Syndax Highlights Acceptance of 19 Revuforj® (revumenib) and Niktimvo™ (axatilimab-csfr) Abstracts, Including 7 for Oral Presentation, at ASH 2026

November 4, 2026

– 14 accepted revumenib abstracts, including 7 for oral presentation, reinforce Syndax's scientific leadership in menin inhibition –

– Revumenib abstracts highlight encouraging activity across multiple acute leukemia subtypes and settings, including frontline, post-transplant maintenance, and MRD relapse –

– Real-world data showcase compelling results in R/R NPM1m or KMT2Ar acute leukemia patients who received revumenib monotherapy or combination therapy –

– 5 accepted axatilimab abstracts, including long-term data that highlight the potential for prolonged clinical benefit with axatilimab in R/R cGVHD –

– Company to host investor event and webcast on Monday, December 14, 2026, at 7:00 a.m. CT/8:00 a.m. ET –

NEW YORK, Nov. 04, 2026 (GLOBE NEWSWIRE) -- Syndax Pharmaceuticals (Nasdaq: SNDX), a commercial-stage biopharmaceutical company advancing innovative cancer therapies, today announced the acceptance of multiple Revuforj® (revumenib) and Niktimvo™ (axatilimab-csfr) abstracts for presentation at the 68th American Society of Hematology (ASH) Annual Meeting taking place in New Orleans, Louisiana, from December 12-15, 2026. A total of nineteen abstracts were accepted, including seven revumenib abstracts accepted for oral presentation.

"The breadth of data accepted for presentation at ASH highlights our scientific leadership in menin and CSF-1R inhibition and deep commitment to advancing the standard of care for menin-dependent acute leukemias and chronic GVHD," said Nick Botwood, MBBS, Head of Research & Development and Chief Medical Officer at Syndax. "Across fourteen revumenib abstracts, including seven oral presentations, we will highlight the growing body of clinical trial and real-world data showing compelling revumenib activity spanning the acute leukemia treatment continuum and multiple genetic subtypes."

Dr. Botwood continued, "We particularly look forward to the presentation of updated frontline data from the BEAT AML, SAVE, and 708 trials showing high rates of remission, MRD negativity, and encouraging survival among patients treated with revumenib in combination with standard of care therapies. These results bolster our confidence that the ongoing pivotal frontline trials of revumenib-based combinations could transform outcomes for newly diagnosed NPM1m or KMT2Ar AML."

The Company will host an in-person investor event, along with a live webcast, at the ASH Annual Meeting on Monday, December 14, 2026, from 7:00–8:30 a.m. CT / 8:00–9:30 a.m. ET to discuss key data presented at the meeting. The live webcast will be available on the Investor section of the Company's website at www.syndax.com, where a replay of the event will also be available for a limited time.

Key abstracts accepted for presentation at ASH 2026:

Revumenib:

- **BEAT AML (oral presentation):** Updated results from a Phase 1b trial of revumenib in combination with venetoclax and azacitidine in newly diagnosed patients with NPM1-mutated (NPM1m) or KMT2A-rearranged (KMT2Ar) acute myeloid leukemia (AML)
- **SAVE (oral presentation):** Updated results from the newly diagnosed cohort in a Phase 1/2 trial of the all-oral combination of revumenib, venetoclax, and decitabine/cedazuridine in patients with NPM1m, KMT2Ar, or NUP98-rearranged (NUP98r) AML
- **SNDX-5613-0708 (poster presentation):** Updated results from a Phase 1 trial of revumenib in combination with intensive chemotherapy in newly diagnosed patients with NPM1m, KMT2Ar, or NUP98r AML
- **Pre- and post-transplant data (oral presentation):** Characterization of disease response and outcomes among relapsed or refractory (R/R) KMT2Ar, NPM1m, and NUP98r patients in the pivotal Phase 1/2 trial of revumenib who proceeded to a stem cell transplant after receiving revumenib
- **Post-transplant maintenance data (oral presentation):** First results from a Phase 1 multicenter trial evaluating revumenib as maintenance following stem cell transplantation in patients with KMT2Ar or NPM1m acute leukemia
- **INTERCEPT (oral presentation):** Updated results from a Phase 1 trial evaluating revumenib as pre-emptive therapy for measurable residual disease (MRD) or early relapse among patients with NPM1m or KMT2Ar AML
- **Real-world evidence (two poster presentations):** Real-world outcomes from multiple centers using revumenib as monotherapy or in combination therapy for patients with KMT2Ar, NPM1m, or NUP98r acute leukemias

Axatilimab:

- **AGAVE-201 (poster presentation):** Updated long-term efficacy, safety, and duration of therapy observed in the pivotal Phase 2 trial of axatilimab in recurrent or refractory chronic graft-versus-host disease (GVHD)

The accepted abstracts listed below will be available on the ASH conference website. Copies of the oral and poster presentations will be made available through the 'Pipeline — Publications & Meetings Presentations' section of the Syndax website after the relevant embargoes lift.

