# Syndax Pharmaceuticals Reports Second Quarter 2022 Financial Results and Provides Clinical and Business Update

August 8, 2022

*– On track to report topline data from revumenib and axatilimab pivotal programs starting in 1H23 –*

*– Updated data from Phase 1 portion of AUGMENT-101 trial expected in 4Q22 –*

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

WALTHAM, Mass., Aug. 8, 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 and provided a business update for the second quarter ended June 30, 2022.

"The coming quarters are poised to be transformational for Syndax with topline data from both the revumenib and axatilimab pivotal programs expected starting in the first half of 2023," said Michael A. Metzger, Chief Executive Officer. "As we continue to advance these programs in areas of significant unmet need, we are focused on executing a broad clinical development plan that fully realizes the potential of both compounds and builds upon the robust datasets presented to date."

"For revumenib, which we believe is positioned to serve as a first-to-market and best-in-class menin inhibitor for patients with mNPM1 and MLLr acute leukemias, we look forward to sharing updated data from the Phase 1 portion of the AUGMENT-101 trial, enrolling patients with relapsed/refractory (R/R) disease, in the fourth quarter of this year. Beyond the R/R setting, we are committed to creating additional value for the revumenib program by expanding into newly diagnosed and maintenance settings in mNPM1 and MLLr acute leukemias, as well as into colorectal cancer (CRC), our first assessment of revumenib in solid tumors. We also expect similarly broad utility with axatilimab, which we believe could have a meaningful impact in multiple fibrotic diseases. Building on the data in chronic graft versus host disease (cGVHD), we are looking forward to initiating a 52-week Phase 2b trial of axatilimab in patients with idiopathic pulmonary fibrosis (IPF) in the fourth quarter of this year."

**Recent Pipeline Progress and Anticipated Milestones**

**Revumenib**

- The pivotal Phase 2 portion of AUGMENT-101 is ongoing and the Company continues to expect completion of enrollment in one of the three pivotal cohorts by year-end. The trials are enrolling 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, AUGMENT-101 may serve as the basis for regulatory filings in each of the three distinct populations. The Company expects to report topline data from the trials starting in the first half of 2023, with the potential for the first New Drug Application filing later in 2023. The Company also anticipates announcing updated data from the Phase 1 portion of the AUGMENT-101 trial in the fourth quarter of 2022.
- Two trials, BEAT-AML and AUGMENT-102, are ongoing and will assess the safety, tolerability, and preliminary anti-leukemic efficacy of revumenib and establish an appropriate Phase 2 dose when used in combination with other approved agents. BEAT-AML is a front-line combination trial of revumenib with venetoclax and azacitidine being conducted as part of the Leukemia & Lymphoma Society's Beat AML® Master Clinical Trial. AUGMENT-102 is a trial assessing revumenib in combination with chemotherapy in patients with R/R mNPM1 or MLLr acute leukemias.
- The Company expects the Australasian Leukaemia and Lymphoma Group (ALLG) to initiate the INTERCEPT trial of revumenib as monotherapy in patients with AML who are minimal residual disease-positive (MRD+) following initial treatment, in the fourth quarter of 2022. The trial is a part of the INTERCEPT AML Master Clinical Trial, a collaborative clinical trial investigating novel therapies to target early relapse and clonal evolution as pre-emptive therapy in AML. Revumenib is the first menin inhibitor to be included in the INTERCEPT AML Master Clinical Trial.
- The Company previously announced it intends to initiate a proof-of-concept clinical trial of revumenib in patients with unresectable metastatic microsatellite stable CRC in the fourth quarter of 2022.

**Axatilimab**

- Enrollment is ongoing in the Company's global pivotal Phase 2 AGAVE-201 trial of axatilimab in patients with cGVHD. The trial is evaluating the safety and efficacy of three dosing regimens 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. The Company remains on track to report topline data in the first half of 2023, with the potential for a Biologics License Application filing later in 2023.
- The Company plans to initiate a Phase 2b trial to assess the efficacy, safety and tolerability of axatilimab in patients with IPF in the fourth quarter of 2022. This 52-week, randomized, double-blind and placebo-controlled trial is expected to enroll approximately 170 patients. The primary endpoint will assess the change from baseline in forced vital capacity, which is the current registrational endpoint in IPF.
- The Company is working with its partner, Incyte, to plan additional trials of axatilimab in earlier lines of cGVHD, and expects that Incyte will initiate a Phase 1 trial of axatilimab in combination with Jakafi® in patients with steroid-refractory cGVHD in the fourth quarter of 2022.

