Syndax Pharmaceuticals Reports Fourth Quarter and Year-end 2016 Financial Results and Provides Clinical and Business Update

Encore 601 refractory melanoma cohort to proceed to second stage of Phase 2; pre-specified objective response criteria satisfied

Enrollment of the first stage of both NSCLC cohorts completed; decision whether to progress each cohort into the second stage of Phase 2 anticipated in 1H2017

WALTHAM, Mass., March 02, 2017 (GLOBE NEWSWIRE) -- Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq:SNDX), a clinical stage biopharmaceutical company focused on developing entinostat and SNDX-6352 in multiple cancer indications, today reported its financial results for the fourth quarter and year ended December 31, 2016. In addition, the Company provided a pipeline update as well as a review of upcoming milestones. As of December 31, 2016, Syndax had $105.3 million in cash, cash equivalents and short-term investments.

"We're pleased to report that the melanoma cohort of ENCORE 601 has met the pre-specified objective response threshold to advance into the second stage of the phase 2 trial and will re-open enrollment immediately," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "The goal of the first stage of the trial was to determine whether the combination of entinostat and Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), could generate a meaningful response in patients enrolled in each cohort. Specifically, in the cohort of melanoma patients who had experienced disease progression while on a PD-1 antagonist, a minimum of 2 out of 13 patients needed to demonstrate a confirmed objective response for this cohort to advance to the next stage. The trial will now enroll an additional 21 patients, with accrual targeted to be completed by the end of the fourth quarter of this year."

"This is an encouraging early signal for entinostat combined with KEYTRUDA®, as this population of patients is poorly served by existing therapies. We are looking forward to seeing the stage one results of this combination in the non-small cell lung cancer cohorts of ENCORE 601 as well," said Michael L. Meyers, M.D., Ph.D., Chief Medical Officer of Syndax.

Pipeline Updates

- According to the Eastern Cooperative Oncology Group-American College of Radiology Imaging Network (ECOG-ACRIN) Cancer Research Group, E2112, a Phase 3 registration trial of entinostat plus Aromasin® (exemestane tablets) in advanced HR+, HER2- breast cancer, continues to enroll. The trial is being conducted in collaboration with ECOG-ACRIN and the National Cancer Institute (NCI) under a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA).
- The Company has completed enrollment in the first stage of the three cohorts in the Phase 2 portion of ENCORE 601, an open-label, Phase 1b/2 clinical trial evaluating the combination of entinostat plus Merck's anti-PD-1 blocking therapy, KEYTRUDA®, in patients with melanoma and NSCLC. Following an analysis of the results from stage one of the two NSCLC cohorts, the Company will make a decision whether to expand either or both of

these cohorts into the second stage of the trial in the first half of 2017.

- The Phase 1b portion of ENCORE 602, a Phase 1b/2 clinical trial evaluating the combination of entinostat plus Genentech's PD-L1 inhibitor, Tecentriq™ (atezolizumab), in patients with triple negative breast cancer (TNBC) has completed enrollment and, following a thorough review of the safety data, the Phase 2 portion of the trial was recently initiated.

- The Company entered into a Cooperative Research and Development Agreement (CRADA) with the NCI of the National Institutes of Health (NIH), and will collaborate with the NCI's Laboratory of Tumor Immunology and Biology to evaluate the therapeutic potential of entinostat, as well as SNDX-6352, the Company's anti-CSF-1R monoclonal antibody currently in development as a treatment for neoplastic diseases.

- Syndax, in collaboration with Pfizer Inc. and Merck KGaA, Darmstadt, Germany, initiated enrollment of patients in the Phase 1b portion of ENCORE 603, a Phase 1b/2 clinical trial evaluating entinostat in combination with an investigational monoclonal antibody targeting PDL-1, avelumab, in patients with ovarian cancer.

- During the fourth quarter of 2016, Syndax commenced enrollment in the Phase 1 single ascending dose clinical trial of SNDX-6352 in healthy volunteers to determine the safety, pharmacokinetics and pharmacodynamics of the anti-CSF-1R monoclonal antibody.

Upcoming Milestones

- Based upon current enrollment trends ECOG-ACRIN anticipates that enrollment in E2112 could be completed and progression-free survival data available by the end of this year.

- Syndax expects to complete enrollment in the second stage of the melanoma cohort in ENCORE 601 by the end of the fourth quarter of 2017, with data anticipated in the first half of 2018.

- The Company expects to present data from the Phase 1 single ascending dose clinical trial of SNDX-6352 at a scientific congress in the fourth quarter of 2017.

