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.[1]

Remission is not the destination, it's the starting point.

With **ONUREG®**, help your patients live longer[1,a]

NCCN Recommends | ONLY NCCN Category 1 preferred National Comprehensive Cancer Network® (NCCN®) treatment option in the maintenance setting for certain patients with AML: oral azacitidine (ONUREG)[2,b]

[a]QUAZAR® AML-001

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]).[1]

[b]NCCN Guidelines®

Category 1 Preferred recommendation applies to patients in the maintenance setting with intermediate or adverse risk AML that are aged ≥55 (category 2A for other age groups) and who have received prior intensive chemotherapy and whose disease is now in remission; completed no consolidation, some consolidation or a recommended course of consolidation; and for whom no allogenic HCT is planned.[2]

Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Myeloid Leukemia Version 6.2023 © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed December 4, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

The definition of continued and maintenance treatment by the FDA and NCCN differ based on the AML treatment period in patients with or without CR.[2,3]

AML, acute myeloid leukemia; **CI**, confidence interval; **CR**, complete remission; **CRi**, complete remission with incomplete blood count recovery; **FDA**, Food and Drug Administration; **HCT**, hematopoietic cell transplantation; **HSCT**, hematopoietic stem cell transplantation; **HR**, hazard ratio; **NCCN**, National Comprehensive Cancer Network® (NCCN®); **OS**, overall survival.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

ONUREG™ (azacitidine) tablets 300 mg • 200 mg

Please see additional Important Safety Information throughout and click here for full Prescribing Information for ONUREG®.

For your patients with AML

Remission is the first milestone[4]

Unfortunately, all patients with AML are at risk for relapse[5,6,a]

- Including younger patients with favorable-risk disease

AML is the most-deadly leukemia[7]

Only **~30%** of patients survive ≥5 years from AML diagnosis[8,b]

Only **~10%** of patients aged 65+ survive ≥5 years from AML diagnosis[8,b]

There is a **~90%** chance that a 65-year-old diagnosed with AML will not celebrate their 70th birthday[8c]

It is important to protect a patient's remission[9]

[a]Among 1,557 adult patients treated in the AML96 trial from 1996 to 2005. The trial protocol defined different treatment strategies for patients 18-60 years of age and for patients >60 years of age. The median age of patients was 67 years (range, 18-87 years) with roughly half older than 60. Relapse rates were ~30-35% in patients aged 18-60 with favorable risk factors, and ~70-80% in patients >60 years of age with adverse risk factors. Patients in the favorable cytogenetic risk category included: t(8;21), inv(16), and t(16;16). Patients in the adverse risk category had either 7, 5, 5q-, 7q-, t(6;9), inv(3q), t(9;22), or three cytogenetic aberrations. [b]SEER statistics. 5-year relative survival from diagnosis, 2013-2019.[8] [c]Derived from SEER 5-year relative survival estimate, 2013-2019, for ages 65+.[8] Among the 65+ population, individual survival estimates may vary.

SEER, Surveillance, Epidemiology, and End Results.

ONUREG™ (azacitidine) tablets 300 mg • 200 mg

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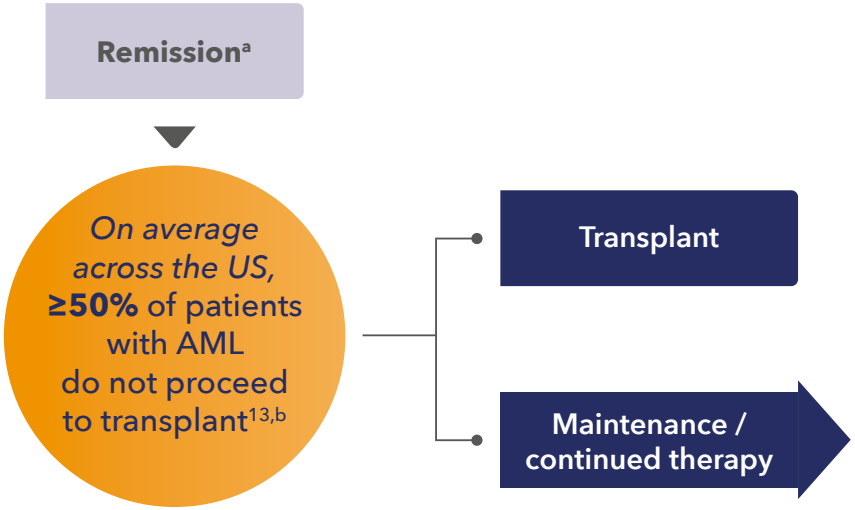
Post-remission treatment plans should reflect the **individual needs** of each patient[10-12]



