

A CLINICAL GUIDE FOR
HEALTHCARE PROFESSIONALS
AS YOU HELP YOUR PATIENTS

FORJ FORWARD

 **Revuforj**[®]
(revumenib) tablets
25 mg • 110 mg • 160 mg

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.

Please see Important Safety Information throughout and Full [Prescribing Information](#), including **BOXED WARNINGS**.

Understanding how Revuforj works

The first and only menin inhibitor with two FDA-approved indications¹

Revuforj has the power to target and disrupt menin-KMT2A protein interactions—a key driver of *NPM1*-mutated AML and acute leukemias with a *KMT2A* translocation.¹⁻³

In nonclinical *in vitro* and *in vivo* studies, revumenib demonstrated anti-proliferative and anti-tumor activity in leukemia cells harboring *KMT2A* fusion proteins. Revumenib also showed anti-proliferative activity *in vitro* in leukemia cells with an *NPM1* mutation¹



The menin-KMT2A interaction has been shown to:

- Upregulate *HOX/MEIS1* gene expression
- Increase proliferation of undifferentiated cells
- Result in leukemogenesis



Menin inhibition has been shown to:

- Downregulate *HOX/MEIS1* gene expression
- Release the differentiation block
- Promote normal cellular differentiation

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Differentiation Syndrome (DS): 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, rash, 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.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Differentiation Syndrome (cont'd): 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%.

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Warnings & precautions

Differentiation syndrome, which can be fatal, has occurred with Revuforj¹

In clinical trials of patients with R/R *KMT2A*-translocated acute leukemia or R/R *NPM1m* AML, differentiation syndrome occurred in 25% of patients (n=60/241):

- Among those with a *KMT2A* translocation, differentiation syndrome occurred in 33% of patients with AML, 33% of patients with MPAL, and 9% of patients with ALL
- Differentiation syndrome occurred in 18% of patients with *NPM1m* AML
- Differentiation syndrome was Grade 3 or 4 in 12% of patients and fatal in 2 patients
- Some patients experienced more than 1 differentiation syndrome event
- The median time to initial onset was 9 days (range 3-41 days)
- Treatment interruption was required for 7% of patients, and treatment was withdrawn for 1%

Symptoms of differentiation syndrome, including those seen in patients treated with Revuforj, include¹:

- Fever
- Dyspnea
- Hypoxia
- Peripheral edema
- Pleuropericardial effusion
- Acute renal failure
- Rash
- Hypotension

Advise patients and their caregivers to call their healthcare team or go to the nearest hospital emergency room immediately if the patient develops any of these symptoms while taking Revuforj.

Reduce the white blood cell count to less than 25 Gi/L prior to starting Revuforj¹

If differentiation syndrome is suspected, immediately initiate treatment with systemic corticosteroids for a **minimum of 3 days** and until resolution of signs and symptoms.

Treatment example:



Patients ≥40 kg:
dexamethasone
10 mg IV every 12 hours



Patients <40 kg:
dexamethasone
0.25 mg/kg/dose IV every 12 hours

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Differentiation Syndrome (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.

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Warnings & precautions (cont'd)

Revuforj can cause QT (QTc) interval prolongation and Torsades de Pointes¹

- Monitor for QTc interval prolongation and manage any abnormalities promptly

Monitoring guidance for before and during treatment¹



Assess blood counts, electrolytes, and liver enzymes

prior to the initiation of Revuforj and monthly thereafter



Perform electrocardiogram (ECG)

prior to the initiation of Revuforj, at least once a week for the first 4 weeks, and at least monthly thereafter

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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%) 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 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.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

QTc Interval Prolongation and Torsades de Pointes (cont'd):

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.

Verify pregnancy status in females of reproductive potential within 7 days prior to initiating Revuforj.

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Dosage form & administration

Convenience of an oral, targeted treatment¹

All Revuforj doses should be taken:



orally, twice daily
at about the same
time each day
(~12 hours apart)



on an empty stomach
at least 2 hours after a
meal and 1 hour before
the next meal*

*As defined by the clinical trial protocol.

