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

THE ONLY oral HMA indicated to treat MDS

The only oral hypomethylating agent (HMA) for intermediate- to high-risk MDS including CMML that can be taken from the convenience and comfort of their own home or wherever they are.

Visit INQOVI.com or reach out to your local Taiho representative for more.

CMML=chronic myelomonocytic leukemia.

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.

SELECTED IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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%.

Please see full Important Safety Information on back cover, and full Prescribing Information in pocket.

THE ONLY oral HMA for MDS, including CMML, that

Patients can take from the comfort of home[1]

Convenient oral dosing

- Fixed-dose combination tablet containing decitabine (35 mg) and cedazuridine (100 mg)
- It is important to remind patients that response to HMA treatment may not be immediate
- Premature discontinuation can limit therapeutic benefits that would otherwise have been reached
- These agents often require 4 to 6 cycles of treatment to achieve a clinical response

28-day dosing cycle

Week 1	Take 1 tablet once daily for 5 days	2 days rest
Week 2	Rest	
Week 3	Rest	
Week 4	Rest	

Tablet shown is not actual size. Actual tablet size is 7.94 mm x 14.29 mm.

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Important dosing reminders

- Patients should avoid eating for 2 hours before and 2 hours after taking INQOVI® (decitabine and cedazuridine) tablets
- Tablets must be swallowed whole—not cut, crushed, or chewed
- Consider administering antiemetics prior to each dose to minimize nausea and vomiting
- Patients should take INQOVI at the same time each day
- Do NOT substitute INQOVI for an intravenous (IV) decitabine product within a cycle

Storage and handling with INQOVI

- Store INQOVI tablets in original packaging at room temperature at 20°C to 25°C (68°F to 77°F); excursions permitted from 15°C to 30°C (59°F to 86°F)

DosePak is 7.35 in x 2.45 in.

A complete or partial response may take longer than 4 cycles.

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THE ONLY oral HMA with equivalent systemic exposure to IV decitabine[1]

99% **Primary endpoint result ratio AUC** (90% CI: 93, 106)

- This ratio is the geometric mean of the 5-day cumulative decitabine AUC between INQOVI® (decitabine and cedazuridine) tablets and IV-administered decitabine when administered once daily for 5 consecutive days

Efficacy results in patients with MDS or CMML (N=133)

21%

of patients achieved a complete response (CR) (95% CI: 15, 29)

7.5 MONTHS

median duration of CR*
(range: 1.6-17.5)

4.3 MONTHS

median time to CR
(range: 2.1-15.2)

*From start of CR until relapse or death.
AUC=area under the curve; CI=confidence interval.

SELECTED IMPORTANT SAFETY INFORMATION

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%.

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Safety results similar to IV decitabine[1]

The most common adverse reactions (≥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 (≥50%) were leukocytes decreased (81%), platelet count decreased (76%), neutrophil count decreased (71%), and hemoglobin decreased (55%).

- Incidence of cytopenias was slightly higher in INQOVI during cycle 1 compared to IV decitabine
- These are not the only adverse reactions or laboratory abnormalities seen with INQOVI

Myelosuppression may occur more frequently in the first or second treatment cycle and may not indicate progression of underlying MDS.

Reference: 1. INQOVI [package insert]. Princeton, NJ: Taiho Oncology, Inc.; 2022.

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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.

TAIHO ONCOLOGY

 05/2022 INQ-PM-US-0333v2

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.

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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).

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