With a rapidly-evolving treatment landscape[14,15]

Prolonged post-remission survival extends the window of hope for patients with AML

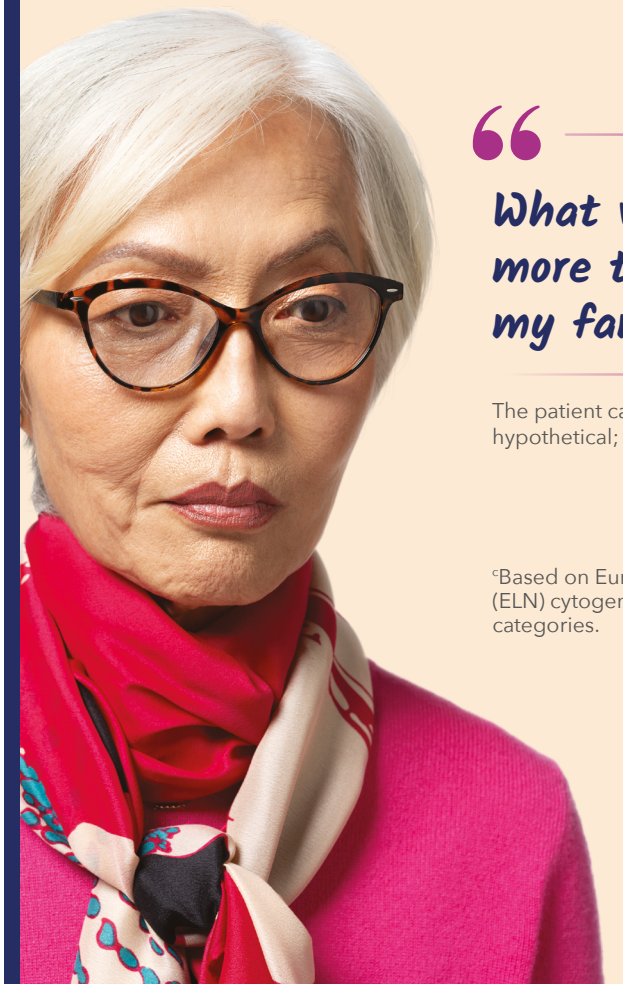
[a]Complete remission or complete remission with incomplete blood count recovery; patients may or may not receive consolidation therapy after remission. [b]In an analysis of the SEER-Medicare 2013–2015 database, 11,142 newly diagnosed adult patients with AML were evaluated and stratified into 2 groups: treatment with chemotherapy (n=4,772) and non-treatment (n=6,370). Within the treatment-with-chemotherapy group, 55.1% of patients aged 66–70 years and 26.6% of patients aged 71–75 years went on to receive HSCT.[13]

Please see additional Important Safety Information throughout and click here for full Prescribing Information for ONUREG®.

Meet Denise, a patient with AML in first remission who wants to live as long as possible

Post-remission treatment considerations

- Favorable-risk AML,[c] *NPM1* gene mutation
- Freelance copywriter nearing retirement
- Would like to live as long as possible to enjoy golf, gardening, and her 3 adult children



What will give me more time with my family?