OR



with a low-fat meal
low-fat meals should be
about 400 calories and
contain 25% or less fat

Continue Revuforj until disease progression or unacceptable toxicity



For patients without disease progression or unacceptable toxicity, **treat for a minimum of 6 months** to allow time for a clinical response

Available in 3 different tablet strengths, allowing for individualized dosing to meet the needs of your patients¹



Bottles and tablets shown are not actual size.

25 mg 110 mg 160 mg

- The recommended dose of Revuforj varies by patient weight and concomitant use of strong CYP3A4 inhibitors
- Advise patients to swallow tablets whole and to not cut or chew tablets
- If patients are unable to swallow tablets, they may be crushed and dispersed in water and taken within 2 hours of preparation. **See Instructions for Use**

If a dose of Revuforj is missed or not taken at the usual time, administer the dose as soon as possible on the same day 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.

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Oral twice-daily dosing

Recommended doses for patients 1 year and older¹:

Without a strong CYP3A4 inhibitor		
Dose level	Patients ≥ 40 kg	Patients < 40 kg*
Starting dose	270 mg BID	160 mg/m ² BID
Reduced dose	160 mg BID	95 mg/m ² BID

With a strong CYP3A4 inhibitor [†]		
Dose level	Patients ≥ 40 kg	Patients < 40 kg*
Starting dose	160 mg BID	95 mg/m ² BID
Reduced dose	110 mg BID	65 mg/m ² BID

*For patients weighing < 40 kg with a BSA ≤ 1.4 m²:

Please see Section 2.2, Table 2 and Section 2.3, Table 6 of the Full Prescribing Information for the recommended dose and the reduced dose.

- If needed, attain the desired dose by combining different strengths of Revuforj tablets
- Concurrent use of standard intrathecal chemotherapy prophylaxis is recommended for patients with risk of central nervous system relapse

[†]If the strong CYP3A4 inhibitor is discontinued, increase the Revuforj dose (after at least 5 half-lives of the strong CYP3A4 inhibitor) to the recommended dosage without strong CYP3A4 inhibitors.

BID=twice a day; BSA=body surface area; CYP3A4=cytochrome P450 3A4.

Prior to the initiation of Revuforj[†]:



Reduce the white blood cell count to less than 25 Gi/L



Correct hypokalemia, hypomagnesemia, and other electrolyte abnormalities



Perform an electrocardiogram (ECG)

If patients are unable to swallow tablets whole:

Review the **Instructions for Use** with patients and their caregivers for how to prepare and break apart the Revuforj tablets in water.

IMPORTANT SAFETY INFORMATION (cont'd)

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

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Adverse reactions

The safety profile of Revuforj reflects exposure in 241 patients (207 adult and 34 pediatric patients) with R/R *KMT2A*-translocated acute leukemia or R/R susceptible *NPM1m* AML¹

Adverse reactions reported in ≥20% (any Grade) or ≥5% (Grade 3 or 4) of patients with R/R acute leukemia (N=241)

Treatment-emergent adverse event (TEAE)	All Grades (%)	Grade 3 or 4 (%)
Gastrointestinal disorders		
Nausea [†]	48	5
Diarrhea [†]	29	5
Constipation	20	0
Vascular disorders		
Hemorrhage* [†]	48	10
Thrombosis [†]	11	6
Infections and infestations		
Infection without identified pathogen [†]	46	30
Bacterial infection [†]	27	18
Viral infection [†]	23	6
Blood and lymphatic system disorders		
Febrile neutropenia	37	35
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain [†]	37	6

TEAE	All Grades (%)	Grade 3 or 4 (%)
Investigations		
Electrocardiogram QT prolonged	36	17
Neoplasms benign, malignant, and unspecified (including cysts and polyps)		
Differentiation syndrome*	25	12
General disorders and administration site conditions		
Fatigue [†]	24	5
Edema [†]	24	0
Metabolism and nutrition disorders		
Decreased appetite	20	5

*Includes the following fatal adverse reactions: differentiation syndrome (n=2); hemorrhage (n=2).

