



Syndax Pharmaceuticals Reports Second Quarter 2017 Financial Results and Provides Clinical and Business Update

- PD-1 Refractory Melanoma Cohort of ENCORE 601 Completes Enrollment –

- First Patient Dosed in ENCORE 601 Colorectal Cancer Cohort -

-Company to Host Conference Call Today at 4:30 p.m. ET-

WALTHAM, Mass., Aug. 10, 2017 (PRNEWswire) -- Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq:SNDX), a clinical stage biopharmaceutical company developing entinostat and SNDX-6352 in multiple cancer indications, today reported its financial results for the second quarter ended June 30, 2017. In addition, the Company provided a clinical and business update. As of June 30, 2017, Syndax had \$130.0 million in cash, cash equivalents and short-term investments.

Enrollment in all cohorts of ENCORE 601 have proceeded rapidly. The second stage of the ENCORE 601 cohort enrolling PD-1 (programmed death receptor-1) refractory melanoma patients has reached its accrual target. Enrollment in the PD-1 refractory non-small cell lung cancer (NSCLC) cohort remains on track, and is expected to be complete in the fourth quarter. The Company also announced that the first patient has been dosed in the ENCORE 601 cohort enrolling microsatellite stable colorectal cancer (CRC) patients.

"The second quarter was marked by continued progress across our clinical pipeline. The initial results from ENCORE 601 provide the first clinical evidence that entinostat may reverse resistance to immune checkpoint therapies," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "We had a productive Type B meeting with the FDA in June to discuss potential registration paths for entinostat when used in combination with a PD-1 inhibitor for the treatment of melanoma patients who have progressed on checkpoint therapy. We are now evaluating the options discussed with the FDA and will provide an update by the end of the year.

Pipeline Updates

- ECOG-ACRIN Cancer Research Group, sponsor of E2112, the Phase 3 registration trial of entinostat plus exemestane in advanced HR+, HER2- breast cancer, expects the progression free survival analysis to be available in the first half of 2018 directly following completion of enrollment. As of the end of July, the trial was 78% enrolled.
- A number of patients enrolled in the ENCORE 601 cohort of NSCLC patients naïve to PD-(L)1 therapy remain on drug, with a determination on whether the cohort has satisfied the pre-specified efficacy criteria for advancement to the second stage of the trial expected by year end. The pre-specified objective response threshold to advance this cohort into the second stage of the Phase 2 trial has been revised to ≥ 4 responses out of 17 (versus the previous benchmark of ≥ 3 responses out of 13) in order to incorporate Phase 1b patients dosed at the recommended 5 mg dose of entinostat. Similarly, the cohort of PD-(L)1 refractory NSCLC patients, announced in May to have met the pre-specified objective response threshold to advance into the second stage of the Phase 2 trial, used revised



criteria requiring ≥ 3 responses out of 31 (versus the previous benchmark of ≥ 2 responses out of 20) in order to incorporate Phase 1b patients dosed at entinostat 5 mg.

- Enrollment in the second stage of the PD-(L)1 refractory melanoma cohort of ENCORE 601 has completed, and the second stage of the PD-(L)1 refractory NSCLC cohort of ENCORE 601 is expected to complete enrollment in the fourth quarter. Syndax expects to present data from stage one of the NSCLC cohorts, as well as biomarker data from the melanoma cohort, at the Society of Immunotherapy of Cancer (SITC) Annual Meeting in the fall, and the full trial data from both the refractory NSCLC and melanoma cohorts at a medical congress in the first half of 2018.
- Dosing has been initiated in the ENCORE 601 cohort of patients with microsatellite stable CRC. This new cohort, announced in April 2017, employs a Simon two-stage design enrolling 13 patients in the first stage, and requires ≥ 2 confirmed objective responses to proceed to the second stage. A decision on whether to advance to the second stage of the CRC cohort is expected in the first half of 2018.
- Enrollment is also progressing in the two additional trials aimed at exploring the ability of entinostat to enhance the efficacy of PD-L1 inhibitor therapies, ENCORE 602 and ENCORE 603. ENCORE 602, the Phase 1b/2 clinical trial evaluating the combination of entinostat plus Genentech's PD-L1 inhibitor, TECENTRIQ[®], in patients with triple negative breast cancer, is expected to complete enrollment in the Phase 2 portion by the end of the fourth quarter. ENCORE 603, the Phase 1b/2 clinical trial evaluating entinostat in combination with Pfizer/Merck KGaA's BAVENCIO[®] in patients with ovarian cancer, recently began enrolling patients into the Phase 2 portion and is expected to complete enrollment in the first half of 2018.
- Enrollment is now complete in the Phase 1 single ascending dose (SAD) clinical trial of SNDX-6352 in healthy volunteers to determine the safety, pharmacokinetics and pharmacodynamics of the anti-CSF-1R monoclonal antibody. The Company expects to present data from this study at a scientific congress in the fourth quarter of 2017. Syndax also plans to initiate a multiple ascending dose (MAD) trial in cancer patients in the third quarter of 2017.

Syndax Expects to Participate in the Following Upcoming Investor Conferences

- Citi 12th Annual Biotech Conference, September 6-7, 2017 in Boston
- Morgan Stanley Healthcare Conference, September 11-13, 2017 in New York
- Cantor Fitzgerald 2017 Global Healthcare Conference, September 25-27, 2017 in New York

Second Quarter 2017 Financial Results

As of June 30, 2017, Syndax had cash, cash equivalents and short-term investments of \$130.0 million and 22,219,843 shares issued and outstanding. This includes aggregate net proceeds of



\$48.7 million, raised in a follow-on offering in May 2017 whereby 3,950,190 shares of common stock were sold at an offering price of \$13.25 per share.