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

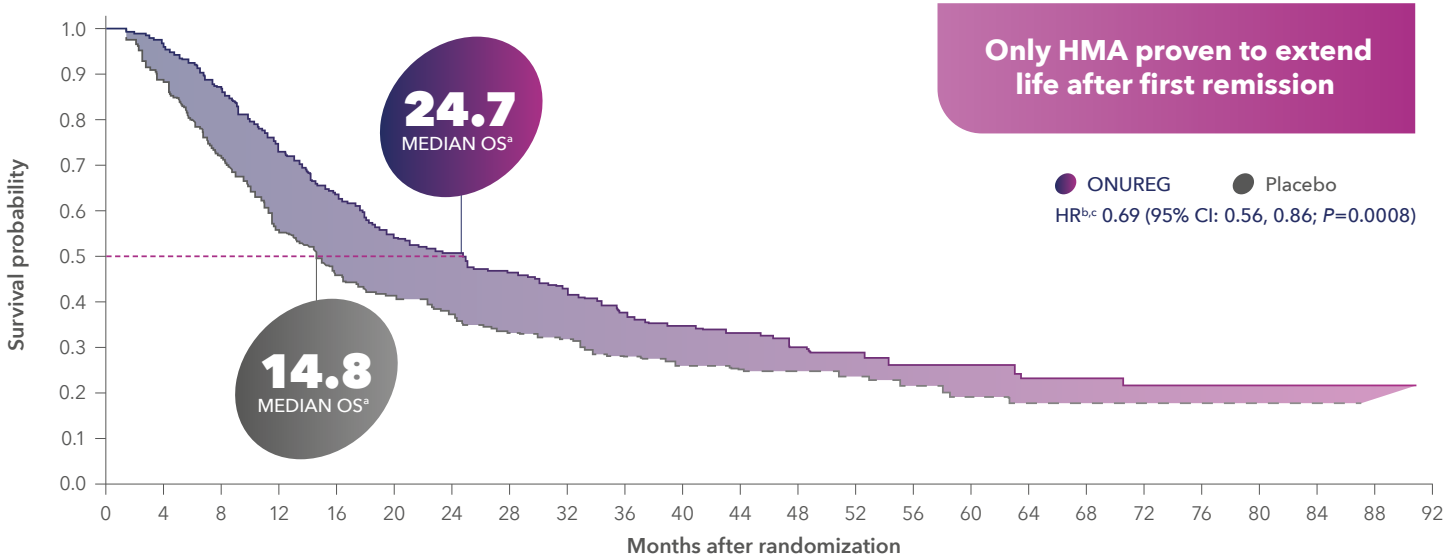
[c]Based on European LeukemiaNet (ELN) cytogenetic risk stratification categories.

ONUREG™ (azacitidine) tablets 300 mg • 200 mg

After first AML remission

Help your patients live longer with ONUREG[1,9,16-17]

Median overall survival was >2 years in patients treated with ONUREG



Only HMA proven to extend life after first remission

ONUREG Placebo

HR[b,c] 0.69 (95% CI: 0.56, 0.86; *P*=0.0008)

Extended follow-up (median 51.7 months from randomization); ITT population.[d]

Number at risk																								
ONUREG	238	224	200	168	147	124	116	106	95	83	73	61	46	37	26	22	16	15	13	8	5	2	1	0
Placebo	234	206	164	127	103	92	82	73	68	57	47	39	30	24	21	16	12	10	9	6	3	1	0	

~Three out of four patients were alive at **1 year**[18]

Estimated OS: 73% (95% CI: 67, 78) (n=168) with ONUREG vs 56% (95% CI: 49, 62) (n=127) with placebo[18]

~One out of four patients was alive at **5 years**[18]

Estimated OS: 27% (95% CI: 21, 33) (n=40) with ONUREG vs 20% (95% CI: 15, 26) (n=20) with placebo[18]

Analysis limitations:
The analysis at the 1-year and 5-year time points was not designed to show a difference between treatment arms.