[†]These represent grouped terms for adverse reactions. Please see Table 7 in the Full Prescribing Information for complete definitions of grouped terms.

IMPORTANT SAFETY INFORMATION (cont'd)

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%).

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Drug interactions



Other drugs may affect the safety and efficacy of Revuforj[†]

Ask patients to tell you or their healthcare provider about any other medicines they are taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Remind patients that taking Revuforj with other medicines may affect each other, causing side effects.

Concomitant use of Revuforj with:	Action
Strong CYP3A4 inhibitors	Reduce Revuforj dose*
Strong or moderate CYP3A4 inducers	Avoid concomitant use with Revuforj
QTc-prolonging drugs	Avoid concomitant use with Revuforj [†]

*See Section 2.2 of the Full Prescribing Information.

[†]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.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

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%).

Laboratory abnormalities

Selected new or worsening laboratory abnormalities in patients with R/R *KMT2A*-translocated acute leukemia or R/R *NPM1m* AML¹

Laboratory abnormality	Grades 1-4 [‡] (%)	Grade 3-4 (%)
Phosphate increased	51	–
Aspartate aminotransferase increased	44	6
Alanine aminotransferase increased	40	8
Creatinine increased	38	2
Potassium decreased	34	12
Parathyroid hormone, intact increased	34	–
Alkaline phosphatase increased	33	<1
Triglycerides increased	27	3
Phosphate decreased	25	–
Cholesterol increased	17	0
Calcium corrected, increased	15	0

[‡]The denominator used to calculate the rate varied from 139 to 240 based on the number of patients with a baseline value and at least 1 post-baseline value.

CYP3A4=cytochrome P450 3A4; ECG=electrocardiogram; *KMT2A*=lysine methyltransferase 2A; R/R=relapsed/refractory.

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Dose modifications

Adverse reaction	Recommended action
Differentiation syndrome	<ul style="list-style-type: none"> • If differentiation syndrome is suspected, administer systemic corticosteroids and initiate hemodynamic monitoring until symptom resolution and for a minimum of 3 days • Interrupt Revuforj if severe signs and/or symptoms persist for more than 48 hours after initiation of systemic corticosteroids, or earlier for life-threatening symptoms such as pulmonary symptoms requiring ventilator support. Resume Revuforj at the same dose when signs and symptoms improve to Grade 1* or lower
Noninfectious leukocytosis	<ul style="list-style-type: none"> • Initiate treatment with hydroxyurea in patients with an elevated or rapidly rising leukocyte count. Add leukapheresis if clinically indicated • Taper hydroxyurea only after leukocytosis improves or resolves
QTc interval greater than 480 msec to 500 msec	<ul style="list-style-type: none"> • Interrupt Revuforj • Check electrolyte levels. Correct hypokalemia and hypomagnesemia • Restart Revuforj at the same dose level after the QTc interval returns to less than or equal to 480 msec

Adverse reaction	Recommended action
QTc interval greater than 500 msec (Grade 3*)	<ul style="list-style-type: none"> • Interrupt Revuforj • Check electrolyte levels. Correct hypokalemia and hypomagnesemia • Restart Revuforj at the reduced dose level† after the QTc interval returns to less than or equal to 480 msec
Potassium 3.6-3.9 mEq/L, and/or Magnesium 1.7-1.9 mg/dL or 0.66-0.81 mmol/L	<ul style="list-style-type: none"> • Supplement potassium and/or magnesium • Continue Revuforj
Potassium ≤3.5 mEq/L, and/or Magnesium ≤1.6 mg/dL or ≤0.65 mmol/L	<ul style="list-style-type: none"> • Supplement potassium and/or magnesium, and recheck levels within 24 hours • On recheck of potassium and magnesium labs within 24 hours, if potassium is greater than 3.5 mEq/L and/or magnesium is greater than 1.6 mg/dL, continue Revuforj. If potassium is less than 3.5 mEq/L and/or magnesium is less than 1.6 mg/dL, hold Revuforj and continue supplementation; resume Revuforj at the same dose level when the correction is complete

Other actions may be necessary based on your clinical judgment.

