There's no place like home

INQOVI® tablets—THE ONLY oral hypomethylating agent (HMA) for the treatment of myelodysplastic syndromes (MDS) and CMML.

Appropriate patients can take their therapy in the convenience and comfort of their own home or wherever they are.[1]

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.

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 on pages 18-19 and full Prescribing Information in pocket or at INQOVI.com/PI.

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

INQOVI is a fixed-dose combination tablet containing decitabine (35 mg) and cedazuridine (100 mg), a cytidine deaminase inhibitor that limits breakdown in the gut and, therefore, enhances oral bioavailability of decitabine and increases its systemic exposure.[1]

ASCERTAIN trial design[1,2]

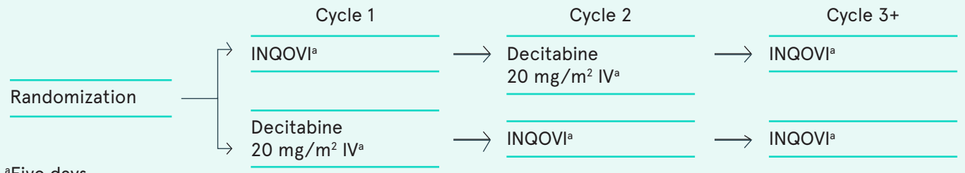
The phase 3 crossover trial was designed to assess systemic decitabine exposure, demethylation activity, and safety between IV decitabine and INQOVI. The trial allowed for intrapatient comparison in the first 2 randomized treatment cycles, and then assessment of the long-term efficacy and safety of INQOVI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

The phase 3 crossover trial had a median follow-up of approximately 2.6 years.[1,2]

	Phase 3[1] N=133	**Phase 3 Long-term Follow-up[2]** 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

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

IPSS=International Prognostic Scoring System; IV=intravenous.

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.

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

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

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)[3]
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)

Transfusion independence

Phase 3 Results[1]

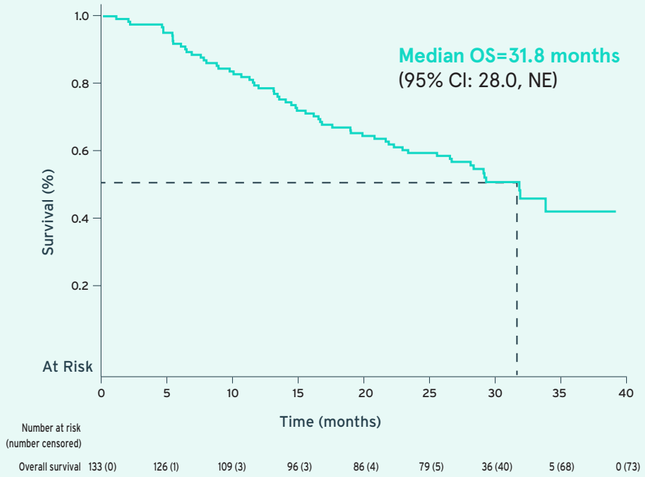
- **53% (30/57)** of patients who were initially **transfusion dependent** achieved post-treatment **RBC and platelet transfusion independence**
- **63% (48/76)** of patients who were initially **RBC and platelet transfusion independent** remained **transfusion independent** post-treatment

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

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

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

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.

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Baseline patient characteristics[1]

Characteristic	Phase 3 (N=133)
Age (years)	
Median (min, max)	71 (44, 88)
Sex	
Male	65%
Female	35%
Race	
White	91%
Black or African-American	3%
Asian	2%
Other or not reported	4%
ECOG performance score	
0	41%
1	59%
2	0
Disease category/IPSS	
MDS intermediate-1 risk	44%
MDS intermediate-2 risk	20%
MDS high risk	16%
MDS low risk	8%
CMML	12%
Prior HMA therapy[a]	
Prior azacitidine	5%
Prior decitabine	3%
Transfusion dependence[b]	
RBC transfusion dependence	39%
Platelet transfusion dependence	8%

[a]One cycle only, per the exclusion criteria.
[b]Defined as documentation of ≥2 units of transfusion within 56 days of the first day of study treatment.
ECOG=Eastern Cooperative Oncology Group.

