TIBSOVO® + AZA significantly extended overall survival in newly diagnosed, IC-ineligible m*IDH1* AML

LASER-FOCUSED ON SURVIVAL



A category 1 preferred treatment option

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend ivosidenib (TIBSOVO) in combination with AZA for newly diagnosed patients ≥18 years of age with m*IDH1* AML who are not candidates for intensive remission induction therapy[3]

[a]TIBSOVO + AZA, (95% CI, 11.3-34.1); AZA, (95% CI, 4.1-11.3).[1] In the primary analysis from the AGILE study, 146 patients were 1:1 randomized: 72 to TIBSOVO + AZA and 74 to placebo + AZA. The data cutoff date was March 2021 with a median follow-up of 15.1 months for the OS analysis.[1,4]

[b]TIBSOVO + AZA, (95% CI, 13.2-NR); AZA, (95% CI, 4.1-11.3).[2] In the long-term follow-up analysis from the AGILE study, 148 patients were 1:1 randomized: 73 to TIBSOVO + AZA and 75 to placebo + AZA. The data cutoff date was June 2022 with a median follow-up of 28.6 months for the OS analysis.[2]

AZA, azacitidine; HR, hazard ratio; IC, induction chemotherapy; mIDH1, mutated IDH1; mOS, median overall survival; NR, not reached; OS, overall survival.

INDICATION

TIBSOVO is indicated for patients with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test with:

Newly Diagnosed Acute Myeloid Leukemia (AML)

- In combination with azacitidine or as monotherapy for the treatment of newly diagnosed AML in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy

IMPORTANT SAFETY INFORMATION

WARNING: DIFFERENTIATION SYNDROME IN AML

Patients treated with TIBSOVO have experienced symptoms of differentiation syndrome, which can be fatal. Symptoms may include fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, hypotension, and hepatic, renal, or multi-organ dysfunction. If differentiation syndrome is suspected, initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.

Please see additional Important Safety Information throughout and Full Prescribing Information, including BOXED WARNING for AML patients.

TIBSOVO IS THE ONLY THERAPY THAT WAS STUDIED IN A PHASE 3 TRIAL SPECIFICALLY DESIGNED FOR NEWLY DIAGNOSED PATIENTS WITH m*IDH1* AML

TIBSOVO + AZA was studied in a global, phase 3, multicenter, randomized (1:1), double-blind, placebo-controlled trial[1,4]

- 146 adult patients with previously untreated m*IDH1* AML who were not candidates for intensive therapy were randomized[1]
- Efficacy was established on the basis of event-free survival (EFS), OS, and rate and duration of complete remission (CR)[1]
  - EFS was defined as time from randomization until treatment failure, relapse from remission, or death from any cause, whichever occurred first
  - Treatment failure was defined as failure to achieve CR by Week 24. A CRh response was considered to be a treatment failure

TIBSOVO + AZA was studied in an IC-ineligible patient population reflective of that seen in clinical practice[1]

	TIBSOVO (500 mg daily) + AZA (n=72)	Placebo + AZA (n=74)
Baseline demographics		
Median age, years (min, max)	76 (58, 84)	76 (45, 94)
Age categories, n (%)		
<65 years	4 (6)	4 (5)
≥65 years to <75 years	29 (40)	27 (36)
≥75 years	39 (54)	43 (58)
Baseline disease characteristics		
ECOG PS, n (%)		
0	14 (19)	10 (14)
1	32 (44)	40 (54)
2	26 (36)	24 (32)
Cytogenetic risk status,[a] n (%)		
Favorable	3 (4)	7 (9)
Intermediate	48 (67)	44 (59)
Poor	16 (22)	20 (27)
Other	3 (4)	1 (1)
Missing	2 (3)	2 (3)
Transfusion dependent at baseline,[b] n (%)	39 (54)	40 (54)
Type of AML, n (%)		
De novo AML	54 (75)	53 (72)
Secondary AML	18 (25)	21 (28)
Therapy-related AML	2 (3)	1 (1)
MDS related	10 (14)	12 (16)
MPN related	4 (6)	8 (11)

[a]Cytogenic risk status: investigators used the NCCN Guidelines®.
[b]Patients were defined as transfusion dependent at BL if they received any RBC or platelet transfusion within 56 days prior to the first dose of study treatment.

