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# Syndax Pharmaceuticals Announces Advancement of ENCORE 601 in Non-Small Cell Lung Cancer Patients with Disease Progression on or After PD-1 Therapies

## Pre-specified objective response criteria met for advancing to second stage

WALTHAM, Mass., May 16, 2017 (GLOBE NEWSWIRE) -- Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq:SNDX), a clinical stage biopharmaceutical company focused on developing entinostat and SNDX-6352 in multiple cancer indications, today reported that the ENCORE 601 non-small cell lung cancer (NSCLC) cohort enrolling patients with disease progression on or after PD-1 therapy (programmed death receptor-1 (PD-1) and/or programmed death ligand 1, (PD-L1)) has met the pre-specified objective response threshold to advance into the second stage of the Phase 2 trial, and will re-open enrollment immediately.

ENCORE 601, a Phase 1b/2 clinical trial evaluating the combination of entinostat plus Merck's anti-PD-1 blocking therapy, KEYTRUDA® (pembrolizumab), is enrolling two distinct cohorts of NSCLC patients: 1) patients who had previously progressed on PD-1 or PD-L1 therapy; and 2) patients naïve to PD-1 or PD-L1 therapy. To advance into the definitive stage of the Phase 2 study, at least 2 out of 20 NSCLC patients who had previously progressed on PD-1 or PD-L1 therapy or 3 out of 13 NSCLC patients previously naïve to PD-1 or PD-L1 therapy need to demonstrate an objective response, defined as either a partial response (PR) or complete response (CR), to entinostat - KEYTRUDA treatment.

The cohort of NSCLC patients who had previously progressed on PD-1 or PD-L1 will now re-open and enroll a total of 56 patients. Completion of enrollment is anticipated in the first half of 2018. Later this quarter, the Company anticipates being able to determine whether to expand the cohort of NSCLC patients naïve to PD-1 or PD-L1 therapy.

"PD-1 therapies have offered important clinical benefit to patients with NSCLC, but unfortunately only a subset of patients respond. There is tremendous need for new combinations to further improve responses to PD-1 therapies. The early data here with several objective responses to the entinostat - pembrolizumab combination in patients with NSCLC who previously progressed on PD-1 therapy is promising and certainly worth additional investigation," said Matthew D. Hellmann, M.D., medical oncologist and immunotherapy expert at Memorial Sloan Kettering Cancer Center.

"We are pleased to report that the entinostat - KEYTRUDA treatment combination has generated objective responses in patients whose disease has progressed on or after PD-1 antagonist therapies," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "This data, along with the responses we observed in the melanoma cohort earlier in the year, give us additional confidence in the ability of entinostat to enhance the patient's response to immunotherapy. We look forward to providing additional details on these patient responses at an appropriate scientific forum."

**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.

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