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. 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.

Please see Important Safety Information throughout this brochure and full Prescribing Information in pocket or at INQOVI.com/PI.

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

Straightforward oral dosing[1]

- **1 tablet, once a day for 5 days per 28-day dosing cycle**
- After 5 days of treatment, patients do not need to take INQOVI tablets for the next 23 days

Fixed-dose combination tablet containing decitabine (35 mg) and cedazuridine (100 mg)
Tablet shown is not actual size. Actual tablet size is 7.94 mm x 14.29 mm.

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	

Storage and handling with INQOVI[1]

- 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)

Easy-to-use blister pack
DosePak is 7.35 in x 2.45 in.

INQOVI is THE ONLY oral HMA for MDS and CMML that patients can take from the convenience of home.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

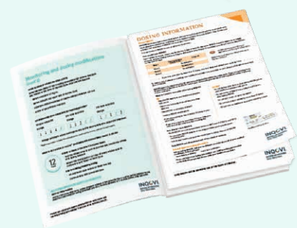
Myelosuppression (continued)
Fatal and serious infectious complications can occur with INQOVI. Pneumonia occurred in 21% of patients, with Grade 3 or 4 occurring in 15%. Sepsis occurred in 14% of patients, with Grade 3 or 4 occurring in 11%. Fatal pneumonia occurred in 1% of patients, fatal sepsis in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

Important dosing reminders[1]

- Tablets should be taken on an empty stomach, **at least 2 hours before or 2 hours after a meal**
- Tablets must be **swallowed whole**—not cut, crushed, or chewed
- Consider administering antiemetics prior to each dose to minimize nausea and vomiting
- Do **NOT** substitute INQOVI for an intravenous (IV) decitabine product **within a cycle**
- Patients should take INQOVI at the same time each day
- Administer growth factors and anti-infective therapies for treatment or prophylaxis as appropriate

A resource to help your patients start and stay on treatment



Dosing Tearpad

A tool to help ensure appropriate dosing and remind patients and caregivers how INQOVI should be taken.

The INQOVI treatment kit

A kit to help patients and caregivers with INQOVI treatment for MDS that includes:

1. Comprehensive patient brochure
2. Accompanying caregiver brochure
3. Blister pack opener
4. Health journal
5. Advocacy support brochure

Treatment kit is approximately 10.125 in x 11.125 in x 1.625 in.

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ASCERTAIN trial design[1,8]

The phase 3 crossover trial was designed to assess systemic decitabine exposure, demethylation activity, and safety between IV decitabine and INQOVI tablets. The trial allowed for intrapatient comparison in the first 2 randomized treatment cycles, and then assessment of the long-term efficacy and safety of INQOVI as a single arm.[1,8]

The phase 3 crossover trial had a median follow-up of approximately 2.6 years.[1,8]

	Phase 3[1] N=133	**Phase 3 Long-term Follow-up[8]** N=133
Primary endpoint	5-day area under the curve (AUC) between oral decitabine-cedazuridine and IV decitabine for Cycles 1 and 2	5-day area under the curve (AUC) between oral decitabine-cedazuridine and IV decitabine for Cycles 1 and 2
Key secondary endpoints	Complete response Rate of conversion from transfusion dependence to transfusion independence	Clinical response, transfusion independence, median overall and leukemia-free survival (LFS), safety, and pharmacodynamics
Other endpoints	Median duration of complete response and best response Median time to complete response	Median duration of complete response and best response Median time to first response

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

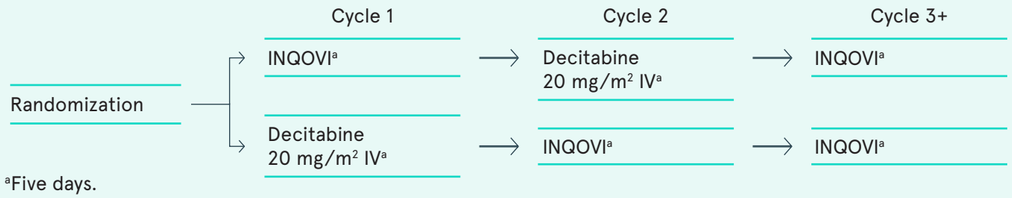
Embryo-Fetal Toxicity
INQOVI can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise patients to use effective contraception during treatment and for 6 months (females) or 3 months (males) after last dose.