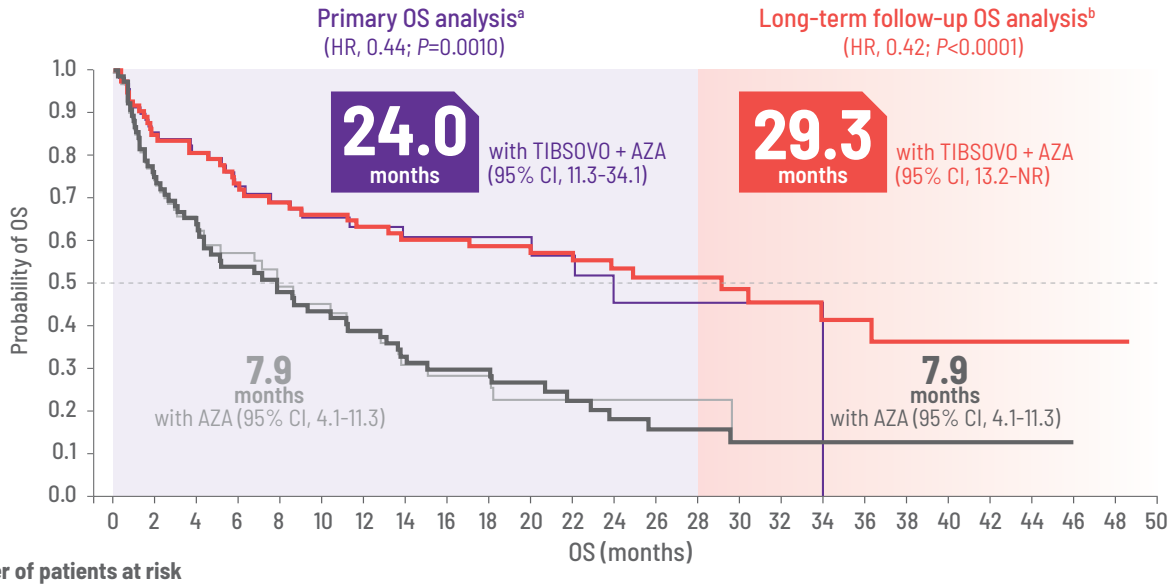
BL, baseline; CRh, complete remission with partial hematologic recovery; ECOG PS, Eastern Cooperative Oncology Group performance status; MDS, myelodysplastic syndromes; MPN, myeloproliferative neoplasms; RBC, red blood cell.

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TIBSOVO + AZA IS PROVEN TO SIGNIFICANTLY INCREASE OS

More than threefold improvement in mOS with TIBSOVO + AZA vs AZA alone[1,2]



Number of patients at risk

Primary OS analysis

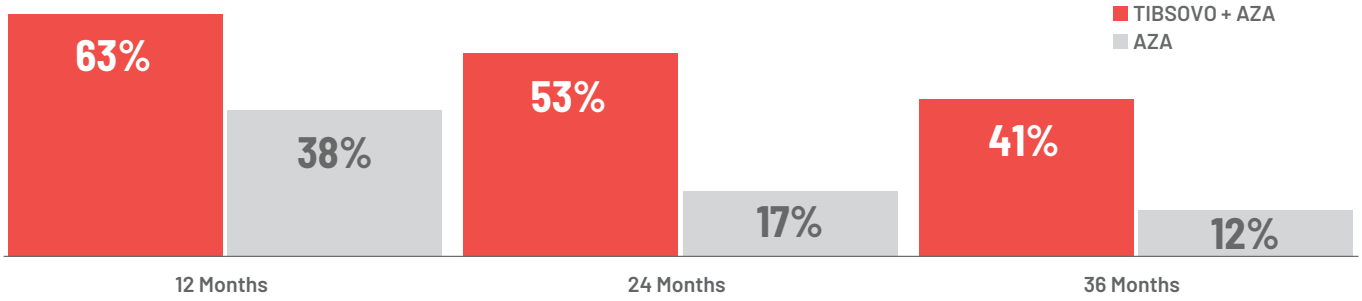
TIBSOVO+AZA	72	58	53	42	38	33	29	24	21	19	15	13	7	4	4	2	2	1	0
PLACEBO+AZA	74	53	38	29	23	21	15	11	9	9	6	5	4	3	3	0			

Long-term follow-up OS analysis

TIBSOVO+AZA	73	60	56	50	47	45	43	40	39	37	36	32	27	23	20	17	13	11	8	5	4	3	3	1	1	0
PLACEBO+AZA	75	55	45	37	32	28	25	21	19	19	13	10	8	6	5	4	4	3	2	2	1	1	1	1	0	

- **56% reduction in risk of death** per the primary OS analysis (95% CI, 0.27-0.73)[1]
- **58% reduction in risk of death** per the long-term follow-up OS analysis (95% CI, 0.27-0.65)[2]

Greater OS benefit with 3x increase in OS rates at 24 and 36 months with TIBSOVO + AZA[2]



[a]In the primary analysis from the AGILE study, 146 patients were 1:1 randomized: 72 to TIBSOVO + AZA and 74 to placebo + AZA. The data cutoff date was March 2021 with a median follow-up of 15.1 months for the OS analysis.[1,4]

