Syndax Pharmaceuticals Reports Fourth Quarter 2017 Financial Results and Provides Clinical and Business Update

- Phase 2 ENCORE 601 PD-(L)1 refractory melanoma cohort data and melanoma registration strategy disclosure forthcoming in 2Q18 -

- ENCORE 601 PD-(L)1 refractory NSCLC cohort data expected 2Q18 -

- Initial data on MSS-CRC cohort of ENCORE 601 to drive decision on advancement into second stage expected in 2Q18 -

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

WALTHAM, Mass., March 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 fourth quarter ended December 31, 2017. In addition, the Company provided a clinical and business update. As of December 31, 2017, Syndax had $133.2 million in cash, cash equivalents and short-term investments.

“In 2017, we continued to advance our pipeline of potentially transformative best-in-class candidates for the treatment of various cancers. We made significant progress on the clinical development of both our lead product candidate, entinostat, and SNDX-6352, our monoclonal antibody that blocks the colony stimulating factor 1 receptor. We also expanded our pipeline with the addition of a portfolio of preclinical, orally-available small molecule Menin-MLL inhibitors,” said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. “We look forward to several key data readouts in the next six months, including progression free survival data from the Phase 3 E2112 trial of entinostat in combination with exemestane for advanced HR+, HER2- breast cancer. We also anticipate results next quarter from the PD-(L)1 refractory melanoma and NSCLC cohorts of ENCORE 601, as well as initial data and a decision on whether to advance to the second stage of the ENCORE 601 cohort of patients with microsatellite stable colorectal cancer.”

Pipeline Updates

- 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, E2112, is 89% enrolled as of the end of February. ECOG-ACRIN Cancer Research Group, the trial sponsor, has notified the Company that the Data Safety Monitoring Committee (DSMC) completed the final progression free survival analysis and the first interim analysis for overall survival in November 2017. The results of this analysis are held confidentially by the ECOG-ACRIN study statistician and the DSMC, and ECOG-ACRIN will release the analysis to the Company upon completion of enrollment. The Company now anticipates enrollment to be complete in the third quarter of 2018.
- In November 2017, the Company presented data at the SITC Annual Meeting from the melanoma and non-small cell lung cancer (NSCLC) cohorts of ENCORE 601 that support

entinostat's potential to enhance immune checkpoint blockade mediated anti-tumor responses in a broad range of tumors.

- In the second quarter of 2018, the Company expects to present full Phase 2 data from the PD-(L)1 refractory melanoma cohort of ENCORE 601. At that time, the Company also plans to communicate a registration strategy for entinostat in this indication.
- Full Phase 2 data from the PD-(L)1 refractory non-small cell lung cancer (NSCLC) cohort of ENCORE 601 are expected in the second quarter of 2018.
- Enrollment in the first stage of the ENCORE 601 cohort of patients with microsatellite stable colorectal cancer (MSS-CRC) is complete. The Company expects to share initial data, as well as a decision on whether to advance this cohort to the second stage of the trial, in the second quarter of 2018.
- ENCORE 602, the Phase 1b/2 clinical trial evaluating the combination of entinostat plus Genentech's PD-(L)1 inhibitor atezolizumab (TECENTRIQ®) in patients with triple negative breast cancer, is expected to complete enrollment of the Phase 2 portion in the second quarter of 2018. Topline results from this trial are anticipated in the second half of 2018.
- In January, the Company announced a new clinical collaboration with Genentech to evaluate the combination of entinostat and TECENTRIQ in patients with second-line HR+, HER2- metastatic breast cancer.
- ENCORE 603, the Phase 1b/2 clinical trial evaluating entinostat in combination with Pfizer/Merck KGaA's BAVENCIO® in patients with ovarian cancer, continues to enroll patients into the Phase 2 portion and is on track to complete enrollment in the second quarter of 2018. Topline results are expected in the first half of 2019.
- Dosing of patients with solid tumors in the Phase 1 multiple ascending dose (MAD) clinical trial of SNDX-6352 is ongoing. The Company anticipates presenting data from this trial and disclosing a Phase 2 strategy in the second half of 2018.
- In February, the Company entered into a clinical collaboration with AstraZeneca to evaluate the efficacy and safety of SNDX-6352 in combination with durvalumab (IMFINZI®), AstraZeneca's human monoclonal antibody directed against PD-(L)1, in multiple solid tumors. Initial work focusing on establishing the safety of this combination is expected to begin in the second quarter of 2018.
- Development of the Company's portfolio of Menin-Mixed Lineage Leukemia (MLL) inhibitors, in-licensed from Vitae Pharmaceuticals, Inc., a subsidiary of Allergan plc, is ongoing. An abstract describing the preclinical efficacy of these therapies in the treatment of MLL-rearranged acute myeloid leukemia (AML) was accepted for oral presentation at the 2018 American Association for Cancer Research (AACR) Annual Meeting being held April 14-18 in Chicago. The Company expects to initiate clinical trials in 2019.