[a] ONUREG (95% CI: 18.7, 30.5); placebo (95% CI: 11.7, 17.6).[1] [b] The HR is from a Cox proportional hazards model stratified by age (55 to 64 vs ≥65 years), cytogenetic risk category at time of induction therapy (intermediate risk vs poor risk), and received consolidation therapy (yes vs no).[1] [c] HR for initial follow-up was 0.69 (95% CI: 0.55, 0.86; *P*=0.0009).[1] [d] Data cutoff for extended follow-up was September 2020.[16] Median follow-up in initial dataset was 41.2 months with data cutoff July 2019.[9]

Kaplan-Meier methods are used to estimate survival probabilities.

HMA, hypomethylating agent; **ITT**, intention-to-treat.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Risks of Substitution with Other Azacitidine Products

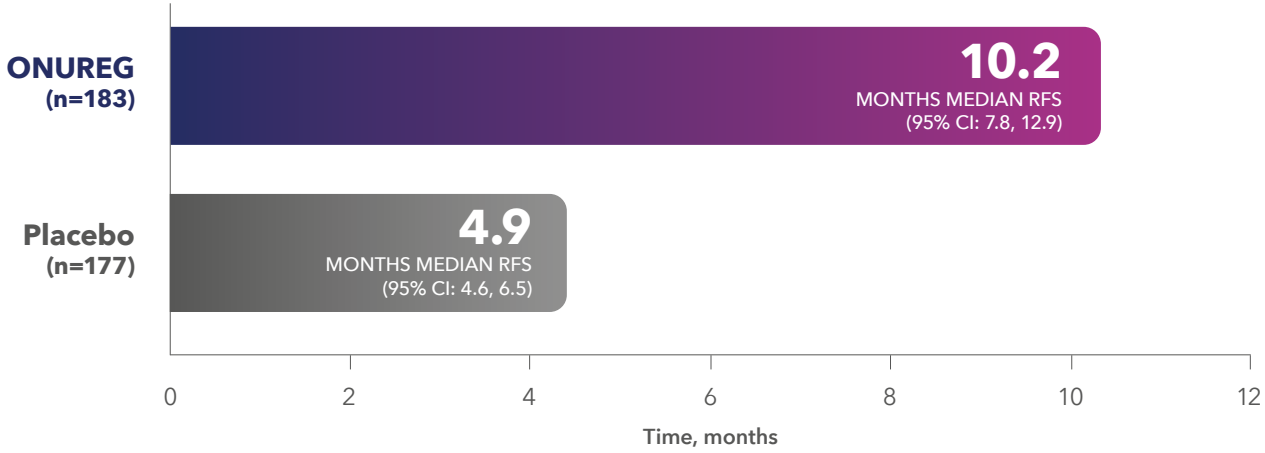
Due to substantial differences in the pharmacokinetic parameters, the recommended dose and schedule for ONUREG® are different from those for the intravenous or subcutaneous azacitidine products. Treatment of patients using intravenous or subcutaneous azacitidine at the recommended dosage of ONUREG® may 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.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for ONUREG®.

ONUREG™ (azacitidine) tablets 300 mg • 200 mg

In a subgroup analysis of RFS in patients with a CR at randomization in QUAZAR AML-001

Median relapse-free survival was 10.2 months in patients treated with ONUREG[19]



Study limitations: Results should be interpreted with caution, as these cohorts were not prospectively defined, and the study was not powered to detect significant differences between subgroups.

Relapse-free survival was defined as the time from date of randomization to the date of documented relapse or death from any cause, whichever occurred first. Patients with CRi at randomization are not included in this analysis.

RFS, relapse-free survival.

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

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for ONUREG®.

