Veeva Vault

Electronic Certificate

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Certification Statement
We certify that the final electronic form of this material is in accordance with the regulations set forth by the health authority for the country of this document, and is a fair and truthful presentation of the facts about the product.

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Sharon Kahlon - Regulatory Specialist Post-PACT Approval (skahlon@celgene.com)	Meaning: As the Regulatory Specialist, I approve this document for use. Date: 03-Sep-2020 15:19:38 GMT+0000

NOW APPROVED

ONUREG™ (azacitidine) tablets 300 mg • 200 mg

THE FIRST AND ONLY FDA-approved continued AML treatment for patients in first remission[1,2]

Bristol Myers Squibb™
Bristol-Myers Squibb Company
86 Morris Avenue Summit, New Jersey 07901

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.

September 2020

Dear Healthcare Provider,

ONUREG® has received **FDA approval** as the FIRST and ONLY continued treatment for acute myeloid leukemia (AML) patients in first remission.[1,2] The information below will provide you with key data and insights about ONUREG®.

Study design

Pivotal phase 3 QUAZAR® AML-001 trial

TRIAL DESIGN

QUAZAR® AML-001 was designed to evaluate ONUREG® vs placebo as continued treatment for adult patients in first CR/CRi.[1]

The efficacy and safety of ONUREG® as continued treatment in AML patients with first remission were evaluated in the QUAZAR® AML-001 trial, a multicenter, placebo-controlled, phase 3 study with a double-blind, randomized, parallel-group design (N=472).[1]

Key inclusion criteria*: adults ≥55 years of age; diagnosed with AML; within 4 months of achieving first CR or CRi with intensive induction chemotherapy with or without consolidation therapy.[1]

*Not a comprehensive list of inclusion criteria.

TREATMENT ARMS

Patients received ONUREG® 300 mg (n=238) or placebo (n=234) once daily orally on Days 1-14 of each 28-day treatment cycle until disease progression or unacceptable toxicity.[1] Patients in both treatment arms received best supportive care as deemed necessary by the investigator.[3]

EFFICACY ENDPOINT

The efficacy of ONUREG® was established on the basis of overall survival (OS).[1]

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

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 Important Safety Information throughout and accompanying full Prescribing Information for ONUREG®.

ONUREG™ (azacitidine) tablets 300 mg • 200 mg

The QUAZAR® AML-001 trial enrolled a broad AML population[1]

Baseline demographics and disease-related characteristics in QUAZAR® AML-001

Parameter	ONUREG® (n=238)	Placebo (n=234)
Age (years)		
Median (min, max)	68.0 (55, 86)	68.0 (55, 82)
Age category, n (%)		
<65 years	66 (28)	68 (29)
65 years to <75 years	144 (61)	142 (61)
≥75 years	28 (12)	24 (10)
Sex, n (%)		
Male	118 (50)	127 (54)
Female	120 (50)	107 (46)
Race, n (%)		
White	216 (91)	197 (84)
Black or African American	2 (1)	6 (3)
Asian	6 (3)	20 (9)
Other	12 (5)	11 (5)
Not collected or reported	2 (1)	0 (0)
ECOG performance status, n (%)		
0	116 (49)	111 (47)
1	101 (42)	106 (45)
2	21 (9)	15 (6)
3	0 (0)	2 (1)
Cytogenetic risk status at diagnosis, n (%)		
Intermediate risk[1]	203 (85)	203 (87)
Poor risk[2]	35 (15)	31 (13)
Initial AML classification, n (%)		
AML with recurrent genetic abnormalities	39 (16)	46 (20)
AML with myelodysplasia-related changes	49 (21)	42 (18)
Therapy-related myeloid neoplasms	2 (1)	0 (0)
AML not otherwise specified	148 (62)	145 (62)
Missing	0 (0)	1 (<1)
Type of AML, n (%)		
Primary (de novo)	213 (89)	216 (92)
Secondary	25 (11)	18 (8)
Induction response		
CR	187 (79)	197 (84)
CRi	51 (21)	37 (16)
Received consolidation following induction therapy		
None	52 (22)	42 (18)
1 cycle	110 (46)	102 (44)
2 cycles	70 (29)	77 (33)
3 cycles	6 (3)	13 (6)
Disease status at study baseline		
CR	185 (78)	181 (77)
CRi	44 (18)	38 (16)
Not in CR or CRi	9 (4)	13 (6)
Not reported	0	2 (1)

72% of patients were 65 years or older

Most patients had an ECOG performance status of 0 or 1

76% of patients received 1 or 2 cycles of consolidation

ECOG, Eastern Cooperative Oncology Group.