Safety profile similar to IV decitabine[1]

Adverse reactions reported in ≥10% of patients in the pooled phase 2 and phase 3 safety population[1]

Adverse reactions[a]	INQOVI Cycle 1 n=107		IV decitabine Cycle 1 n=106		INQOVI all cycles n=208[c]	
	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)
General disorders and administration site conditions						
Fatigue[b]	29	2	25	0	55	5
Hemorrhage[b]	24	2	17	0	43	3
Edema[b]	10	0	11	0	30	0.5
Pyrexia	7	0	7	0	19	1
Gastrointestinal disorders						
Constipation[b]	20	0	23	0	44	0
Mucositis[b]	18	1	24	2	41	4
Nausea	25	0	16	0	40	0.5
Diarrhea[b]	16	0	11	0	37	1
Transaminase increased[b]	12	1	3	0	21	3
Abdominal pain[b]	9	0	7	0	19	1
Vomiting	5	0	5	0	15	0
Musculoskeletal and connective tissue disorders						
Myalgia[b]	9	2	16	1	42	3
Arthralgia[b]	9	1	13	1	40	3
Respiratory, thoracic, and mediastinal disorders						
Dyspnea[b]	17	3	9	3	38	6
Cough[b]	7	0	8	0	28	0
Blood and lymphatic system disorders						
Febrile neutropenia	10	10	13	13	33	32
Skin and subcutaneous tissue disorders						
Rash[b]	12	1	11	1	33	0.5

[a]Please see full Prescribing Information for complete list of adverse reactions occurring during all cycles.
[b]Includes multiple adverse reaction terms.
[c]Includes adverse reactions that occurred during all cycles, including during treatment with 1 cycle of IV decitabine.

Please see Important Safety Information on pages 18-19 and full Prescribing Information in pocket or at INQOVI.com/PI.

Safety profile similar to IV decitabine[1] (continued)

Adverse reactions reported in ≥10% of patients in the pooled phase 2 and phase 3 safety population[1] (continued)

Adverse reactions[a]	INQOVI Cycle 1 n=107		IV decitabine Cycle 1 n=106		INQOVI all cycles n=208[c]	
	All grades (%)	Grades 3–4 (%)	All grades (%)	Grades 3–4 (%)	All grades (%)	Grades 3–4 (%)
Nervous system disorders						
Dizziness[b]	16	1	11	0	33	2
Headache[b]	22	0	13	0	30	0
Neuropathy[b]	4	0	8	0	13	0
Metabolism and nutritional disorders						
Decreased appetite	10	1	6	0	24	2
Infections and infestations						
Upper respiratory tract infection[b]	6	0	3	0	23	1
Pneumonia[b]	7	7	7	5	21	15
Sepsis[b]	6	6	2	1	14	11
Cellulitis[b]	4	1	3	2	12	5
Investigations						
Renal impairment[b]	9	0	8	1	18	0
Weight decreased	5	0	3	0	10	1
Injury, poisoning, and procedural complications						
Fall	4	0	1	0	12	1

[a]Please see full Prescribing Information for complete list of adverse reactions occurring during all cycles.
[b]Includes multiple adverse reaction terms.
[c]Includes adverse reactions that occurred during all cycles, including during treatment with 1 cycle of IV decitabine.

Adverse reactions reported in ≥10% of patients in the pooled phase 2 and phase 3 safety population[1] (continued)

Adverse reactions[a]	INQOVI Cycle 1 n=107		IV decitabine Cycle 1 n=106		INQOVI all cycles n=208[c]	
	All grades (%)	Grades 3–4 (%)	All grades (%)	Grades 3–4 (%)	All grades (%)	Grades 3–4 (%)
Psychiatric disorders						
Insomnia	6	0	2	0	12	0.5
Vascular disorders						
Hypotension[b]	4	0	6	1	11	2
Cardiac disorders						
Arrhythmia[b]	3	0	2	0	11	1

- Safety results were similar to those in patients receiving IV decitabine with no unexpected adverse reactions reported in the first 2 cycles[1]
- Incidence of cytopenias was slightly higher in patients taking INQOVI tablets during Cycle 1 compared to IV decitabine[1,5]
- In the pooled safety population of phases 2 and 3, 61% of patients receiving INQOVI were exposed for ≥6 months and 24% were exposed for >1 year[1]
- **Long-term follow-up study:** Adverse reaction profile was similar to what was observed in the pooled safety population[2]
  - The incidence of serious adverse reactions in Cycles 1 and 2 was 31% (40 of 130 participants) with oral decitabine-cedazuridine and 18% (24 of 132 participants) with IV decitabine

Please see Important Safety Information on pages 18–19 and full Prescribing Information in pocket or at INQOVI.com/PI.

