Syndax Pharmaceuticals Reports First Quarter 2019 Financial Results and Provides Clinical and Business Update

– E2112 trial passes fourth interim analysis for OS; trial to continue, with next preplanned analysis expected in 4Q19 –

– IND filing for targeted menin inhibitor SNDX-5613 on track for 2Q19 –

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

WALTHAM, Mass., May 6, 2019 (PRNEWSWIRE) -- Syndax Pharmaceuticals, Inc. (Nasdaq: SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today reported its financial results for the first quarter ended March 31, 2019. In addition, the Company provided a clinical and business update. As of March 31, 2019, Syndax had $92.7 million in cash, cash equivalents and short-term investments.

“We are pleased to report that E2112, our Phase 3 registration trial of entinostat plus exemestane in HR+, HER2- breast cancer, has passed its fourth interim overall survival analysis,” said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. “E2112 was designed to replicate the compelling overall survival results obtained in the Phase 2b ENCORE 301 trial which led to Breakthrough Therapy designation. The next overall survival assessment is expected in the fourth quarter of this year. We remain confident in the potential that the addition of entinostat to exemestane will result in a positive survival benefit, which would allow us to file for full regulatory approval in this indication.”

Dr. Morrison added, “We also look forward to filing an IND for SNDX-5613, our targeted menin inhibitor, later this quarter. Supported by a robust preclinical dataset, we believe this therapeutic class has the potential to make a meaningful impact for patients with genetically-defined acute leukemias for whom limited effective therapies exist.”

Pipeline Updates

Entinostat

ECOG-ACRIN has informed the Company that following its fourth preplanned interim overall survival (OS) analysis, the E2112 trial will continue as planned until either an OS benefit is observed, or the final target number of events occur. E2112 is Syndax’s 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. The next interim analysis for the OS endpoint is scheduled for 4Q19, with a final OS assessment, if necessary, to be conducted in 2Q20. 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.

At the American Association of Cancer Research (AACR) Annual Meeting held March 29 - April 3, 2019, Syndax presented data from the non-small cell lung cancer (NSCLC) and melanoma cohorts of the ENCORE 601 trial of entinostat in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy. These data provided further evidence that the addition of entinostat to pembrolizumab may overcome resistance to immunotherapy in melanoma and NSCLC patients whose disease progressed on or after anti-PD-1 therapy. As the Company has previously indicated, following availability of positive E2112 OS results, it will determine whether to advance its entinostat-PD-1 combination programs into one or more registration trials.

SNDX-5613

Syndax continues to expect to file an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for its targeted menin inhibitor, SNDX-5613, later this quarter, with the initiation of a Phase 1 clinical trial in a defined subset of acute leukemia patients expected to follow shortly thereafter.

SNDX-6352

The Company continues to anticipate initial results from the Phase 1 dose escalation trial of SNDX-6352, Syndax'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.

First Quarter 2019 Financial Results

As of March 31, 2019, Syndax had cash, cash equivalents and short-term investments of $92.7 million and 31.6 million shares and share equivalents issued and outstanding.

In March 2019, Syndax issued 4.5 million shares of its common stock and prefunded warrants at an offering price of $6.00, as well as warrants to purchase up to 4.5 million shares of its common stock, with half at an exercise price of $12.00 per share and the remaining half at an exercise price of $18.00 per share. As a result of the offering, Syndax received aggregate net proceeds of approximately $27.4 million.

First quarter 2019 research and development expenses decreased to $11.3 million from $15.3 million. The first quarter decrease was primarily due to reduced CMC activities and decreased clinical activities.

General and administrative expenses for the first quarter 2019 decreased to $3.9 million from $4.8 million. The decrease was primarily due to decreased pre-commercialization expenses and decreased professional fees.

For the three months ended March 31, 2019, Syndax reported a net loss attributable to common stockholders of $14.3 million or $0.53 per share compared to $19.4 million or $0.79 per share for the prior year period.

Financial Guidance

Today the Company provided operating expense guidance for the second quarter and full year 2019. For the second quarter and full year 2019, research and development expenses are expected to be $9 to $10 million and $46 to $50 million, respectively, and total operating expenses are expected to be $13 to $14 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, Monday, May 6, 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: 4292817
Domestic Dial-in Number: 855-251-6663
International Dial-in Number: 281-542-4259
Live Webcast: https://edge.media-server.com/m6/p/2ahgcwxy

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 has evaluated it in combination with 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 second quarter and full-year 2019 net cash used in research and development and operating activities; and the amount of Syndax's cash, cash equivalents and marketable securities at the end of 2019. 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)	March 31, 2019	December 31, 2018
Cash, cash equivalents, short-term and long-term investments	$ 92,742	$ 80,911
Total assets	$ 99,392	$ 83,938
Total liabilities	$ 30,766	$ 30,891
Total stockholders' equity (deficit)	$ 68,626	$ 53,047
Common stock outstanding	27,095,779	24,835,951
Common stock and common stock equivalents*	41,819,938	31,088,934
*Common stock and common stock equivalents:		
Common stock	27,095,779	24,835,951
Common stock warrants (pre-funded)	4,500,000	2,000,000
Common stock and pre-funded stock warrants	31,595,779	26,835,951
Options to purchase common stock	5,629,120	4,252,983
Common stock warrants (series 1 and 2)	4,595,039	-
Total common stock and common stock equivalents	41,819,938	31,088,934

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(unaudited)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)	Three Months Ended March 31, 2019	2018
License fee revenue	$ 379	$ 379
Operating expenses:		
Research and development	11,279	15,339
General and administrative	3,911	4,791
Total operating expenses	15,190	20,130
Loss from operations	(14,811)	(19,751)
Other income, net	509	353
Net loss	$ (14,302)	$ (19,398)
Net loss attributable to common stockholders	$ (14,302)	$ (19,398)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.53)	$ (0.79)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	27,023,466	24,478,269

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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