Syndax Pharmaceuticals Highlights 2020 Clinical and Corporate Outlook

January 10, 2020

- Final OS analysis for pivotal Phase 3 E2112 trial in HR+, HER2- breast cancer expected 2Q20 -

- Phase 1 data presentation from AUGMENT-101 trial of SNDX-5613 in acute leukemias expected 4Q20; potential for interim results throughout 2020-

- SNDX-6352 Phase 2 expansion trial in cGVHD initiated; Presentation of phase 1 trial results expected in 4Q20 -

WALTHAM, Mass., Jan. 10, 2020 /PRNewswire/ -- Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq:SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today announced a strategic outlook for 2020 outlining key priorities for its broad pipeline.

"We expect 2020 to be an exciting and transformative year for the Company, with significant data read outs anticipated for all three of our innovative pipeline programs, each addressing an unmet need for some of today's most underserved patient populations," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "Notably, this includes the final overall survival readout for E2112, our Phase 3 registration trial of entinostat plus exemestane in HR+, HER2- breast cancer, which we expect in the second quarter of 2020. Based on compelling survival data from the Phase 2b ENCORE 301 trial, we believe that the combination of entinostat and exemestane has strong potential to serve as an effective therapeutic option for the substantial number of patients who have progressed on first line hormone treatment. We are on track to file for regulatory approval in 2020 and to become a fully-integrated oncology company with the launch of entinostat in HR+ breast cancer expected in 2021."

Dr. Morrison added, "In 2020, we also expect meaningful data readouts from the Phase 1/2 AUGMENT-101 trial of SNDX-5613, our potent, highly selective, oral Menin inhibitor, in adults with relapsed/refractory acute leukemias and the Phase 1 dose escalation trial of SNDX-6352, our anti-CSF-1R monoclonal antibody, in patients with cGVHD."

Anticipated Key Milestones for 2020

Entinostat

The Company continues to anticipate that the E2112 trial will reach 410 death events in the second quarter of 2020, triggering the final overall survival (OS) analysis. E2112 is Syndax's NCI-sponsored, ECOG-ACRIN-led Phase 3 registration trial of entinostat, a Class I selective HDAC inhibitor, plus exemestane in advanced hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+, HER2-) breast cancer.

A positive OS assessment would enable the Company to file for full regulatory approval in the U.S. The E2112 trial design was informed by the Phase 2b ENCORE 301 trial, the results of which led to entinostat's Breakthrough Therapy designation in HR+ breast cancer, in which patients receiving the entinostat/exemestane combination demonstrated a clinically meaningful OS benefit over treatment with exemestane alone. The Company continues to actively engage in expanding its commercial and medical affairs activities, to support the planned launch of entinostat in the U.S.

SNDX-5613

Syndax anticipates presenting initial clinical data from its Phase 1/2 open-label AUGMENT-101 trial of SNDX-5613, the Company's potent, highly selective oral Menin inhibitor, at a medical conference in the fourth quarter of 2020. Given that the AUGMENT-101 trial is open-label, meaningful interim data including pharmacokinetic, pharmacodynamic and efficacy data may be available earlier in the year.

The Phase 1 dose escalation portion of AUGMENT-101 is enrolling adults with relapsed/refractory acute leukemias, including patients with MLL-rearrangements and NPM1c mutations, to establish a recommended Phase 2 dose. The Phase 2 portion will evaluate efficacy, as defined by Complete Response rate (per International Working Group response criteria), across three expansion cohorts: MLL-rearranged (MLL-r) acute lymphoblastic leukemia, MLL-r acute myeloid leukemia (AML), and NPM1 mutant AML.

SNDX-6352

The Company has also initiated a Phase 2 expansion cohort for SNDX-6352, its anti-CSF-1R monoclonal antibody, for the treatment of chronic graft versus host disease (cGVHD). The decision to move to the Phase 2 expansion was driven by recently announced encouraging proof of concept results from the ongoing Phase 1 dose escalation trial in which the Company observed responses in all evaluable patients as of the data cutoff date, with no dose limiting toxicities reported.

The Phase 2 expansion cohort is expected to enroll up to 22 patients to further characterize the safety and efficacy at an initial dosing schedule of 1.0 mg/kg of SNDX-6352 administered every two weeks. The Company expects to present results from the Phase 1 trial, for which dose escalation remains ongoing, in the second half of 2020.

About Syndax Pharmaceuticals, Inc.

Syndax Pharmaceuticals is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. The Company's lead product candidate, entinostat, a once-weekly, oral, small molecule, class I HDAC inhibitor, is being evaluated in a Phase 3 combination trial with exemestane for the treatment of advanced HR+, HER2- breast cancer, and has been evaluated in combination with 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, which is currently being evaluated in chronic graft versus host disease (cGVHD) and solid tumors, and SNDX-5613, a potent, selective, small molecule inhibitor of the Menin-MLL binding interaction that is being developed for the treatment of MLL-rearranged (MLL-r) acute leukemias, including acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML). 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. 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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