ONUREG™ (azacitidine) tablets 300 mg • 200 mg

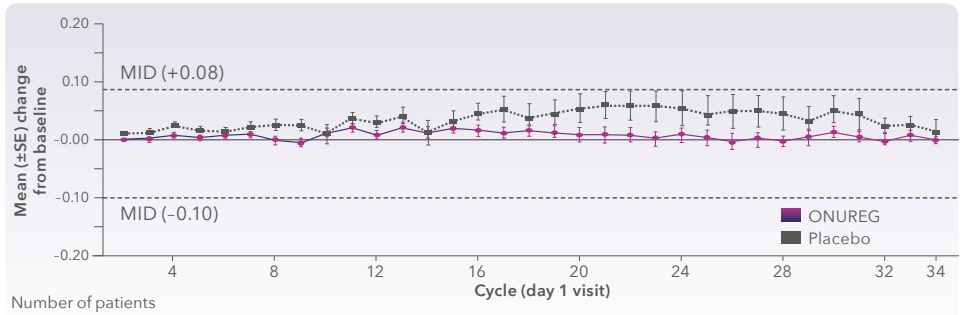
In an exploratory analysis of QUAZAR AML-001,

Patients had preserved quality of life[20,21,a]

Mean EQ-5D-3L scores and mean FACIT-Fatigue scores remained at or above **baseline levels** at almost all assessments[20,21,a]

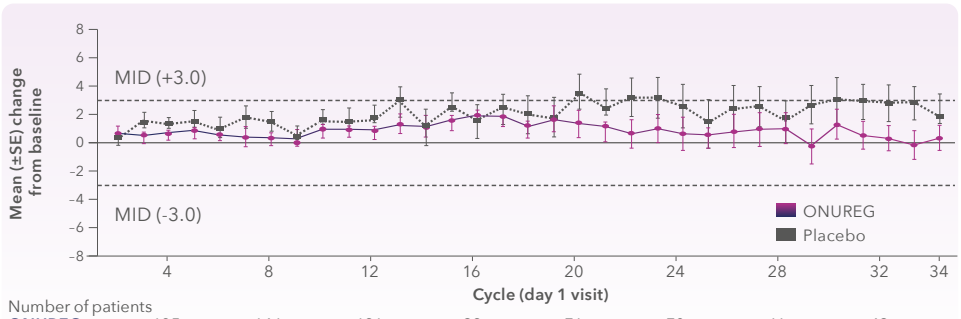
The EQ-5D-3L is a generic instrument that includes a descriptive questionnaire that assesses impairment across 5 dimensions at 3 levels (no/some/extreme problems):[22]

● Mobility ● Pain/Discomfort ● Self-care ● Anxiety/Depression ● Usual activities



Number of patients								
ONUREG	183	145	121	92	76	70	61	49
Placebo	158	99	68	51	40	34	31	29

The FACIT-Fatigue Scale is a 13-item questionnaire that measures an individual's level of fatigue during daily activities over the previous week.[23]



Number of patients								
ONUREG	185	146	121	92	76	70	61	49
Placebo	160	100	71	51	40	34	31	29

Study limitations: This is an exploratory analysis and definitive conclusions should not be drawn. HRQoL data are not in the Prescribing Information and should be interpreted with caution. The completion rates, based on the number of subjects in the ITT population, declined over time for both groups, with the ONUREG group having a significantly higher proportion of completion than the placebo group at the Cycle 4 Day 1 visit and thereafter. Additionally, HRQoL assessments were conducted on Day 1 of each 28-day treatment cycle, allowing for 14 days of recovery after each 14-day dosing period.[20]

EQ-5D-3L limitation: The EQ-5D-3L assessment is not associated with AML or the individual patient's treatment. This assessment is related to the individual patient's general health status.[22]

Fatigue Scale limitation: The FACIT-Fatigue Scale is considered relevant to the disease state (AML) rather than the treatment.[23]

[a]Data are presented up to Cycle 34, the last cycle with ≥25 patients in both treatment groups.[21] Clinically meaningful improvement and worsening was defined by: an ≥0.08- and ≤0.10-point change from baseline, respectively, for the EQ-5D-3L; and a ≥3-point change from baseline for the FACIT-Fatigue Scale at the individual level.[20]

EQ-5D-3L, European quality of life-five dimensions-tree levels; **FACIT**, functional assessment of chronic illness therapy; **HRQoL**, health-related quality of life; **MID**, minimally important difference; **SE**, standard error.

