FDA Approves Tabrecta for Metastatic Non-Small Cell Lung Cancer

Capmatinib shrank tumors in 68% of people with metastatic non-small-cell lung cancer with a specific MET mutation.

May 8, 2020 By Food and Drug Administration (FDA)

FDA grants accelerated approval to capmatinib for metastatic non-small cell lung cancer

On May 6, 2020, the Food and Drug Administration granted accelerated approval to capmatinib (TABRECTA, Novartis) for 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.

Today, FDA also approved the FoundationOne CDx assay (Foundation Medicine, Inc.) as a companion diagnostic for capmatinib.

Efficacy was demonstrated in the GEOMETRY mono-1 trial (NCT02414139), a multicenter, non-randomized, open-label, multicohort study enrolling 97 patients with metastatic NSCLC with confirmed MET exon 14 skipping. Patients received capmatinib 400 mg orally twice daily until disease progression or unacceptable toxicity.

The main efficacy outcome measures were overall response rate (ORR) determined by a blinded independent review committee using RECIST 1.1 and response duration. Among the 28 treatment-naïve patients, the ORR was 68% (95% CI: 48, 84) with a response duration of 12.6 months (95% CI: 5.5, 25.3). Among the 69 previously treated patients, the ORR was 41% (95% CI: 29, 53) with a response duration of 9.7 months (95% CI: 5.5, 13.0).

The most common adverse reactions (≥ 20% of patients) were peripheral edema, nausea, fatigue, vomiting, dyspnea, and decreased appetite. Capmatinib can also cause interstitial lung disease, hepatotoxicity, photosensitivity, and embryo-fetal toxicity. Based on a clear positive signal for phototoxicity in early laboratory studies in cells, patients may be more sensitive to sunlight and should be advised to take precautions to cover their skin, use sunscreen, and not tan while taking capmatinib.

The recommended capmatinib dose is 400 mg orally twice daily with or without food.

View full prescribing information for TABRECTA.

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

This review used the Assessment Aid, a voluntary submission from the applicant to facilitate FDA's assessment. The FDA approved this application 3 months ahead of the FDA goal date.

FDA granted capmatinib orphan drug and breakthrough therapy designation. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

This announcement was originally published on the Food and Drug Administration website on May 6, 2020.