Full list of abstracts accepted for presentation at ASH 2026 (all times in CT):

Revumenib

Abstract Titles	Presentation Details
Frontline combinations	
Azacitidine, venetoclax, and revumenib in newly diagnosed *NPM1*-mutated (*NPM1m*) or *KMT2A*-rearranged (*KMT2Ar*) acute myeloid leukemia (AML): final analysis of Beat AML phase 1b study	**Oral Presentation** Publication Number: 662 Sunday, December 13th Session Time: 4:30–6:00 PM
Update on the phase II study of the all-oral combination of revumenib (SNDX-5613) with decitabine/cedazuridine (ASTX727) and venetoclax (SAVE) in newly diagnosed AML	**Oral Presentation** Publication Number: 904 Monday, December 14th Session Time: 2:45–4:15 PM
Revumenib + intensive chemotherapy for newly diagnosed acute myeloid leukemia harboring genetic alterations in *NPM1*, *KMT2A*, or *NUP98*: updated phase 1/2 and pharmacokinetic results from SNDX-5613-0708	Poster Presentation Publication Number: 3406 Sunday, December 13th Session Time: 6:00–8:00 PM
Pre- and post-transplant data	
Revumenib monotherapy enables patients with relapsed/refractory acute leukemia to proceed to hematopoietic stem cell transplant	**Oral Presentation** Publication Number: 905 Monday, December 14th Session Time: 2:45–4:15 PM
A multicenter phase 1 trial of revumenib as post-transplant maintenance after allogeneic stem cell transplant in patients with *KMT2A*-rearranged or *NPM1*-mutated acute leukemia	**Oral Presentation** Publication Number: 715 Sunday, December 13th Session Time: 4:30–6:00 PM
MRD relapse	
Revumenib as pre-emptive therapy for measurable residual disease in *NPM1* mutated or *KMT2A* rearranged AML: the ALLG AMLM26 INTERCEPT platform trial	**Oral Presentation** Publication Number: 388 Saturday, December 12th Session Time: 4:00–5:30 PM
Real-world evidence	
Revumenib in real-world practice for relapsed/refractory acute leukemia: second interim findings from the multicenter ROAR study	Poster Presentation Publication Number: 3403 Sunday, December 13th Session Time: 6:00–8:00 PM
Real-world outcomes with revumenib across diverse molecular subtypes and treatment settings in acute myeloid leukemia: a single-center experience	Poster Presentation Publication Number: 3424 Sunday, December 13th Session Time: 6:00–8:00 PM
Relapsed/refractory	
Clinical activity of revumenib in relapsed/refractory therapy-related *KMT2A*-rearranged acute myeloid leukemia	Poster Presentation Publication Number: 1669 Saturday, December 12th Session Time: 5:30–7:30 PM
Impact of revumenib on transfusion dependence in patients with relapsed/refractory *NPM1*-mutated acute myeloid leukemia	Poster Presentation Publication Number: 5170 Monday, December 14th Session Time: 6:00–8:00 PM
Clinical pharmacology	
Exposure-response analysis and quantitative systems pharmacology modeling for recommended phase 3 dose selection of revumenib in newly diagnosed AML	Poster Presentation Publication Number: 3408 Sunday, December 13th Session Time: 6:00–8:00 PM
Pipeline programs & preclinical data	
Phase Ib/II study of revumenib as monotherapy or in combination with JAK inhibitors in patients with myelofibrosis	Poster Presentation Publication Number: 5557 Monday, December 14th Session Time: 6:00–8:00 PM
Differential drug responses to menin inhibitors in *KMT2A*-rearranged ALL and AML	**Oral Presentation** Publication Number: 47 Saturday, December 12th Session Time: 9:30–11:00 AM
Beyond *MEN1*: mutations in *KMT2A* and *LEDGF* drive cross-resistance to menin inhibitors in preclinical models	**Oral Presentation** Publication Number: 760 Monday, December 14th Session Time: 10:30 AM–12:00 PM

Axatilimab

Abstract Titles	Presentation Details
Long-term efficacy and safety of axatilimab among patients with chronic graft-versus-host disease in AGAVE-201	Poster Presentation Publication Number: 5995 Monday, December 14th Session Time: 6:00–8:00 PM
Axatilimab demonstrated clinical benefit without baseline corticosteroid use in patients with chronic graft-versus-host-disease: a subgroup analysis of the AGAVE-201 study	Poster Presentation Publication Number: 2478 Saturday, December 12th Session Time: 5:30–7:30 PM
Immune reprogramming with axatilimab: CSF-1R–dependent myeloid modulation and reduced $CD4^+$ T-cell activation in chronic graft-versus-host disease	Poster Presentation Publication Number: 6012 Monday, December 14th Session Time: 6:00–8:00 PM
Molecular signatures associated with clinical improvement in patients with chronic graft-versus-host disease receiving axatilimab: a correlation analysis from AGAVE-201	Poster Presentation Publication Number: 4252 Sunday, December 13th Session Time: 6:00–8:00 PM
Assessments of bone mineral density in patients with chronic graft-versus-host disease treated with axatilimab in AGAVE-201	Online publication only

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 underway across the acute leukemia treatment continuum, including in combination with standard of care therapies in newly diagnosed patients with NPM1m or KMT2Ar AML.