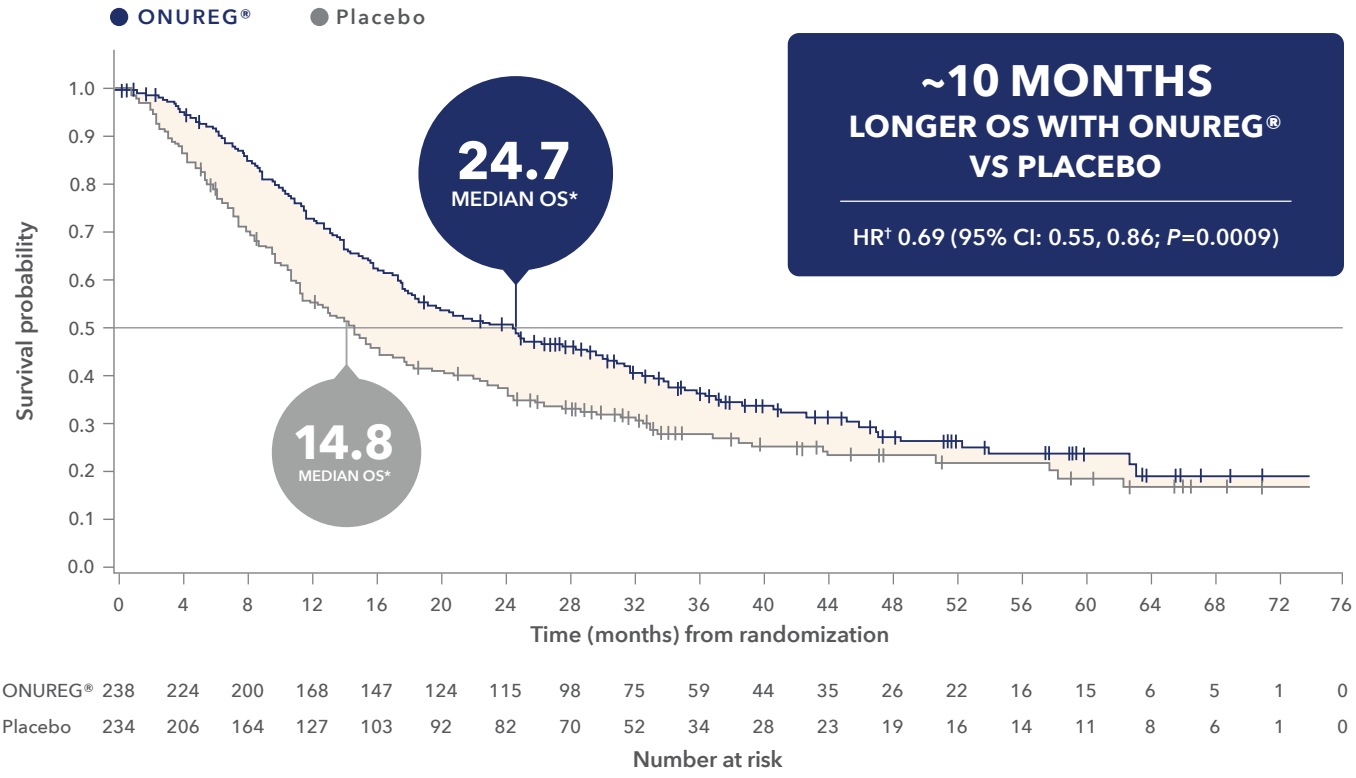
[1]Intermediate risk was defined as normal cytogenetics +8, t(9;11), or other undefined.
[2]Poor risk was defined as complex (≥3 abnormalities): -5; 5q-; -7; 7q-; 11q23 - non t(9;11); inv(3); t(3;3); t(6;9); or t(9;22).

Source for Intermediate and Poor Risk: NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Myeloid Leukemia. National Comprehensive Cancer Network® (NCCN®) website. Available at http://www.nccn.org/professionals/physician_gls/PDF/aml.pdf. Accessed March 1, 2011.

Efficacy

ONUREG® demonstrated >2 years median overall survival for AML patients in first remission[1]

Kaplan-Meier curve for OS: ITT population in QUAZAR® AML-001[1]



CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat.

*ONUREG® (95% CI: 18.7, 30.5); placebo (95% CI: 11.7, 17.6).

†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).

