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

08.03.23

– Announced positive topline results from the pivotal AGAVE-201 trial of axatilimab in cGVHD –

– 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., Aug. 3, 2023 /PRNewswire/ -- Syndax Pharmaceuticals (Nasdaq: SNDX), a clinical-stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today reported its financial results for the quarter ended June 30, 2023, and provided a business update.

"On the heels of recently reported positive data from our pivotal AGAVE-201 trial of axatilimab in chronic graft-versus-host disease, we remain on track to achieve several additional important milestones for both of our programs in what is proving to be a transformational year for Syndax," said Michael A. Metzger, Chief Executive Officer. "The AGAVE-201 data underscore axatilimab's ability to provide meaningful benefit to patients suffering from cGVHD, and we are working with our partners at Incyte to potentially submit a BLA filing by the end of 2023."

Mr. Metzger added, "Additionally, we remain on track to report topline pivotal data from the KMT2Ar cohorts of the Phase 2 AUGMENT-101 trial of revumenib for acute leukemias this quarter, followed by a potential NDA filing by the end of this year. We continue to be focused on executing our robust clinical development plans for both axatilimab and revumenib to fully realize their potential as best-in-class medicines."

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 nucleophosmin mutant (mNPM1) acute myeloid leukemia (AML), patients with KMT2Ar AML, and patients with KMT2Ar acute lymphocytic leukemia (ALL). The Company expects to share topline data from a pooled analysis of the KMT2Ar cohorts in the third quarter of 2023 and submit a New Drug Application (NDA) filing by the end of 2023. The Company also expects to complete enrollment of the mNPM1 AML cohort by year-end 2023.
- The Company has several trials of revumenib ongoing across the treatment landscape in mNPM1 and KMT2Ar acute leukemias that include the following:
    - BEAT-AML: Evaluating the combination of revumenib with VENCLEXTA® 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 receive initial safety data at a potential recommended Phase 2 dose (RP2D) by year-end 2023.
    - SAVE: Evaluating the combination of revumenib with VENCLEXTA® and INQOVI® in R/R AML or mixed phenotype acute leukemias. The trial is being conducted by investigators from the MD Anderson Cancer Center.
    - AUGMENT-102: Evaluating the combination of revumenib with chemotherapy in patients with R/R acute leukemias. The Company expects to provide an update on initial safety data along with the RP2D from the trial by year-end 2023.
    - INTERCEPT: Evaluating revumenib as a monotherapy in patients with AML who are minimal residual disease-positive following initial treatment as part of the INTERCEPT AML Master Clinical Trial.
- The Company plans to initiate a trial of revumenib with 7+3 cytarabine and daunorubicin chemotherapy followed by maintenance treatment in newly diagnosed patients with mNPM1 or KMT2Ar acute leukemias by year-end 2023.
- A proof-of-concept clinical trial of revumenib in patients with unresectable metastatic microsatellite stable colorectal cancer is enrolling patients, and the Company expects to provide an update on the Phase 1 trial by year-end 2023.

Axatilimab

- In July 2023, the Company and its partner, Incyte, announced positive topline data from the pivotal Phase 2 AGAVE-201 trial of axatilimab, Syndax's anti-CSF-1R antibody, in patients with chronic graft-versus-host disease (cGVHD) following two or more prior lines of therapy. All three dose cohorts, 0.3 mg/kg every two weeks, 1.0 mg/kg every two weeks and 3.0 mg/kg every four weeks, met the primary endpoint by demonstrating overall response rate within the first six months of treatment of 74%, 67% and 50%, respectively (95% Confidence Interval [CI]: [63,83], [55,77] and [39,61], respectively). Responses were durable and accompanied by a reduction in symptom burden in a notably advanced and heavily pretreated patient population. Furthermore, axatilimab was generally well tolerated and the most common adverse events were consistent with on target effects and prior trials. Syndax and Incyte expect to submit a Biologics License Application (BLA) filing by year-end 2023, pending agreement from regulatory authorities.

- Incyte and Syndax expect to initiate a trial assessing axatilimab in combination with Jakafi® in cGVHD by year-end 2023.
- The Company expects to initiate a randomized, double-blind and placebo-controlled Phase 2 trial that assesses the efficacy, safety and tolerability of axatilimab in patients with idiopathic pulmonary fibrosis (IPF) by year-end 2023.

Second Quarter 2023 Financial Results

As of June 30, 2023, Syndax had cash, cash equivalents, and short- and long-term investments of $418.3 million and 69.7 million common shares and prefunded warrants outstanding.

Second quarter 2023 research and development expenses increased to $34.8 million from $29.7 million for the comparable prior year period. The increase in research and development expenses was primarily due to increased employee-related expenses, professional fees and clinical expenses, partially offset by decreased manufacturing activities.

Second quarter 2023 general and administrative expenses increased to $14.9 million from $8.0 million for the comparable prior year period. The increase is primarily due to employee-related expenses and professional fees.

For the three months ended June 30, 2023, Syndax reported a net loss attributable to common stockholders of $44.6 million, or $0.64 per share, compared to a net loss attributable to common stockholders of $37.6 million, or $0.62 per share, for the comparable prior year period.

Financial Update and Guidance

For the third quarter of 2023, the Company expects research and development expenses to be $39 to $43 million and total operating expenses to be $57 to $62 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, Thursday, August 3, 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: SNDX2Q23
Domestic Dial-in Number: 800-245-3047
International Dial-in Number: 203-518-9765
Live webcast: https://www.veracast.com/webcasts/syndax/events/SNDX2Q23.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

Syndax 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. 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 third quarter and full year research and development expenses, and expected third 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; 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

(In thousands)	June 30, 2023	December 31, 2022
Cash, cash equivalents, short and long-term investments	$ 418,284	$ 481,271
Total assets	$ 431,340	$ 497,236
Total liabilities	$ 31,299	$ 29,787
Total stockholders' equity	$ 400,041	$ 467,449
Common stock outstanding	69,431,198	68,111,385
Common stock and common stock equivalents*	83,976,323	77,460,706
*Common stock and common stock equivalents:		
Common stock	69,431,198	68,111,385
Common stock warrants (pre-funded)	285,714	1,142,856
Common stock and pre-funded stock warrants	69,716,912	69,254,241
Options to purchase common stock	13,732,675	7,981,677
Restricted Stock Units	526,736	224,788
Total common stock and common stock equivalents	83,976,323	77,460,706

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

(In thousands, except share and per share data)	Three Months Ended June 30, 2023	2022
Operating expenses:		
Research and development	$ 34,764	$ 29,734
General and administrative	14,914	7,990
Total operating expenses	49,678	37,724
Loss from operations	(49,678)	(37,724)
Other income, net	5,063	152
Net loss	$ (44,615)	$ (37,572)
Net loss attributable to common stockholders	$ (44,615)	$ (37,572)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.64)	$ (0.62)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	69,638,427	60,156,653

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