Syndax Pharmaceuticals Announces Presentation of Data from Immuno-oncology Clinical Trials at the Society for Immunotherapy of Cancer 32nd Annual Scientific Meeting

- ENCORE 601 data continue to support increased immune responsiveness in both PD-(L)1 refractory and PD-(L)1 naïve NSCLC patients treated with entinostat and KEYTRUDA® (pembrolizumab)–

- Biomarker data from PD-1 refractory melanoma cohort shows conversion of a non-inflamed to inflamed tumor microenvironment following treatment with entinostat and KEYTRUDA -

WALTHAM, Mass., November. [11], 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 announced results from the non-small cell lung cancer (NSCLC) and melanoma cohorts of ENCORE 601, an open-label, Phase 1b/2 clinical trial employing a Simon two-stage design to evaluate the combination of entinostat, the Company's class I selective HDAC inhibitor, plus Merck's (also known as MSD outside of the United States and Canada) anti-PD-1 (programmed death receptor-1) therapy, KEYTRUDA®. In addition, data from the single ascending dose (SAD) trial of SNDX-6352, the Company's anti-CSF-1R monoclonal antibody, in healthy volunteers were presented at the Society of Immunotherapy of Cancer (SITC) Annual Scientific Meeting being held November 8-12, 2017 in National Harbor, Maryland.

ENCORE 601 Updates

In an oral presentation titled, "ENCORE-601: Phase 1b/2 study of entinostat (ENT) in combination with pembrolizumab in patients with non-small cell lung cancer (NSCLC)," Leena Gandhi, M.D., Ph.D., director of the Thoracic Medical Oncology Program at NYU Langone's Perlmutter Cancer Center, shared data from the first stage of both NSCLC cohorts of ENCORE 601, including patients with PD-(L)1 refractory disease, as well as PD-(L)1 naïve patients. The observed overall response rate was 10% (95% CI: 2%-26%) in patients who had progressed on prior anti-PD-1 or PD-(L)1 therapy and 24% (95% CI: 7%-50%) in patients naïve to PD-1 or PD-(L)1 therapy. Across both NSCLC cohorts, the responders with known PD-(L)1 expression levels were all observed to be low (1-49%) or negative expressors (< 1%). Three patients from each cohort remain on therapy, and two of the six have been on the combination for over one year.

"The responses observed in patients receiving entinostat with pembrolizumab who had previously progressed on prior checkpoint blockade are encouraging, particularly in those who did not achieve responses on their prior PD-1 therapy. While the numbers of patients treated to date are small, these initial results support further exploring this combination to potentially address an unmet medical need for these patients," noted Dr. Gandhi.

In addition to the NSCLC data, the poster, "Analysis of biomarkers from a cohort of advanced melanoma patients previously exposed to immune checkpoint inhibition treated with entinostat (ENT) and pembrolizumab" containing updated data highlighting the clinical activity and novel translational research findings from the ENCORE 601 cohort of melanoma patients whose disease had progressed on prior PD-1 therapy was presented today. As of early September, four of 13 patients in this PD-1 refractory cohort remained on study, two of whom have received more than a year of the combination treatment. Pre-treatment tumor biopsies were obtained for all

patients and matched post-treatment biopsies were available from nine patients. Gene expression, PD-1 and immunofluorescence analysis of tissue samples demonstrate that entinostat combined with KEYTRUDA may generate immune responsiveness in tumors previously resistant to immune checkpoint inhibition.

“Data presented at SITC continue to support our hypothesis that entinostat has the potential to enhance immune checkpoint blockade mediated anti-tumor responses in a broad range of tumors,” said Briggs Morrison, M.D., Chief Executive Officer of Syndax. “Of note, in the melanoma cohort of ENCORE 601, we are encouraged to see conversion of a non-inflamed to inflamed tumor microenvironment after treatment with entinostat and KEYTRUDA in two of the three responders for whom we had both pre- and post-treatment tumor biopsies. We are also excited by the rapid accrual into the second stage of the PD-(L)1 refractory NSCLC cohort, which we believe speaks to the interest in, and need for, novel approaches to address such unmet needs. We look forward to sharing full Phase 2 data from the NSCLC and melanoma cohorts in the first half of 2018, and in the same time frame, we expect to share a registration plan for entinostat in combination with a PD-1 inhibitor for patients with PD-1 refractory melanoma.”

SNDX-6352 Updates

The poster, “First in human, single ascending dose study in healthy volunteers of SNDX-6352, a humanized IgG4 monoclonal antibody targeting colony stimulating factor-1 receptor (CSF-1R),” containing safety, pharmacokinetic and pharmacodynamic data from the first in human, SAD trial of SNDX-6352, was also presented during the SITC annual meeting. Three dose levels of 0.15 mg/kg, 1 mg/kg, and 3 mg/kg were administered during the SAD trial, and increases in CSF-1 and IL-34, and transient reduction of circulating non-classical monocytes were observed, consistent with binding of SNDX-6352 to CSF-1R. The safety profile of SNDX-6352 was as expected, with mild to moderate adverse effects observed consistent with other agents in this class.

The SITC presentations are available in the Publications section of the Company’s website, linked here.

About ENCORE 601

ENCORE 601 is an open-label, Phase 1b/2 clinical trial employing a Simon two-stage design to evaluate the combination of entinostat, the Company’s class I selective HDAC inhibitor, plus Merck's anti-PD-1 (programmed death receptor-1) blocking therapy, KEYTRUDA®. The trial is evaluating four patient populations: Patients with non-small cell lung cancer (NSCLC) who have not previously received a PD-1 antagonist (cohort 1); patients with NSCLC who have progressed on a PD-1 antagonist (cohort 2); patients with advanced melanoma who have progressed on a PD-1 antagonist (cohort 3); and microsatellite stable colorectal cancer who have not previously been treated with a PD-1 antagonist (cohort 4). The Company previously announced that cohorts 1, 2 and 3 have met the pre-specified objective response threshold to advance into the second stage of the Phase 2 trial, and cohorts 2 and 3 have completed enrollment of the second stage of the trial. A decision on the advancement of cohort 4 is expected in the first half of 2018.

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 in combination with exemestane 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 clinical stage product candidate, SNDX-6352, is a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor and may also block the function of immune suppressive cells in the tumor microenvironment. SNDX-6352 is being evaluated in a 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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