Syndax Showcases Revuforj® (revumenib) Clinical Activity in Multiple Acute Leukemia Subtypes and Settings at EHA 2026

June 11, 2026

– Real-world study of revumenib shows 82% (9/11) ORR and 64% (7/11) CR/CRh rate among R/R NPM1m or KMT2Ar patients treated with revumenib monotherapy or combinations –

– Ph 1 trial of revumenib with intensive chemotherapy in newly diagnosed NPM1m or KMT2Ar AML shows 97% (34/35) CRc and 86% (25/29) MRD negativity among CRc responders –

– Post-hoc analysis of patients with R/R NPM1m, KMT2Ar, or NUP98r acute leukemia in the AUGMENT-101 trial who resumed revumenib post-HSCT shows an observed 1-year OS of 95% –

– Phase 1 trial and expanded access experience shows 28% (7/25) ORR in R/R NUP98r acute leukemia, a subtype with a poor prognosis and high unmet need –

– Ph 2 SAVE trial of revumenib with venetoclax and decitabine/cedazuridine in R/R NPM1m, KMT2Ar, or NUP98r AML shows 88% (37/42) ORR, 68% (25/37) MRD negativity among responders, and 45% (19/42) transplant rate –

NEW YORK, June 11, 2026 (GLOBE NEWSWIRE) -- Syndax Pharmaceuticals (Nasdaq: SNDX), a commercial-stage biopharmaceutical company advancing innovative cancer therapies, today highlighted key Revuforj® (revumenib) data presented at the European Hematology Association (EHA) 2026 Congress in Stockholm, Sweden. In total, 12 abstracts focused on revumenib, the Company's first-in-class, FDA-approved menin inhibitor, were accepted for EHA 2026. The data presented span multiple acute leukemia subtypes and settings, including new real-world, post-transplant, and combination data from the relapsed/refractory (R/R) and frontline setting.

"Collectively, the new data presented at EHA showcase the robust activity observed with revumenib across multiple acute leukemia subtypes and settings, highlighting the potential for revumenib to transform patient outcomes," said Nick Botwood, MBBS, Head of Research & Development and Chief Medical Officer at Syndax. "In particular, we are encouraged to observe deep and durable remissions among patients with NPM1m, KMT2Ar, or NUP98r acute leukemia who received revumenib in combination with standard of care therapies in clinical trials or the real-world. The breadth of data presented at EHA highlights physicians' enthusiasm for revumenib and bolsters our conviction that our ongoing pivotal frontline combination trials are positioned to deliver paradigm-changing results."

Overview of key revumenib data presented at EHA 2026:

Abstract title: Revumenib in the real world: interim findings from the ROAR study in relapsed/refractory acute leukemia
Abstract #: PF542

- At the first interim analysis from ROAR, a multicenter real-world study of revumenib, 11 heavily pretreated patients with R/R NPM1 mutated (NPM1m) or KMT2A-rearranged (KMT2Ar) acute leukemia (median of 2 prior lines of therapy) were response evaluable. Among this population, 64% (7/11) received revumenib monotherapy and 36% (4/11) received revumenib combination therapy.
- 82% (9/11) overall response rate[1] (ORR) and 64% (7/11) complete remission plus complete remission with partial hematological recovery (CR/CRh) rate among the response-evaluable population.
- 36% (4/11) of the response-evaluable population proceeded to a hematopoietic stem cell transplant (HSCT), of which 50% (2/4) had resumed revumenib post-HSCT at the data cut off.
- Revumenib was generally well-tolerated, with real-world safety findings consistent with the established safety profile for revumenib. There were no events of differentiation syndrome (DS) or QTc prolongation above Grade 3 and no patient discontinued revumenib due to DS or QTc.

Abstract title: Revumenib + intensive chemotherapy for newly diagnosed acute myeloid leukemia harboring genetic alterations in KMT2A, NPM1, or NUP98: updated phase 1 results from SNDX-5613-0708
Abstract #: PF489

- 97% (34/35) composite complete remission (CRc) and 77% (27/35) complete remission (CR) rate observed among newly diagnosed patients with NPM1m or KMT2Ar AML who received revumenib at dose level (DL) 1 or 2 in combination with intensive chemotherapy. DL1 was revumenib 110 or 220 mg q12hr with/without strong CYP3A4i. DL2 was the FDA-approved monotherapy dose of 160 or 270 mg q12hr with/without strong CYP3A4i. Response rates were similar across both dose levels.
- 86% (25/29) measurable residual disease (MRD) negativity among those with CRc and 87% (20/23) MRD negativity among those with CR, as determined by local testing.
- Durability data are still maturing. At the data cutoff, the median follow-up was 4.8 months and 2.9 months in DL1 and DL2, respectively.
- 60% (9/15) of patients in DL1 and 10% (2/20) in DL2 had proceeded to HSCT as of the data cutoff (this difference may be due to a higher proportion of patients with KMT2Ar and longer follow-up in DL1 than DL2); of the patients in DL1 who proceeded to HSCT, 67% (6/9) resumed revumenib post-HSCT.

- Safety profile was broadly consistent across both revumenib dose levels and comparable with intensive chemotherapy alone. There were no treatment-emergent adverse events (TEAEs) of DS or QTc prolongation above Grade 3. No clinically meaningful pruritus was reported.