ONUREG® survival estimates at 1 year and 2 years[4]

1 year		2 years	
ONUREG®	Placebo	ONUREG®	Placebo
73%	**56%**	**51%**	**37%**
(n=168) (95% CI: 67, 78)	(n=127) (95% CI: 49, 62)	(n=115) (95% CI: 44, 57)	(n=82) (95% CI: 31, 43)

Analysis limitation

The analysis at these time points was not designed to show a difference between treatment arms.

Kaplan-Meier methods are used to estimate the 1-year and 2-year survival probabilities.

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 of patients using 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®, respectively. Febrile neutropenia occurred in 12%. A 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 complete blood counts and modify the dosage as recommended. Provide standard supportive care, including hematopoietic growth factors, if myelosuppression occurs.

Increased Early Mortality in Patients with Myelodysplastic Syndromes (MDS)

In AZA-MDS-003 (NCT01566695), 216 patients with red blood cell transfusion-dependent anemia and thrombocytopenia due to myelodysplastic syndromes were randomized to ONUREG® or placebo. 107 patients 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 patients who received ONUREG® compared with placebo. The most frequent fatal adverse reaction was sepsis. The safety and effectiveness of ONUREG® for treatment of myelodysplastic syndromes have not been established. Treatment of patients with myelodysplastic syndromes with ONUREG® is not recommended outside of controlled trials.

Embryo-Fetal Toxicity

Based on the mechanism of action and findings in animals, ONUREG® can cause fetal harm when administered to a pregnant woman. Azacitidine administered to pregnant rats via a single intraperitoneal dose less than the recommended human daily dose of oral azacitidine on a mg/m^2 basis caused fetal death and anomalies.

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.

ONUREG® safety was assessed in the QUAZAR® AML-001 trial[1]

The majority of adverse reactions (ARs) were mild to moderate (Grade 1 or 2) with ONUREG®

ARs (≥5%) in patients with AML who received ONUREG® with a difference between arms of >2% compared with placebo in QUAZAR® AML-001

AR	ONUREG® (n=236)		Placebo (n=233)	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 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

[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.

- 1 fatal AR (sepsis) occurred in a patient who received ONUREG®
- Serious ARs occurred in 15% of patients receiving ONUREG®
  - Serious ARs in ≥2% of patients who received ONUREG® were pneumonia (8%) and febrile neutropenia (7%)

Selected hematological laboratory abnormalities that worsened from baseline in patients who received ONUREG® in QUAZAR® AML-001

Laboratory abnormality	ONUREG®		Placebo	
	Baseline Grade 0-2 N	Post-Baseline Grade 3 or 4 n (%)	Baseline Grade 0-2 N	Post-Baseline Grade 3 or 4 n (%)
Neutropenia	223	109 (49)	217	50 (23)
Thrombocytopenia	222	46 (21)	212	22 (10)
Anemia	229	10 (4)	223	7 (3)

Discontinuations and dose modifications in the QUAZAR® AML-001 trial with ONUREG®[1]

Permanent discontinuation due to an AR occurred in **8%** of patients

ARs which resulted in permanent discontinuation in >1% of patients included:

- **2.1%** Nausea
- **1.7%** Diarrhea
- **1.3%** Vomiting

Treatment interruptions due to an AR occurred in **35%** of patients

ARs requiring treatment interruption in >5% of patients included:

- **20%** Neutropenia
- **8%** Thrombocytopenia
- **6%** Nausea

Dose reductions due to an AR occurred in **14%** of patients

ARs requiring dose reduction in >1% of patients included:

- **6%** Neutropenia
- **3.4%** Diarrhea
- **1.7%** Thrombocytopenia
- **1.7%** Nausea

Treatment duration for ONUREG® in the QUAZAR® AML-001 trial[1]

Patients received a median number of **12 cycles*** of treatment

- **71%** of patients were exposed for ≥6 months
- **49%** of patients were exposed for >1 year

*1 cycle=28 days (median).

ONUREG® offers convenient, once-daily, oral dosing that patients can take at home[1]

The recommended dosage of ONUREG® is one 300 mg tablet orally, once daily with or without food on Days 1-14 of each 28-day treatment cycle

RECOMMENDED DOSAGE

2 WEEKS ON
WEEKS OFF

300 MG ON DAYS 1–14
OF EACH 28-DAY TREATMENT CYCLE

Continue ONUREG® until disease progression or unacceptable toxicity

Do not substitute ONUREG® for intravenous or subcutaneous azacitidine. The indications and dosing regimen for ONUREG® differ from that of intravenous or subcutaneous azacitidine

