FDA Grants Regular Approval of Venclexta Regimen For Untreated Acute Myeloid Leukemia

The regimen is approved for adults age 75 or older and those who cannot use intensive induction chemotherapy.

October 19, 2020 By Food and Drug Administration (FDA)

FDA grants regular approval to venetoclax in combination for untreated acute myeloid leukemia

On October 16, 2020, the Food and Drug Administration granted regular approval to venetoclax (VENCLEXTA, AbbVie Inc. and Genentech Inc.) in combination with azacitidine, decitabine, or low-dose cytarabine (LDAC) for newly-diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities precluding intensive induction chemotherapy.

Venetoclax was initially granted accelerated approval for this indication in November 2018.

Efficacy was confirmed in two randomized, double-blind, placebo-controlled trials in patients with AML described above.

In VIALE-A (NCT02993523), patients were randomized to receive venetoclax plus azacitidine (n=286) or placebo plus azacitidine (n=145). Efficacy was established based on an improvement in overall survival (OS). The median OS was 14.7 months (95% CI: 11.9, 18.7) in patients treated with venetoclax plus azacitidine compared to 9.6 months (95% CI: 7.4, 12.7) in those receiving placebo plus azacitidine (HR 0.66; 95% CI: 0.52, 0.85; p<0.001). Patients treated with venetoclax plus azacitidine also demonstrated an improvement in complete remission (CR) rate: 37% (95% CI: 31%, 43%) versus 18% (95% CI: 12%, 25%).

In VIALE-C (NCT03069352), patients were randomized to receive venetoclax plus LDAC (n=143) or placebo plus LDAC (n=68). Efficacy was based on CR rate and duration of CR. The CR rate on the venetoclax plus LDAC arm was 27% (95% CI: 20%, 35%) with a median duration of 11.1 months (95% CI: 6.1, not reached) compared to 7.4% (95% CI: 2.4%, 16%) with a median duration of 8.3 months (95% CI: 3.1, not reached) in those receiving placebo plus LDAC. Venetoclax plus LDAC did not significantly improve OS versus placebo plus LDAC (HR 0.75; 95% CI 0.52, 1.07; p=0.114).

The most common adverse reactions of venetoclax in combination with azacitidine, decitabine, or low-dose cytarabine (≥30% in any trial) were nausea, diarrhea, thrombocytopenia, constipation,

neutropenia, febrile neutropenia, fatigue, vomiting, edema, pyrexia, pneumonia, dyspnea, hemorrhage, anemia, rash, abdominal pain, sepsis, musculoskeletal pain, dizziness, cough, oropharyngeal pain, and hypotension.

The recommended venetoclax dose depends upon the combination regimen and is described in prescribing information.

View full prescribing information for Venclexta.

This review was conducted under Project Orbis, an initiative of the FDA Oncology Center of Excellence. Project Orbis provides a framework for concurrent submission and review of oncology drugs among international partners. For this review, FDA collaborated with the Australian Therapeutic Goods Administration (TGA), the Brazilian Health Regulatory Agency (ANVISA), Health Canada, and Switzerland's Swissmedic. The application reviews are ongoing at the other regulatory agencies.

This review used the Real-Time Oncology Review (RTOR) pilot program and the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment. The FDA approved this application 5 weeks ahead of the FDA goal date.

FDA granted this application priority review, breakthrough designation, and orphan drug 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.

For assistance with single-patient INDs for investigational oncology products, healthcare professionals may contact OCE's Project Facilitate at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

This announcement was originally published on the Food and Drug Administration website on October 16, 2020.

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