[b]In the long-term follow-up analysis from the AGILE study, 148 patients were 1:1 randomized: 73 to TIBSOVO + AZA and 75 to placebo + AZA. The data cutoff date was June 2022 with a median follow-up of 28.6 months for the OS analysis.[2]

NR, not reached.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

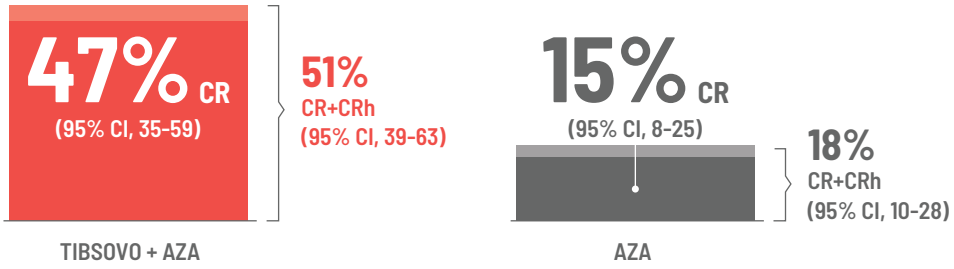
Differentiation Syndrome in AML: Differentiation syndrome is associated with rapid proliferation and differentiation of myeloid cells and may be life-threatening or fatal. Symptoms of differentiation syndrome in patients treated with TIBSOVO included noninfectious leukocytosis, peripheral edema, pyrexia, dyspnea, pleural effusion, hypotension, hypoxia, pulmonary edema, pneumonitis, pericardial effusion, rash, fluid overload, tumor lysis syndrome and creatinine increased.

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TIBSOVO + AZA DEMONSTRATED RAPID AND DURABLE REMISSIONS

TIBSOVO + AZA demonstrated significantly higher rates of CR and CR+CRh compared with AZA (*P*<0.0001)[1]

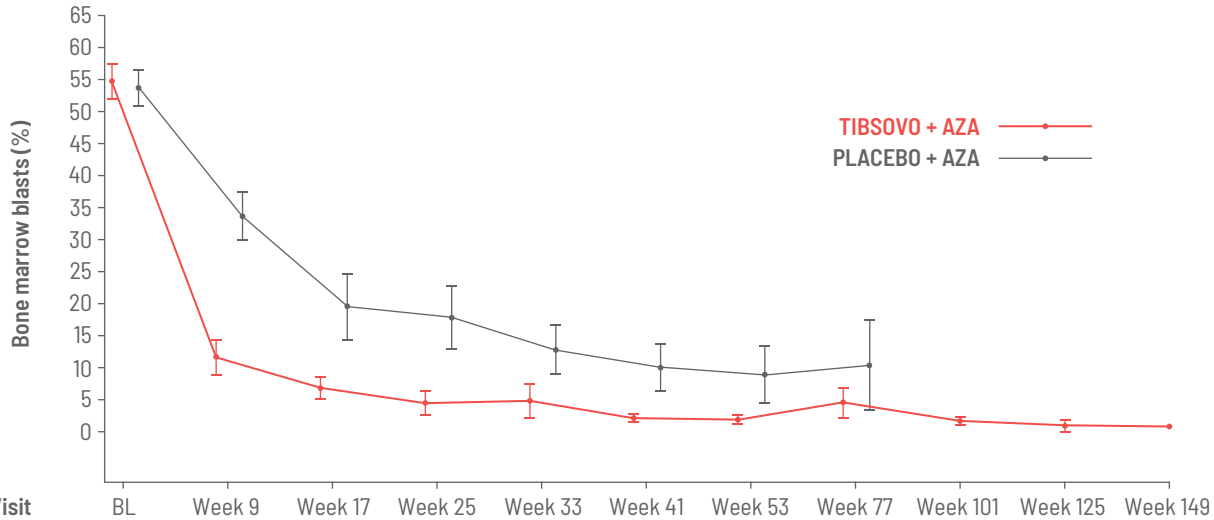


- Median duration of complete response was not estimable (NE) as of the data cutoff date in the TIBSOVO + AZA arm (95% CI,13.0-NE) and was 11.2 months in the AZA arm (95% CI, 3.2-NE)[1]
- Of the patients who achieved CR or CRh **with TIBSOVO + AZA, 88% remained in remission at 12 months (95% CI, 67.5-96.2), and 59% remained in remission at 24 months** (95% CI, 17.7-85.1) per Kaplan-Meier estimation[4,5]
- 38% of patients receiving TIBSOVO + AZA achieved CR by Week 24 compared with 11% of patients in the AZA arm[6]

Median time to response with TIBSOVO + AZA

- First response (CR, CRi, CRp, PR, or MLFS): 2 months (range, 2-8)[5]
- CR: 4 months (range, 2-12)[1]
- CR+CRh: 4 months (range, 2-12)[1]

TIBSOVO + AZA resulted in decreased bone marrow blasts from BL[5]



Visit		BL	Week 9	Week 17	Week 25	Week 33	Week 41	Week 53	Week 77	Week 101	Week 125	Week 149
TIBSOVO + AZA	n =	70	50	41	34	26	24	21	13	5	2	1
PLACEBO + AZA	n =	72	42	27	22	18	11	6	4			

BL is defined as the last assessment before start of study treatment; error bars indicate mean ± standard error.

