Syndax Pharmaceuticals Reports Fourth Quarter 2021 Financial Results and Provides Clinical and Business Update

March 1, 2022

- Enrollment remains on track for pivotal programs of SNDX-5613 and axatilimab; topline data expected starting in 1H23 -

- Initiation of three new trials of SNDX-5613 in NPM1 and MLLr acute leukemias, including in the first-line and maintenance settings, expected in 1H22 -

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

WALTHAM, Mass., March 1, 2022 /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 fourth quarter ended December 31, 2021. In addition, the Company provided a clinical and business update.

"2021 was marked by substantial progress advancing our pipeline of novel cancer therapies, including the initiation of our two pivotal programs for which we expect to report topline data starting in the first half of 2023," said Michael A. Metzger, Chief Executive Officer. "We believe SNDX-5613 is poised to serve as a first-to-market and best-in-class menin inhibitor for patients with genetically defined acute leukemias. With our first regulatory filing for SNDX-5613 expected in 2023, we are keenly focused on laying the groundwork for the potential commercial launch, while concurrently expanding into the frontline and maintenance settings, with three new trials expected to begin in the first half of this year."

Mr. Metzger continued, "Enrollment remains on track in our global pivotal Phase 2 AGAVE-201 trial of axatilimab in chronic graft-versus-host disease (cGVHD), with topline data expected in the first half of 2023 and a potential Biologic License Application (BLA) filing in 2023. Beyond cGVHD, we are also working to unlock axatilimab's full potential in additional fibrotic diseases where the monocyte-macrophage lineage plays a vital role, with commencement of a Phase 2 trial in idiopathic pulmonary fibrosis (IPF) expected in the fourth quarter of this year."

Recent Pipeline Progress and Anticipated Milestones

SNDX-5613

- During an oral presentation at the 63rd American Society of Hematology (ASH) Annual Meeting in December 2021, the Company reported positive data demonstrating continued robust clinical activity with durable responses in the Phase 1 portion of the AUGMENT-101 trial of SNDX-5613, the Company's highly selective oral menin inhibitor, in relapsed/refractory (R/R) patients with mutant nucleophosmin (NPM1) or mixed lineage leukemia rearranged (MLLr) acute leukemias.
- The pivotal Phase 2 portion of AUGMENT-101 is ongoing and the Company expects to complete enrollment in at least one of the three pivotal cohorts later this year. The trials are expected to enroll a total of 64 adult and up to 10 pediatric patients across each of three distinct trial populations: patients with NPM1 mutant acute myeloid leukemia (AML), patients with MLLr AML, and patients with MLLr acute lymphocytic leukemia (ALL). Based on discussions with the U.S. Food and Drug Administration (FDA), AUGMENT-101 may serve as the basis for regulatory filings in each of the three distinct populations. The Company expects to receive initial topline data from the trials starting in the first half of 2023, with the potential for the first NDA filing in 2023.
- In December 2021, the Company announced that the European Commission granted Orphan Drug Designation (ODD) to SNDX-5613 for the treatment of AML. SNDX-5613 was previously granted ODD for the treatment of adult and pediatric AML by the U.S. FDA.
- The Company expects to initiate three additional trials in the first half of 2022 to assess the safety, tolerability, and preliminary anti-leukemic efficacy of SNDX-5613 in combination with venetoclax and azacitidine as part of the Leukemia & Lymphoma Society's Beat® AML Master Clinical Trial, in combination with chemotherapy in patients with R/R NPM1 or MLLr acute leukemias in the AUGMENT-102 trial, and in NPM1 or MLLr patients with measurable residual disease progression following initial treatment as part of the Australian Leukemia and Lymphoma Group (ALLG) INTERCEPT Master Clinical Trial.

Axatilimab

- In December 2021, the Company reported updated positive data demonstrating broad activity and tolerability of axatilimab, its anti-CSF-1R monoclonal antibody, in a Phase 1/2 trial in patients with cGVHD. The data were presented during an oral session at the 63rd ASH Annual Meeting.
- Enrollment is ongoing in the Company's global pivotal Phase 2 AGAVE-201 trial of axatilimab in patients with cGVHD, with topline data expected in the first half of 2023. The trial is evaluating the safety and efficacy of three doses and schedules of axatilimab. The primary endpoint will assess objective response rate based on the 2014 NIH consensus criteria for cGVHD, with key secondary endpoints including duration of response and improvement in modified Lee Symptom Scale score. Topline data from the trial are expected in the first half of 2023, with the potential for a BLA filing in 2023.
- In December 2021, Syndax and Incyte closed its previously announced exclusive worldwide collaboration and license

agreement to develop and commercialize axatilimab. Closing of the agreement triggered a $117 million upfront payment by Incyte to Syndax, as well as Incyte's $35 million equity investment in Syndax.

