Syndax Pharmaceuticals Reports Second Quarter 2018 Financial Results and Provides Clinical and Business Update

– PFS results from pivotal Phase 3 E2112 trial of entinostat plus exemestane in HR+, HER2- breast cancer expected in 3Q18 –

– Phase 1 trial of SNDX-6352 in chronic graft versus host disease expected to commence by the end of the year –

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

WALTHAM, Mass., August 7, 2018 (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 second quarter ended June 30, 2018. In addition, the Company provided a clinical and business update. As of June 30, 2018, Syndax had $98.4 million in cash, cash equivalents and short-term investments.

“We made great progress across multiple programs during the first half of this year, including presentation of data from all three cohorts of ENCORE 601 and completion of target enrollment in ENCORE 602 and 603. We also initiated the first combination trial for the SNDX-6352 program, which will evaluate its safety in combination with durvalumab (IMFINZI®),” said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. “We continue to expect the progression free survival results from E2112, our ongoing Phase 3 trial of entinostat plus exemestane in HR+, HER2- breast cancer, later this quarter, and the third prespecified interim analysis of overall survival in November. We also anticipate sharing next steps for the entinostat-KEYTRUDA® (pembrolizumab) combination program in both non-small cell lung cancer and melanoma by the end of the year.”

The Company also announced today that it plans to initiate a Phase 1 trial of its monoclonal antibody inhibitor of Colony-Stimulating Factor 1 Receptor (CSF-1R), SNDX-6352, in patients with chronic graft versus host disease (cGVHD). Enrollment in this trial is anticipated to begin by the end of the year, with initial data expected in the second half of 2019.

“We are excited to begin the evaluation of SNDX-6352 as a treatment for cGVHD, a novel clinical path for a CSF1-R inhibitor,” said Michael L. Meyers, M.D., Ph.D., Chief Medical Officer of Syndax. “Preclinical findings support that CSF-1R inhibition may serve as an effective approach for treating this debilitating, often deadly side effect of allogenic hematopoietic stem cell transplantation. We look forward to learning more about the potential of SNDX-6352 in this indication.”

Pipeline Updates

- The Phase 3 registration trial of entinostat plus exemestane in advanced hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+, HER2-) breast cancer, E2112, is 98% enrolled as of the end of July. ECOG-ACRIN Cancer Research Group, the trial sponsor, had notified the Company that the Data Safety Monitoring Committee (DSMC) completed the final progression free survival (PFS) analysis in November 2017. The trial is proceeding as planned, and Syndax continues to anticipate that enrollment will be complete in the third quarter of 2018, at which time the result of the PFS analysis will be released to

the Company. In addition, interim overall survival (OS) analyses are scheduled to occur every May and November. Two interim OS analyses have already occurred, with the next analysis expected this November.

- The Company presented data from a subset of PD-(L)1 refractory non-small cell lung cancer (NSCLC) patients enrolled in the expanded Phase 2 ENCORE 601 cohort (n = 57) at the American Society of Clinical Oncology (ASCO) Annual Meeting in June. Updated data from all patients (n = 76) enrolled in this cohort will be presented at the World Conference on Lung Cancer Meeting in Toronto next month, including updated results from the Company's biomarker analyses. The Company expects to communicate its development plans for entinostat in this indication in the fourth quarter.

- The Company presented data from a subset of PD-1 refractory melanoma patients enrolled in the expanded Phase 2 ENCORE 601 cohort (n = 34) at the ASCO Annual Meeting in June. Updated results from the full cohort (n = 55) are expected by the end of this year, at which time the Company will make a decision on registration plans for entinostat in this indication.

- Enrollment in the expanded stage 1 ENCORE 601 cohort of patients with microsatellite stable colorectal cancer (MSS-CRC, n = 37) is expected to complete in the third quarter. A decision on whether to continue to the second stage of this cohort is expected in the first half of 2019.

- Target enrollment in both the Phase 2 portion of ENCORE 602, the Phase 1b/2 clinical trial evaluating the combination of entinostat plus Genentech's PD-L1 inhibitor, atezolizumab (TECENTRIQ®), in patients with triple negative breast cancer, and the Phase 2 portion of ENCORE 603, evaluating entinostat in combination with Pfizer/Merck KGaA's PD-L1 inhibitor, avelumab (BAVENCIO®), in patients with ovarian cancer, is complete. Topline results from each study are anticipated in the first half of 2019.

- ENCORE 606, the Phase 1b/2 trial evaluating entinostat in combination with NKTR-214, Nektar's CD122-biased agonist, is expected to begin enrolling patients in the first half of 2019.

