

ONUREG® is indicated for continued treatment of adults with AML in first CR or CRi following intensive induction chemotherapy who are unable to complete intensive curative therapy.<sup>1</sup>

## Find out which of your patients with AML may be right for ONUREG®

### Do you see patients like these in your practice?



> **Denise, 64**

- Favorable-risk AML<sup>a</sup>
- Transplant-ineligible
- Gene mutation: *NPM1*

< **Tony, 57**

- Intermediate-risk AML<sup>a</sup>
- Gene mutation: biallelic *CEBPA*
- Avid traveler and remote worker



<sup>a</sup>Based on European LeukemiaNet (ELN) cytogenetic risk stratification categories.

AML, acute myeloid leukemia.

The patient cases presented are hypothetical; not actual patients.

**Learn why James McCloskey, MD chose ONUREG for his patient in first AML remission.**



[Watch the video](#)

#### INDICATION

ONUREG® is indicated for continued treatment of adult 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.

#### IMPORTANT SAFETY INFORMATION

##### CONTRAINDICATIONS

ONUREG® is contraindicated in patients with known severe hypersensitivity to azacitidine or its components.

Please see additional Important Safety Information throughout and full [Prescribing Information](#) for ONUREG.

[www.ONUREGpro.com](http://www.ONUREGpro.com)

 **ONUREG**<sup>™</sup>  
(azacitidine) tablets  
300mg • 200mg

# Denise is a transplant-ineligible patient who wants to proactively treat her AML while it is in remission

“  
I’m not a candidate for transplant, but I don’t want to sit around and wait for the AML to return  
”



The patient case presented is hypothetical; not an actual patient.

## De novo AML

- Favorable risk disease<sup>a</sup>
- ECOG PS: 1
- Gene mutation: *NPM1*

Age: 64

## Comorbidities:

- Hyperlipidemia
- Diabetes Mellitus type 2

Transplant-ineligible

“  
I’m looking forward to Thanksgiving with my family  
”



Achieved **complete remission** after 1 induction cycle



In collaboration with her doctor, decided **ONUREG®** was the right treatment choice for her:<sup>1</sup>

- Completed only 2 of 4 planned cycles of consolidation due to an infection
- **Transplant-ineligible**
- Favorable-risk AML<sup>a</sup>



Has been taking **ONUREG** at home for 18 months<sup>1</sup>

- With an **antiemetic** before each dose<sup>b</sup> and an **anti-diarrheal** as needed



Cytopenias identified during Cycle 3 were **resolved** after a treatment interruption

<sup>a</sup>Based on European LeukemiaNet (ELN) cytogenetic risk stratification categories. <sup>b</sup>For the first 4 cycles. All patients should receive antiemetics for at least the first 2 cycles; antiemetic prophylaxis may be omitted after 2 cycles if there has been no nausea and vomiting.<sup>1</sup>

**AML**, acute myeloid leukemia; **ECOG PS**, Eastern Cooperative Oncology Group performance status.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS

#### Risks of Substitution with Other Azacitidine Products

Due to substantial differences in the pharmacokinetic parameters, the recommended dose and schedule for ONUREG® are different from those for the intravenous or subcutaneous azacitidine products. Treatment of patients using intravenous or subcutaneous azacitidine at the recommended dosage of ONUREG® may result in a fatal adverse reaction. Treatment with ONUREG® at the doses recommended for intravenous or subcutaneous azacitidine may not be effective. Do not substitute ONUREG® for intravenous or subcutaneous azacitidine.

#### Myelosuppression

New or worsening Grade 3 or 4 neutropenia and thrombocytopenia occurred in 49% and 22% of patients who received ONUREG®. Febrile neutropenia occurred in 12%. A dose reduction was required for 7% and 2% of patients due to neutropenia and thrombocytopenia. Less than 1% of patients discontinued ONUREG® due to either neutropenia or thrombocytopenia. Monitor complete blood counts and modify the dosage as recommended. Provide standard supportive care, including hematopoietic growth factors, if myelosuppression occurs.

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# Tony is a patient who wants to understand which AML treatment is right for him

“  
Depending on what treatment I choose, what will that mean for my plans?  
”



The patient case presented is hypothetical; not an actual patient.

