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## The Safety and Efficacy of Revuforj in R/R NPM1m AML: A Clinical Overview

### Presented by

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### Host Information

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### When

4/2/2026 6:00 PM Central Time

### Program Location

**This event is hosted Live**

Rye Restaurant  
308 W College Ave  
Appleton, WI 54911

### RSVP

Please register by visiting us online at

<https://veev.io/7rumcnqaddw3>



### INDICATIONS

Revuforj® (revumenib) is a menin inhibitor indicated for the treatment of:

- relapsed or refractory (R/R) acute leukemia with a lysine methyltransferase 2A gene (*KMT2A*) translocation as determined by an FDA-authorized test in adult and pediatric patients 1 year and older
- relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (*NPM1*) mutation in adult and pediatric patients 1 year and older who have no satisfactory alternative treatment options

### IMPORTANT SAFETY INFORMATION

#### WARNING: DIFFERENTIATION SYNDROME, QTc PROLONGATION, and TORSADES DE POINTES

Differentiation syndrome, which can be fatal, has occurred with Revuforj. Signs and symptoms may include fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, hypotension, and renal dysfunction. If differentiation syndrome is suspected, immediately initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.

QTc prolongation and Torsades de Pointes have occurred in patients receiving Revuforj. Correct hypokalemia and hypomagnesemia prior to and during treatment. Do not initiate Revuforj in patients with QTcF > 450 msec. If QTc interval prolongation occurs, interrupt, reduce, or permanently discontinue Revuforj.

### WARNINGS AND PRECAUTIONS

**Differentiation Syndrome:** Revuforj can cause fatal or life-threatening differentiation syndrome (DS). Symptoms of DS, including those seen in patients treated with Revuforj, include fever, dyspnea, hypoxia, peripheral edema, pleuropericardial effusion, acute renal failure, and/or hypotension.

In clinical trials, DS occurred in 60 (25%) of 241 patients treated with Revuforj at the recommended dosage for relapsed or refractory acute leukemia. Among those with a *KMT2A* translocation, DS

occurred in 33% of patients with acute myeloid leukemia (AML), 33% of patients with mixed-phenotype acute leukemia (MPAL), and 9% of patients with acute lymphoblastic leukemia (ALL); DS occurred in 18% of patients with *NPM1m* AML. DS was Grade 3 or 4 in 12% of patients and fatal in 2 patients. The median time to initial onset was 9 days (range 3–41 days). Some patients experienced more than 1 DS event. Treatment interruption was required for 7% of patients, and treatment was withdrawn for 1%.

**Please see additional Important Safety Information on the reverse side, and accompanying Full Prescribing Information, including BOXED WARNINGS.**

## IMPORTANT SAFETY INFORMATION (cont'd)

Reduce the white blood cell count to less than 25 Gi/L prior to starting Revuforj. If DS is suspected, immediately initiate treatment with systemic corticosteroids (e.g., dexamethasone 10 mg IV every 12 hours in adults or dexamethasone 0.25 mg/kg/dose IV every 12 hours in pediatric patients weighing less than 40 kg) for a minimum of 3 days and until resolution of signs and symptoms. Institute supportive measures and hemodynamic monitoring until improvement. Interrupt Revuforj if severe signs and/or symptoms persist for more than 48 hours after initiation of systemic corticosteroids, or earlier if life-threatening symptoms occur such as pulmonary symptoms requiring ventilator support. Restart steroids promptly if DS recurs after tapering corticosteroids.

**QTc Interval Prolongation and Torsades de Pointes:** Revuforj can cause QT (QTc) interval prolongation and Torsades de Pointes.

Of the 241 patients treated with Revuforj at the recommended dosage for relapsed or refractory acute leukemia in clinical trials, QTc interval prolongation was reported as an adverse reaction in 86 (36%) of patients. QTc interval prolongation was Grade 3 in 15% and Grade 4 in 2%. The heart-rate corrected QT interval (using Fridericia's method) (QTcF) was greater than 500 msec in 10%, and the increase from baseline QTcF was greater than 60 msec in 24%. Revuforj dose reduction was required for 7% due to QTc interval prolongation. QTc prolongation occurred in 21% of the 34 patients less than 17 years old, 35% of the 146 patients 17 years to less than 65 years old, and in 46% of the 61 patients 65 years or older. One patient had a fatal outcome of cardiac arrest, and one patient had non-sustained Torsades de Pointes.