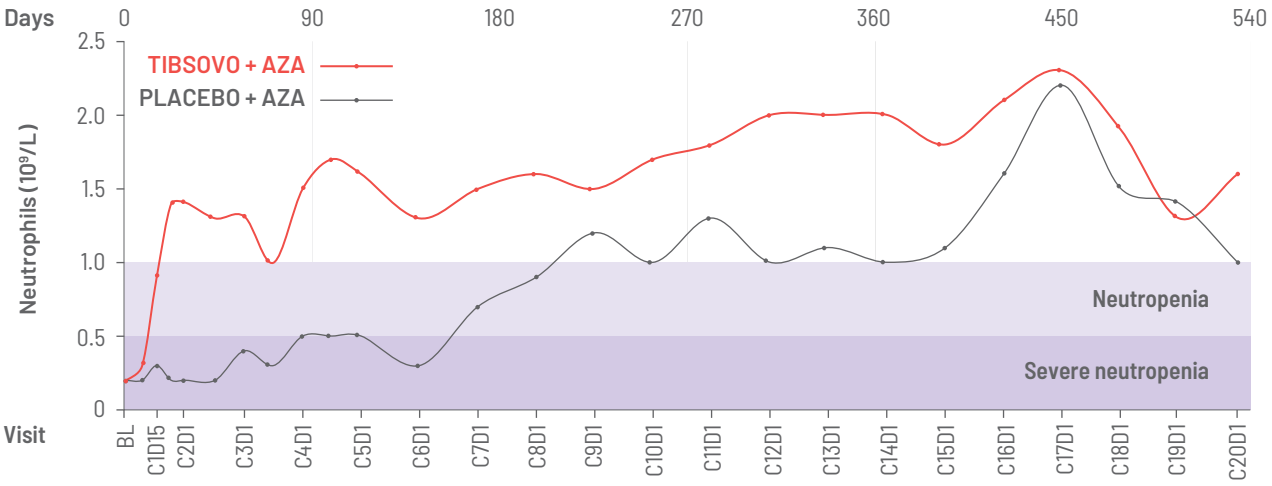
CRi, CR with incomplete hematologic recovery; CRp, complete remission with incomplete platelet recovery; HI, hematologic improvement; PR, partial remission; MLFS, morphologic leukemia-free state.

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TIBSOVO + AZA RESULTED IN RAPID AND SUSTAINED NEUTROPHIL RECOVERY

TIBSOVO + AZA resulted in rapid neutrophil recovery with increased median absolute neutrophil count (ANC) over time[5,7]



TIBSOVO + AZA	n =	70	62	57	50	45	44	39	36	31	29	28	27	24	22	22	20	19	15	13	12	9
PLACEBO + AZA	n =	72	67	55	38	34	27	23	19	16	15	14	11	9	7	7	7	6	4	4	3	3

- By the end of Cycle 1, **the TIBSOVO + AZA median value reached 1.0 x 10^9/L and was sustained throughout the treatment duration**[7]

TIBSOVO + AZA demonstrated an increase in mean ANC from BL[5,6]



TIBSOVO + AZA	n =	70	65	62	60	57	53	50	48	45	44	44	39	36	31	29	28	27
PLACEBO + AZA	n =	72	67	67	58	55	50	38	35	34	30	27	23	19	16	15	14	11

BL is defined as the last assessment before start of study treatment; error bars indicate mean ± standard error.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

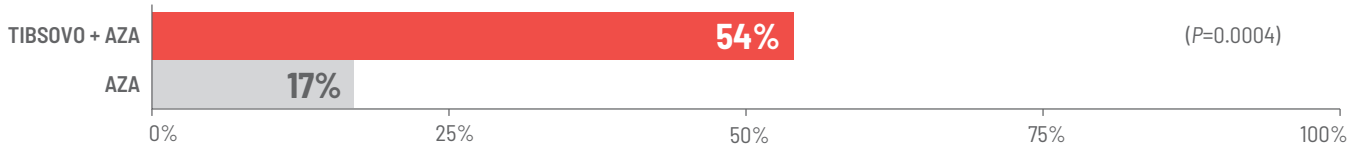
If differentiation syndrome is suspected, initiate dexamethasone 10 mg IV every 12 hours (or an equivalent dose of an alternative oral or IV corticosteroid) and hemodynamic monitoring until improvement. If concomitant noninfectious leukocytosis is observed, initiate treatment with hydroxyurea or leukapheresis, as clinically indicated.