## De novo AML

- Intermediate risk disease<sup>a</sup>
- ECOG PS: 1
- Gene mutation: **biallelic CEBPA**

Age: 57

Comorbidities: None

Avid traveler and IT consultant **with flexibility to work remotely**

“  
My life has fewer interruptions with an at-home oral treatment  
”



## Achieved **complete remission** after **1 induction cycle**

- Received 4 cycles of consolidation



## In collaboration with his doctor, decided **ONUREG®** was the right treatment choice for him:<sup>1</sup>

- Imperfect transplant donor match
- Treatment delivery/convenience
- Personal goals



## Has been taking **ONUREG** at home for 12 months<sup>1</sup>

- With an **antiemetic** before each dose<sup>b</sup> and whenever he experiences nausea



## Laboratory monitoring completed remotely<sup>2</sup> while Tony was traveling

<sup>a</sup>Based on European LeukemiaNet (ELN) cytogenetic risk stratification categories. <sup>b</sup>All patients should receive antiemetics for at least the first 2 cycles; antiemetic prophylaxis may be omitted after 2 cycles if there has been no nausea and vomiting.<sup>1</sup>

**AML**, acute myeloid leukemia; **ECOG PS**, Eastern Cooperative Oncology Group performance status.

## IMPORTANT SAFETY INFORMATION (cont'd)

### Increased Early Mortality in Patients with Myelodysplastic Syndromes (MDS)

In AZA-MDS-003, 216 patients with red blood cell transfusion-dependent anemia and thrombocytopenia due to MDS were randomized to ONUREG® or placebo. 107 received a median of 5 cycles of ONUREG® 300 mg daily for 21 days of a 28-day cycle. Enrollment was discontinued early due to a higher incidence of early fatal and/or serious adverse reactions in the ONUREG® arm compared with placebo. The most frequent fatal adverse reaction was sepsis. Safety and effectiveness of ONUREG® for MDS have not been established. Treatment of MDS with ONUREG® is not recommended outside of controlled trials.

### Embryo-Fetal Toxicity

ONUREG® can cause fetal harm when administered to a pregnant woman. Azacitidine caused fetal death and anomalies in pregnant rats via a single intraperitoneal dose less than the recommended human daily dose of oral azacitidine on a mg/m<sup>2</sup> basis. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ONUREG® and for at least 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with ONUREG® and for at least 3 months after the last dose.

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Choose **ONUREG**  
to help your patients  
live longer<sup>1,a</sup>

<sup>a</sup>The efficacy of ONUREG was evaluated in QUAZAR AML-001, a multicenter, randomized, double-blind, placebo-controlled, phase III study. Eligible patients were aged 55 years or older, had AML, and were within 4 months of achieving first CR or CRi with intensive chemotherapy. Patients were excluded if they were candidates for HSCT at the time of screening. A total of 472 patients who completed induction with or without consolidation therapy were randomized 1:1 to receive ONUREG 300 mg (n=238) or placebo (n=234) orally on Days 1 through 14 of each 28-day cycle. Efficacy was established based on overall survival (OS). ONUREG demonstrated a statistically significant improvement vs placebo in median OS: 24.7 months (95% CI: 18.7, 30.5) vs 14.8 months (95% CI: 11.7, 17.6), respectively (HR: 0.69 [95% CI: 0.55, 0.86; P=0.0009]).<sup>1</sup>

**References:** **1.** ONUREG® (Prescribing Information). Summit, NJ: Celgene Corporation; 2022. **2.** Lloyd J, Lee CJ. Use of telemedicine in care of hematologic malignancy patients: challenges and opportunities. *Curr Hematol Malig Rep.* 2022;17(1):25-30.

**AML**, acute myeloid leukemia; **CI**, confidence interval; **CR**, complete remission; **CRi**, complete remission with incomplete blood count recovery; **HSCT**, hematopoietic stem cell transplantation; **HR**, hazard ratio.

## IMPORTANT SAFETY INFORMATION (cont'd)

### ADVERSE REACTIONS

Serious adverse reactions occurred in 15% of patients who received ONUREG®. Serious adverse reactions in ≥2% included pneumonia (8%) and febrile neutropenia (7%). One fatal adverse reaction (sepsis) occurred in a patient who received ONUREG®. 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%), pain in extremity (11%, 5%).

### LACTATION

There are no data regarding the presence of azacitidine in human milk or the effects on the breastfed child or milk production. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with ONUREG® and for 1 week after the last dose.

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