**Corporate Updates**

- In June 2022, the Company announced the appointment of Keith A. Goldan as Chief Financial Officer. Mr. Goldan brings to Syndax nearly thirty years of leadership and operational experience at several pharmaceutical, biotechnology, and medical technology companies.

**Second Quarter 2022 Financial Results**

As of June 30, 2022, Syndax had cash, cash equivalents, short-term and long-term investments of $378.9 million and 60.4 million shares outstanding, that included 4.0 million pre-funded warrants.

Second quarter 2022 research and development expenses increased to $29.7 million from $16.9 million for the prior year period. The increase was

primarily due to increased clinical and manufacturing activities for revumenib and axatilimab.

General and administrative expenses for the second quarter 2022 increased to $8.0 million from $5.8 million for the prior year period. The increase is primarily due to increased employee related expenses and professional fees.

For the three months ended June 30, 2022, Syndax reported a net loss attributable to common stockholders of $37.6 million, or $0.62 per share, compared to a net loss attributable to common stockholders of $22.9 million, or $0.44 per share, for the prior year period.

**Financial Update and Guidance**

For the third quarter of 2022, the Company expects research and development expenses to be $25 to $30 million, and total operating expenses to be $35 to $40 million. For the full year of 2022, the Company continues to expect research and development expenses to be $130 to $140 million and total operating expenses to be $160 to $170 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, August 8, 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. Alternatively, the conference call may be accessed through the following:

Conference ID: SYNDAXQ2
Domestic Dial-in Number: 800-225-9448
International Dial-in Number: 203-518-9708
Live webcast: https://www.veracast.com/webcasts/OpenEx/General/syndaxq2.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 (SNDX-5613), a highly selective inhibitor of the Menin–MLL 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 third quarter and full year 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.

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

| (In thousands) | June 30, 2022 | December 31, 2021 |
|---|---|---|
| Cash, cash equivalents, short and long-term investments | $ 378,916 | $ 439,936 |
| Total assets | $ 406,437 | $ 449,657 |
| Total liabilities | $ 44,497 | $ 41,289 |
| Total stockholders' equity (deficit) | $ 361,940 | $ 408,368 |
| | | |
| Common stock outstanding | 56,399,734 | 54,983,105 |
| Common stock and common stock equivalents* | 68,681,287 | 66,011,976 |
| | | |
| *Common stock and common stock equivalents: | | |
| Common stock | 56,399,734 | 54,983,105 |

| | | |
|---|---|---|
| Common stock warrants (pre-funded) | 3,975,024 | 3,975,024 |
| Common stock and pre-funded stock warrants | 60,374,758 | 58,958,129 |
| Options to purchase common stock | 8,046,741 | 6,921,514 |
| Restricted Stock Units | 259,788 | 132,333 |
| Total common stock and common stock equivalents | 68,681,287 | 66,011,976 |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| **(In thousands, except share and per share data)** | **2022** | **2021** | **2022** | **2021** |
| License fee revenue | $ - | $ 379 | $ - | $ 758 |
| Operating expenses: | | | | |
| Research and development | 29,734 | 16,871 | 59,756 | 38,742 |
| General and administrative | 7,990 | 5,842 | 14,827 | 11,513 |
| Total operating expenses | 37,724 | 22,713 | 74,583 | 50,255 |
| Loss from operations | (37,724) | (22,334) | (74,583) | (49,497) |
| Other (expense) income, net | 152 | (576) | (158) | (1,136) |
| Net loss | $ (37,572) | $ (22,910) | $ (74,741) | $ (50,633) |
| Net loss attributable to common stockholders | $ (37,572) | $ (22,910) | $ (74,741) | $ (50,633) |
| Net loss per share attributable to common stockholders--basic and diluted | $ (0.62) | $ (0.44) | $ (1.25) | $ (0.98) |
| Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted | 60,156,653 | 51,603,286 | 59,570,888 | 51,551,844 |

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