Select hematologic lab abnormalities[1]

>20% in the pooled safety population[1]

Lab parameter[a]	INQOVI Cycle 1[b]		IV decitabine Cycle 1[b]		INQOVI all cycles[b]	
	All grades (%)	Grades 3–4 (%)	All grades (%)	Grades 3–4 (%)	All grades (%)	Grades 3–4 (%)
Hematology						
Leukocytes decreased	79	65	77	59	87	81
Platelet count decreased	79	65	77	67	82	76
Neutrophil count decreased	70	65	62	59	73	71
Hemoglobin decreased	58	41	59	36	71	55

[a]Includes any lab abnormalities that worsened by ≥1 grades. Grades 3 to 4 include any lab abnormalities that worsened to grade 3 or grade 4.
[b]The denominator used to calculate the rate varied from 103 to 107 for INQOVI Cycle 1, from 102 to 106 for the IV decitabine cycle, and from 203 to 208 for INQOVI (all cycles) based on the number of patients with a baseline value and ≥1 post-treatment value.

Please see full Prescribing Information for chemistry lab safety parameters.

Discontinuation rate[1,2]

- **5%** **of patients discontinued** treatment with INQOVI due to an adverse reaction
  - Treatment discontinuations due to an adverse reaction during the first 2 treatment cycles were low (1 participant in each group)[2]
  - Overall treatment discontinuations due to an adverse reaction were also low (1 of 132 with IV decitabine and 2 of 130 with oral decitabine-cedazuridine)[2]
- The most frequent adverse reactions resulting in permanent discontinuation were febrile neutropenia (1%) and pneumonia (1%)[1]
- The most common reason for treatment discontinuation was undergoing allogeneic hematopoietic stem-cell transplantation (HSCT) (27 [20%])[2]

Additional safety profile information[1,2]

- **Clinically relevant adverse reactions** in <10% of patients who received INQOVI included: acute febrile neutrophilic dermatosis (Sweet's syndrome) (1%) and tumor lysis syndrome (0.5%)[1]
- **Serious adverse reactions** occurred in 68% of patients who received INQOVI. Serious adverse reactions in >5% of patients included febrile neutropenia (30%), pneumonia (14%), and sepsis (13%)[1]
  - In the long-term follow-up study, there were 5 treatment-related deaths; 2 deemed related to oral therapy (sepsis and pneumonia) and 3 to IV treatment (septic shock [n=2] and pneumonia [n=1])[2]
- **Fatal adverse reactions** occurred in 6% of patients, and included sepsis (1%), pneumonia (1%),[1] respiratory failure (1%), septic shock (1%), and 1 case each of cerebral hemorrhage and sudden death
  - In the long-term follow-up study, 11 (8%) of 133 participants had fatal treatment-emergent serious adverse reactions during the study[2]
- **Dose interruptions** due to an adverse reaction occurred in 41% of patients who received INQOVI. Adverse reactions requiring dosage interruptions in >5% of patients who received INQOVI included neutropenia (18%), febrile neutropenia (8%), thrombocytopenia (6%), and anemia (5%)[1]
- **Dose reductions** due to an adverse reaction occurred in 19% of patients who received INQOVI. Adverse reactions requiring dosage reductions in >2% of patients who received INQOVI included neutropenia (12%), anemia (3%), and thrombocytopenia (3%)[1]

IMPORTANT SAFETY INFORMATION

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 (≥ 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%).

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

Straightforward oral dosing[1]

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

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	

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.

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)

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.

Scan the QR code to learn more about INQOVI dosing

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS (continued)

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%).

Important dosing reminders

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

Decitabine and cedazuridine (INQOVI®) is the **only FDA-approved oral HMA option in MDS** (IPSS Intermediate-1 and above) that the **National Comprehensive Cancer Network® (NCCN®) recommends** could be a substitution for IV decitabine[1,6]

Oral decitabine and cedazuridine (DEC-C) (NCCN Category 2A*) could be a substitution for intravenous decitabine in patients with IPSS intermediate-1 and above in the *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myelodysplastic Syndromes*.

- Do not substitute decitabine and cedazuridine (INQOVI) for an IV decitabine product within a cycle[1]

*Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[6]

NCCN=National Comprehensive Cancer Network.

