCLC. Patients with *MET*ex14 (n=97) comprised 2 cohorts: treatment naive (n=28) and treated previously with 1 or 2 prior lines of therapy (n=69). Patients received TABRECTA 400 mg twice daily. Treatment was continued until disease progression, intolerance, or investigator-led discontinuation. Evaluable patients were defined as those who completed at least 6 cycles of treatment (18 weeks) or discontinued treatment earlier. The major efficacy outcome was ORR, and DOR was an additional efficacy outcome as determined by a blinded independent review committee (BIRC) according to RECIST 1.1. Other efficacy outcomes included DCR and PFS.[1,2]

## Highlights of Important Safety Information

- TABRECTA has Warnings and Precautions for interstitial lung disease (ILD/pneumonitis), hepatotoxicity, risk of photosensitivity, and embryo-fetal toxicity
- The most common ARs (≥20%) are peripheral edema, nausea, fatigue, vomiting, dyspnea, and decreased appetite

ALK, anaplastic lymphoma kinase; AR, adverse reaction; CR, complete response; EGFR, epidermal growth factor receptor; MET, mesenchymal-epithelial transition; mNSCLC, metastatic non-small cell lung cancer; NE, not estimable; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.

## Indication

TABRECTA™ (capmatinib) tablets is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping 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 trials.

## Important Safety Information

**Interstitial Lung Disease (ILD)/Pneumonitis.** ILD/pneumonitis, which can be fatal, occurred in patients treated with TABRECTA. ILD/pneumonitis occurred in 4.5% of patients treated with TABRECTA in the GEOMETRY mono-1 study, with 1.8% of patients experiencing grade 3 ILD/pneumonitis and 1 patient experiencing death (0.3%). Eight patients (2.4%) discontinued TABRECTA due to ILD/pneumonitis.

**Please see full Important Safety Information on page 2.**

**Please click here for full Prescribing Information for TABRECTA.**

TABRECTA™ (capmatinib) tablets 150 mg · 200 mg

# 1st FDA APPROVED:
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Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever). Immediately withhold TABRECTA in patients with suspected ILD/pneumonitis and permanently discontinue if no other potential causes of ILD/pneumonitis are identified.

**Hepatotoxicity.** Hepatotoxicity occurred in patients treated with TABRECTA. Increased alanine aminotransferase (ALT)/aspartate aminotransferase (AST) occurred in 13% of patients treated with TABRECTA in GEOMETRY mono-1. Grade 3 or 4 increased ALT/AST occurred in 6% of patients. Three patients (0.9%) discontinued TABRECTA due to increased ALT/AST.

Monitor liver function tests (including ALT, AST, and total bilirubin) prior to the start of TABRECTA, every 2 weeks during the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop increased transaminases or bilirubin. Based on the severity of the adverse reaction, withhold, reduce dose, or permanently discontinue TABRECTA.

**Risk of Photosensitivity.** Based on findings from animal studies, there is a potential risk of photosensitivity reactions with TABRECTA. In GEOMETRY mono-1, it was recommended that patients use precautionary measures against ultraviolet exposure, such as use of sunscreen or protective clothing, during treatment with TABRECTA. Advise patients to limit direct ultraviolet exposure during treatment with TABRECTA.

**Embryo-Fetal Toxicity.** Based on findings from animal studies and its mechanism of action, TABRECTA can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TABRECTA and for 1 week after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with TABRECTA and for 1 week after the last dose.

**Most Common Adverse Reactions.** The most common adverse reactions (≥20%) were peripheral edema (52%), nausea (44%), fatigue (32%), vomiting (28%), dyspnea (24%), and decreased appetite (21%). The most common grade 3 adverse reactions (≥2%) were peripheral edema (9%), fatigue (8%), dyspnea (7%), nausea (2.7%), vomiting (2.4%), and noncardiac chest pain (2.1%). Grade 4 dyspnea was reported in 0.6% of patients.

**Clinically Relevant Adverse Reactions.** Clinically relevant adverse reactions observed in <10% of patients were pruritus (allergic and generalized), ILD/pneumonitis, cellulitis, acute kidney injury (including renal failure), urticaria, and acute pancreatitis.

**Laboratory Abnormalities.** Select laboratory abnormalities (≥20%) worsening from baseline in patients who received TABRECTA were decreased albumin (68%), increased creatinine (62%), decreased lymphocytes (44%), increased ALT (37%), increased alkaline phosphatase (32%), increased amylase (31%), increased gamma-glutamyltransferase (29%), increased lipase (26%), increased AST (25%), decreased hemoglobin (24%), decreased leukocytes (23%), decreased sodium (23%), decreased phosphate (23%), increased potassium (23%), and decreased glucose (21%).

**Please click here for full Prescribing Information for TABRECTA.**

**References: 1.** Tabrecta [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2020. **2.** Data on file. Study CINC280A2201. Novartis Pharmaceuticals Corp; 2019. **3.** Data on file. Study CINC280A2201, January 2020. Novartis Pharmaceuticals Corp; 2020.

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