- Dosing of patients with solid tumors in the Phase 1/1b trial evaluating the safety of SNDX-6352 continues as planned. Testing of SNDX-6352 in combination with durvalumab (IMFINZI®), AstraZeneca's human monoclonal antibody directed against PD-L1, was recently initiated, and dosing of patients with SNDX-6352 as a monotherapy is ongoing. The Company anticipates identifying the recommended Phase 2 dose and schedule for SNDX-6352 monotherapy and in combination with durvalumab in the first half of 2019.

- The Company expects to commence enrollment in a Phase 1 dose escalation trial of SNDX-6352 in patients with cGVHD by the end of the year. The objectives of this trial are to evaluate the safety and preliminary efficacy of SNDX-6352 in cGVHD and to identify a recommended Phase 2 dose and schedule. Initial results are anticipated in the second half of 2019.

- Development of the Company's portfolio of Menin-Mixed Lineage Leukemia (MLLr) inhibitors is ongoing. The Company continues to expect clinical trials to initiate in the first half of 2019.

Second Quarter 2018 Financial Results

As of June 30, 2018, Syndax had cash, cash equivalents and short-term investments of $98.4 million and 22,705,794 shares issued and outstanding.

On June 18, 2018, the Company signed an exchange agreement with Biotechnology Value Fund and certain affiliated funds ("BVF") under which BVF exchanged 2,000,000 shares of common stock for 2,000,000 Warrant Shares. BVF can exercise the Warrant Shares at an exercise price per share equal to $0.0001 per share. The warrant is issued for a period of 20 years.

In the third quarter of 2018, through August 6th, the Company sold 633,231 shares of its common stock with net proceeds of approximately $4.4 million pursuant to its at-the-market arrangement.

Second quarter 2018 research and development expenses increased to $14.9 million from $9.9 million for the comparable period in the prior year. The increases were primarily due to increased activities in manufacturing for SNDX-6352, increased development activities for the Menin-MLLr and ENCORE 602 programs partially offset by completion of pharmacology trials and lower program cost for E2112. Employee compensation increased due to increased headcount.

General and administrative expenses totaled $4.5 million during the second quarter of 2018, compared to $4.3 million for the comparable period in the prior year. The increase in general and administrative expenses was primarily due to increased pre-commercialization activities and increased patent related legal expenses.

For the three months ended June 30, 2018, Syndax reported a net loss attributable to common stockholders of $18.4 million or $0.74 per share compared to $13.6 million or $0.70 per share for the comparable prior year period.

Financial Guidance

Today the Company provided operating expense guidance for the third quarter and full year 2018. For the third quarter and full year 2018, research and development expenses are expected to be $14 to $16 million and $59 to $62 million, respectively, and total operating expenses are expected to be $18 to $20 million and $77 to $81 million, respectively. Total operating expenses for 2018 are expected to include approximately $6 million of non-cash stock compensation expense.

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, August 7, 2018.

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: 4980058
Domestic Dial-in Number: 1- 855-251-6663
International Dial-in Number: 281-542-4259
Live webcast: https://edge.media-server.com/m6/p/ddzyph54

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 is developing its lead product candidate, entinostat, a once-weekly, oral, small molecule, class I HDAC inhibitor, in combination with exemestane and several approved PD-1/PD-L1 antagonists. The Company's pipeline also includes SNDX-6352, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, as well as a portfolio of potent and selective inhibitors targeting the binding interaction of Menin with MLLr. 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, and Syndax's second quarter and full-year 2018 net cash used in research and development and total operating activities. 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.

SYNDAX PHARMACEUTICALS, INC.

(unaudited)

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	June 30, 2018	December 31, 2017
Cash, cash equivalents, short-term and long-term investments	$ 98,385	$ 133,220
Total assets	$ 105,370	$ 137,186
Total liabilities	$ 35,018	$ 32,867
Total stockholders' equity	$ 70,352	$ 104,319
Common stock outstanding	22,705,794	24,390,033
Common stock and common stock equivalents*	28,938,384	28,139,705
*Common stock and common stock equivalents:		
Common stock	22,705,794	24,390,033
Options to purchase common stock	4,232,590	3,391,832
Common stock warrants	2,000,000	357,840
	28,938,384	28,139,705

SYNDAX PHARMACEUTICALS, INC.

(unaudited)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
License fee revenue	$ 379	$ 305	$ 758	$ 610
Operating expenses:				
Research and development	14,851	9,862	30,190	19,414
General and administrative	4,479	4,285	9,270	8,215
Total operating expenses	19,330	14,147	39,460	27,629
Loss from operations	(18,951)	(13,842)	(38,702)	(27,019)
Other income, net	563	203	917	409
Net loss	$ (18,388)	$ (13,639)	$ (37,785)	$ (26,610)
Net loss attributable to common stockholders	$ (18,388)	$ (13,639)	$ (37,785)	$ (26,610)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.74)	$ (0.70)	$ (1.54)	$ (1.41)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	24,705,441	19,497,581	24,592,483	18,868,089

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