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

March 7, 2019

- Next interim OS assessment for Phase 3 E2112 trial in HR+, HER2- metastatic breast cancer expected in 2Q19 -
- IND filing for targeted therapy SNDX-5613, the Company's Menin inhibitor, expected in 2Q19 -
- Company to host conference call today at 4:30 p.m. ET -

WALTHAM, Mass., March 7, 2019 /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 fourth quarter ended December 31, 2018. In addition, the Company provided a clinical and business update. As of December 31, 2018, Syndax had $80.9 million in cash, cash equivalents and short-term investments.

"We expect the coming months to be a very exciting, milestone-rich time for Syndax as we continue to work towards our mission of realizing a future in which cancer patients live longer and better lives than previously possible," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "We remain highly encouraged by the potential for a positive overall survival readout in E2112, our Phase 3 registration trial of entinostat plus exemestane in HR+, HER2- breast cancer, and expect the next interim analysis in the second quarter. As a reminder, any positive overall survival result would allow us to file for full regulatory approval in an indication for which existing therapies have failed to show a survival benefit. In addition, we continue to expect to file an IND in the second quarter for our targeted therapy, SNDX-5613, an inhibitor of the Menin-MLL interaction. Preclinical data from our Menin inhibitor program has provided strong, consistent support for the therapeutic potential of this class in patients with genetically-defined acute leukemias, a disease area lacking effective options."

Syndax also today announced that both 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 (TNBC), and ENCORE 603, the Phase 1b/2 trial evaluating entinostat in combination with BAVENCIO® (avelumab), an anti-PD-(L)1 co-developed and co-commercialized by Merck KGaA Darmstadt, Germany and Pfizer, in patients with ovarian cancer, failed to meet their respective primary endpoints of demonstrating an improvement in progression free survival (PFS).

With results across the entire ENCORE program now in hand, Syndax has decided to defer advancement of the entinostat-PD-1 combination program, including the previously announced ENCORE 607 registration trial in non-small cell lung cancer (NSCLC). Going forward, the Company will primarily focus its resources on advancing entinostat in HR+ breast cancer and SNDX-5613, a Menin inhibitor being developed for genetically-defined population of acute leukemias. Following availability of positive E2112 OS results, the Company will determine whether to advance its entinostat-PD-1 combination programs into one or more registration trials.

Dr. Morrison added, "While we are encouraged by ENCORE 601 entinostat-KEYTRUDA® combination data in NSCLC and melanoma which suggests that entinostat has the ability to overcome resistance in PD-1 refractory patients, we believe that it is in the best interest of our stakeholders to prioritize our resources ahead of the E2112 OS readout, at which time we will make a determination on next steps for the I-O combination program. We are highly committed to advancing the balance of our pipeline programs, with an emphasis on our targeted therapy, SNDX-5613, and the E2112 registrational trial for HR+ breast cancer."

Pipeline Updates

Entinostat

- The Company continues to anticipate the next interim OS analysis for E2112, its NCI-sponsored, ECOG-ACRIN led Phase 3 registration trial of entinostat, a Class I selective HDAC inhibitor, plus exemestane in advanced hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+, HER2-) breast cancer, in the second quarter of 2019. Additional interim analyses will be conducted by ECOG-ACRIN approximately every six months until either an OS benefit is observed, or the final target number of events occur. Any positive OS assessment would enable the Company to file for full regulatory approval. The E2112 trial design was informed by the Phase 2b ENCORE 301 trial, the results of which led to entinostat's Breakthrough Therapy designation in HR+, HER2- breast cancer, in which patients receiving the entinostat/exemestane combination demonstrated a statistically significant OS benefit.

- As previously announced, data from the NSCLC and melanoma cohorts of the ENCORE 601 trial will each be featured during oral presentations at the American Association of Cancer Research (AACR) Meeting later this month. Data to be presented will include the Company's most recent insights into the potential mechanisms that allow entinostat to enhance the benefit of immune checkpoint therapy.

- The Phase 1b/2 ENCORE 603 trial, which evaluated entinostat in combination with avelumab in patients with heavily pretreated advanced epithelial ovarian cancer, and the Phase 1b/2 ENCORE 602 trial, which evaluated entinostat in combination with atezolizumab in patients with PD-1 naïve, previously treated TNBC, each failed to meet its respective primary endpoint of a statistically significant improvement in PFS.

- Based on the activity observed to date, the Company has decided not to advance the ENCORE 601 cohort of patients with microsatellite stable colorectal cancer (MSS-CRC) to the second stage of the trial.

SNDX-5613

- Preclinical data supporting the Company's Menin-Mixed Lineage Leukemia (MLL) inhibitor program were presented during an oral session at the 60thAmerican Society of Hematology (ASH) Annual Meeting in December 2018.

