Syndax Pharmaceuticals Reports Third Quarter 2018 Financial Results and Provides Clinical and Business Update

– Next assessment of primary endpoint of overall survival in E2112 trial expected in the second quarter of 2019 –

– Topline data across ENCORE I/O combinations and IND for Menin-MLLr inhibitor expected during the 1H19 –

– Company to host conference call today at 4:30 p.m. ET –

WALTHAM, Mass., November 5, 2018 (PRNEWSWIRE) -- Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq: SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today reported its financial results for the third quarter ended September 30, 2018. In addition, the Company provided a clinical and business update. As of September 30, 2018, Syndax had $89.6 million in cash, cash equivalents and short-term investments.

“The last several months have been marked by exciting progress across multiple programs, culminating with our recent announcement of plans to commence what will become our second registration study: a focused, biomarker-driven registration trial to evaluate entinostat in combination with pembrolizumab in patients with non-small cell lung cancer whose disease has progressed after PD-1 therapy,” said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. “We remain highly encouraged by the potential for a positive overall survival readout for E2112, our Phase 3 registration trial of entinostat plus exemestane in HR+, HER2- breast cancer, which would allow us to file for full regulatory approval in this indication. We look forward to reporting on multiple exciting value inflection points across our ENCORE I/O combination trials in the coming months.”

Pipeline Updates

Entinostat

- At the International Association for the Study of Lung Cancer (IASLC) 19th World Conference on Lung Cancer (WCLC) in September, the Company presented data from the full cohort of PD-(L)1 refractory non-small cell lung cancer (NSCLC) patients enrolled in the ENCORE 601 trial of entinostat in combination with KEYTRUDA® (pembrolizumab). The data continued to support the prior observation of enhanced clinical benefit in a subpopulation of patients with elevated baseline levels of peripheral classical blood monocytes. In October, the Company announced plans to commence a focused, biomarker-driven, randomized registration trial comparing the entinostat-pembrolizumab combination to standard of care chemotherapy in patients whose disease has progressed after both platinum-based chemotherapy and PD-1 antagonist therapy. The trial will seek to validate peripheral classical monocytes as a marker of response to the combination and to determine whether the combination can improve progression free survival (PFS) over standard of care chemotherapy in the high monocyte population. The Company anticipates beginning the trial in the first half of 2019.

- In October, Syndax announced that enrollment has concluded in E2112, the Phase 3 registration trial of entinostat plus exemestane in advanced hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+, HER2-) breast cancer, with a total of 608 patients enrolled. ECOG-ACRIN Cancer Research Group and the National Cancer Institute informed the Company that the trial did not meet the statistical hurdle for the first primary endpoint of improving PFS, which would have provided the earliest regulatory filing opportunity. Following the most recent interim overall survival (OS) analysis conducted by the trial's Data Safety Monitoring Committee, ECOG-ACRIN also informed Syndax that the trial is continuing as planned, with the next interim analysis for the OS primary endpoint scheduled for the second quarter of 2019. Additional interim analyses will be conducted every six months until either an OS benefit is observed, or the final target number of events occur. E2112 was designed, and obtained Breakthrough Therapy Designation for this indication, based on positive Phase 2b OS results. Any positive OS assessment would enable the Company to file for full regulatory approval.

- The Company will make a decision later this year on next steps for entinostat in combination with KEYTRUDA® in melanoma patients whose disease has progressed following PD-1 therapy.

- Enrollment in the expanded stage 1 ENCORE 601 cohort of patients with microsatellite stable colorectal cancer (MSS-CRC, n = 37) is now complete. A decision on whether to continue to the second stage of this cohort is expected in the first quarter of 2019.

- As previously communicated, target enrollment is complete in both the Phase 2 portion of ENCORE 602, the Phase 1b/2 clinical trial evaluating the combination of entinostat plus Genentech's PD-(L)1 inhibitor, TECENTRIQ® (atezolizumab), in patients with triple negative breast cancer, and the Phase 2 portion of ENCORE 603, evaluating entinostat in combination with Pfizer/Merck KGaA's PD-(L)1 inhibitor, BAVENCIO® (avelumab), in patients with ovarian cancer. Topline results for ENCORE 603 are expected in the first quarter of 2019, with topline results from ENCORE 602 to follow in the second quarter of 2019.

- ENCORE 606, the Phase 1b/2 trial evaluating entinostat in combination with NKTR-214, Nektar's CD122-biased agonist, is expected to begin enrolling patients with melanoma whose disease has progressed after PD-1 antagonist therapy in the second quarter of 2019.

SNDX-6352

- Enrollment has recently been initiated in the Phase 1 dose escalation trial of SNDX-6352, the Company's anti-CSF-1R monoclonal antibody, in patients with chronic graft versus host disease (cGVHD). The objectives of this trial are to evaluate the safety and preliminary efficacy of SNDX-6352 in cGVHD and to identify a recommended Phase 2 dose and schedule. Initial results are anticipated in the second half of 2019.

- A Phase 1/1b dose escalation study evaluating the safety of SNDX-6352 remains ongoing with patients continuing to receive doses of SNDX-6352 alone or in combination with IMFINZI® (durvalumab), AstraZeneca's human monoclonal antibody directed against PD-

L1. The Company anticipates identifying the recommended Phase 2 dose and schedule for SNDX-6352 monotherapy and in combination with durvalumab in the second quarter of 2019.