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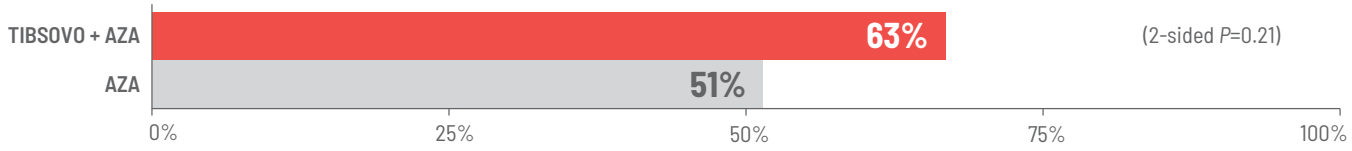
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MORE THAN HALF OF PATIENTS ACHIEVED TRANSFUSION INDEPENDENCE WITH TIBSOVO + AZA

Among patients who were transfusion dependent at BL (~54%), a higher percentage of patients converted to transfusion independence with TIBSOVO + AZA than with AZA[2,a]



Postbaseline RBC and platelet transfusion independence regardless of BL transfusion status[6,a]



[a]Postbaseline transfusion independence is defined as a period of ≥56 days with no transfusion after the start of study treatment and on or before the end of study treatment + 28 days, disease progression, confirmed relapse, death, or data cutoff date, whichever was earlier.[2]

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Taper corticosteroids and hydroxyurea after resolution of symptoms and administer corticosteroids for a minimum of 3 days. Symptoms of differentiation syndrome may recur with premature discontinuation of corticosteroid and/or hydroxyurea treatment. If severe signs and/or symptoms persist for more than 48 hours after initiation of corticosteroids, interrupt TIBSOVO until signs and symptoms are no longer severe.

QTc Interval Prolongation: Patients treated with TIBSOVO can develop QT (QTc) prolongation and ventricular arrhythmias. Concomitant use of TIBSOVO with drugs known to prolong the QTc interval (eg, anti-arrhythmic medicines, fluoroquinolones, triazole anti-fungals, 5-HT_3 receptor antagonists) and CYP3A4 inhibitors may increase the risk of QTc interval prolongation. Conduct monitoring of electrocardiograms (ECGs) and electrolytes. In patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval, more frequent monitoring may be necessary.

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TIBSOVO + AZA DELIVERED MEANINGFUL IMPROVEMENT IN EFS VS AZA

Treatment with TIBSOVO + AZA resulted in significant improvement in EFS compared with AZA[1]

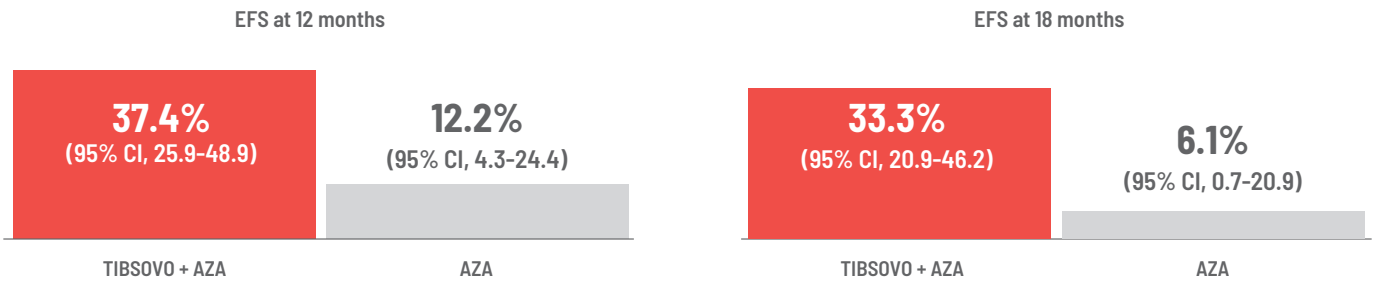
	TIBSOVO (500 mg daily) + AZA (n=72)	Placebo + AZA (n=74)
EFS, events (%)	47 (65)	62 (84)
Treatment failure	43 (60)	59 (80)
Relapse	3 (4)	2 (3)
Death	1 (1)	1 (1)
HR[a] (95% CI)	0.35 (0.17-0.72)	
P value[b]	0.0038	

Two-sided *P* value boundary for EFS is 0.0095.