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.

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Monitoring and dosing modifications[1]

To quickly identify any potential reductions in blood counts at the start of treatment, it is recommended to closely monitor patients during Cycle 1 of treatment with INQOVI tablets.[1]

Dose interruptions due to an adverse reaction occurred in **41% of patients** who received INQOVI.
Dose reductions due to an adverse reaction occurred in **19% of patients** who received INQOVI.

- The most frequent cause of dose reduction or interruption was myelosuppression (thrombocytopenia, neutropenia, anemia, and febrile neutropenia)

Monitor response[1]

- Obtain complete blood cell counts prior to initiating INQOVI and before each cycle
- Manage toxicity using dose delay, dose modification, growth factors, and anti-infective therapies for treatment or prophylaxis as needed

When to delay or reduce the dose[1]

Delay the next cycle if absolute neutrophil count (ANC) is <1000/µL and platelets are <50,000/µL in the absence of active disease. Monitor complete blood cell counts until ANC is ≥1000/µL and platelets are ≥50,000/µL.

If hematologic recovery does not occur within 2 weeks of achieving remission:

- **Delay INQOVI for up to 2 additional weeks, AND**
- **Resume at a reduced dose by administering INQOVI on days 1 through 4**
- **Consider further dose reductions** (listed on the next page) **if myelosuppression persists after first dose reduction**
- **Maintain or increase dose in subsequent cycles as clinically indicated**

IMPORTANT SAFETY INFORMATION

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.

When to delay or reduce the dose[1] (continued)

Delay the next cycle for the following nonhematologic adverse reactions and resume at the same or reduced dose once they are resolved:

- Serum creatinine ≥2 mg/dL
- Serum bilirubin ≥2x upper limit of normal (ULN)
- Aspartate aminotransferase or alanine aminotransferase ≥2x ULN
- Active or uncontrolled infection

Recommended dose reductions for myelosuppression[1]*

1st dose reduction Dosage:	2nd dose reduction Dosage:	3rd dose reduction Dosage:
1 day, 2 day, 3 day, 4 day, ~~5 day~~	1 day, 2 day, 3 day, ~~4 day~~, ~~5 day~~	1 day, ~~2 day~~, 3 day, ~~4 day~~, 5 day

- Manage persistent severe neutropenia and febrile neutropenia with supportive treatment

*Myelosuppression includes thrombocytopenia, neutropenia, anemia, and febrile neutropenia.[1]

If vomiting occurs following dosing[1]:

- No additional dose should be taken that day
- Continue with next scheduled dose

What to do if a dose of INQOVI is missed[1]

Within 12 hours of the time INQOVI is usually taken:

- Take the missed dose as soon as possible and resume the normal daily dosing schedule
- Extend the dosing period by 1 day for every missed dose to complete 5 daily doses for each cycle

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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 (≥ 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. 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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35mg / 100mg tablets

Taiho Oncology Patient Support™ for you and your patients

Taiho Oncology Patient Support™ offers personalized services to help patients, caregivers, and healthcare professionals access Taiho Oncology products. This includes insurance coverage determination and help with medication affordability. For more information, please visit or refer patients to **TaihoPatientSupport.com**.

TAIHO ONCOLOGY PATIENT SUPPORT
Supporting your treatment journey

Meeting the access needs of your patients
Getting patients access to their medicine is an important step.
Taiho Oncology Patient Support™ strives to make this process as simple as possible.

Taiho Oncology Patient Support™ can assist with:

Insurance Coverage Support

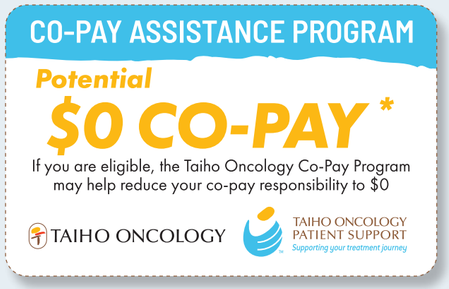
- Benefits investigation
- Prior authorization assistance
- Appeals assistance
- Coordination of prescriptions with pharmacies

Patient Affordability Assistance*

- $0 co-pay program enrollment for eligible commercially insured patients
- Patient assistance program designed to provide free medication to eligible patients who are uninsured or underinsured
- Referrals to third-party foundations for co-pay or other assistance based on eligibility and additional criteria
- Referrals to Medicare Part D Low-Income Subsidy (LIS)/Extra Help Program

Personalized Nurse Support†
One-on-one nurse educational support for patients, available via opt-in

Taiho Oncology Patient Support™ Co-pay Program
Eligible, privately insured patients can enroll in the Taiho Oncology Patient Support™ Co-pay program, which may help reduce out-of-pocket expenses to $0 for their treatment with INQOVI® (decitabine and cedazuridine) tablets.



