Syndax Highlights Revuforj® (revumenib) Data Presented at ASCO 2026, Including an Oral Presentation of Post-Transplant Data

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– Pooled analysis of 24 adults and children with KMT2Ar, NPM1m, or NUP98r acute leukemia who resumed revumenib post-transplant shows favorable outcomes, including a 2-year overall survival rate of 90% vs historical benchmark of 51% –

– Company also presented data highlighting unique aspects of revumenib's PK profile, including the ability to administer it with gastric acid reducing agents without the risk of reduced efficacy –

NEW YORK, June 02, 2026 (GLOBE NEWSWIRE) -- Syndax Pharmaceuticals (Nasdaq: SNDX), a commercial-stage biopharmaceutical company advancing innovative cancer therapies, today highlighted key Revuforj® (revumenib) data that was presented at the American Society of Clinical Oncology (ASCO) 2026 Annual Meeting in Chicago, including the oral presentation of new data from the post hematopoietic stem cell transplant (HSCT) setting. Revuforj is the first and only menin inhibitor that is FDA approved for patients one year and older with relapsed/refractory (R/R) acute leukemia with a KMT2A translocation or R/R acute myeloid leukemia (AML) with a susceptible NPM1 mutation (NPM1m) who have no satisfactory alternative treatment options.

"The selection of the revumenib post-transplant data for oral presentation at ASCO underscores the clinical importance of this dataset and the potential for revumenib to advance the treatment paradigm," said Nick Botwood, MBBS, Head of Research & Development and Chief Medical Officer at Syndax. "Building on the data presented at ASCO and other ongoing trials, we look forward to pioneering further research in the post-transplant setting, including the planned MenTain study, the first randomized, placebo-controlled trial specifically focused on evaluating revumenib as post-transplant maintenance."

"We are encouraged by the long-term outcomes observed among a cohort of 24 heavily pretreated patients with KMT2Ar, NPM1m, or NUP98r acute leukemia who resumed revumenib as maintenance after stem cell transplantation," said Ghayas C. Issa, M.D., Associate Professor of Leukemia at The University of Texas MD Anderson Cancer Center. "Among this population at high-risk for relapse and poor outcomes, we observed a 2-year overall survival rate of 90%, almost double the historical rate observed prior to the introduction of revumenib. While the sample size is small, these results are promising and strongly support further evaluation of revumenib as post-transplant maintenance."

Overview of key revumenib data presented at the 2026 ASCO Annual Meeting

Abstract title: Revumenib as maintenance for AML following allogeneic stem cell transplantation
Abstract #: 6505

- Pooled analysis of 24 patients (13 adults and 11 children) who resumed revumenib as maintenance after receiving a HSCT. 71% (17/24) had KMT2A-rearranged, 25% (6/24) had NPM1 mutated, and 4% (1/24) had NUP98-rearranged acute myeloid leukemia. This was a heavily pretreated cohort with a median of 3 prior lines of therapy (range: 1-11); 54% (13/24) had undergone prior HSCT. At current HSCT, 25% (6/24) of patients were in first complete remission (CR1) and 75% (18/24) were in second complete remission or beyond (CR2+).
- Median time to initiate revumenib post-HSCT was 82 days (range: 42 – 174 days). Median duration of revumenib therapy post-HSCT was 10 months (range: 0.5 – 36 months). At last follow-up, 29% (7/24) of patients remained on revumenib.
- With a median follow-up of 21 months, median overall survival (OS) and event-free survival from the time of HSCT were not reached.
- In this single-arm study, a 2-year overall survival (OS) rate of 90% was observed in the overall population. In contrast, in a historical cohort of patients with the same genetic subtypes of acute leukemia treated prior to the advent of revumenib, a 2-year OS rate of 51% was observed.
- The 1-year cumulative relapse rate was 0% and 17% among patients transplanted in CR1 and CR2+, respectively. In contrast, in a historical cohort of patients, the 1-year cumulative relapse rate was 12% and 40% among patients transplanted in CR1 and CR2+, respectively.
- The most common any grade adverse event was thrombocytopenia, leading to dose modification in 46% (11/24) and discontinuation in 13% (3/24) of patients. No other significant toxicities were observed.
- Outcomes appear favorable compared to historical cohorts, supporting prospective evaluation of revumenib as maintenance in the post-HSCT setting.

Abstract title: Pharmacokinetic (PK) assessment of revumenib in patients with relapsed/refractory (R/R) acute leukemias harboring a KMT2A rearrangement (KMT2Ar) or NPM1 mutation (NPM1m): Impact of food and concomitant medications
Abstract #: 6528

- PK data were obtained from 335 patients (286 adults and 49 children) with acute leukemia, including those with KMT2Ar and NPM1m, who were enrolled in the Phase 1/2 AUGMENT-101 trial.
- Results highlight differentiating aspects of revumenib's PK profile, including the ability to:
  - Administer revumenib with commonly prescribed gastric acid reducing agents, such as proton pump inhibitors, without the risk of reduced exposure and efficacy

- Maintain optimal exposure in the presence of strong CYP3A4 inhibitors using a clear revumenib dose adjustment strategy
- Administer revumenib with a low-fat meal or under a fasted state

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 leukemia with a KMT2A translocation as determined by an FDA-authorized test or R/R acute myeloid leukemia (AML) with a susceptible NPM1 mutation who have no satisfactory alternative treatment options.

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.

Syndax Contact

Sharon Klahre
Syndax Pharmaceuticals, Inc.
sklahre@syndax.com
Tel 781.684.9827

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Syndax