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

November 7, 2019

- E2112 trial passed final interim OS analysis; trial continues, with final OS analysis expected in 2Q20 -

- First patient dosed in Phase 1/2 AUGMENT-101 trial of SNDX-5613, Company's highly selective Menin inhibitor, for treatment of MLL-rearranged acute leukemias and NPM1-mutant AML -

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

WALTHAM, Mass., Nov. 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 third quarter ended September 30, 2019. In addition, the Company provided a clinical and business update. As of September 30, 2019, Syndax had $72.2 million in cash, cash equivalents and short-term investments.

"We are pleased to have passed the final interim futility analysis of overall survival for E2112, our Phase 3 registration trial of entinostat plus exemestane in HR+, HER2- breast cancer, and anticipate the final overall survival readout in the second quarter of 2020," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "Supported by highly compelling survival data from the Phase 2b ENCORE 301 trial, leading to Breakthrough Therapy designation for entinostat in HR+ breast cancer, we believe the combination of entinostat and exemestane has the potential to improve outcomes for patients with this difficult to treat disease."

Pending a positive overall survival (OS) assessment in E2112, Syndax intends to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for entinostat plus exemestane for the treatment of HR+, HER2- breast cancer.

Dr. Morrison added, "Beyond entinostat, patient dosing is now underway in the Phase 1/2 open-label AUGMENT-101 trial of SNDX-5613, our potent, highly selective, oral Menin inhibitor, in adults with relapsed/refractory acute leukemias. We look forward to establishing a safe dose that provides the appropriate target coverage to advance into the Phase 2 portion of the trial. We are committed to bringing this promising therapeutic option to patients, and expect to report initial data from this trial in 2020."

Pipeline Updates

Entinostat

In October 2019, Syndax reported that the E2112 trial passed its fifth and final interim OS analysis. 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 Company continues to anticipate the trial will reach 410 death events in 2Q20, which will trigger the final E2112 OS analysis. A positive OS assessment at that time would enable the Company to file for full regulatory approval in the U.S. 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+ breast cancer, in which patients receiving the entinostat/exemestane combination demonstrated a strong OS benefit.

SNDX-5613

Earlier this week, the Company announced that the first patient has been dosed in the Phase 1/2 open-label AUGMENT-101 trial of orally administered SNDX-5613. The Phase 1 dose escalation portion of AUGMENT-101 will enroll adults with relapsed/refractory acute leukemias, including patients with MLL-rearrangements and NPM1c mutations, and establish a recommended Phase 2 dose. The Phase 2 portion will evaluate efficacy, as defined by Complete Response rate (per International Working Group response criteria), across three expansion cohorts: MLL-rearranged (MLL-r) acute lymphoblastic leukemia (ALL), MLL-r AML and NPM1 mutant AML. The Company expects to report initial clinical data from the trial in 2020.

SNDX-6352

Syndax today announced that the FDA has agreed to a recent request to amend enrollment criteria for its ongoing 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). Consistent with the evolving treatment paradigm for this patient population, the majority of patients will no longer be required to have progressed on prior IMBRUVICA® (ibrutinib) therapy in order to enroll in the study. In addition, the FDA has agreed to expand enrollment to include adolescents.

Enrollment in this trial is ongoing, and Syndax continues to anticipate results in the second half of 2020. The trial is designed to evaluate the safety and preliminary efficacy of SNDX-6352 in cGVHD and to identify a recommended Phase 2 dose and schedule.

Third Quarter 2019 Financial Results

As of September 30, 2019, Syndax had cash, cash equivalents and short-term investments of $72.2 million and 31.6 million shares of common stock and prefunded warrants issued and outstanding.

Third quarter 2019 research and development expenses decreased to $9.9 million from $14.1 million for the prior year period. The decrease was primarily due to decreased activity in the ENCORE and SNDX-6352 clinical programs, decreased CMC activities for SNDX-6352, and decreased professional expenses and stock compensation, partly offset by increased activity in the Menin clinical program.

General and administrative expenses for the third quarter 2019 decreased to $3.6 million from $4.1 million for the prior year period. The decrease was primarily due to decreased legal and professional fees and decreased compensation expenses.

For the three months ended September 30, 2019, Syndax reported a net loss attributable to common stockholders of $12.8 million or $0.41 per share compared to $17.3 million or $0.68 per share for the prior year period.

Financial Guidance

For the fourth quarter and full year 2019, research and development expenses are expected to be $11 to $12 million and $45 to $46 million, respectively, and total operating expenses are expected to be $15 to $16 million and $60 to $62 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, November 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: 9065948
Domestic Dial-in Number: 855-251-6663
International Dial-in Number: 281-542-4259
Live Webcast: https://edge.media-server.com/mmc/p/g4sc7qxz

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's lead product candidate, entinostat, a once-weekly, oral, small molecule, class I HDAC inhibitor, is being tested in a Phase 3 combination trial with exemestane for treatment of advanced HR+, HER2- breast cancer and has been evaluated 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, and SNDX-5613, a highly selective inhibitor of the Menin–MLL binding interaction. 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 operating expense guidance for the fourth quarter and full year 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.

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

(In thousands)	**September 30, 2019**	**December 31, 2018**
Cash, cash equivalents and short-term investments	$ 72,238	$ 80,911
Total assets	$ 76,381	$ 83,938
Total liabilities	$ 32,338	$ 30,891
Total stockholders' equity (deficit)	$ 44,043	$ 53,047
Common stock outstanding	27,140,484	24,835,951
Common stock and common stock equivalents*	42,289,177	31,088,934
*Common stock and common stock equivalents:		
Common stock	27,140,484	24,835,951
Common stock warrants (pre-funded)	4,500,000	2,000,000
Common stock and pre-funded stock warrants	31,640,484	26,835,951
Options to purchase common stock	6,053,654	4,252,983
Common stock warrants (series 1 and 2)	4,595,039	-
Total common stock and common stock equivalents	42,289,177	31,088,934

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except share and per share data)	**2019**	**2018**	**2019**	**2018**
License fee revenue	$ 379	$ 379	$ 1,138	$ 1,138
Operating expenses:				
Research and development	9,923	14,095	33,492	44,286
General and administrative	3,605	4,125	10,980	13,395
Total operating expenses	13,528	18,220	44,472	57,681
Loss from operations	(13,149)	(17,841)	(43,334)	(56,543)
Other income, net	320	503	1,287	1,419
Net loss	$ (12,829)	$ (17,338)	$ (42,047)	$ (55,124)
Net loss attributable to common stockholders	$ (12,829)	$ (17,338)	$ (42,047)	$ (55,124)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.41)	$ (0.68)	$ (1.40)	$ (2.21)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	31,630,639	25,471,587	30,103,338	24,888,738

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