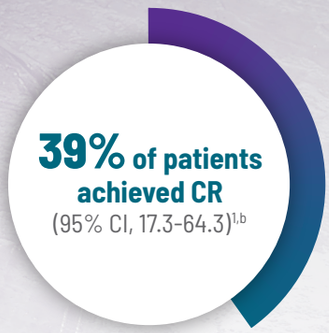
In patients with R/R m*IDH1* MDS

TIBSOVO® IS THE FIRST-IN-CLASS mIDH1 INHIBITOR PROVEN TO DELIVER DEEP AND DURABLE REMISSIONS

OVER 6 YEARS #1 PRESCRIBED mIDH1 INHIBITOR[a] OF REAL-WORLD EXPERIENCE



Rapid remissions: median time to CR was 1.9 months (range, 1.0-5.6)[1]

- **Median DOCR was not reached** by data cutoff (range, 1.9-80.8+ months; 95% CI, 1.9-NE)[1,2,c]

of patients who achieved CR remained in remission at 12 months[2,d]

of patients who achieved CR remained in remission for more than 5 years[2,d]

Patients treated with TIBSOVO achieved hematologic improvements, including rapid neutrophil recovery[2,3]

- **Rapid neutrophil recovery** was seen in all patients with CR and more than half of patients (4/7) who did not achieve CR (57%)[2,3]
  - **Median time to neutrophil recovery** was 0.97 months[3]
- Of the 8 patients who experienced marrow CR, **50% experienced hematologic improvements in ≥1 lineage**, including RBC, platelet, and/or neutrophil[2,e]

Ivosidenib (TIBSOVO) is recommended by the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) as a targeted treatment option for certain patients with R/R MDS with *IDH1* mutations[4,f]

Scan here or visit TibsovoPro.com/mds to learn more

[a]Claims data as of 11/2024.[3]
[b]CR was defined as bone marrow ≤5% myeloblasts with normal maturation of all cell lines, hemoglobin ≥11 g/dL, platelets ≥100 x 10^9/L, neutrophils ≥1.0 x 10^9/L, and response lasting at least 4 weeks.[2,3] 43% of CR responders had baseline bone marrow blasts <5%.[1]
[c]DOCR was derived based on Kaplan-Meier method and is the date of the first documented CR (lasting ≥4 weeks) to the date of the first documented relapse or death, whichever was earlier.[1] Plus sign (+) indicates a censored observation.
[d]Per Kaplan-Meier estimation.[2]
[e]Of those experiencing hematologic improvements in >1 lineage, 25% (2/8) had improved RBC counts, 25% (2/8) had improved platelet counts, and 50% (4/8) had improved neutrophil counts.[2]
[f]Category 2A recommendation for lower-risk disease with symptomatic anemia, or with clinically relevant thrombocytopenia or neutropenia when used in the third line after immunosuppressive therapy (+/- eltrombopag), azacitidine, or decitabine, and for higher-risk disease in transplant patients when used as a single agent following no response to initial treatment, or in non-transplant patients when used following no response, intolerance, or relapse to initial treatment.[4] Category 2B recommendation for lower-risk disease with clinically relevant thrombocytopenia and neutropenia when used in the second line following disease progression, no response, or relapse.

CR, complete remission; DOCR, duration of CR; mIDH1, mutated IDH1; NCCN, National Comprehensive Care Network® (NCCN®); NE, not estimable; RBC, red blood cell; R/R, relapsed or refractory.

INDICATION

TIBSOVO is indicated for the treatment of adult patients with relapsed or refractory myelodysplastic syndromes (MDS) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

IMPORTANT SAFETY INFORMATION

WARNING: DIFFERENTIATION SYNDROME IN MDS
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 on back cover and Full Prescribing Information, including BOXED WARNING for MDS patients, accompanying this document or at TibsovoPro.com.

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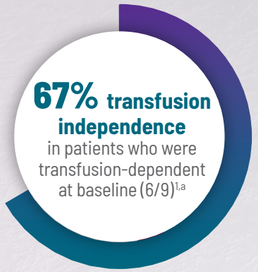
MAJORITY OF PATIENTS ACHIEVED OR MAINTAINED TRANSFUSION INDEPENDENCE WITH TIBSOVO



Median time to transfusion independence was 2.43 months in patients who were transfusion-dependent at baseline[2,3]

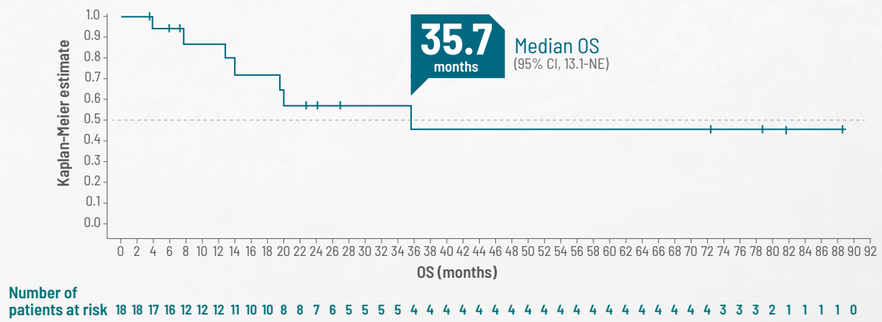
78% **of patients** (7/9) who were transfusion-independent at baseline **maintained transfusion independence**[1]