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.

Phase 3 crossover design[1]

Open-label, randomized, 2-cycle, 2-sequence, crossover clinical trial in treatment-experienced or -naive patients with MDS and CMML (IPSS intermediate-1, -2, or high-risk). Patients were allowed to have 1 prior cycle of decitabine or azacitidine, and there was no limit for body weight or surface area.



[a]Five days.

- Patients were randomized 1:1 to INQOVI (decitabine 35 mg/cedazuridine 100 mg) or IV decitabine 20 mg/m² daily from day 1 through day 5 of each 28-day cycle
- In Cycle 1, patients received one agent and then crossed over to receive the other agent in Cycle 2
- After Cycle 2, all patients received INQOVI and treatment continued until disease progression or unacceptable toxicity

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS (continued)

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%).

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.

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The only oral HMA with equivalent systemic exposure to IV decitabine[1-3]

Primary endpoint results[1,2]

99% **ratio of oral to IV 5-day decitabine AUC (indicating equivalent pharmacokinetic exposure)**
(90% CI: 93, 106)

- This ratio is the geometric mean of the 5-day cumulative decitabine AUC between INQOVI tablets and IV-administered decitabine when administered once daily for 5 consecutive days[1]

Efficacy results in patients with MDS and CMML[1-3]

	Phase 3[1] (N=133)	Phase 3 Long-term Follow-up[2] (N=133)
Median follow-up time	12.6 months	~32 months
Patients who achieved CR (CI)[a]	21% (95% CI: 15, 29)	25% (95% CI: 17, 34)[b]
Median duration of CR[c]	7.5 months (range: 1.6-17.5)	14.1 months (range: 11.7-18.7)
Median time to CR[a]	4.3 months (range: 2.1-15.2)	4.5 months (range: 2.1-18.7)
Patients who went on to receive stem cell transplant (n/N)[d]	20% (27/133)	20% (27/133)
Median duration of best response[a]	NE	12.2 months (95% CI: 9.5, 14.4)
Median time to first response	NE	58 days (IQR: 35-116)

[a]Complete or partial response may take longer than 4 cycles.[1]
[b]Of the evaluable 117 participants, 25% (29/117) achieved a CR.[2]
[c]From start of CR until relapse or death.[1]
[d]No apparent difference between survival of those transplanted vs those who continued oral decitabine/cedazuridine treatment.[4]

Transfusion independence

Phase 3 Results[1]

- **53% (30/57)** of patients who were initially **transfusion dependent** achieved post-treatment **RBC and platelet transfusion independence**
- **63% (48/76)** of patients who were initially **RBC and platelet transfusion independent** remained **transfusion independent** post-treatment

Phase 3 Long-term Follow-up Results[2]

- **52% (28/54)** of patients who were initially **transfusion dependent** achieved post-treatment **RBC transfusion independence**
- **50% (6/12)** of patients who were initially **transfusion dependent** achieved post-treatment **platelet transfusion independence**
- **33%** of participants in each transfusion category were **transfusion independent** for at least 112 consecutive days