Menin-MLLr Inhibitor Portfolio

- Development of the Company's portfolio of Menin-Mixed Lineage Leukemia (MLLr) inhibitors is ongoing, and the Company has selected a lead compound, SNDX-5613, to continue through Investigational New Drug (IND)-enabling studies. The Company expects to file an IND with the FDA and initiate a Phase 1 clinical trial in patients with a defined subset of acute leukemias in the second quarter of 2019.

- Syndax's Menin-MLLr program will be featured in two presentations at the upcoming 60th American Society of Hematology (ASH) Annual Meeting & Exposition being held December 1-4, 2018 in San Diego.

Third Quarter 2018 Financial Results

As of September 30, 2018, Syndax had cash, cash equivalents and short-term investments of $89.6 million and 26.1 million shares issued and outstanding (including a prefunded warrant for 2.0 million shares).

In the third quarter of 2018 and through November 2, 2018, the Company sold 2.1 million shares of its common stock with net proceeds of approximately $15.5 million pursuant to its at-the-market arrangement.

Third quarter 2018 research and development expenses increased to $14.1 million from $12.2 million for the comparable period in the prior year, an increase of $1.9 million, or 16%, due to an increase in development activities of $0.8 million and increased employee compensation expense of $1.1 million. The increase in development activities was primarily related to the development of the Menin-MMLr program and increased activities in the 602 ENCORE trial partly offset by the completion of Phase 1 clinical pharmacology trials and decrease in E2112 costs. The increase in employee compensation costs was primarily due to increased headcount.

General and administrative expenses increased to $4.1 million during the third quarter of 2018, compared to $3.6 million for the comparable period in the prior year, an increase of $0.6 million, or 16%. The increase in general and administrative expenses was primarily due to an increase employee related expenses of $0.3 million and in professional and legal fees of $0.2 million.

For the three months ended September 30, 2018, Syndax reported a net loss attributable to common stockholders of $17.3 million or $0.68 per share compared to $15.1 million or $0.68 per share for the comparable prior year period.

Financial Guidance

Today, the Company provided operating expense guidance for the fourth quarter and full year 2019. For the fourth quarter of 2018, research and development expenses are expected to be $13 to $15 million and total operating expenses are expected to be $17 to $19 million. Total operating expenses for the fourth quarter of 2018 are expected to include approximately $1.5 million of non-

cash stock compensation expense. The year-end 2018 cash balance is expected to be approximately $80 million.

For the full year 2019, research and development expenses are expected to be $54 to $58 million, and total operating expenses are expected to be $68 to $73 million. Total operating expenses for 2019 are expected to include approximately $6 million of non-cash stock compensation expense.

Conference Call and Webcast

In connection with the earnings release, Syndax's management team will host a conference call and live audio webcast at 4:30 p.m. ET today, Monday, November 5, 2018.

The live audio webcast and accompanying slides may be accessed through the Events & Presentations page in the Investors section of the Company's website at www.syndax.com. Alternatively, the conference call may be accessed through the following:

Conference ID: 8397904
Domestic Dial-in Number: 855-251-6663
International Dial-in Number: 281-542-4259
Live Webcast: https://edge.media-server.com/m6/p/c9yprfxf

For those unable to participate in the conference call or webcast, a replay will be available for 30 days on the Investors section of the Company's website, www.syndax.com.

About Syndax Pharmaceuticals, Inc.

Syndax Pharmaceuticals is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. The Company is developing its lead product candidate, entinostat, a once-weekly, oral, small molecule, class I HDAC inhibitor, in combination with exemestane and several approved PD-1/PD-(L)1 antagonists. The Company's pipeline also includes SNDX-6352, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, as well as a portfolio of potent and selective inhibitors targeting the binding interaction of Menin with MLLr. For more information, please visit www.syndax.com or follow the Company on Twitter and LinkedIn.

Syndax's Cautionary Note on 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 "may," "will," "expect," "plan," "anticipate," "estimate," "intend," "believe" 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 and the reporting of clinical data for Syndax's product candidates, the potential use of our product candidates to treat various cancer indications, and Syndax's third quarter and full-year 2018 net cash used in research and development and total operating activities. 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 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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SYNDAX PHARMACEUTICALS, INC.

(unaudited)

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	September 30, 2018	December 31, 2017
Cash, cash equivalents, short-term and long-term investments	$ 89,599	$ 133,220
Total assets	$ 96,467	$ 137,186
Total liabilities	$ 32,193	$ 32,867
Total stockholders' equity	$ 64,274	$ 104,319
Common stock outstanding	24,051,364	24,390,033
Common stock and common stock equivalents*	30,324,010	28,139,705
*Common stock and common stock equivalents:		
Common stock	24,051,364	24,390,033
Options to purchase common stock	4,272,646	3,391,832
Common stock warrants	2,000,000	357,840
	30,324,010	28,139,705

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SYNDAX PHARMACEUTICALS, INC.

(unaudited)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
License fee revenue	$ 379	$ 305	$ 1,138	$ 915
Operating expenses:				
Research and development	14,095	12,188	44,286	31,603
General and administrative	4,125	3,563	13,395	11,777
Total operating expenses	18,220	15,751	57,681	43,380
Loss from operations	(17,841)	(15,446)	(56,543)	(42,465)
Other income, net	503	358	1,419	766
Net loss	$ (17,338)	$ (15,088)	$ (55,124)	$ (41,699)
Net loss attributable to common stockholders	$ (17,338)	$ (15,088)	$ (55,124)	$ (41,699)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.68)	$ (0.68)	$ (2.21)	$ (2.08)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	25,471,587	22,239,996	24,888,738	20,004,409

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