100% **of patients** who were platelet transfusion-independent at baseline **maintained transfusion independence**[2]

TIBSOVO delivered sustained transfusion independence[3]

- 67% of patients (4/6) who were transfusion-dependent at baseline and achieved transfusion independence **had a duration of transfusion independence >4 months**, with the longest lasting 272+ days, and maintained it through the end of treatment[3]
- Of the 72% of patients who achieved or maintained transfusion independence, **median duration of transfusion independence was not reached, but ranged between 1.9 and 78.8 months**[2,3,a,b]

Median OS was estimated to be 35.7 months[2,c]



- 87% survival rate at 12 months per Kaplan-Meier estimation[2]
- Because there was no control arm in this study, OS results should be interpreted cautiously[1]

[a]Postbaseline transfusion independence was defined as a period of ≥56 days with no RBC and/or platelet transfusions after the start of study treatment and on or before the end of study treatment.[2,3]
[b]Nine observations were censored.[3]
[c]Median OS follow-up was 27.1 months.[2]
AML, acute myeloid leukemia; HCT, hematopoietic cell transplantation; HI, hematologic improvement; HMA, hypomethylating agent; IC, induction chemotherapy; INV, investigational agent; mCR, marrow CR; OS, overall survival; PD, prior disease; PR, partial remission; PT, prior therapy; SD, stable disease.

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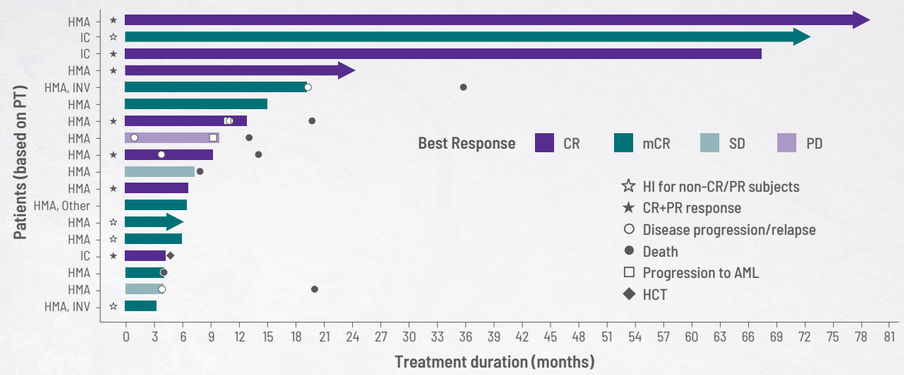
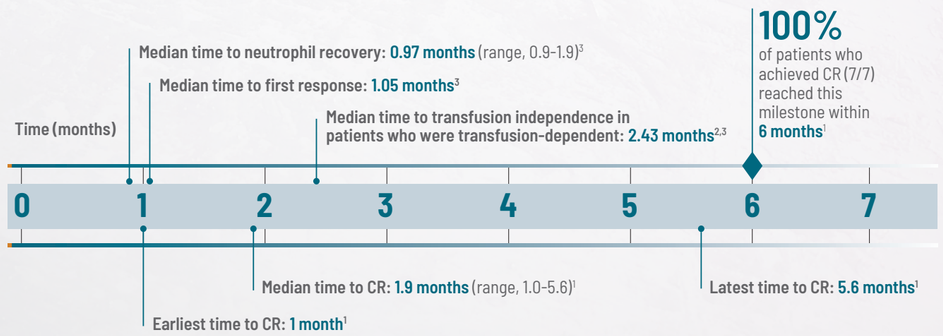
MOST PATIENTS ACHIEVED KEY RESPONSES WITH TIBSOVO

Treatment duration and overall response (N=18)[2]



- **One patient (6%) went on to receive stem cell transplantation** following treatment with TIBSOVO[2]
- **11% of patients** progressed from MDS to AML[2]

Patients who achieved CR reached key milestones within 6 months with TIBSOVO



- TIBSOVO is a nonmyelosuppressive regimen.[1] For patients without disease progression or unacceptable toxicity, **treat for a minimum of 6 months to allow time for clinical response**

References: 1. Tibsovo. Package insert. Servier Pharmaceuticals LLC; 2023. **2.** DiNardo CD, Roboz GJ, Watts JM, et al. Final phase I substudy results of ivosidenib in patients with mutant IDH1 relapsed/refractory myelodysplastic syndrome. *Blood Adv*. 2024;8(15):4209-4220. doi:10.1182/bloodadvances.2023012302 **3.** Data on file. Servier Pharmaceuticals LLC. **4.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myelodysplastic Syndromes Version 2.2025.

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WARNINGS AND PRECAUTIONS

Differentiation Syndrome in MDS: 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.

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. 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.

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.

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.

ADVERSE REACTIONS

The most common adverse reactions including laboratory abnormalities (≥25%) in patients with relapsed or refractory MDS are creatinine increased, hemoglobin decreased, arthralgia, albumin decreased, aspartate aminotransferase increased, fatigue, diarrhea, cough, sodium decreased, mucositis, decreased appetite, myalgia, phosphate decreased, pruritus, and rash.

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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SERVIER

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