Syndax Pharmaceuticals Reports First Quarter 2020 Financial Results and Provides Clinical and Business Update

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

- Preliminary Phase 1 results from AUGMENT-101 trial of menin inhibitor SNDX-5613 represent first clinical evidence that inhibition of the menin-MLL1 interaction can induce response in patients with MLL-r acute leukemias –

- Recently completed a follow-on offering with net proceeds of $93.7M -

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

WALTHAM, Mass., May 7, 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 first quarter ended March 31, 2020. In addition, the Company provided a clinical and business update.

“During the first quarter, we generated significant momentum that we believe will take us through what we expect will be a transformational year for Syndax, with key data readouts expected across the entirety of our portfolio,” said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. “We continue to anticipate the final overall survival readout from E2112, our Phase 3 registration trial of entinostat plus exemestane in HR+, HER2- breast cancer later this quarter, with a potential regulatory filing for entinostat in HR+ breast cancer by year end. 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. While we await this final readout, we remain focused on preparations to establish ourselves as a fully integrated oncology company, with a potential launch expected in 2021.”

Dr. Morrison added, “Beyond entinostat, we were pleased to recently announce initial Phase 1 data from the AUGMENT-101 trial of SNDX-5613, our oral menin inhibitor, in adults with relapsed/refractory acute leukemias. These data provide the first clinical evidence that inhibition of the menin-MLL1 interaction can induce response in patients with MLL-r acute leukemias. We believe that SNDX-5613 has great potential to serve as an effective intervention for both MLL-r acute leukemias and NPM1 mutant AML, and we look forward to presenting additional data from this trial in the fourth quarter of this year. With a strong balance sheet, which includes proceeds from our recent follow-on offering, we believe we are well positioned to execute on upcoming milestones.”

Pipeline Updates

Entinostat

- Syndax continues to anticipate that the E2112 trial will reach 410 death events this quarter, 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 initial clinical data from the Phase 1 portion of its ongoing open-label Phase 1/2 AUGMENT-101 trial of SNDX-5613, the Company's potent, highly selective oral menin inhibitor. Data presented serve as the first clinical evidence that inhibition of the menin-MLL1 interaction can induce response in patients with mixed lineage leukemia rearranged (MLL-r) acute leukemias. The presentation, which was featured at the 2020 American Association for Cancer Research (AACR) Virtual Annual Meeting I, also highlighted preclinical findings, including data recently published in Cancer Cell and Science magazine, supporting the potential of single-agent menin-MLL inhibition to serve as an effective intervention for both MLL-r acute leukemias and nucleophosmin (NPM1) mutant acute myeloid leukemia (AML). A copy of the presentation is available on Syndax's website under Publications, Menin-MLLR Inhibitors.

  The AUGMENT-101 trial is a Phase 1/2 open-label trial designed to evaluate the safety, tolerability, pharmacokinetics and efficacy of orally administered SNDX-5613. The Phase 1 dose escalation portion of AUGMENT-101 was recently separated into two cohorts based on concomitant treatment with a strong CYP3A4 inhibitor. Arm A will enroll patients not receiving a strong CYP3A4 inhibitor, while Arm B will enroll patients receiving a strong CYP3A4 inhibitor. The Phase 1 dose escalation portion of AUGMENT-101 is currently enrolling adults with relapsed/refractory acute leukemias including MLL-r and NPM1 mutant acute leukemias and is expected to establish a recommended Phase 2 dose for both cohorts by the fourth quarter of 2020. 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 acute lymphoblastic leukemia (ALL), MLL-r AML and NPM1 mutant AML. The Company expects to present additional results from AUGMENT-101 at a medical conference in the fourth quarter of 2020.

- The Company recently announced that SNDX-5613 was granted Orphan Drug Designation for the treatment of adult and pediatric AML by the FDA.

Axatilimab

- Enrollment continues across the Company’s Phase 1/2 trial evaluating axatilimab, its anti-CSF-1R monoclonal antibody, for the treatment of chronic graft versus host disease (cGVHD). The Phase 1 portion continues to explore alternate dose and schedules, while the Phase 2 expansion is evaluating the benefit of treatment at 1 mg/kg every two weeks.

The Company expects to present additional results from the Phase 1/2 trial in the fourth quarter of 2020.