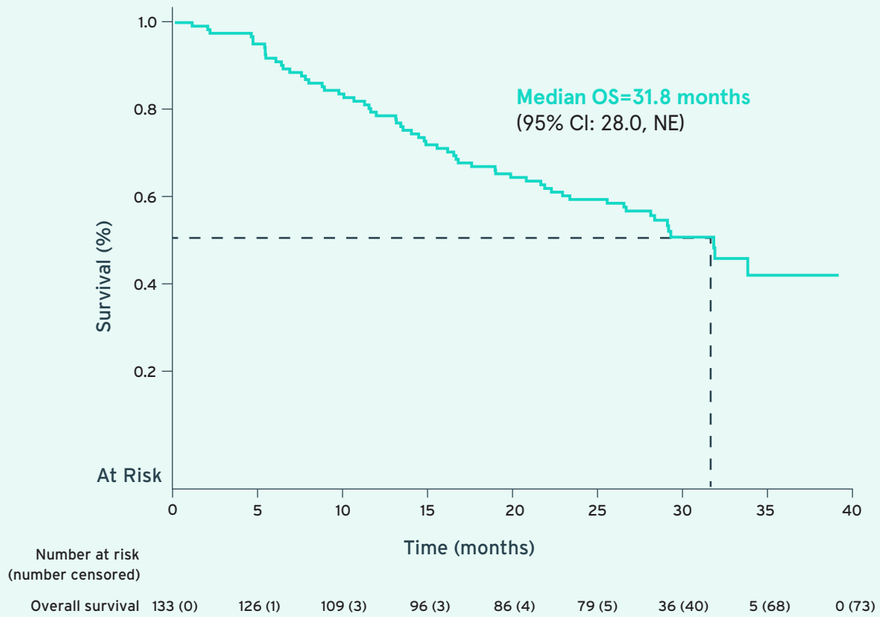
CI=confidence interval; CR=complete response; IQR=interquartile range; NE=not evaluated; RBC=red blood cell.

IMPORTANT SAFETY INFORMATION

Renal Impairment (continued)

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).

Secondary endpoint: overall survival (OS) (N=133)[2]



- Median follow-up was **~32 months**[2]
- Clinical response rate was a secondary endpoint that included complete response, marrow complete response, partial response, and hematologic improvement[2]
  - Of the evaluable participants with MDS, **70%** ([95% CI: 50, 69] 82 of 117 participants) displayed a clinical response[2]
- Overall survival and clinical response were secondary endpoints that are not reflected in the full Prescribing Information
- Due to potential variability in the natural history of the disease, a single-arm study may not adequately characterize this time-to-event endpoint, and the results may not be interpretable
- This data presentation is not intended to draw conclusions regarding the efficacy of INQOVI

Similar safety profile to IV decitabine with no unexpected adverse reactions[2]

- Incidence of cytopenias was slightly higher with INQOVI tablets during Cycle 1 compared to IV decitabine[1,5]
- 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%)

These are not the only adverse reactions or laboratory abnormalities seen with INQOVI. Please see full Prescribing Information for complete safety profile.

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35mg / 100mg tablets

Consider INQOVI, THE ONLY oral HMA for the treatment of MDS and CMML[1]

Visit INQOVI.com/hcp to learn more

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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References: 1. INQOVI [package insert]. Princeton, NJ: Taiho Oncology, Inc.; 2022. **2.** Garcia-Manero G, McCloskey J, Griffiths EA, et al. Oral decitabine-cedazuridine versus intravenous decitabine for myelodysplastic syndromes and chronic myelomonocytic leukaemia (ASCERTAIN): a registrational, randomised, crossover, pharmacokinetics, phase 3 study. *Lancet Haematol*. 2024;11(1):e15-e26. doi:10.1016/S2352-3026(23)00338-1. **3.** Data on file. Taiho Oncology Inc., Princeton, NJ. **4.** Savona MR, McCloskey JK, Griffiths EA, et al. Prolonged survival observed in 133 MDS patients treated with oral decitabine/cedazuridine. Poster presented at 16th International Congress on Myelodysplastic Syndromes (MDS). Virtual meeting; September 23-26, 2021. Abstract P48. https://astx.com/wp-content uploads/2021/09/2021_ASTX727_Poster_MDS-abst-P48_Savona_final.pdf. Accessed March 11, 2024. **5.** Kim N, Norsworthy KJ, Subramaniam S, et al. FDA approval summary: decitabine and cedazuridine tablets for myelodysplastic syndromes. *Clin Cancer Res*. 2022;28(16):3411-3416. doi:10.1158/1078-0432.CCR-21-4498.

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