Second quarter 2017 research and development expenses increased to \$9.9 million from \$6.1 million for the comparable period in the prior year due to increases in clinical trial activities of \$2.3 million, employee compensation expense of \$0.8 million, and legal and consultant expenses of \$0.6 million. The increase in clinical trial activities was primarily due to increases in spending related to the additional cohorts added to ENCORE 601, increased activities in ENCORE 602 and ENCORE 603, start-up costs related to SNDX-6352, our Phase 1 clinical pharmacology trials and CMC activities. The increase in employee compensation costs was primarily due to increased headcount.

General and administrative expenses totaled \$4.3 million during the second quarter of 2017 compared with \$2.8 million in the comparable period in the prior year. The increase in general and administrative expenses was primarily due to an increase in employee compensation of \$1.0 million combined with increases in consulting expenses of \$0.4 million. The increase in employee compensation of \$1.0 million was primarily due to increases in non-cash stock-based compensation of \$0.6 million, combined with an increase in salary expense of \$0.4 million due to increased headcount.

For the three months ended June 30, 2017, Syndax reported a net loss attributable to common stockholders of \$13.6 million, or \$0.70 per share, compared to \$8.4 million, or \$0.47 per share, for the comparable prior year period.

Financial Guidance

Today the Company provided operating expense guidance for the third quarter and full year 2017. For the third quarter and full year 2017, research and development expenses are expected to be \$12.0 to \$14.0 million and \$46.0 to \$51.0 million, respectively, and total operating expenses are expected to be \$16.0 to \$18.0 million and \$63.0 to \$68.0 million, respectively.

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 10, 2017.

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: 53140486

Domestic Dial-in Number: 1-855-251-6663

International Dial-in Number: 281-542-4259

Live webcast: <http://edge.media-server.com/m/p/pko7iyj3>

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 is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. Our lead product candidate, entinostat, which was granted Breakthrough Therapy designation by the FDA following positive results from our Phase 2b clinical trial, ENCORE 301, is currently being evaluated in a Phase 3 clinical trial for advanced hormone receptor positive, human epidermal growth factor receptor 2 negative breast cancer. Given its potential ability to block the function of immune suppressive cells in the tumor microenvironment, entinostat is also being evaluated in combination with approved PD-1 antagonists. Ongoing Phase 1b/2 clinical trials combine entinostat with KEYTRUDA from Merck & Co., Inc. for non-small cell lung cancer melanoma and colorectal cancer; with TECENTRIQ[®] from Genentech, Inc. for triple negative breast cancer; and with BAVENCIO[®] from Pfizer Inc. and Merck KGaA, Darmstadt, Germany, for ovarian cancer. Our second product candidate, SNDX-6352, is a monoclonal antibody that blocks the CSF-1 receptor and may also block the function of immune suppressive cells in the tumor microenvironment. SNDX-6352 is being evaluated in a single ascending dose Phase 1 clinical trial and is expected to be developed to treat a variety of cancers.

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, and the potential use of our product candidates to treat various cancer indications. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical studies, 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 STATEMENTS OF OPERATIONS DATA

(In thousands, except share and per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
License fee revenue	\$ 305	\$ 305	\$ 610	\$ 610
Operating expenses:				
Research and development	9,862	6,131	19,414	10,917
General and administrative	4,285	2,808	8,215	7,080
Total operating expenses	<u>14,147</u>	<u>8,939</u>	<u>27,629</u>	<u>17,997</u>
Loss from operations	(13,842)	(8,634)	(27,019)	(17,387)
Other income (expense), net	203	276	409	(1,301)
Net loss	<u>\$ (13,639)</u>	<u>\$ (8,358)</u>	<u>\$ (26,610)</u>	<u>\$ (18,688)</u>
Net loss attributable to common stockholders	<u>\$ (13,639)</u>	<u>\$ (8,358)</u>	<u>\$ (26,610)</u>	<u>\$ (21,286)</u>
Net loss per share attributable to common stockholders--basic and diluted	<u>\$ (0.70)</u>	<u>\$ (0.47)</u>	<u>\$ (1.41)</u>	<u>\$ (1.91)</u>
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	<u>19,497,581</u>	<u>17,769,514</u>	<u>18,868,089</u>	<u>11,155,525</u>



SYNDAX PHARMACEUTICALS, INC.

(unaudited)

CONDENSED CONSOLIDATED BALANCE SHEETS DATA

(In thousands)	<u>June 30, 2017</u>	<u>December 31, 2016</u>
ASSETS		
Cash, cash equivalents, and short-term investments	\$ 129,955	\$ 105,330
Other assets	4,711	3,683
Total assets	<u>\$ 134,666</u>	<u>\$ 109,013</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	\$ 11,505	\$ 10,366
Deferred revenue, less current portion	13,610	14,220
Other liabilities	214	288
Total liabilities	<u>25,329</u>	<u>24,874</u>
Total stockholders' equity	<u>109,337</u>	<u>84,139</u>
Total liabilities and stockholders' equity	<u>\$ 134,666</u>	<u>\$ 109,013</u>



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