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

- Final OS analysis for Phase 3 E2112 trial in HR+, HER2- metastatic breast cancer expected in 2Q20; potential NDA filing later this year -

- Phase 1 data presentation from AUGMENT-101 trial of SNDX-5613 in acute leukemias expected 4Q20; potential for interim results throughout 2020 -

- SNDX-6352 granted generic name axatilamab; presentation of additional cGVHD results expected 4Q20 -

- 1Q 2020 financings of $55 million extend cash runway into 2021, through all key milestones -

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

WALTHAM, Mass., March 3, 2020 -- 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, 2019. In addition, the Company provided a clinical and business update. As of December 31, 2019, Syndax had $59.8 million in cash, cash equivalents and short-term investments.

“With meaningful data readouts expected for each of our innovative pipeline candidates aimed at addressing unmet need in some of the most underserved patient populations, 2020 is poised to be an exciting and transformative year for the Company,” said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. “Of note, this includes the final overall survival readout from E2112, our Phase 3 registration trial of entinostat plus exemestane in HR+, HER2- breast cancer, in the second quarter of this year. Supported by the compelling overall survival benefit observed in the Phase 2b ENCORE 301 trial, we believe the combination of entinostat and exemestane has strong potential to serve as a much-needed option in a setting for which existing therapies are inadequate. We remain on track to file for the regulatory approval of entinostat in HR+ breast cancer by year end, with a potential launch expected in 2021, positioning us as a fully-integrated oncology company.”

Dr. Morrison added, “In 2020, we also expect to present the first clinical data from the AUGMENT-101 trial of SNDX-5613, our oral Menin inhibitor, in adults with relapsed/refractory acute leukemias. Supported by a robust body of preclinical data, including two recently published articles in *Cancer Cell* and *Science* magazine, we believe SNDX-5613 has the potential to serve as an effective intervention for both NPM1 mutant AML and MLL-r acute leukemias. A presentation of additional results from our ongoing Phase 1/2 trial of axatilamab, our anti-CSF-1R monoclonal antibody in patients with cGVHD, is also anticipated in the fourth quarter of this year.”

Pipeline Updates

Entinostat

Syndax continues to anticipate that the E2112 trial will reach 410 death events in the second quarter of 2020, which will trigger the final overall survival (OS) analysis. E2112 is the Company'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. A positive OS assessment would allow 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 clinically meaningful OS benefit over treatment with exemestane alone. In preparation for the potential launch of entinostat in the U.S. in 2021, the Company is actively engaged in the expansion of its commercial and medical affairs functions.

SNDX-5613

Syndax recently announced two preclinical publications in *Cancer Cell* and *Science* magazine supporting the potential for inhibitors of the MLL1-Menin interaction to serve as a treatment of acute leukemia patients with mixed lineage leukemia rearranged (MLL-r) or nucleophosmin (NPM1) mutations. These findings provide additional support for the Company's ongoing AUGMENT-101 trial, a Phase 1/2 open-label trial of SNDX-5613, the Company's potent, highly selective oral Menin inhibitor, in adults with relapsed/refractory acute leukemias, including MLL-r acute lymphoblastic leukemia (ALL), MLL-r acute myeloid leukemia (AML) and NPM1 mutant AML.

Enrollment is ongoing in the Phase 1 dose escalation portion of AUGMENT-101. Following completion of the Phase 1 portion of the trial, which will 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-r ALL, MLL-r AML, and NPM1 mutant AML.

As previously communicated, the Company anticipates presenting initial clinical data from AUGMENT-101 at a medical conference in the fourth quarter of 2020. Due to the open-label nature of the trial, meaningful interim data, including pharmacokinetic, pharmacodynamic and efficacy data, may be available earlier in the year.

Axatilamab (SNDX-6352)

Enrollment of patients to the Phase 2 expansion cohort of axatilamab, the Company's anti-CSF-1R monoclonal antibody, for the treatment of chronic graft versus host disease (cGVHD) is underway. The decision to move to the Phase 2 expansion was driven by recently reported encouraging proof of concept results from the Phase 1 portion of the trial, in which responses were observed in all evaluable patients as of the data cutoff date, with no dose limiting toxicities reported.

The Phase 2 expansion cohort is expected to enroll up to 22 patients to further characterize the safety and efficacy of 1.0 mg/kg of axatilamab administered every two weeks. The Company expects to present additional results from the Phase 1/2 trial in the fourth quarter of 2020.

Syndax

Fourth Quarter 2019 Financial Results

As of December 31, 2019, Syndax had cash, cash equivalents and short-term investments of $59.8 million and 31.6 million shares issued and outstanding, which includes 27.1 million shares of common stock and pre-funded warrants to purchase 4.5 million shares of common stock.