- Data from the Phase 1 trials exploring axatilimab, both as a monotherapy and in combination with IMFINZI® (durvalumab) in patients with locally-advanced or metastatic solid tumors, were summarized in two oral presentations at the AACR Virtual Annual Meeting I. The data indicate that axatilimab is tolerated well in solid tumor patients and provide evidence of its ability to deplete circulating pro-inflammatory monocytes. A recommended Phase 2 dose of axatilimab for the treatment of patients with solid tumors was determined as monotherapy and in combination with IMFINZI® (durvalumab). A copy of each presentation is available on Syndax's website under Publications, Axatilimab.

Financial Update and Guidance

As of March 31, 2020, Syndax had cash, cash equivalents and short-term investments of $99.0 million and 36.1 million shares and share equivalents issued and outstanding which included 30.2 million shares of common stock and pre-funded warrants to purchase 5.8 million shares of common stock.

In May 2020, Syndax closed an underwritten public offering whereby the Company sold 5,555,556 shares of common stock at a price of $18.00 per share. The aggregate net proceeds received by the Company were $93.7 million, net of underwriting discounts and commissions and estimated offering expenses payable by the Company. The offering allows for an additional 833,333 shares to be issued pursuant to the underwriters' exercise of their option to purchase additional shares of common stock.

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 $34.9 million.

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

First quarter 2020 research and development expenses decreased to $9.6 million from $11.3 million for the prior year period. The first quarter decrease was primarily due to reduced CMC activities and a net decrease in clinical activities.

General and administrative expenses for the first quarter 2020 increased to $5.9 million from $3.9 million for the prior year period. The increase was primarily due to increased pre-commercialization expenses and increased employee related expenses.

For the three months ended March 31, 2020, Syndax reported a net loss attributable to common stockholders of $19.1 million or $0.56 per share compared to $14.3 million or $0.53 per share for the prior year period.

Financial Guidance

Today the Company provided operating expense guidance for the second quarter of 2020. Financial guidance for the second half of 2020 will be issued after the Company announces the result of the E2112 study. The Company expects operating expenses for the second quarter of 2020 to increase over the quarterly operating expenses reported for the first quarter of 2020. Research and development (R&D) expenses will increase, primarily due to increased development activities for SNDX-5613. Second quarter G&A expenses are expected to be similar to the first quarter G&A expenses. For the second quarter of 2020, R&D expenses are expected to be $12 to $14 million, and total operating expenses are expected to be $18 to $20 million. Given its cash operating expense guidance, the Company expects to end the second quarter of 2020 with approximately $175 million of cash, which provides the financial flexibility to take advantage of key development milestones.

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, May 7, 2020.

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: 5579109
Domestic Dial-in Number: (855) 251-6663
International Dial-in Number: (281) 542-4259
Live webcast: https://edge.media-server.com/mmc/p/pnyq8m58

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 axatilimab (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 expected second quarter research and development expenses, and expected total operating expenses. 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, the COVID-19 pandemic may disrupt our business and that of the third parties on which we depend, including delaying or otherwise disrupting our clinical trials and preclinical studies, manufacturing and supply chain, or impairing employee productivity, , 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, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 99,005	$ 59,775
Total assets	$ 105,155	$ 63,525
Total liabilities	$ 51,646	$ 31,925
Total stockholders' equity (deficit)	$ 53,509	$ 31,600
Common stock outstanding	27,140,484	27,140,484
Common stock and common stock equivalents*	47,571,966	42,292,534
*Common stock and common stock equivalents:		
Common stock	30,240,838	27,140,484
Common stock warrants (pre-funded)	5,838,287	4,500,000
Common stock and pre-funded stock warrants	36,079,125	31,640,484
Options to purchase common stock	6,897,802	6,057,011
Series 1 and 2 warrants	4,595,039	4,595,039
Total common stock and common stock equivalents	47,571,966	42,292,534

SYNDAX PHARMACEUTICALS, INC.

(unaudited)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)	Three Months Ended March 31, 2020	2019
License fee revenue	$ 379	$ 379
Operating expenses:		
Research and development	9,562	11,279
General and administrative	5,917	3,911
Total operating expenses	15,479	15,190
Loss from operations	(15,100)	(14,811)
Other (expense) income, net	(136)	509
Net loss	$ (15,236)	$ (14,302)
Net loss attributable to common stockholders	$ (19,142)	$ (14,302)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.56)	$ (0.53)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	34,328,640	27,023,466

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