FDA Approves Onureg for Acute Myeloid Leukemia

The new drug improved overall survival for people who could not complete curative chemotherapy.

September 4, 2020 By Food and Drug Administration (FDA)

On September 1, 2020, the Food and Drug Administration approved azacitidine tablets (ONUREG, Celgene Corporation) for continued treatment of patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy.

Efficacy was investigated in QUAZAR (NCT01757535), a multicenter, randomized, double-blind, placebo-controlled trial. Patients (n=472) who achieved CR or CRi with intensive induction chemotherapy with or without receiving subsequent consolidation therapy were randomized 1:1 to receive Onureg 300 mg (n=238) or placebo (n=234) orally on days 1 to 14 of each 28-day cycle.

The main efficacy outcome measure was overall survival (OS). Median OS was 24.7 months (95% CI: 18.7, 30.5) in the Onureg arm and 14.8 months (95% CI: 11.7, 17.6) in the placebo arm (HR 0.69; 95% CI: 0.55, 0.86; p=0.0009). A subgroup analysis showed consistency in the OS benefit for patients in either CR or CRi.

Adverse reactions in ≥10% patients receiving Onureg were nausea, vomiting, diarrhea, fatigue/asthenia, constipation, pneumonia, abdominal pain, arthralgia, decreased appetite, febrile neutropenia, dizziness, and pain in extremity.

The recommended Onureg dose is 300 mg orally once daily with or without food on days 1 through 14 of each 28-day cycle. Continue Onureg until disease progression or unacceptable toxicity.

View full prescribing information for ONUREG.

This application was granted priority review and Onureg was granted 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.

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