FDA Approves Tecentriq Combo for Advanced Melanoma

Tecentriq plus two targeted medications extended progression-free survival by 4.5 months.

August 3, 2020 By Food and Drug Administration (FDA)

FDA approves atezolizumab for BRAF V600 unresectable or metastatic melanoma

On July 30, 2020, the Food and Drug Administration approved atezolizumab (Tecentriq, Genentech, Inc.) in combination with cobimetinib and vemurafenib for patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

Efficacy in combination with cobimetinib and vemurafenib was evaluated in a double-blind, randomized (1:1), placebo-controlled, multicenter trial (IMspire150, NCT02908672) in 514 patients.

After a 28-day cycle of cobimetinib and vemurafenib, patients received atezolizumab 840 mg intravenous infusion every 2 weeks in combination with cobimetinib 60 mg orally once daily and vemurafenib 720 mg orally twice daily, or placebo in combination with cobimetinib 60 mg orally once daily (21 days on/7 days off) and vemurafenib 960 mg orally twice daily.

The primary efficacy outcome measure was investigator-assessed progression-free survival (PFS) per RECIST 1.1. Median PFS was 15.1 months (95% CI: 11.4, 18.4) in the atezolizumab arm and 10.6 months (95% CI: 9.3, 12.7) in the placebo arm (HR 0.78; 95% CI: 0.63, 0.97; p=0.0249).

The most common adverse reactions (≥ 20%) with atezolizumab in combination with cobimetinib and vemurafenib in patients with melanoma were rash, musculoskeletal pain, nausea, fatigue, hepatotoxicity, pyrexia, nausea pruritus, edema, stomatitis, hypothyroidism, and photosensitivity reaction.

The recommended atezolizumab dose, following completion of a 28-day cycle of cobimetinib and vemurafenib, is 840 mg every 2 weeks with cobimetinib 60 mg orally once daily (21 days on /7 days off) and vemurafenib 720 mg orally twice daily.

View full prescribing information for TECENTRIQ.

This review used the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment. The FDA approved this application 6 weeks ahead of the FDA goal date.

The FDA collaborated with Switzerland's Swissmedic on the review of this application as part of Project Orbis.

This application was granted priority review and atezolizumab was granted orphan product 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 July 30, 2020.
