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

Enrollment of second stage of melanoma cohort in Phase 2 ENCORE 601 trial proceeding ahead of schedule; expected to be completed in the third quarter

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

WALTHAM, Mass., May. 8, 2017 (GLOBE NEWSWIRE) -- Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq:SNDX), a clinical stage biopharmaceutical company developing entinostat and SNDX-6352 in multiple cancer indications, today reported its financial results for the first quarter ended March 31, 2017. In addition, the Company provided a clinical and business update. As of March 31, 2017, Syndax had $92.8 million in cash, cash equivalents and short-term investments.

During the first quarter, the Company continued to advance its ENCORE immuno-oncology clinical programs. The Company reported that enrollment in the second stage of the melanoma cohort in ENCORE 601 is proceeding ahead of schedule, with completion of enrollment expected by the end of the third quarter of 2017. Results for the melanoma cohort from the first stage of ENCORE 601 will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June.

The Company also recently announced the expansion of ENCORE 601, a Phase 2 clinical collaboration with a subsidiary of Merck, known as MSD outside the United States and Canada, to include a cohort of patients with microsatellite stable colorectal cancer who have not previously been treated with an anti-PD-1 (programmed death receptor-1) therapy. These cancers represent about 85% of all colon cancers and have shown minimal response to anti-PD-1 therapy. The expansion was based in part on clinical responses observed in the PD-1 refractory melanoma cohort of ENCORE 601. Enrollment is expected to begin mid-2017.

“Our pipeline of innovative therapeutic candidates for cancer continues to make meaningful progress, and the recent melanoma results, as well as the expansion of ENCORE 601 into colorectal cancer, highlight the potential application of entinostat to a broad range of cancers. We believe the substantial unmet medical need in melanoma patients who have failed treatment with a PD-1 antagonist represents a fast to market opportunity for an effective and well tolerated therapy, and we look forward to presenting updated results from the melanoma cohort of ENCORE 601 at ASCO. In addition, we have secured a Type B meeting with the FDA in late June to discuss the development path for entinostat in melanoma,” said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. “Later this quarter, we anticipate determining whether either of the non-small cell lung cancer cohorts have met the prespecified criteria to advance to the second stage of the trial.”

"Based on updates from the Eastern Cooperative Oncology Group regarding enrollment in the ongoing E2112 Phase 3 registration trial, completion of enrollment and progression free survival analysis are anticipated in the first half of 2018. This trial of entinostat plus exemestane in advanced HR+, HER2- breast cancer is being conducted with ECOG-ACRIN and the National Cancer Institute under a Special Protocol Assessment with the FDA,” said Michael L. Meyers, M.D., Ph.D., Chief Medical Officer of Syndax.

Pipeline Updates

- E2112, the Phase 3 registration trial of entinostat plus exemestane in advanced HR+, HER2- breast cancer is 73% enrolled as of the end of April. The Eastern Cooperative Oncology Group-American College of Radiology Imaging Network (ECOG-ACRIN) Cancer Research Group, the trial sponsor, has now advised that completion of enrollment and progression free survival analysis are anticipated in the first half of 2018, which is an update to the previously communicated guidance of year end of 2017.

- Syndax announced a poster presentation featuring data from the melanoma cohort of ENCORE 601 at the upcoming 2017 ASCO Annual Meeting in Chicago. The poster, titled "ENCORE 601: A phase II study of entinostat (ENT) in combination with pembrolizumab (PEMBRO) in patients with melanoma", will be presented on June 3, 2017 between 1:15-4:45p CT during a Melanoma/Skin Cancers poster session.

- Enrollment in the second stage of the melanoma cohort in ENCORE 601 is proceeding ahead of schedule. The second stage will enroll an additional 21 melanoma patients beyond the initial cohort of 13 patients in stage one. Syndax expects to complete enrollment in the second stage of the melanoma cohort of ENCORE 601 by the end of the third quarter of 2017, with data from the second stage of the trial expected to be presented at a medical congress in the first half of 2018.

- A Type B pre-NDA meeting has been scheduled with the U.S. Food and Drug Administration (FDA) in late June, at which Syndax will seek input on the clinical development of entinostat in patients with advanced melanoma.

- In April, ENCORE 601 was expanded to include a cohort of patients with microsatellite stable colorectal cancer who have not previously been treated with an anti-PD-1 therapy. The cohort will employ a Simon two-stage trial design enrolling 13 patients in the first stage and requiring a minimum of two confirmed objective responses to proceed to the second stage, with a target accrual of 34 patients into the cohort. Syndax expects enrollment in the colorectal cancer cohort of ENCORE 601 to begin mid-2017.

- As previously noted, ENCORE 601 is also enrolling two distinct NSCLC cohorts, those who have not previously received a PD-1 antagonist (cohort 1), and those with NSCLC who have progressed on a PD-1 antagonist (cohort 2). The Company expects to decide whether to expand either or both of the non-small cell lung cancer cohorts into the second stage of the ENCORE 601 trial by the end of the second quarter.