Syndax Expects to Participate in the Following Upcoming Conferences

- Cowen & Co. 37th Annual Healthcare Conference, March 6-8, 2017 in Boston.

- 29th Annual ROTH Capital Partners Healthcare Conference, March 12-15, 2017 in Orange County, CA.

- 27th Annual Oppenheimer & Co. Healthcare Conference, March 21-22, 2017 in New York.

Fourth Quarter and Year-end 2016 Financial Results

As of December 31, 2016, Syndax had cash, cash equivalents and short-term investments of $105.3 million and 18,223,723 shares issued and outstanding.

Fourth quarter 2016 research and development expenses increased to $8.5 million from $2.6 million for the comparable period in the prior year. Research and development expenses for the year ended December 31, 2016 increased to $31.7 million compared to $9.5 million for the prior year. These increases were primarily due to increased patient accrual costs in E2112, higher expenses associated with the Phase 2 expansion of ENCORE 601, and the commencement of ENCORE 602 as well as the upfront payment related to expanding the pipeline with SNDX-6352 and initiation of a Phase 1 trial.

General and administrative expenses totaled $3.0 million during the fourth quarter of 2016 and $13.3 million for the year, similar to the $2.4 million and $11.6 million expense level for the respective prior year periods.

For the three months ended December 31, 2016, Syndax reported a net loss attributable to common stockholders of $10.8 million or $0.59 per share compared to $8.8 million or $105.57 per share for the comparable prior year period. For the year ended December 31, 2016, Syndax reported a net loss attributable to common stockholders of $47.1 million or $3.22 per share, compared to $103.8 million or $1,519.27 per share for the prior year period.

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 2, 2017.

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: 63366789
Domestic Dial-in Number: 1-855-251-6663
International Dial-in Number: 281-542-4259
Live webcast: http://edge.media-server.com/m/p/6txfuwhh

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 is a clinical stage biopharmaceutical company focused on developing an innovative pipeline of combination therapies in multiple cancer indications. Our lead product candidate, entinostat, which was granted Breakthrough Therapy designation by the FDA following positive results from our Phase 2b clinical trial, ENCORE 301, is currently being evaluated in a Phase 3 clinical trial for advanced hormone receptor positive, human epidermal growth factor receptor 2 negative breast cancer. Syndax is developing entinostat, which has direct effects on both cancer cells and immune regulatory cells, and SNDX-6352, an anti-CSF-1R monoclonal antibody, to enhance the body's immune response on tumors that have shown sensitivity to immunotherapy. Entinostat is being evaluated as a combination therapeutic in Phase 1b/2 clinical trials with Merck & Co., Inc. for non-small cell lung cancer and melanoma; with Genentech, Inc. for TNBC; and with Pfizer Inc. and Merck KGaA, Darmstadt, Germany, for ovarian cancer. SNDX-6352 is being evaluated in a single ascending dose Phase 1 clinical trial and is expected to be developed to treat a variety of cancers. For more information on Syndax, please visit www.syndax.com.

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, and the potential use of SNDX-6352 to treat various cancer indications. 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 PHARMACEUTICALS, INC.
(unaudited)
CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31,	
(In thousands)	**2016**	**2015**
Cash, cash equivalents, and short-term investments	$ 105,330	$ 86,489
Total assets	$ 109,013	$ 89,903
Total liabilities	$ 24,874	$ 23,205
Total stockholders' equity (deficit)	$ 84,139	$ (252,415)
Common stock outstanding	18,223,723	100,124
Common stock and common stock equivalents*	21,142,300	15,856,356
*Common stock and common stock equivalents:		
Common stock	18,223,723	100,124
Convertible preferred stock	-	12,872,551
Options to purchase common stock	2,560,737	2,606,195
Common stock warrants	357,840	277,486
	21,142,300	15,856,356

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)	**2016**	**2015**	**2016**	**2015**
License fee revenue	$ 305	$ 305	$ 1,220	$ 627
Operating expenses:				
Research and development	8,474	2,587	31,665	9,549
General and administrative	2,972	2,397	13,321	11,591
Total operating expenses	11,446	4,984	44,986	21,140
Loss from operations	(11,141)	(4,679)	(43,766)	(20,513)
Other income (expense), net	326	(584)	(706)	(3,606)
Net loss	$ (10,815)	$ (5,263)	$ (44,472)	$ (24,119)
Net loss attributable to common stockholders	$ (10,815)	$ (8,779)	$ (47,070)	$ (103,845)

Net loss per share attributable to common stockholders--basic and diluted	$ (0.59)	$ (105.57)	$ (3.22)	$ (1,519.27)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	18,193,027	83,157	14,619,716	68,352

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