[a]HR was estimated using a Cox proportional hazards model stratified by the randomization stratification factors (type of AML and geographic region) with placebo + AZA as the denominator.

[b]Two-sided *P* value was calculated from the log-rank test stratified by the randomization stratification factors (type of AML and geographic region).

TIBSOVO + AZA demonstrated higher EFS rates compared to AZA alone[5]



IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Interrupt TIBSOVO if QTc increases to greater than 480 msec and less than 500 msec. Interrupt and reduce TIBSOVO if QTc increases to greater than 500 msec. Permanently discontinue TIBSOVO in patients who develop QTc interval prolongation with signs or symptoms of life-threatening arrhythmia.

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TIBSOVO HAS A WELL-CHARACTERIZED SAFETY PROFILE STUDIED IN MORE THAN 270 PATIENTS WITH m*IDH1* AML

Adverse reactions (≥10%) in patients with AML who received TIBSOVO + AZA with a difference of ≥2% between arms compared with placebo + AZA[1]

	TIBSOVO + AZA (n=71)		Placebo + AZA (n=73)	
Body system Adverse reaction	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)
Gastrointestinal disorders				
Nausea	30 (42)	2 (3)	28 (38)	3 (4)
Vomiting	29 (41)	0	20 (27)	1 (1)
Investigations				
Electrocardiogram QT prolonged	14 (20)	7 (10)	5 (7)	2 (3)
Psychiatric disorders				
Insomnia	13 (18)	1 (1)	9 (12)	0
Blood system and lymphatic system disorders				
Differentiation syndrome[a]	11 (15)	7 (10)	6 (8)	6 (8)
Leukocytosis	9 (13)	0	1 (1)	0
Vascular disorders				
Hematoma	11 (15)	0	3 (4)	0
Hypertension	9 (13)	3 (4)	6 (8)	1 (1)
Musculoskeletal and connective tissue disorders				
Arthralgia	21 (30)	3 (4)	6 (8)	1 (1)
Respiratory, thoracic, and mediastinal disorders				
Dyspnea	14 (20)	2 (3)	11 (15)	4 (5)
Nervous system disorders				
Headache	8 (11)	0	2 (3)	0

[a]Differentiation syndrome can be associated with other commonly reported events such as peripheral edema, leukocytosis, pyrexia, dyspnea, pleural effusion, hypotension, hypoxia, pulmonary edema, pneumonia, pericardial effusion, rash, fluid overload, tumor lysis syndrome, and creatinine increased.

- TIBSOVO + AZA was associated with a lower rate of infection of any grade compared with AZA (28% vs 49%)[4]

ECG, electrocardiogram.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Guillain-Barré Syndrome: Guillain-Barré syndrome can develop in patients treated with TIBSOVO. Monitor patients taking TIBSOVO for onset of new signs or symptoms of motor and/or sensory neuropathy such as unilateral or bilateral weakness, sensory alterations, paresthesias, or difficulty breathing. Permanently discontinue TIBSOVO in patients who are diagnosed with Guillain-Barré syndrome.

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TIBSOVO + AZA LABORATORY ASSESSMENTS AND DOSE MODIFICATIONS

Select laboratory abnormalities (≥10%) that worsened from BL in patients with AML who received TIBSOVO + AZA[1,a,b]

	TIBSOVO + AZA (n=71)		Placebo + AZA (n=73)	
Parameter	All grades n (%)	Grade ≥3 n (%)	All grades n (%)	Grade ≥3 n (%)
Hematology parameters				
Leukocytes decreased	46 (65)	39 (55)	47 (64)	42 (58)
Platelets decreased	41 (58)	30 (42)	52 (71)	42 (58)
Hemoglobin decreased	40 (56)	33 (46)	48 (66)	42 (58)
Neutrophils decreased	18 (25)	16 (23)	25 (35)	23 (32)
Lymphocytes increased	17 (24)	1 (1)	7 (10)	1 (1)
Chemistry parameters				
Glucose increased	40 (56)	9 (13)	34 (47)	8 (11)
Phosphate decreased	29 (41)	7 (10)	25 (34)	9 (12)
Aspartate aminotransferase increased	26 (37)	0	17 (23)	0
Magnesium decreased	25 (35)	0	19 (26)	0
Alkaline phosphatase increased	23 (32)	0	21 (29)	0
Potassium increased	17 (24)	2 (3)	9 (12)	1 (1)

[a]Laboratory abnormality was defined as new or worsened by at least one grade from BL or if BL was unknown.
[b]The denominator used to calculate percentages is the number of treated patients who could be evaluated for Common Terminology Criteria for Adverse Events for each parameter in each arm.

