Syndax Reports Preliminary 2025 Financial Highlights and Provides Business Updates at the 44th Annual J.P. Morgan Healthcare Conference

January 12, 2026

– Approximately $44 million and $125 million in preliminary (unaudited) Revuforj® (revumenib) 4Q25 and full year 2025 net revenue, respectively –

– Continued acceleration in demand following approval in R/R NPM1m AML, with an approximate 38% increase in Revuforj net revenue in 4Q25 vs. 3Q25 -

– $56 million and $152 million in preliminary (unaudited) Niktimvo™ (axatilimab-csfr) 4Q25 and full year 2025 net revenue, respectively; Syndax will report its share of the Niktimvo net profit when it reports full year 2025 results –

– Ended 2025 with approximately $394 million in cash, cash equivalents and marketable securities (unaudited); fully funded through profitability –

– Syndax to present at the 44th Annual J.P. Morgan Healthcare Conference on Monday, January 12, 2026, at 3:00 p.m. PT/ 6:00 p.m. ET. –

NEW YORK, Jan. 12, 2026 (GLOBE NEWSWIRE) -- Syndax Pharmaceuticals (Nasdaq: SNDX), a commercial-stage biopharmaceutical company advancing innovative cancer therapies, today announced preliminary, unaudited fourth quarter and full year 2025 financial results and provided additional business updates ahead of its presentation at the 44th Annual J.P. Morgan Healthcare conference.

"2025 was a transformational year for Syndax as we secured our third FDA approval and successfully executed the launches of Revuforj and Niktimvo, proving our ability to deliver innovative therapies for patients and advancing the company towards profitability," said Michael A. Metzger, Chief Executive Officer of Syndax. "With strong momentum and further acceleration of growth going into 2026, we look forward to continuing to build Revuforj and Niktimvo into industry leading franchises and advancing our lifecycle and frontline programs designed to expand our patient impact and unlock the multi-billion-dollar potential of both medicines."

Preliminary 2025 Financial Highlights & Recent Business Updates

Revuforj® (revumenib)

- Approximately $44 million and $125 million in preliminary (unaudited) fourth quarter and full-year 2025 Revuforj net revenue, respectively. Revuforj net revenue increased by approximately 38% in the fourth quarter of 2025 compared to the third quarter of 2025. The Company observed continued acceleration in demand following the FDA's approval of Revuforj in R/R NPM1m AML on October 24, 2025, with an approximately 35% increase in total Revuforj prescriptions in the fourth quarter of 2025 compared to the third quarter 2025.
- Received the 'Best New Drug' award for Revuforj at the Scrip Awards 2025. The award recognizes excellence in pharmaceutical development and the drug that represents the best therapeutic advance in its area.
- Initiated REVEAL-ND, a Phase 3, randomized, double-blind, placebo-controlled trial of revumenib in combination with intensive chemotherapy in newly diagnosed patients with NPM1m AML in November 2025. The trial has dual primary endpoints of measurable residual disease (MRD) negative complete remission (CR) and event free survival (EFS) to support the potential for accelerated approval and full approval, respectively.
- Initiated a multi-regional Managed Access Program which will expand access to Revuforj outside the U.S. This program enables physicians to prescribe Revuforj to appropriate patients outside the U.S. where the drug is not approved but access to novel medicines is permitted by local regulations and where funding can be secured.

Niktimvo™ (axatilimab-csfr)

- $56 million and $152 million in preliminary (unaudited) fourth quarter and full-year 2025 Niktimvo net revenue, respectively. Syndax will report its 50% share of the Niktimvo net commercial profit, defined as net product revenue minus the cost of sales and commercial expenses, when the Company reports its full year 2025 results. The Company expects its share of the product contribution to amount to approximately 25-30% of Niktimvo net revenue.

Cash Position & 2026 Financial Guidance

- Preliminary (unaudited) year-end 2025 cash, cash equivalents, and marketable securities of approximately $394 million.
- For the full year of 2026, the Company expects total research and development plus selling, general and administrative expenses to be approximately $400 million, excluding the impact of $50 million in estimated non-cash stock compensation expense.
- Syndax expects that its cash position, combined with its anticipated product revenue, interest income, and stable operating expense base, will enable the company to reach profitability.

**The preliminary fourth quarter and full year 2025 financial results are preliminary, unaudited, subject to adjustment, and provided as an approximation in advance of the Company's announcement of complete financial results in early 2026.*

Key 2026 Priorities & Anticipated Milestones

- Drive Revuforj and Niktimvo net revenue growth and invest thoughtfully in pipeline development and data generation to fuel further growth.

- Complete enrollment in MAXPIRe Phase 2 trial of axatilimab in idiopathic pulmonary fibrosis (IPF) in January 2026, with topline data on track for the second half of 2026.
- Advance global enrollment in EVOLVE-2 (unfit NPM1m and KMT2Ar AML) and REVEAL-ND (fit NPM1m), two Phase 3 frontline trials of revumenib in combination with low-intensity and high-intensity regimens, respectively.
- Initiate RAVEN, a Phase 2 collaborative trial of revumenib in combination with venetoclax and azacitidine in newly diagnosed KMT2Ar patients who would be considered eligible, or fit, for intensive chemotherapy in 2026.
- Further leadership in menin and CSF-1R inhibition through the publication and presentation of clinical trial data and real-world evidence, including revumenib data from the frontline and post-HSCT maintenance setting.
- Initiate a program in 2026 designed to generate proof-of-principle clinical data with revumenib in myelofibrosis (MF).

J.P. Morgan Healthcare Conference Presentation and Webcast

Michael Metzger, Chief Executive Officer of Syndax, will discuss these updates as part of a webcast presentation at the 44th Annual J.P. Morgan Healthcare Conference on Monday, January 12, 2026, at 3:00 p.m. PT/ 6:00 p.m. ET. A live webcast of the event can be accessed from 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.

About Revuforj® (revumenib)

Revuforj (revumenib) is an oral, first-in-class menin inhibitor that is FDA approved 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 one year and older. Revuforj is also indicated for the treatment of R/R acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (NPM1) mutation in adult and pediatric patients one year and older 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.

Revumenib was previously granted Orphan Drug Designation for the treatment of AML, ALL and acute leukemias of ambiguous lineage (ALAL) by the U.S. FDA and for the treatment of AML by the European Commission. The U.S. FDA also granted Fast Track designation to revumenib for the treatment of adult and pediatric patients with R/R acute leukemias harboring a KMT2A rearrangement or NPM1 mutation and Breakthrough Therapy Designation for the treatment of adult and pediatric patients with R/R acute leukemia harboring a KMT2A rearrangement.

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. Axatilimab is also being studied in an ongoing Phase 2 trial in patients with idiopathic pulmonary fibrosis (NCT06132256).

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, as amended, relating to our business, operations, and financial conditions, including but not limited to our preliminary financial results for the fourth quarter and full year 2025 for both Revuforj and Niktimvo, preliminary year-end 2025 cash, cash equivalents, restricted cash and marketable securities, current beliefs, as well as expectations and assumptions regarding the future of our business, future plans and strategies, our development and commercialization plans. 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.

Contact

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

SNDX-G

Source: Syndax Pharmaceuticals, Inc.