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CLINICAL UPDATE

Brand Name	Onureg
Generic Name	azacitidine
Drug Manufacturer	QUAZAR

Clinical Update

Clinical update: FDA Approves Onureg (azacitidine tablets) as Continued Treatment for Adults in First Remission with Acute Myeloid Leukemia.

FDA approval date: September 1, 2020

Overview

Onureg is indicated for continued treatment of adult patients with acute myeloid leukemia (AML) 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

The approval of Onureg is based on results from the Phase 3 QUAZAR AML-001 study, an international, randomized, double-blind, placebo-controlled study evaluating the agent as maintenance therapy in patients 55 years of age and older who are in their first AML remission, following induction therapy.

Efficacy was investigated in QUAZAR (NCT01757535), a multi-center, 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.

Safety

Onureg is contraindicated in patients with known severe hypersensitivity to azacitidine or its components.
Most common (≥10%) adverse reactions with Onureg vs placebo were nausea (65%, 24%), vomiting (60%, 10%), diarrhea (50%, 21%), fatigue/asthenia (44%, 25%), constipation (39%, 24%), pneumonia (27%, 17%), abdominal pain (22%, 13%), arthralgia (14%, 10%), decreased appetite (13%, 6%), febrile neutropenia (12%, 8%), dizziness (11%, 9%), and pain in extremity (11%, 5%).

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