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for ONUREG®.

ONUREG™ (azacitidine) tablets 300 mg • 200 mg

Denise wants to proactively treat her AML while it is in remission

Achieved CR after 1 induction cycle

Received 2 of 4 planned cycles of consolidation

In collaboration with her doctor, decided **ONUREG** was the right treatment choice for her[1]

- In first AML remission
- Experienced infection during Cycle 2 of consolidation
- **Transplant-ineligible**
- **Favorable-risk disease**

> *"I'm also worried about side effects with another treatment, but my doctor has a plan to help manage them"*

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

QUAZAR AML-001 included patients with an ***NPM1* mutation** like Denise.
Visit ONUREG to learn more

IMPORTANT SAFETY INFORMATION (continued)

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/m2 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.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for ONUREG®.

ONUREG™ (azacitidine) tablets 300 mg • 200 mg

In QUAZAR AML-001

The majority of ONUREG adverse reactions were mild to moderate (Grade 1 or 2)[1]

ARs (≥5%) in patients who received ONUREG with a difference between arms of >2% compared with placebo[1]

AR	ONUREG (n=236)		Placebo (n=233)	
	All Grades %	Grades 3 or 4 %	All Grades %	Grades 3 or 4 %
Gastrointestinal (GI) disorders				
Nausea	**65**	**3**	24	<1
Vomiting	**60**	**3**	10	0
Diarrhea	**50**	**5**	21	1
Constipation	**39**	**1**	24	0
Abdominal pain[a]	**22**	**2**	13	<1
General disorders and administration site conditions				
Fatigue/asthenia[b]	**44**	**4**	25	1
Infections				
Pneumonia[c]	**27**	**9**	17	5
Musculoskeletal and connective tissue disorders				
Arthralgia	**14**	**1**	10	<1
Pain in extremity	**11**	**<1**	5	0
Metabolism and nutrition disorders				
Decreased appetite	**13**	**1**	6	1
Blood and lymphatic disorders				
Febrile neutropenia	**12**	**11**	8	8
Nervous system disorders				
Dizziness	**11**	**0**	9	0

- **1 fatal adverse reaction** (sepsis) occurred in a patient who received ONUREG[1]
- **Serious adverse reactions** occurred in 15% of patients receiving ONUREG[1]
  - Serious ARs in ≥2% of patients who received ONUREG were pneumonia (8%) and febrile neutropenia (7%)
- **Myelosuppression** in patients receiving ONUREG
  - New or worsening Grade 3 or 4 neutropenia and thrombocytopenia occurred in 49% and 22% of patients, respectively. Febrile neutropenia occurred in 12%
  - Dose reduction was required for 7% and 2% of patients due to neutropenia and thrombocytopenia, respectively. <1% of patients discontinued ONUREG due to either neutropenia or thrombocytopenia
  - Monitor CBC and modify dosage as recommended. Provide standard supportive care if myelosuppression occurs

[a]Grouped term includes abdominal pain, abdominal pain upper, abdominal discomfort, and GI pain. [b]Grouped term includes fatigue and asthenia. [c]Broad scope term includes influenza, pneumonia, respiratory tract infection, respiratory tract infection viral, bronchopulmonary aspergillosis, lung infection, Staphylococcal infection, atypical pneumonia, lower respiratory tract infection, lung abscess, *Pneumocystis jirovecii* pneumonia, pneumonia bacterial, pneumonia fungal, Pseudomonas infection, hemoptysis, productive cough, pleural effusion, atelectasis, pleuritic pain, rales, Enterobacter test positive, and Haemophilus test positive.

AR, adverse reaction;
GI, gastrointestinal.