Correct electrolyte abnormalities, including hypokalemia and hypomagnesemia, prior to and throughout treatment with Revuforj. Perform an electrocardiogram (ECG) prior to initiation of Revuforj, and do not initiate Revuforj in patients with QTcF >450 msec. Perform an ECG at least once weekly for the first 4 weeks and at least monthly thereafter. 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 ECG monitoring may be necessary. Concomitant use with drugs known to prolong the QTc interval may increase the risk of QTc interval prolongation.

- Interrupt Revuforj if QTcF increases >480 msec and <500 msec, and restart Revuforj at the same dose twice daily after the QTcF interval returns to ≤480 msec
- Interrupt Revuforj if QTcF increases >500 msec or by >60 msec from baseline, and restart Revuforj twice daily at the lower-dose level after the QTcF interval returns to ≤480 msec
- Permanently discontinue Revuforj in patients with ventricular arrhythmias and in those who develop QTc interval prolongation with signs or symptoms of life-threatening arrhythmia

**Embryo-Fetal Toxicity:** Revuforj can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with Revuforj and for 4 months after the last dose of Revuforj.

## ADVERSE REACTIONS

**Fatal adverse reactions** occurred in 9 (4%) patients who received Revuforj, including 4 with sudden death, 2 with differentiation syndrome, 2 with hemorrhage, and 1 with cardiac arrest.

**Serious adverse reactions** were reported in 184 (76%) patients. The most frequent serious adverse reactions (≥10%) were infection (29%), febrile neutropenia (20%), bacterial infection (15%), differentiation syndrome (13%), and hemorrhage (11%).

The most **common adverse reactions** (≥20%) including laboratory abnormalities, were phosphate increased (51%), hemorrhage (48%), nausea (48%), infection without identified pathogen (46%), aspartate aminotransferase increased (44%), alanine aminotransferase increased (40%), creatinine increased (38%), musculoskeletal pain (37%), febrile neutropenia (37%), electrocardiogram QT prolonged (36%), potassium decreased (34%), parathyroid hormone intact increased (34%), alkaline phosphatase increased (33%), diarrhea (29%), bacterial infection (27%), triglycerides increased (27%), phosphate decreased (25%), differentiation syndrome (25%), fatigue (24%), edema (24%), viral infection (23%), decreased appetite (20%), and constipation (20%).

## DRUG INTERACTIONS

Drug interactions can occur when Revuforj is concomitantly used with:

- Strong CYP3A4 inhibitors: reduce Revuforj dose
- Strong or moderate CYP3A4 inducers: avoid concomitant use with Revuforj
- QTc-prolonging drugs: avoid concomitant use with Revuforj. If concomitant use is unavoidable, obtain ECGs when initiating, during concomitant use, and as clinically indicated. Withhold Revuforj if the QTc interval is >480 msec. Restart Revuforj after the QTc interval returns to ≤480 msec

## SPECIFIC POPULATIONS

**Lactation:** advise lactating women not to breastfeed during treatment with Revuforj and for 1 week after the last dose.

**Pregnancy and testing:** Revuforj can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential within 7 days prior to initiating Revuforj.

**Infertility: based** on findings in animals, Revuforj may impair fertility. The effects on fertility were reversible.

**Pediatric:** monitor bone growth and development in pediatric patients.

**Geriatric:** no overall differences were observed in the effectiveness of Revuforj between patients who were 65 years and older, and younger patients. Compared to younger patients, the incidences of QTc prolongation and edema were higher in patients 65 years and older.

**To report SUSPECTED ADVERSE REACTIONS, contact Syndax Pharmaceuticals at 1-888-539-3REV or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**Please see accompanying Full Prescribing Information, including BOXED WARNINGS.**

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