To determine patient eligibility, go to **TaihoOncologyCopay.com** or call **1-844-TAIHO-4U** (1-844-824-4648).

Support starts with an easy-to-complete Enrollment Form that can be downloaded at TaihoPatientSupport.com/how-to-enroll.

To register or learn more, visit or refer patients to **TaihoPatientSupport.com** or call **1-844-TAIHO-4U** (1-844-824-4648) Monday to Friday, 8 AM to 8 PM ET.

*Visit TaihoPatientSupport.com to see full eligibility criteria.
†If selected on the Patient Enrollment Form, a Nurse Navigator will be assigned to provide telephone support and will address general inquiries about INQOVI treatment.

Please see Important Safety Information on pages 18-19 and full Prescribing Information in pocket or at INQOVI.com/PI.

Patient advocacy organizations

These organizations offer patients information, support, and community.
Feel free to share the following resources with your patients:

The Aplastic Anemia and MDS International Foundation (AAMDSIF)
Visit aamds.org or call 1-800-747-2820

The Leukemia & Lymphoma Society (LLS)
Visit lls.org or call 1-800-955-4572

The Myelodysplastic Syndromes (MDS) Foundation, Inc.
Visit mds-foundation.org or call 1-800-MDS-0839 (1-800-637-0839)

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. **6.** Referenced with permission from the *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myelodysplastic Syndromes Version 1.2024*. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed February 20, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.

Important things to remember while patients are treated with INQOVI[1,5]

INQOVI tablets **can be substituted for IV decitabine, but not within a cycle.**[1]

Patients should be closely monitored during treatment with INQOVI, **especially during the early cycles.**[1]

- Incidence of cytopenias was slightly higher with INQOVI during cycle 1 compared to IV decitabine[1,5]

A response to INQOVI tablets may not be immediate. A complete or partial response **may take longer than 4 cycles.**[1]

Antiemetics (prior to each dose), growth factors, and anti-infective therapies **can be administered for treatment or prophylaxis as appropriate.**[1]

IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS (continued)

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 Important Safety Information on pages 18-19 and full Prescribing Information in pocket or at INQOVI.com/PI.

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

Consider INQOVI, **THE ONLY** oral HMA for the treatment of MDS and CMML[1,2,5]

For your patients who want to take their treatment in the comfort of home or wherever they are

- **One pill, taken once daily for 5 days per 28-day cycle**[1]
- **Primary endpoint: 99% geometric mean ratio of oral to IV 5-day decitabine AUC**[1,2]
- Demonstrated **equivalent** systemic exposure and a **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]

Pivotal trial data[1]

- **Complete response was achieved in 21% of patients** (95% CI: 15, 29; N=133)
- **53% (30/57)** of patients who were initially **transfusion dependent** achieved post-treatment **RBC and platelet transfusion independence**
- **20% (27/133)** of patients went on to receive **stem cell transplantation** after taking INQOVI tablets

Long-term follow-up data[2]

- **Complete response was achieved in 25% of patients** (95% CI: 17, 34)*
- **52% (28/54)** of patients who were initially **transfusion dependent** achieved post-treatment **RBC transfusion independence**
- **20% (27/133)** of patients went on to receive **stem cell transplantation** after taking INQOVI

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.

*Of the evaluable 117 participants, 25% (29/117) achieved a complete response.[2]

For questions about treatment with INQOVI, call **1-844-878-2446** or go to **INQOVI.com/hcp**

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Myelosuppression: Fatal and serious myelosuppression and infectious complications can occur. Obtain complete blood cell counts prior to initiation of INQOVI, prior to each cycle, and as clinically indicated to monitor for response and toxicity.

Embryo-Fetal Toxicity: Can cause fetal harm.

Please see Important Safety Information, including information on myelosuppression and embryo-fetal toxicity, on pages 18-19 and full Prescribing Information in pocket or at INQOVI.com/PI.

TAIHO ONCOLOGY

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(decitabine and cedazuridine)
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