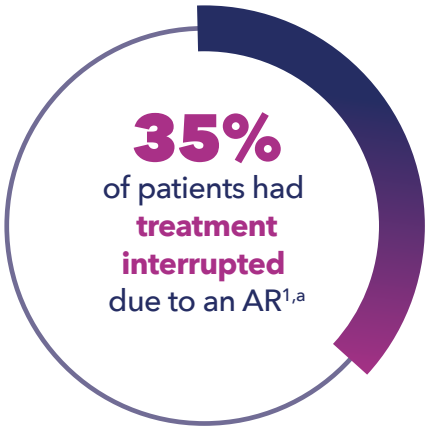
ONUREG™ (azacitidine) tablets 300 mg • 200 mg

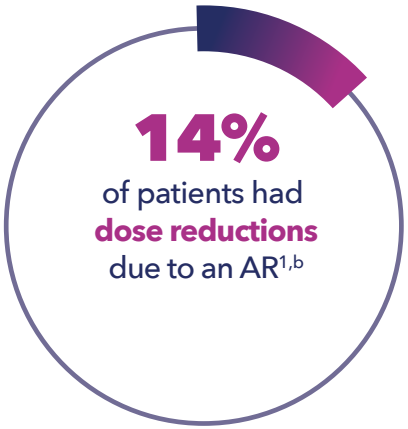
Please see additional Important Safety Information throughout and click here for full Prescribing Information for ONUREG®.

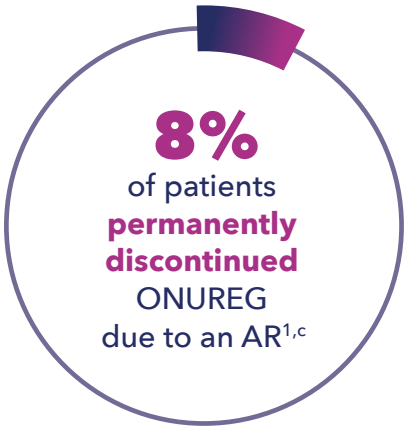
In QUAZAR AML-001

Many adverse reactions were managed with treatment interruptions or dose modifications[1]

Permanent discontinuation due to an adverse reaction was 8%[1]







To give your patients the best opportunity to benefit from ONUREG:

- Ensure they take antiemetics prophylactically[1,d]
- Manage adverse reactions with dose modifications and supportive care[1,24]

Visit ONUREG to review recommended dose modifications to **help your patients manage ARs**

[a]ARs requiring treatment interruption in >5% of patients included: neutropenia (20%), thrombocytopenia (8%), and nausea (6%).[1] [b]ARs requiring dose reductions in >1% of patients included: neutropenia (6%), diarrhea (3.4%), thrombocytopenia (1.7%), and nausea (1.7%).[1] [c]ARs resulting in permanent discontinuation in >1% of patients included: nausea (2.1%), diarrhea (1.7%), and vomiting (1.3%).[1] [d]For at least the first 2 cycles.[1]

IMPORTANT SAFETY INFORMATION (continued)

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%).

Please see additional Important Safety Information throughout and click here for full Prescribing Information for ONUREG®.

ONUREG™ (azacitidine) tablets 300 mg • 200 mg

ONUREG® is a convenient once-daily at-home oral treatment[1]

Recommended dosage: one 300 mg tablet, once daily **with or without food** on **Days 1–14** of each 28-day treatment cycle

How to start–*and help keep*–patients on ONUREG[1]

Prescribe a prophylactic antiemetic
- For patients to take 30 minutes prior to each dose of ONUREG
- For at least the first 2 cycles[a]

Discuss pregnancy risks with appropriate patients
- Recommend testing for pregnancy before starting treatment
- Advise use of effective contraception

Monitor CBCs for signs of myelosuppression
- Before beginning treatment
- Every other week for the first 2 cycles
- Prior to each cycle after Cycle 2

Monitor ANC on Day 1 of cycle
- Do not administer ONUREG if <0.5 Gi/L

Manage adverse reactions
- Interrupt treatment, modify dosage, or reduce duration as recommended
- Provide standard supportive care

Increase monitoring
- After any dose reduction
- In patients with severe renal impairment (CLcr 15-29 mL/min)

Refer your patients to an AML advocacy organization such as Know AML, the HealthTree Foundation, or the Leukemia & Lymphoma Society

300 mg tablet is not actual size.