About Niktimvo™ (axatilimab-csfr)

Niktimvo (axatilimab-csfr) is a first-in-class colony stimulating factor-1 receptor (CSF-1R)-blocking antibody approved for use in the U.S. for the treatment of chronic graft-versus-host disease (GVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg (88.2 lbs).

In 2016, Syndax licensed exclusive worldwide rights to develop and commercialize axatilimab from UCB. In September 2021, Syndax and Incyte entered into an exclusive worldwide co-development and co-commercialization license agreement for axatilimab in chronic GVHD and any future indications.

Axatilimab is being studied in frontline combination trials in chronic GVHD – a Phase 2 combination trial with ruxolitinib (NCT06388564) and a Phase 3 combination trial with steroids (NCT06585774) are underway.

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.**

Niktimvo (axatilimab-csfr)

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS
Infusion-Related Reactions
Niktimvo™ (axatilimab-csfr) can cause infusion-related reactions. Infusion-related reactions, including hypersensitivity reactions, occurred in 18% of patients who received Niktimvo in the clinical trial (AGAVE-201), with Grade 3 or 4 reactions in 1.3%.

Premedicate with an antihistamine and an antipyretic for patients who have previously experienced an infusion-related reaction to Niktimvo. Monitor patients for signs and symptoms of infusion-related reactions, including fever, chills, rash, flushing, dyspnea, and hypertension. Interrupt or slow the rate of infusion or permanently discontinue Niktimvo based on severity of the reaction.

Embryo-Fetal Toxicity
Based on its mechanism of action, Niktimvo may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with Niktimvo and for 30 days after the last dose.

ADVERSE REACTIONS
Serious adverse reactions occurred in 44% of patients who received Niktimvo (N=79). Serious adverse reactions in >2 patients included infection (pathogen unspecified) (14%), viral infection (14%) and respiratory failure (5.1%). Permanent discontinuation of Niktimvo due to an adverse reaction occurred in 10% of patients and dose reduction due to adverse reaction occurred in 8% of patients. Dose interruptions due to an adverse reaction occurred in 44% of patients. The adverse reactions leading to dose interruption in >2 patients were viral infection, infection (pathogen unspecified), bacterial infection, musculoskeletal pain, and pyrexia.

The most common (≥15%) adverse reactions, including laboratory abnormalities, were increased aspartate aminotransferase (AST), infection (pathogen unspecified), increased alanine aminotransferase (ALT), decreased phosphate, decreased hemoglobin, viral infection, increased gamma glutamyl transferase (GGT), musculoskeletal pain, increased lipase, fatigue, increased amylase, increased calcium, increased creatine phosphokinase (CPK), increased alkaline phosphatase (ALP), nausea, headache, diarrhea, cough, bacterial infection, pyrexia, and dyspnea.

Clinically relevant adverse reactions in <10% of patients who received Niktimvo included:

- *Eye disorders:* periorbital edema
- *Skin and subcutaneous skin disorders:* pruritus
- *Vascular disorders:* hypertension

Immunogenicity: Anti-Drug Antibody–Associated Adverse Reactions
Across treatment arms in patients with cGVHD who received Niktimvo in clinical trials, among the patients who developed anti-drug antibodies (ADAs), hypersensitivity reactions occurred in 26% (13/50) of patients with neutralizing antibodies (NAb) and in 4% (2/45) of those without NAb.

USE IN SPECIFIC POPULATIONS
Lactation
Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment and for 30 days after the last dose of Niktimvo.

Females and Males of Reproductive Potential
Pregnancy Testing
Verify pregnancy status in females of reproductive potential prior to initiating Niktimvo.

Contraception
Females
Advise females of reproductive potential to use effective contraception during treatment with Niktimvo and for 30 days after the last dose of Niktimvo.

DOSAGE AND ADMINISTRATION
Dosage Modifications for Adverse Reactions
Monitor aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), creatine phosphokinase (CPK), amylase, and lipase prior to the start of Niktimvo therapy, every 2 weeks for the first month, and every 1 to 2 months thereafter until abnormalities are resolved. See Table 1 in the Prescribing Information for more recommendations.

Please see the full Prescribing Information for Niktimvo.

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.

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