- TIBSOVO + AZA was associated with fewer severe cytopenias compared with AZA[1,4]

Dose modifications seen with TIBSOVO[1]

- Adverse reactions leading to discontinuation of TIBSOVO in ≥2% of patients were differentiation syndrome (3%) and pulmonary embolism (3%)
- The most common (>5%) adverse reactions leading to dose interruption of TIBSOVO were neutropenia (25%), electrocardiogram QT prolonged (7%), and thrombocytopenia (7%)
- Adverse reactions leading to dose reduction of TIBSOVO included electrocardiogram QT prolonged (8%), neutropenia (8%), and thrombocytopenia (1%)

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

- **In patients with AML,** the most adverse reactions including laboratory abnormalities (≥25%) are leukocytes decreased, diarrhea, hemoglobin decreased, platelets decreased, glucose increased, fatigue, alkaline phosphatase increased, edema, potassium decreased, nausea, vomiting, phosphate decreased, decreased appetite, sodium decreased, leukocytosis, magnesium decreased, aspartate aminotransferase increased, arthralgia, dyspnea, uric acid increased, abdominal pain, creatinine increased, mucositis, rash, electrocardiogram QT prolonged, differentiation syndrome, calcium decreased, neutrophils decreased, and myalgia

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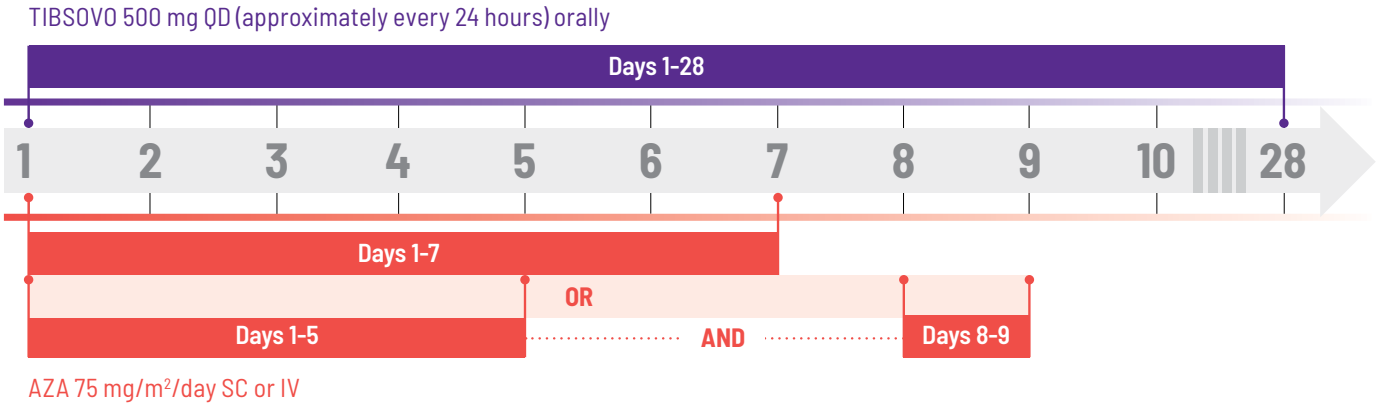
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TIBSOVO + AZA OFFERS A STRAIGHTFORWARD DOSING REGIMEN

Dosing and administration of TIBSOVO + AZA[1]

- The recommended dose of TIBSOVO is 500 mg taken orally once daily until disease progression or unacceptable toxicity
  - No dose titration required at treatment initiation
- Start TIBSOVO administration on Cycle 1 Day 1 in combination with AZA 75 mg/m^2 subcutaneously (SC) or intravenously (IV) once daily on Days 1-7 (or Days 1-5 and 8-9) of each 28-day cycle

Dosing schedule for TIBSOVO + AZA[1]



- Administer TIBSOVO with or without food. Do not administer TIBSOVO with a high-fat meal[a]
- Do not split, crush, or chew TIBSOVO tablets
- Administer TIBSOVO tablets orally about the same time each day
- If a dose of TIBSOVO is vomited, do not administer a replacement dose; wait until the next scheduled dose is due. If a dose of TIBSOVO is missed or not taken at the usual time, administer the dose as soon as possible and at least 12 hours prior to the next scheduled dose. Return to the normal schedule the following day. Do not administer 2 doses within 12 hours
- For patients without disease progression or unacceptable toxicity, treat for a minimum of 6 months to allow time for clinical response

Monitoring and dose modifications[1]

- Obtain an ECG prior to treatment initiation. Monitor ECGs at least once weekly for the first 3 weeks of therapy and then at least once monthly for the duration of therapy. Manage any abnormalities promptly
- Assess blood counts and blood chemistries prior to the initiation of TIBSOVO at least once weekly for the first month, once every other week for the second month, and once monthly for the duration of therapy
- Monitor blood creatine phosphokinase weekly for the first month of therapy
- Interrupt dosing or reduce dose for toxicities. See Full Prescribing Information for dose modification guidelines

[a]An example of a high-fat meal includes 2 eggs fried in butter, 2 strips of bacon, 2 slices of white bread with butter, 1 croissant with 1 slice of cheese, and 8 ounces of whole milk (approximately 1000 calories and 58 grams of fat).