- The Company continues to expect to file an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for its Menin inhibitor, SNDX-5613, in the second quarter of 2019, with the initiation of a Phase 1 clinical trial in a defined subset of acute leukemias patients expected to follow.

SNDX-6352

- The Company continues to anticipate initial results from 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) in the second half of the year. 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.

- The Company continues to anticipate identifying a recommended Phase 2 dose and schedule for SNDX-6352 monotherapy and in combination with IMFINZI® (durvalumab), AstraZeneca's human monoclonal antibody directed against PD-L1, in the second quarter of 2019. The dose selections will be based on the results of the ongoing Phase 1/1b ascending dose trial evaluating the safety of SNDX-6352 alone or in combination with durvalumab.

Fourth Quarter 2018 Financial Results

As of December 31, 2018, Syndax had cash, cash equivalents and short-term investments of $80.9 million and 26.8 million shares issued and outstanding.

License fee revenue decreased to $0.4 million in the fourth quarter 2018 from $1.2 million for the prior year fourth quarter, and for 2018 decreased to $1.5 million compared to $2.1 million for the prior year. The decreases are due to the ratable recognition of a $5.0 million payment from KHK for the achievement of a development milestone in the fourth quarter of 2017.

Fourth quarter 2018 research and development expenses decreased to $15.8 million from $16.6 million, and for the full year increased to $60.1 million compared to $48.2 million for 2017. The fourth quarter decrease was primarily due to expensing a payment of $5.0 million to Allergan to acquire SNDX-5613 in the fourth quarter of 2017, offset by an increase in SNDX-6352 manufacturing expenses. The increase for the full year was primarily due to increased expenses for SNDX-6352 manufacturing, SNDX-5613 program expenses and increased headcount, offset by the payment of $5.0 million to Allergan in 2017.

General and administrative expenses for the fourth quarter 2018 decreased to $3.9 million from $4.1 million, and, for the year ended December 31, 2018 increased to $17.3 million compared to $15.9 million for the prior year. The full year increase was primarily due to increased pre-commercialization expenses.

For the three months ended December 31, 2018, Syndax reported a net loss attributable to common stockholders of $18.8 million or $0.70 per share compared to $19.1 million or $0.80 per share for the prior year period. For the year ended December 31, 2018, Syndax reported a net loss attributable to common stockholders of $74.0 million or $2.92 per share, compared to $60.8 million or $2.90 per share for the prior year.

Financial Guidance

Today the Company provided operating expense guidance for the first quarter and full year 2019. For the first quarter and full year 2019, research and development expenses are expected to be $11 to $13 million and $46 to $50 million, respectively, and total operating expenses are expected to be $15 to $17 million and $60 to $64 million, respectively.

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, Thursday, March 7, 2019.

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: 8252397
Domestic Dial-in Number: 855-251-6663
International Dial-in Number: 281-542-4259
Live Webcast: https://edge.media-server.com/m6/p/a45g2tx3

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 MLL-r, including its lead candidate SNDX-5613. 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, Syndax's fourth quarter and full-year 2018 net cash used in research and development and total operating activities, and first quarter and full year 2019 operating expense guidance. 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.

SYNDAX PHARMACEUTICALS, INC.
(unaudited)
CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31,	
(In thousands)	**2018**	**2017**
Cash, cash equivalents, short-term and long-term investments	$ 80,911	$ 133,220
Total assets	$ 83,938	$ 137,186
Total liabilities	$ 30,891	$ 32,867
Total stockholders' equity (deficit)	$ 53,047	$ 104,319
Common stock outstanding	24,835,951	24,390,033
Common stock and common stock equivalents*	31,088,934	28,139,705
*Common stock and common stock equivalents:		
Common stock	24,835,951	24,390,033
Options to purchase common stock	4,252,983	3,391,832
Common stock warrants	2,000,000	357,840
	31,088,934	28,139,705

SYNDAX PHARMACEUTICALS, INC.
(unaudited)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Year Ended December 31,	
(In thousands, except share and per share data)	**2018**	**2017**	**2018**	**2017**
License fee revenue	$ 380	$ 1,193	$ 1,517	$ 2,108
Operating expenses:				
Research and development	15,821	16,599	60,106	48,201
General and administrative	3,892	4,083	17,287	15,861
Total operating expenses	19,713	20,682	77,393	64,062
Loss from operations	(19,333)	(19,489)	(75,876)	(61,954)
Other income (expense), net	496	385	1,915	1,152
Net loss	$ (18,837)	$ (19,104)	$ (73,961)	$ (60,802)
Net loss attributable to common stockholders	$ (18,837)	$ (19,104)	$ (73,961)	$ (60,802)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.70)	$ (0.80)	$ (2.92)	$ (2.90)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	26,804,089	23,943,241	25,371,511	20,997,211

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