Syndax Highlights 2019 Clinical and Corporate Outlook

– Data from ENCORE I/O combination program in melanoma and ovarian cancer expected in 1Q19, TNBC in 2Q19 –

– Next interim OS assessment in Phase 3 E2112 trial in HR+, HER2- metastatic breast cancer expected in 2Q19 –

– IND filing for lead Menin-MLLr inhibitor, SNDX-5613, expected in 2Q19 –

WALTHAM, Mass., January 7, 2019 (PRNEWSWIRE) -- Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq: SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today provided a 2019 clinical and corporate outlook.

“2019 is slated to be a milestone-rich time for Syndax, with data expected from multiple trials within our ENCORE program of entinostat in combination with checkpoint therapy in platinum resistant ovarian cancer, triple negative breast cancer, and anti-PD-1-pretreated melanoma, all of which we believe represent underserved areas with significant market opportunity,” said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. “We also eagerly anticipate the next interim overall survival analysis in the second quarter from the Phase 3 E2112 trial of entinostat plus exemestane in HR+, HER2- breast cancer and remain highly encouraged by the potential to provide a survival benefit for HR+, HER2- breast cancer patients who have stopped responding to first line treatment with hormone therapy. Any positive overall survival assessment would enable the company to file for full regulatory approval.”

Dr. Morrison added, “In addition, we remain on track for an IND filing for our Menin inhibitor, SNDX-5613, in the second quarter of 2019, followed by initiation of the clinical trial program. Acute leukemias characterized by MLL-rearrangements and nucleophosmin mutations represent areas of high unmet medical need, and the preclinical data we’ve generated thus far provide strong support that menin inhibition has the potential to serve as an effective therapy for patients lacking viable options. Finally, we continue to expect initial efficacy results for SNDX-6352 in chronic graft versus host disease in the second half of 2019.”

Anticipated Key Milestones for 2019:

Entinostat

- Topline results from the randomized Phase 2 portion of the ENCORE 603 trial of entinostat in combination with Pfizer/Merck KGaA's PD-L1 inhibitor, BAVENCIO® (avelumab), in patients with ovarian cancer are expected in the first quarter of 2019.
- Presentation of clinical, biomarker and gene analysis data from the anti-PD-1 pretreated melanoma cohort of the Phase 2 ENCORE 601 trial of entinostat in combination with KEYTRUDA® (pembrolizumab) is expected in the first quarter of 2019.
- A decision on whether to advance to the second stage of the ENCORE 601 cohort of patients with microsatellite stable colorectal cancer (MSS-CRC) naïve to PD-1 therapy is expected in the first quarter of 2019.

- Topline results from the randomized Phase 2 portion of the ENCORE 602 trial of entinostat in combination with Genentech's PD-L1 inhibitor, TECENTRIQ® (atezolizumab), in patients with triple negative breast cancer are expected in the second quarter of 2019.
- The next interim analysis for the overall survival (OS) primary endpoint of E2112, 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, is expected in the second quarter of 2019. Additional interim analyses will be conducted every six months until either an OS benefit is observed, or the final target number of events occur. Any positive OS assessment would enable the Company to file for full regulatory approval.
- Syndax plans to commence a focused, biomarker-driven, randomized registration trial comparing the entinostat-pembrolizumab combination to standard of care chemotherapy in non-small cell lung cancer (NSCLC) patients whose disease has progressed after both platinum-based chemotherapy and PD-1 antagonist therapy in the first half of 2019. The trial will seek to validate peripheral classical monocytes as a marker of response to the combination and to determine whether the combination can improve progression free survival (PFS) over standard of care chemotherapy in the high monocyte population.

SNDX-6352

- Topline results and a recommended Phase 2 dose and schedule from the Phase 1/1b trial of SNDX-6352, Syndax's anti-CSF-1R monoclonal antibody, alone or in combination with IMFINZI® (durvalumab), AstraZeneca's human monoclonal antibody directed against PD-L1, are expected in the second quarter of 2019.
- Topline results and a recommended Phase 2 dose and schedule from the Phase 1 trial of SNDX-6352 in patients with chronic graft versus host disease (cGVHD) are expected in the third quarter of 2019.

Menin-MLLr Inhibitor Portfolio

- An Investigational New Drug (IND) filing with the FDA for SNDX-5613, the Company's lead Menin inhibitor compound, is expected in the second quarter of 2019, followed by the initiation of a Phase 1 clinical trial in patients with a genetically defined subset of acute leukemias.

Financial Guidance

Syndax ended 2018 with cash, cash equivalents and short-term investments of approximately $80 million. For 2019, research and development expenses are expected to be $54 to $58 million, and total operating expenses are expected to be $68 to $73 million. Research and development expenses and total operating expenses for 2019 are expected to include approximately $2 million and $6 million, respectively, of non-cash stock compensation. The Company plans to announce financial results from the fourth quarter and full-year 2018 later this quarter.

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-(L)1 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 MLL-r, including its lead candidate SNDX-5613. 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, and the potential use of our product candidates to treat various cancer indications, Syndax's full-year 2018 net cash used in research and development and total operating activities, and Syndax's expected 2019 research and development and total operative expenses and 2019 non-cash stock compensation. 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 Contacts

Investor Contact
Melissa Forst
Argot Partners
melissa@argotpartners.com

Tel 212.600.1902

Media Contact
David Rosen
Argot Partners
david.rosen@argotpartners.com
Tel 212.600.1902

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