[a]Antiemetic prophylaxis may be omitted after 2 cycles if there has been no nausea and vomiting.

ANC, absolute neutrophil count; **CBC**, complete blood count; **CLcr**, creatinine clearance.

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for ONUREG®.

ONUREG™ (azacitidine) tablets 300 mg • 200 mg

Denise has been taking ONUREG at home for 18 months

She takes 1 ONUREG 300 mg tablet once-a-day[1]...

For each 28-day treatment cycle:
2 weeks on | 2 weeks off[1]

... with GI supportive care ...

During the first 4 cycles, she took an **antiemetic** before each dose[a] and an **anti-diarrheal** as needed

... and regular CBC monitoring

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

> *"I'm looking forward to Thanksgiving with my family"*

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

BMS is committed to helping appropriate patients like Denise access ONUREG.
Visit ONUREG to learn more

[a]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.[1]

ONUREG™ (azacitidine) tablets 300 mg • 200 mg

Please see additional Important Safety Information throughout and click here for full Prescribing Information for ONUREG®.

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.[1]

Remission is not the destination, it's the starting point.

Listen to experts discuss the pivotal QUAZAR® AML-001 trial of ONUREG.
Visit ONUREG to watch the video

Live longer[1]

Median overall survival was >2 years in patients treated with ONUREG[a]

Preserved quality[20,21]

No clinically meaningful decline in quality of life measures across visits[b]

Convenience[1]

Once-daily, at-home, oral dosing
2 weeks on | 2 weeks off

The majority of adverse reactions were mild to moderate (Grade 1 or 2)[1]

CHOOSE ONUREG to help your patients live longer[1]

[a]24.7 months (95% CI: 18.7, 30.5) with ONUREG vs 14.8 months (95% CI: 11.7, 17.6) with placebo (P=0.0009).[1] [b]HRQoL in QUAZAR AML-001 was assessed by patient-reported FACIT-Fatigue Scale scores and EQ-5D-3L index scores. At almost all assessments throughout the study, quality of life scores remained at or above baseline levels, with no clinically meaningful mean decreases in FACIT-FATIGUE Scale scores or EQ-5D-3L index scores observed in the ONUREG or placebo treatment arms across visits.[20,21] Mixed-effect models for repeated measures (MMRM) analyses showed the overall LS mean [95% CI] change from baseline in the ONUREG treatment arm for FACIT-Fatigue scale was -0.60 [-2.19, 0.99] and for the placebo arm 0.29 [-1.44, 2.02]; and for EQ-5D-3L health utility index -0.01 [-0.03, 0.01] and 0.00 [-0.02, 0.02], respectively.[25]

Study limitations: The HRQoL analysis is exploratory and definitive conclusions should not be drawn. HRQoL data are not in the Prescribing Information and should be interpreted with caution. The completion rates, based on the number of subjects in the ITT population, declined over time for both groups, with the ONUREG group having a significantly higher proportion of completion than the placebo group at the Cycle 4 Day 1 visit and thereafter. Additionally, HRQoL assessments were conducted on Day 1 of each 28-day treatment cycle, allowing for 14 days of recovery after each 14-day dosing period.[20] **EQ-5D-3L limitation:** The EQ-5D-3L assessment is not associated with AML or the individual patient's treatment. This assessment is related to the individual patient's general health status.[22] **FACIT-Fatigue Scale limitation:** The FACIT-Fatigue Scale is considered relevant to the disease state (AML) rather than the treatment.[23]

LS, least squares.

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Please see additional Important Safety Information throughout and click here for full Prescribing Information for ONUREG®.

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