Syndax Pharmaceuticals Reports First Quarter 2023 Financial Results and Provides Clinical and Business Update

May 8, 2023

– Topline data from the pivotal AGAVE-201 trial of axatilimab in cGVHD on track for mid-2023 –

– Topline data from the pivotal AUGMENT-101 trial of revumenib in KMT2Ar acute leukemia on track for the third quarter of 2023 –

– Two U.S. registrational filings expected by the end of 2023 –

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

WALTHAM, Mass., May 8, 2023 /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 quarter ended March 31, 2023 and provided a business update.

"Syndax is at an important inflection point with pivotal data readouts and subsequent U.S. registrational filings from each of our two potential first- and best-in-class product candidates expected by year-end," said Michael A. Metzger, Chief Executive Officer. "As we continue to advance our mission to realize a future in which people with cancer live longer and better than ever before, we look forward to reporting topline data from our AGAVE-201 pivotal trial of axatilimab in chronic graft versus host disease (cGVHD) in mid-2023 as well as topline data from our AUGMENT-101 pivotal trial in patients with KMT2A-rearranged (KMT2Ar) acute leukemia in the third quarter of this year."

Recent Pipeline Progress and Anticipated Milestones

Revumenib

- The pivotal Phase 2 portion of AUGMENT-101 is enrolling relapsed/refractory (R/R) patients across distinct trial populations: patients with KMT2Ar acute myeloid leukemia (AML), patients with KMT2Ar acute lymphocytic leukemia (ALL) and patients with nucleophosmin mutant (mNPM1) AML. The Company plans to pool data from the AUGMENT-101 cohorts enrolling adult and pediatric patients with R/R KMT2Ar AML and R/R KMT2Ar ALL to file a single New Drug Application (NDA) for the treatment of adult and pediatric KMT2Ar acute leukemia. The Company expects to share topline data from the KMT2Ar pooled analysis in the third quarter of 2023 and submit an NDA filing by the end of 2023. The Company also expects to complete enrollment of the NPM1 AML cohort in the second half of 2023.
- The Company has obtained U.S. Food and Drug Administration (FDA) agreement on a recommended Phase 2 dose (RP2D) of 276 mg of revumenib every 12 hours for patients not receiving a strong CYP3A4 inhibitor.
- The Company has several Phase 1 trials of revumenib ongoing that will provide data across the treatment landscape in acute leukemia. These include the following:
    - BEAT-AML: A combination trial of revumenib with venetoclax and azacitidine in front-line AML patients being conducted as part of the Leukemia & Lymphoma Society's Beat AML® master clinical trial. The Company expects to report initial safety data from the trial by year-end 2023.
    - AUGMENT-102: A combination trial of revumenib with chemotherapy in adult and pediatric patients with R/R mNPM1 or KMT2Ar acute leukemia. The Company expects to report initial safety data along with an RP2D from the trial by year-end 2023.
    - INTERCEPT: A trial to test the use of revumenib monotherapy as maintenance therapy in AML patients who are minimal residual disease-positive following initial treatment, being conducted by the Australasian Leukaemia and Lymphoma Group as part of the INTERCEPT AML master clinical trial. The trial continues to enroll patients.
- A proof-of-concept clinical trial of revumenib in patients with unresectable metastatic microsatellite stable colorectal cancer is enrolling patients and we expect to have preliminary data by year-end 2023.

Axatilimab

- The Company and its partner, Incyte, remain on track to report topline data from the pivotal AGAVE-201 trial evaluating axatilimab in patients with cGVHD following two or more prior lines of therapy in mid-2023, with a Biologics License Application (BLA) filing expected by year-end 2023.
- The Company plans to present axatilimab data demonstrating encouraging clinical activity in cGVHD-related bronchiolitis obliterans syndrome at the upcoming 2023 American Thoracic Society (ATS) Conference on May 19-24 in Washington, D.C. The abstract is now available on the ATS website.
- Syndax and Incyte expect to initiate a Phase 1 trial assessing axatilimab in combination with ruxolitinib in cGVHD in the second half of 2023.
- The Company expects to initiate a randomized, double-blind and placebo-controlled Phase 2 trial to assess the efficacy, safety and tolerability of axatilimab in patients with idiopathic pulmonary fibrosis (IPF) in the second half of 2023.