QD, once a day.

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IDH1 MUTATIONS ARE DRIVER MUTATIONS THAT OCCUR IN 6% TO 16% OF PATIENTS WITH AML

m*IDH1* incidence

- *IDH1* mutations are driver mutations that occur in up to 16% of patients with AML[10]
- mIDH1 contributes to oncogenesis by catalyzing the production of D-2-hydroxyglutarate, which leads to disruption of cellular metabolism and epigenetic regulation[11]
- Several studies have suggested that m*IDH1* AML is associated with a poor prognosis[11,12]

Guideline recommendations

- Both the NCCN Guidelines® and ASH-CAP Guidelines recommend testing for *IDH1* mutations in patients with AML[3,13]
  - "To appropriately stratify available intensive therapy options, expedite test results of molecular and cytogenetic analyses for immediately actionable mutations or chromosomal abnormalities (eg, *CBF*, *FLT3* [ITD and TKD], *NPM1*, *IDH1*, *IDH2*)"—NCCN Guidelines[3]
- NCCN Guidelines recommends ivosidenib (TIBSOVO) + AZA as a **category 1 preferred** treatment option for newly diagnosed patients ≥18 years of age with m*IDH1* AML who are not candidates for intensive remission induction therapy[3]

Give your AML patients the chance for **improved OS—test and obtain m*IDH1* results** to inform prescribing options.[1]

ASH, American Society of Hematology; CAP, College of American Pathologists.

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS

Strong or Moderate CYP3A4 Inhibitors: Reduce TIBSOVO dose with strong CYP3A4 inhibitors. Monitor patients for increased risk of QTc interval prolongation.

Strong CYP3A4 Inducers: Avoid concomitant use with TIBSOVO.

Sensitive CYP3A4 substrates: Avoid concomitant use with TIBSOVO.

QTc Prolonging Drugs: Avoid concomitant use with TIBSOVO. If co-administration is unavoidable, monitor patients for increased risk of QTc interval prolongation.

LACTATION

Advise women not to breastfeed.

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Please see additional Important Safety Information throughout and Full Prescribing Information, including BOXED WARNING for AML patients.

TIBSOVO® ivosidenib tablets 250mg

TIBSOVO + AZA in newly diagnosed, IC-ineligible m*IDH1* AML



EARLY USE OF TIBSOVO + AZA MAY OFFER YOUR m*IDH1* AML PATIENTS THE CHANCE FOR IMPROVED OUTCOMES

- **More than threefold improvement in mOS with TIBSOVO + AZA vs AZA alone**[1,2]
  - 24 months vs 7.9 months with AZA alone in the primary analysis (HR, 0.44; *P*=0.0010)[1]
  - 29.3 months vs 7.9 months with AZA alone in the long-term follow-up analysis (HR, 0.42; *P*<0.0001)[2]
- **Rapid and sustained increase in median absolute neutrophil recovery** were observed with TIBSOVO + AZA[5-7]
- **TIBSOVO is the #1 prescribed mIDH1 inhibitor with over 5 years of real-world experience**[1]
  - Built on a broad body of evidence studied in nearly 300 m*IDH1* AML patients[1]
  - More than 2300 AML patients have been treated with TIBSOVO since FDA approval in July 2018[5]
- **Ivosidenib (TIBSOVO) in combination with AZA is recommended as a category 1 preferred treatment option by the NCCN Guidelines**[3]
  - National Comprehensive Cancer Network® (NCCN®) recommends ivosidenib (TIBSOVO) in combination with AZA for newly diagnosed patients ≥18 years of age with m*IDH1* AML who are not candidates for intensive remission induction therapy

Visit **TibsovoPro.com/aml** to see more data

INDICATION

TIBSOVO is indicated for patients with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test with:

Newly Diagnosed Acute Myeloid Leukemia (AML)

- In combination with azacitidine or as monotherapy for the treatment of newly diagnosed AML in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy

IMPORTANT SAFETY INFORMATION

WARNING: DIFFERENTIATION SYNDROME IN AML
Patients treated with TIBSOVO have experienced symptoms of differentiation syndrome, which can be fatal. Symptoms may include fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, hypotension, and hepatic, renal, or multi-organ dysfunction. If differentiation syndrome is suspected, initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.

Please see additional Important Safety Information throughout and Full Prescribing Information, including BOXED WARNING for AML patients.

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