Corporate Updates

- Earlier today, the Company announced the appointment of Kate Madigan, M.D., as Chief Medical Officer. Dr. Madigan brings to Syndax over 20 years of clinical hematology expertise and broad experience in the design and execution of early to late-stage clinical programs across oncology and rare diseases.
- In February 2022, the Company announced the transition of Michael A. Metzger to the role of Chief Executive Officer and Briggs W. Morrison, M.D., to President, Head of Research and Development. Mr. Metzger and Dr. Morrison, who both serve on the Company's Board of Directors, joined Syndax together in 2015.

Fourth Quarter 2021 Financial Results

As of December 31, 2021, Syndax had cash, cash equivalents and short-term investments of $439.9 million and 59.0 million shares and share equivalents issued and outstanding. This includes 4.0 million pre-funded warrants.

Fourth quarter 2021 research and development expenses increased to $23.9 million from $15.5 million, and for the full year increased to $88.2 million compared to $50.4 million for 2020. The fourth quarter and full year increases were primarily due to increased clinical trial and CMC activities.

General and administrative expenses for the fourth quarter 2021 increased to $6.9 million from $4.7 million, and, for the year ended December 31, 2021, increased to $25.2 million compared to $22.5 million for the prior year. The fourth quarter and full year increases were primarily due to increased professional fees and employee related expenses.

License revenue for the fourth quarter 2021 increased to $126.6 million from $0.4 million, and, for the year ended December 31, 2021, increased to $139.7 million compared to $1.5 million for the prior year due to revenue related to the license and collaboration agreement with Incyte and the termination of the Company's license agreement with KKC.

For the three months ended December 31, 2021, Syndax reported a net profit attributable to common stockholders of $96.2 million or $1.81 per share compared to a net loss attributable to common stockholder of $20.4 million or $0.44 per share for the prior year period. For the year ended December 31, 2021, Syndax reported a net profit attributable to common stockholders of $24.9 million or $0.48 per share, compared to a net loss attributable to common stockholders of $77.8 million or $1.87 per share for the prior year.

Financial Update and Guidance

In December 2021, Syndax issued 4,945,000 shares of its common stock and pre-funded warrants to purchase shares of its common stock at approximately $17.50 per share. As a result, Syndax received gross proceeds of approximately $86.5 million. Syndax also issued 1,421,523 shares of its common stock in connection with the Share Purchase Agreement with Incyte Pharmaceuticals at a 30% premium to market for proceeds of $35.0 million.

For the first quarter of 2022, research and development expenses are expected to be $30 to $35 million, and total operating expenses are expected to be $38 to $42 million. For the full year of 2022, research and development expenses are expected to be $130 to $140 million, and total operating expenses are expected to be $160 to $170 million. This does not include any potential cost offsets due to the Incyte collaboration.

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 1, 2022.

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: 4019975
Domestic Dial-in Number: (855) 251-6663
International Dial-in Number: (281) 542-4259
Live webcast: https://edge.media-server.com/mmc/p/pqahpntn

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 pipeline includes SNDX-5613, a highly selective inhibitor of the Menin–MLL binding interaction, axatilimab, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, and entinostat, a class I HDAC inhibitor. For more information, please visit www.syndax.com or follow the Company on Twitter and LinkedIn.

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, the reporting of clinical data for Syndax's product candidates, the potential use of our product candidates to treat various cancer indications and fibrotic diseases, Syndax's fourth quarter and full-year 2021 net cash used in research and development and total operating activities, and first quarter and full year 2022 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; 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.

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

	December 31,	
(In thousands)	**2021**	**2020**
Cash, cash equivalents and short-term investments	$ 439,936	$ 293,065
Total assets	$ 449,657	$ 300,613
Total liabilities	$ 41,289	$ 48,425
Total stockholders' equity (deficit)	$ 408,368	$ 252,188
Common stock outstanding	54,983,105	47,881,223
Common stock and common stock equivalents*	66,011,976	57,836,910
*Common stock and common stock equivalents:		
Common stock	54,983,105	47,881,223
Options to purchase common stock	6,921,514	6,379,235
Restricted Stock Units	132,333	18,500
Pre-funded warrants	3,975,024	3,557,952
	66,011,976	57,836,910

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

	Three Months Ended December 31,		Year Ended December 31,	
(In thousands, except share and per share data)	**2021**	**2020**	**2021**	**2020**
License fee revenue	$ 126,576	$ 380	$ 139,709	$ 1,517
Operating expenses:				
Research and development	23,900	15,522	88,248	50,435
General and administrative	6,927	4,718	25,241	22,505
Total operating expenses	30,827	20,240	113,489	72,940
Loss from operations	95,749	(19,860)	26,220	(71,423)
Other income (expense), net	449	(563)	(1,294)	(1,735)
Net income (loss)	$ 96,198	$ (20,423)	$ 24,926	$ (73,158)
Net income (loss) attributable to common stockholders	$ 96,198	$ (20,423)	$ 24,926	$ (77,064)
Net income (loss) per share attributable to common stockholders--basic	$ 1.81	$ (0.44)	$ 0.48	$ (1.87)
Weighted-average number of common stock				

used to compute net loss per share attributable to common stockholders--basic	53,176,334	46,054,850	52,064,809	41,308,242

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