ADMINISTRATION

- Administer an antiemetic 30 minutes prior to each dose of ONUREG® for the first 2 cycles. Antiemetic prophylaxis may be omitted after 2 cycles if there has been no nausea and vomiting
- If the absolute neutrophil count (ANC) <0.5 Gi/L on Day 1 of a cycle, do not administer ONUREG®. Delay the start of the cycle until the ANC is ≥0.5 Gi/L

Instruct patients on the following:

Take a dose about the same time each day

Do not split, crush, or chew tablets*

- If a dose of ONUREG® is missed, or not taken at the usual time, take the dose as soon as possible on the same day, and resume the normal schedule the following day. Do not take 2 doses on the same day
- If a dose is vomited, do not take another dose on the same day. Resume the normal schedule the following day

*ONUREG® is a hazardous drug. Follow applicable special handling and disposal procedures. If powder comes in contact with skin, immediately and thoroughly wash with soap and water. If powder comes in contact with mucous membranes, immediately flush the area with water.

Dosage modifications for adverse reactions[1]

Recommended dosage modifications for ARs

Monitor complete blood count every other week for the first 2 cycles and prior to the start of each cycle thereafter. Increase monitoring to every other week for the 2 cycles after any dose reduction for myelosuppression.

MYELOSUPPRESSION

NEUTROPHILS
<0.5 Gi/L

NEUTROPHILS
<1 Gi/L with fever at any time

PLATELETS
<50 Gi/L with bleeding

DAY 1 OF CYCLE

INTERRUPT

RESUME
at 300 mg
once neutrophils return to 0.5 Gi/L or higher

1ST OCCURRENCE

INTERRUPT

RESUME
at 300 mg
once neutrophils return to 1 Gi/L or higher or platelets return to 50 Gi/L or higher

2 CONSECUTIVE CYCLES OF OCCURRENCE

INTERRUPT

RESUME
at reduced dose of 200 mg
once neutrophils return to 1 Gi/L or higher or platelets return to 50 Gi/L or higher

REDUCE
treatment duration by 7 days
if a patient continues to experience the toxicity after dose reduction

DISCONTINUE
if the toxicity reoccurs after dose and schedule reduction

GI TOXICITY OR OTHER ARs

NAUSEA, VOMITING, OR DIARRHEA
Grade 3 or 4

OTHER ARs
Grade 3 or 4

1ST OCCURRENCE

INTERRUPT
Provide medical support for other Grade 3 or 4 ARs

RESUME
at 300 mg
once toxicity has resolved to Grade 1 or lower

2ND OCCURRENCE

INTERRUPT
until toxicity has resolved to Grade 1 or lower

RESUME
at reduced dose of 200 mg

REDUCE
treatment duration by 7 days
if a patient continues to experience the toxicity after dose reduction

DISCONTINUE
if the toxicity continues or reoccurs after dose and schedule reduction

Authorized distributors

The following distributors are authorized to sell ONUREG® and are able to service qualified accounts.

AUTHORIZED DISTRIBUTOR NETWORK

COMMUNITY PRACTICES

Cardinal Health Specialty Pharmaceutical Distribution
Phone: 1-877-453-3972 | https://specialtyonline.cardinalhealth.com/

McKesson Specialty Health
Phone: 1-800-482-6700 | Fax: 1-800-289-9285 | https://mscs.mckesson.com

Oncology Supply
Phone: 1-800-633-7555 | Fax: 1-800-248-8205 | https://oncologysupply.com

SPECIALTY PHARMACIES AND INSTITUTIONS/HOSPITAL OUTPATIENT FACILITIES

ASD Healthcare
Phone: 1-800-746-6273 | Fax: 1-800-547-9413 | https://www.asdhealthcare.com

Cardinal Health Specialty Pharmaceutical Distribution
Phone: 1-866-677-4844 | Fax: 1-614-553-6301 | https://orderexpress.cardinalhealth.com

McKesson Plasma and Biologics
Phone: 1-877-625-2566 | Fax: 1-888-752-7626 | https://connect.mckesson.com

PUERTO RICO HOSPITALS AND ONCOLOGY CLINICS

Cardinal Puerto Rico
Phone: 1-787-625-4100 | Fax: 1-787-625-4398 | https://www.cardinalhealth.pr

Cesar Castillo Inc.
Phone: 1-787-999-1616 | Fax: 1-787-999-1618 | https://www.facilfarmaciacci.com

ONUREG® package configurations, NDC numbers, and how supplied/stored[1]

NDC number	Package configuration	Tablet strength
59572-730-14	**200-mg tablets:** Bottles of 14 with 2 desiccant canisters	200-mg film-coated tablet: pink, oval tablet with debossed "200" on one side and "ONU" on the other side
59572-740-14	**300-mg tablets:** Bottles of 14 with 2 desiccant canisters	300-mg film-coated tablet: brown, oval tablet with debossed "300" on one side and "ONU" on the other side

How ONUREG® is supplied, stored, and handled[1]

ONUREG® tablets are supplied in 2 strengths for once-daily, oral dosing

RECOMMENDED DOSE: 300-MG TABLET

200-MG TABLET

(Modified dose if ARs occur)

ONUREG® tablets are supplied in bottles of 14 tablets with 2 desiccant canisters.