Abstract Title: Revumenib therapy post hematopoietic stem cell transplant for patients with relapsed/refractory KMT2Ar, NPM1m, and NUP98r acute myeloid leukemia: post hoc analysis of outcomes from AUGMENT-101
Abstract #: PS1631

- Post-hoc analysis included 19 heavily pretreated adults and children with R/R NPM1m, KMT2Ar, or NUP98r acute leukemia who resumed revumenib post-HSCT in the multicenter AUGMENT-101 trial.
- Median time from HSCT to resuming revumenib was 65 (range: 34-181) days. The median duration of revumenib therapy post-HSCT was 20 (range: 2-137) weeks at the data cutoff. Three patients remained on therapy, including two patients who had received more than two years of revumenib post-HSCT.
- Median overall survival (OS) and median relapse-free survival (RFS) were not reached, regardless of genetic subtype. The estimated 12-month OS and RFS rates were 95% and 79%, respectively.
- Safety profile was consistent with the established safety profile for revumenib. Treatment emergent adverse events leading to revumenib discontinuation were low at 5% of patients. No patients discontinued treatment due to cytopenias.
- These results build on data presented at EHA 2026 and ASCO 2026 from a pooled analysis of 24 adults and children who resumed revumenib post-transplant at a single-center.

Abstract title: Clinical activity of revumenib in patients with relapsed/refractory NUP98-rearranged acute leukemias
Abstract #: PS1607

- 28% (7/25) ORR observed among heavily pretreated adults and children with R/R NUP98r acute leukemia (median of 3 prior lines of therapy) who received revumenib in the Phase 1 portion of the AUGMENT-101 trial or via an expanded access program. The median duration of response was 6.7 months.
- 43% (3/7) of responders proceeded to HSCT and all resumed revumenib post-HSCT.
- Safety profile was consistent with the established safety profile for revumenib. No TEAEs led to treatment discontinuation.

Abstract Title: Phase 1/2 study of the all-oral combination of revumenib (SNDX-5613) with decitabine/cedazuridine (ASTX727) and venetoclax (SAVE) in relapsed/refractory AML
Abstract #: PF495

Results from the R/R cohort enrolled in the SAVE trial were recently published in the Journal of Clinical Oncology and simultaneously presented at EHA 2026. Key results include:

- 88% (37/42) ORR, 71% (30/42) CRc, and 60% CR/CRh (25/42) observed among heavily pretreated patients with R/R NPM1m, KMT2Ar, or NUP98r AML (median of two prior lines of therapy).
- 45% (19/42) of patients proceeded to HSCT, of which 63% (12/19) had resumed revumenib as post-HSCT maintenance at the data cutoff.
- The rates of MRD negativity by flow cytometry were 68% (25/37) among evaluable responders, 80% (24/30) among those with CRc, and 80% (20/25) among those with CR/CRh.
- With a median follow-up of 22 months, the median duration of response in patients with CR/CRh was 10.7 months among NPM1m patients, not reached among KMT2Ar patients, and 5.9 months among NUP98r patients.
- Revumenib was generally well-tolerated in combination with decitabine/cedazuridine and venetoclax. The most common TEAEs were consistent with the established safety profile for revumenib and the combination partners.

About Revuforj® (revumenib)

Revuforj (revumenib) is the first and only menin inhibitor that is FDA approved for the treatment of adult and pediatric patients one year and older with relapsed or refractory (R/R) acute myeloid leukemia (AML) with a susceptible NPM1 mutation who have no satisfactory alternative treatment options or R/R acute leukemia with a KMT2A translocation as determined by an FDA-authorized test.

Multiple trials of revumenib are ongoing or planned across the treatment landscape, including in combination with standard of care therapies in newly diagnosed patients with NPM1m or KMT2Ar AML.

Revuforj (revumenib)

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, 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. 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%.

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%) 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.

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**.**

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

About Syndax

Syndax Pharmaceuticals is a commercial-stage biopharmaceutical company advancing innovative cancer therapies. Highlights of the Company's pipeline include Revuforj® (revumenib), an FDA-approved menin inhibitor, and Niktimvo™ (axatilimab-csfr), an FDA-approved monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor. Fueled by our commitment to reimagining cancer care, Syndax is working to unlock the full potential of its pipeline and is conducting several clinical trials across the continuum of treatment. For more information, please visit www.syndax.com or follow the Company on X and LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative or plural of those terms, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Syndax's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the progress, timing, clinical development and scope of clinical trials, the reporting of clinical data for Syndax's product candidates, the acceptance of Syndax and its partners' products in the marketplace, sales, marketing, manufacturing and distribution requirements, and the potential use of its product candidates to treat various cancer indications and fibrotic diseases. Many factors may cause differences between current expectations and actual results, including: unexpected safety or efficacy data observed during preclinical or clinical trials; clinical trial site activation or enrollment rates that are lower than expected; changes to Revuforj's or Niktimvo's commercial availability; changes in expected or existing competition; changes in the regulatory environment; failure of Syndax's collaborators to support or advance collaborations or product candidates; and unexpected litigation or other disputes. Other factors that may cause Syndax's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Syndax's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, Syndax assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

References

1. Overall response rate (ORR) includes CR, CRh, CRp, CRi, MLFS, and PR; Composite complete remission (CRc) includes CR, CRh, CRp, and CRi.
   CR = Complete remission
   CRh = Complete remission with partial hematologic recovery
   CRp = Complete remission with incomplete platelet recovery
   CRi = Complete remission with incomplete count recovery
   MLFS = Morphologic leukemia-free state
   PR = Partial response

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