- Enrollment continues on track in the ongoing ENCORE 602 and ENCORE 603 trials, both of which are aimed at exploring the ability of entinostat to enhance the efficacy of checkpoint (PD-L1) inhibitor therapies. ENCORE 602, a Phase 1b/2 clinical trial evaluating the combination of entinostat plus Genentech's PD-L1 inhibitor, TECENTRIQ®, in patients with triple negative breast cancer, is expected to complete enrollment by the end of year. ENCORE 603, a Phase 1b/2 clinical trial evaluating entinostat in combination with Pfizer/Merck KGaA's BAVENCIO® in patients with ovarian cancer, is expected to begin the Phase 2 portion of the trial in the third quarter of 2017.

- Multiple posters highlighting the ability of entinostat to modulate the tumor microenvironment and enhance immunotherapeutic approaches in renal, lung, breast, and pancreatic cancer models were presented at the recent 2017 American Association for Cancer Research Annual Meeting in Washington, D.C.

- Enrollment continues in the Phase 1 single ascending dose (SAD) clinical trial of SNDX-6352 in healthy volunteers to determine the safety, pharmacokinetics and pharmacodynamics of the anti-CSF-1R monoclonal antibody. The Company expects to present data from the ongoing Phase 1 SAD clinical trial of SNDX-6352 at a scientific congress in the fourth quarter of 2017. Syndax also plans to initiate a multiple ascending dose (MAD) trial in cancer patients in the third quarter of 2017.

Syndax Expects to Participate in the Following Upcoming Investor Conferences

- UBS Global Healthcare Conference, May 22-24, 2017 in New York

- JMP Securities Life Sciences Conference, June 20-21, 2017 in New York

First Quarter 2017 Financial Results

As of March 31, 2017, Syndax had cash, cash equivalents and short-term investments of $92.8 million and 18,244,917 shares issued and outstanding.

First quarter 2017 research and development expenses increased to $9.6 million from $4.8 million for the comparable period in the prior year. The increase was primarily due to increased clinical trial activities of $3.4 million, employee compensation expense of $0.8 million, legal and consultant expenses of $0.5 million and facility costs of $0.1 million.

General and administrative expenses totaled $3.9 million during the first quarter of 2017 compared with $4.3 million in the comparable period in the prior year. The decrease in general and administrative expenses was primarily due to a decrease in employee compensation of $0.7 million partially offset by increases in consulting expenses and other costs related to being a public company of $0.3 million. The decrease in employee compensation of $0.7 million was primarily due to decreases in non-cash stock-based compensation of $0.9 million and bonus expense of $0.2 million, partially offset by an increased salary expense of $0.3 million due to increased headcount.

For the three months ended March 31, 2017, Syndax reported a net loss attributable to common stockholders of $13.0 million, or $0.71 per share, compared to $12.9 million, or $2.85 per share, for the comparable prior year period.

Financial Guidance

Today the Company provided operating expense guidance for the second quarter and full year 2017. For the second quarter and full year 2017, research and development expenses are expected to be $11.0 – $13.0 million and $52.0 - $57.0 million, respectively, and total operating expenses are expected to be $15.0 – $17.0 million and $68.0 - $73.0, 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, May 8, 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: 8354328
Domestic Dial-in Number: 1-855-251-6663
International Dial-in Number: 281-542-4259
Live webcast: http://edge.media-server.com/m/p/b3dado7a

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 developing an innovative pipeline of cancer therapies. 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. Given its potential ability to block the function of immune suppressive cells in the tumor microenvironment, entinostat is also being evaluated in combination with approved PD-1 antagonists. Ongoing Phase 1b/2 clinical trials combine entinostat with KEYTRUDA® from Merck & Co., Inc. for non-small cell lung cancer and melanoma; with TECENTRIQ® from Genentech, Inc. for TNBC; and with BAVENCIO™ from Pfizer Inc. and Merck KGaA, Darmstadt, Germany, for ovarian cancer. Our second product candidate, SNDX-6352, is a monoclonal antibody that blocks the CSF-1 receptor and may also block the function of immune suppressive cells in the tumor microenvironment. 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.

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 our product candidates 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

(In thousands)	March 31, 2017	December 31, 2016
ASSETS		
Cash, cash equivalents, and short-term investments	$ 92,785	$ 105,330
Other assets	4,882	3,683
Total assets	$ 97,667	$ 109,013
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	$ 10,989	$ 10,366
Deferred revenue, less current portion	13,915	14,220
Other liabilities	148	288
Total liabilities	25,052	24,874
Total stockholders' equity	72,615	84,139
Total liabilities and stockholders' equity	$ 97,667	$ 109,013

SYNDAX PHARMACEUTICALS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
(In thousands, except share and per share data)	2017	2016
License fee revenue	$ 305	$ 305
Operating expenses:		
Research and development	9,552	4,786
General and administrative	3,930	4,272
Total operating expenses	13,482	9,058
Loss from operations	(13,177)	(8,753)
Other income (expense), net	206	(1,577)
Net loss	$ (12,971)	$ (10,330)
Net loss attributable to common stockholders	$ (12,971)	$ (12,928)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.71)	$ (2.85)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	18,231,602	4,541,536

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