Corporate Updates

- In March 2023, the Company announced the appointment of Neil Gallagher, M.D., Ph.D., as President, Head of Research and Development. Dr. Gallagher brings to Syndax over 20 years of experience as a leading oncology drug developer.
- Syndax today announced the appointment of Kevin McManus as Chief People Officer. Mr. McManus brings to Syndax over 30 years of experience in human resources and an extensive track record in leadership roles growing organizations and attracting great talent.

First Quarter 2023 Financial Results

As of March 31, 2023, Syndax had cash, cash equivalents, short- and long-term investments of $449.0 million and 69.6 million common shares and prefunded warrants outstanding.

First quarter 2023 research and development expenses increased to $34.1 million from $30.0 million for the comparable prior year period. The increase in research and development expenses was primarily due to increased employee-related expenses and professional fees offset by decreased clinical and manufacturing expenses.

First quarter 2023 general and administrative expenses increased to $12.0 million from $6.8 million for the comparable prior year period. The increase is primarily due to employee-related expenses and professional fees.

For the three months ended March 31, 2023, Syndax reported a net loss attributable to common stockholders of $41.1 million, or $0.59 per share, compared to a net loss attributable to common stockholders of $37.2 million, or $0.63 per share, for the comparable prior year period.

Financial Update and Guidance

For the second quarter of 2023, the Company expects research and development expenses to be $38 to $43 million and total operating expenses to be $53 to $58 million. For the full year of 2023, the Company continues to expect research and development expenses to be $160 to $175 million and total operating expenses to be $225 to $240 million.

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 8, 2023.

The live audio webcast and accompanying slides may be accessed through the Events & Presentations page in the Investors section of the Company's website. Alternatively, the conference call may be accessed through the following:

Conference ID: SNDX1Q23
Domestic Dial-in Number: 800-579-2543
International Dial-in Number: 785-424-1789
Live webcast: https://www.veracast.com/webcasts/syndax/events/SNDX1Q23.cfm

For those unable to participate in the conference call or webcast, a replay will be available on the Investors section of the Company's website at www.syndax.com approximately 24 hours after the conference call and will be available for 90 days following the call.

About Syndax Pharmaceuticals, Inc.

Syndax Pharmaceuticals is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. Highlights of the Company's pipeline include revumenib, a highly selective inhibitor of the Menin–KMT2A binding interaction, and axatilimab, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, both currently in pivotal trials. For more information, please visit www.syndax.com or follow the Company on Twitter and LinkedIn.

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, and Syndax's expected first quarter and full year research and development expenses, and expected first quarter and full year 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 Contact

Sharon Klahre

Syndax Pharmaceuticals, Inc.
sklahre@syndax.com
Tel 781.684.9827

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

(In thousands)	March 31, 2023	December 31, 2022
Cash, cash equivalents, short and long-term investments	$ 448,954	$ 481,271
Total assets	$ 459,826	$ 497,236
Total liabilities	$ 24,321	$ 29,787
Total stockholders' equity	$ 435,505	$ 467,449
Common stock outstanding	68,495,426	68,111,385
Common stock and common stock equivalents*	83,841,884	77,460,706
*Common stock and common stock equivalents:		
Common stock	68,495,426	68,111,385
Common stock warrants (pre-funded)	1,056,856	1,142,856
Common stock and pre-funded stock warrants	69,552,282	69,254,241
Options to purchase common stock	13,897,314	7,981,677
Restricted Stock Units	392,288	224,788
Total common stock and common stock equivalents	83,841,884	77,460,706

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

(In thousands, except share and per share data)	Three Months Ended March 31, 2023	2022
Operating expenses:		
Research and development	$ 34,054	$ 30,022
General and administrative	11,961	6,836
Total operating expenses	46,015	36,858
Loss from operations	(46,015)	(36,858)
Other income (expense), net	4,889	(311)
Net loss	$ (41,126)	$ (37,169)
Net loss attributable to common stockholders	$ (41,126)	$ (37,169)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.59)	$ (0.63)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	69,438,890	58,978,615

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