Storage

STORE BOTTLES

68°F to 77°F (20°C to 25°C)

- Excursions permitted between 59°F to 86°F (15°C to 30°C) (see USP Controlled Room Temperature)
- Keep bottle tightly closed
- Store and dispense in the original bottle (with 2 desiccant canisters)

Handling and disposal

ONUREG® is a hazardous drug. Follow applicable special handling and disposal procedures. If powder comes in contact with skin, immediately and thoroughly wash with soap and water. If powder comes in contact with mucous membranes, immediately flush the area with water.

Learn more, sign up for updates, and find out how to access ONUREG® at:
ONUREGpro.com/NowAvailable

Billing codes for ONUREG® (cont'd)

AML ICD-10-CM diagnosis codes[a]

ICD-10-CM code	Descriptor
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.01	Acute myeloblastic leukemia, in remission
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.51	Acute myelomonocytic leukemia, in remission
C92.60	Acute myeloid leukemia with 11q23-abnormality, not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality, in remission
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia, in remission
C92.Z0	Other myeloid leukemia, not having achieved remission
C92.Z1	Other myeloid leukemia, in remission
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.91	Myeloid leukemia, unspecified, in remission
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.01	Acute monoblastic/monocytic leukemia, in remission
C94.00	Acute erythroid leukemia, not having achieved remission
C94.01	Acute erythroid leukemia, in remission
C94.20	Acute megakaryoblastic leukemia, not having achieved remission
C94.21	Acute megakaryoblastic leukemia, in remission

[a]These codes are not all-inclusive.

The information contained herein is not intended to provide specific coding and reimbursement advice for any specific patient or situation. You should check with your coding specialist to ensure appropriate submissions.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

Product information

National Drug Codes (NDC) and packaging information

HCPCS code	Descriptor	10-digit NDC	11-digit NDC[a]
200 mg	Bottles of 14 with 2 desiccant canisters	59572-730-14	59572-0730-14
300 mg	Bottles of 14 with 2 desiccant canisters	59572-740-14	59572-0740-14

[a]The red zero converts the 10-digit NDC to the 11-digit NDC. Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires use of the 11-digit NDC.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

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.

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^2 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.

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.

Please see additional safety on the first page and accompanying full Prescribing Information for ONUREG®.

References: 1. ONUREG® [Prescribing Information]. Summit, NJ: Celgene Corporation; 2020. **2.** U.S. Food and Drug Administration approves Onureg® (azacitidine tablets), a new oral therapy, as continued treatment for adults in first remission with acute myeloid leukemia [press release]. Bristol Myers Squibb website. https://news.bms.com/press-release/corporatefinancial-news/us-food-and-drug-administration-approves-onureg-azacitidine-ta. Published September 1, 2020. Accessed September 1, 2020. **3.** Efficacy of Oral Azacitidine Plus Best Supportive Care as Maintenance Therapy in Subjects With Acute Myeloid Leukemia in Complete Remission (QUAZAR AML-001). Clinical Trials website. https://clinicaltrials.gov/ct2/show/NCT01757535. Published December 31, 2012. Updated October 24, 2019. Accessed August 31, 2020. **4.** Wei AH, Döhner H, Pocock C, et al. The QUAZAR AML-001 maintenance trial: results of a phase III international, randomized, double-blind, placebo-controlled study of CC-486 in patients with acute myeloid leukemia (AML) in first remission [oral presentation at ASH 2019]. *Blood*. 2019;134(Suppl 2):LBA-3.

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Access and reimbursement resources to support your patients on ONUREG®

Bristol Myers Squibb™ Access Support®

Three Simple Ways to Get Support

Contact your Access & Reimbursement Manager for general assistance and to schedule an office visit

Call Bristol Myers Squibb Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, to speak with a regionally assigned specialist

Visit www.BMSAccessSupport.com for information and resources, including the enrollment form, to help you and your patients with access to Bristol Myers Squibb products

Bristol Myers Squibb is committed to helping appropriate patients get access to our medications by providing access and reimbursement support services.

Bristol Myers Squibb™

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