*Grade 1 is mild, Grade 2 is moderate, Grade 3 is severe, Grade 4 is life-threatening. Severity as defined by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE version 5.0).

†See Tables 4, 5, and 6 in the Full Prescribing Information for the reduced dose levels.

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Forj forward

Adverse reaction	Recommended action
<p>QTc interval prolongation with signs/symptoms of life-threatening arrhythmia, Torsades de pointes, polymorphic ventricular tachycardia (Grade 4*); Grade 3* or higher allergic reactions</p>	<ul style="list-style-type: none"> Permanently discontinue Revuforj
<p>Other nonhematological adverse reactions Grade ≥3*</p>	<ul style="list-style-type: none"> Interrupt Revuforj until recovery to Grade 1* or baseline If recovered in ≤7 days, restart Revuforj at the same dose level. If the same Grade ≥3* toxicity recurs, interrupt Revuforj until recovery to Grade 1* or baseline. Restart Revuforj at the reduced dose level[†] If recovered in >7 days, restart Revuforj at the reduced dose level.[†] If the same Grade ≥3* toxicity recurs, discontinue Revuforj
<p>Grade 4* neutropenia or thrombocytopenia</p>	<ul style="list-style-type: none"> Interrupt Revuforj until recovery to Grade ≤2* or baseline Restart Revuforj at the same dose level If Grade 4* neutropenia or thrombocytopenia recurs without attributable cause, interrupt Revuforj until recovery to Grade ≤3.* Restart Revuforj at the reduced dose level[†]

Other actions may be necessary based on your clinical judgment.

*Grade 1 is mild, Grade 2 is moderate, Grade 3 is severe, Grade 4 is life-threatening. Severity as defined by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE version 5.0).

[†]See Tables 4, 5, and 6 in the Full Prescribing Information for the reduced dose levels.

Tips that may help your patients while on Revuforj

- Advise patients and caregivers to read the FDA-approved Medication Guide and Instructions for Use
- Inform patients and caregivers that serious adverse reactions may occur with Revuforj, including differentiation syndrome and QTc prolongation
- Advise patients to inform their healthcare provider if they are pregnant or plan to become pregnant as Revuforj can harm their unborn baby
- Educate patients and caregivers on the symptoms of differentiation syndrome and QTc prolongation, as well as the importance of reporting any suspected adverse reaction early and often. Remind patients to carry the Differentiation Syndrome Wallet Card at all times
- Encourage patients and caregivers to contact their healthcare team or go to the nearest hospital emergency room if they develop any symptoms of differentiation syndrome
- Advise patients to inform their healthcare provider of all concomitant products, including over-the-counter products and supplements
- Remind patients that a dose modification or dose delay in treatment is acceptable due to an adverse reaction. Patients who experience severe reactions may need to permanently discontinue treatment

SyndAccess[®]

Learn more about the SyndAccess[®] Patient Support Program and what's available to support your patients



SyndAccess.com/hcp
1-888-567-SYND (7963)

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GET MORE INFORMATION AT

[Revuforjhcp.com](https://www.revuforjhcp.com)

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Please see Important Safety Information throughout and Full Prescribing Information, including BOXED WARNINGS.

References: 1. Revuforj[®] [Prescribing Information]. Syndax Pharmaceuticals, Inc.; October 2025. 2. Arellano ML, et al. *Blood*. 2025;146(9):1065-1077. 3. Issa GC, et al. *Leukemia*. 2021;35:2482-2495.



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