Fourth Quarter 2017 Financial Results

As of December 31, 2017, Syndax had cash, cash equivalents and short-term and long-term investments of $133.2 million and 24,390,033 shares issued and outstanding.

License fee revenue increased to $1.2 million in the fourth quarter 2017 from $0.3 million for the comparable period in the prior year. License fee revenue for the year ended December 31, 2017 increased to $2.1 million compared to $1.2 million for the prior year. The increases are due to the ratable recognition of a $5.0 million milestone payment from KHK for the achievement of a development milestone.

Fourth quarter 2017 research and development expenses increased to $16.6 million from $8.5 million for the comparable period in the prior year. Research and development expenses for the year ended December 31, 2017 increased to $48.2 million compared to $31.7 million for the prior year. The increases were primarily due to increased clinical trial activities related to our Phase 1 clinical pharmacology trials, increased enrollment in ENCORE 601, costs related to SNDX-6352 trials, increased activities in ENCORE 602 and ENCORE 603, and CMC activities, increased headcount, legal and consultant expenses, facility costs and travel costs. In 2017 Syndax expensed a nonrefundable upfront payment of $5.0 million to Allergan for the Menin Assets and in 2016 Syndax expensed a nonrefundable upfront payment of $5.0 million related to the UCB license agreement.

General and administrative expenses totaled $4.1 million during the fourth quarter of 2017 and $15.9 million for the year, similar to the $3.0 million and $13.3 million expense level for the respective prior year periods. The increase in general and administrative expenses was primarily due to increases in headcount, increases in pre-commercialization work, professional fees and other costs related to being a public company. These increases were partially offset by decreases in legal expenses.

For the three months ended December 31, 2017, Syndax reported a net loss attributable to common stockholders of $19.1 million or $0.80 per share compared to $10.8 million or $0.59 per share for the comparable prior year period. For the year ended December 31, 2017, Syndax reported a net loss attributable to common stockholders of $60.1 million or $2.90 per share, compared to $47.1 million or $3.22 per share for the prior year period.

Financial Guidance

Today the Company provided operating expense guidance for the first quarter and full year 2018. For the first quarter and full year 2018, research and development expenses are expected to be $18 to $22 million and $67 to $76 million, respectively, and total operating expenses are expected to be $22 to $26 million and $86 to $96 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, Monday, March 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: 5589398
Domestic Dial-in Number: 1-855-251-6663
International Dial-in Number: 281-542-4259
Live webcast: https://edge.media-server.com/m6/p/tbzo2gon

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-L1 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 first 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 studies, 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

SYNDAX PHARMACEUTICALS, INC.

(unaudited)

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	December 31, 2017	December 31, 2016
Cash, cash equivalents, short-term and long-term investments	$ 133,220	$ 105,330
Total assets	$ 137,186	$ 109,013
Total liabilities	$ 32,867	$ 24,874
Total stockholders' equity (deficit)	$ 104,319	$ 84,139
Common stock outstanding	24,390,033	18,223,723
Common stock and common stock equivalents*	28,139,705	21,142,300
*Common stock and common stock equivalents:		
Common stock	24,390,033	18,223,723
Options to purchase common stock	3,391,832	2,560,737
Common stock warrants	357,840	357,840
	28,139,705	21,142,300

SYNDAX PHARMACEUTICALS, INC.

(unaudited)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
License fee revenue	$ 1,193	$ 305	$ 2,108	$ 1,220
Operating expenses:				
Research and development	16,599	8,474	48,201	31,665
General and administrative	4,083	2,972	15,861	13,321
Total operating expenses	20,682	11,446	64,062	44,986
Loss from operations	(19,489)	(11,141)	(61,954)	(43,766)
Other income (expense), net	385	326	1,152	(706)
Net loss	$ (19,104)	$ (10,815)	$ (60,802)	$ (44,472)
Net loss attributable to common stockholders	$ (19,104)	$ (10,815)	$ (60,802)	$ (47,070)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.80)	$ (0.59)	$ (2.90)	$ (3.22)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	23,943,241	18,193,027	20,997,211	14,619,716

Syndax Contacts

Investor Contact
Melissa Forst
Argot Partners
melissa@argotpartners.com
Tel 212.600.1902

Media Contact
David Rosen
Argot Partners
david.rosen@argotpartners.com
Tel 212.600.1902

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