

DIANE, 74

Diagnosis

- Diagnosed 6 months ago with intermediate-risk MDS
- Tests revealed moderate anemia, neutropenia; there was a prior diagnosis of renal disease
- 11.2% blasts
- Initiated MDS treatment with IV HMA therapy
- Began transfusions for anemia, and monitored progress
- Has since achieved transfusion independence and is stable

Blood test results

- Hemoglobin: 6.5 g/dL
 - Red blood cells: 3.6 M/ μ L
 - White blood cells: 4.0 K/ μ L
 - ANC: 800 cells/ μ L*
 - Platelets: 103 x 10⁹/L
 - Neutrophils: 18%
 - Cytogenetic category: Very good
- IPSS-R score of 4.5 points=intermediate

About Diane

- She does not have a full-time caregiver or family member to help with travel; she has been unable to get to the infusion center to complete her most recent cycle
- She needed a treatment option she could take at home
- ECOG performance status of 2 prior to beginning INQOVI[®] (decitabine and cedazuridine) tablets

Treatment history

- Received 6 cycles of IV decitabine before starting treatment for MDS with INQOVI

*Bands: 2%.

ANC=absolute neutrophil count; ECOG=Eastern Cooperative Oncology Group; HMA=hypomethylating agent; IPSS-R=Revised International Prognostic Scoring System; IV=intravenous; MDS=myelodysplastic syndromes.

INDICATIONS

INQOVI is indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Myelosuppression

Fatal and serious myelosuppression can occur with INQOVI.

Please see Important Safety Information on back cover and full Prescribing Information in pocket or at [INQOVI.com/PI](https://www.inqovi.com/PI).



Actor portrayal.

INQOVI[®]
(decitabine and cedazuridine)
35mg / 100mg tablets

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Myelosuppression

Fatal and serious myelosuppression can occur with INQOVI. Based on laboratory values, new or worsening thrombocytopenia occurred in 82% of patients, with Grade 3 or 4 occurring in 76%. Neutropenia occurred in 73% of patients, with Grade 3 or 4 occurring in 71%. Anemia occurred in 71% of patients, with Grade 3 or 4 occurring in 55%. Febrile neutropenia occurred in 33% of patients, with Grade 3 or 4 occurring in 32%. Myelosuppression (thrombocytopenia, neutropenia, anemia, and febrile neutropenia) is the most frequent cause of INQOVI dose reduction or interruption, occurring in 36% of patients. Permanent discontinuation due to myelosuppression (febrile neutropenia) occurred in 1% of patients. Myelosuppression and worsening neutropenia may occur more frequently in the first or second treatment cycles and may not necessarily indicate progression of underlying MDS.

Fatal and serious infectious complications can occur with INQOVI. Pneumonia occurred in 21% of patients, with Grade 3 or 4 occurring in 15%. Sepsis occurred in 14% of patients, with Grade 3 or 4 occurring in 11%. Fatal pneumonia occurred in 1% of patients, fatal sepsis in 1%, and fatal septic shock in 1%.

Obtain complete blood cell counts prior to initiation of INQOVI, prior to each cycle, and as clinically indicated to monitor response and toxicity. Administer growth factors and anti-infective therapies for treatment or prophylaxis as appropriate. Delay the next cycle and resume at the same or reduced dose as recommended.

Embryo-Fetal Toxicity

INQOVI can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise patients to use effective contraception during treatment and for 6 months (females) or 3 months (males) after last dose.

ADVERSE REACTIONS

Serious adverse reactions in > 5% of patients included febrile neutropenia (30%), pneumonia (14%), and sepsis (13%). Fatal adverse reactions included sepsis (1%), septic shock (1%), pneumonia

(1%), respiratory failure (1%), and one case each of cerebral hemorrhage and sudden death.

The most common adverse reactions ($\geq 20\%$) were fatigue (55%), constipation (44%), hemorrhage (43%), myalgia (42%), mucositis (41%), arthralgia (40%), nausea (40%), dyspnea (38%), diarrhea (37%), rash (33%), dizziness (33%), febrile neutropenia (33%), edema (30%), headache (30%), cough (28%), decreased appetite (24%), upper respiratory tract infection (23%), pneumonia (21%), and transaminase increased (21%). The most common Grade 3 or 4 laboratory abnormalities ($\geq 50\%$) were leukocytes decreased (81%), platelet count decreased (76%), neutrophil count decreased (71%), and hemoglobin decreased (55%).

USE IN SPECIFIC POPULATIONS

Lactation

Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with INQOVI and for 2 weeks after the last dose.

Renal Impairment

No dosage modification of INQOVI is recommended for patients with mild or moderate renal impairment (creatinine clearance [CLcr] of 30 to 89 mL/min based on Cockcroft-Gault). Due to the potential for increased adverse reactions, monitor patients with moderate renal impairment (CLcr 30 to 59 mL/min) frequently for adverse reactions. INQOVI has not been studied in patients with severe renal impairment (CLcr 15 to 29 mL/min) or end-stage renal disease (ESRD: CLcr <15 mL/min).

Please see full Prescribing Information in pocket or at INQOVI.com/PI.

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