Fourth quarter 2019 research and development expenses decreased to $9.5 million from $15.8 million, and for the full year decreased to $43.0 million compared to $60.1 million for 2018. The fourth quarter and full year decreases were primarily due to decreased clinical trial activities and professional fees.

General and administrative expenses for the fourth quarter 2019 increased to $5.1 million from $3.9 million, and, for the year ended December 31, 2019, decreased to $16.1 million compared to $17.3 million for the prior year. The fourth quarter increase is primarily due to increased pre-commercialization expenses. The decrease for the full year was primarily due to decreased professional fees and legal spending.

For the three months ended December 31, 2019, Syndax reported a net loss attributable to common stockholders of $14.0 million or $0.44 per share compared to $18.8 million or $0.70 per share for the prior year period. For the year ended December 31, 2019, Syndax reported a net loss attributable to common stockholders of $56.0 million or $1.84 per share, compared to $74.0 million or $2.92 per share for the prior year.

Financial Update and Guidance

In February 2020, Syndax issued 3,036,719 shares of its common stock and 1,338,287 pre-funded warrants to purchase common stock at $8.00 per share, representing a premium of 20% to the share price at market close on Thursday, January 30, 2020. As a result of the offering, Syndax received net proceeds of approximately $35.0 million. Following the offering, as of March 3, 2020, shares outstanding totaled 36.0 million, including 30.2 million shares of common stock and pre-funded warrants to purchase 5.8 million shares of common stock.

In February 2020 the Company entered into an agreement with Hercules Capital, Inc. (NYSE: HTGC) for a term loan of up to $30.0 million, consisting of an initial tranche of $20.0 million that was funded at the closing with the potential for a second tranche of $10.0 million subject to satisfaction of certain terms and conditions. Including the $35 million of proceeds from the equity offering and the $20 million draw of the term loan, our year-end cash of $60 million has been supplemented by this additional $55 million.

Today, the Company provided operating expense guidance for the first and second quarters of 2020. Financial guidance for the second half of 2020 will be issued after we get the result of the E2112 study. We expect our operating expenses for the first two quarters of 2020 to increase over the quarterly operating expenses we reported for the second half of 2019. R&D expenses will increase, primarily due to increased development activities for SNDX-5613, our menin inhibitor, and for axatilamab. G&A expenses will increase, primarily due to increased entinostat pre-commercial activities. For each of the first and second quarters of 2020, research and development expenses are expected to be $12 to $14 million, and total operating expenses are expected to be $17 to $19 million. Given our cash operating expense guidance, we expect to end

the second quarter of 2020 with more than $80 million of cash, which gives us the financial flexibility to take advantage of key development milestones well into 2021.

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, Tuesday, March 3.

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: 2786075
Domestic Dial-in Number: (855) 251-6663
International Dial-in Number: (281) 542-4259
Live webcast: https://edge.media-server.com/mmc/p/xxe75xdw

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, Syndax's fourth quarter and full-year 2019 net cash used in research and development and total operating activities, and first quarter and full year 2020 operating expense and cash guidance. 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

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

(In thousands)	December 31, 2019	2018
Cash, cash equivalents, short-term investments	$ 59,775	$ 80,911
Total assets	$ 63,525	$ 83,938
Total liabilities	$ 31,925	$ 30,891
Total stockholders' equity (deficit)	$ 31,600	$ 53,047
Common stock outstanding	27,140,484	24,835,951
Common stock and common stock equivalents*	37,697,495	31,088,934
*Common stock and common stock equivalents:		
Common stock	27,140,484	24,835,951
Options to purchase common stock	6,057,011	4,252,983
Series 1 and 2 warrants	4,595,039	-
Pre-funded warrants	4,500,000	2,000,000
	37,697,495	31,088,934

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

(In thousands, except share and per share data)	Three Months Ended December 31, 2019	2018	Year Ended December 31, 2019	2018
License fee revenue	$ 380	$ 380	$ 1,517	$ 1,517
Operating expenses:				
Research and development	9,502	15,821	42,994	60,106
General and administrative	5,083	3,892	16,062	17,287
Total operating expenses	14,585	19,713	59,056	77,393
Loss from operations	(14,205)	(19,333)	(57,539)	(75,876)
Other income (expense), net	205	496	1,492	1,915
Net loss	$ (14,000)	$ (18,837)	$ (56,047)	$ (73,961)
Net loss attributable to common stockholders	$ (14,000)	$ (18,837)	$ (56,047)	$ (73,961)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.44)	$ (0.70)	$ (1.84)	$ (2.92)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	31,640,484	26,804,089	30,490,783	25,371,511

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