May 17, 2017

Syndax Announces Results from Phase 2 ENCORE 601 Trial of Entinostat in Combination with KEYTRUDA® (pembrolizumab) for the Treatment of Advanced Melanoma

-31% objective response rate for first stage of the Phase 2 melanoma cohort of ENCORE 601-

-Enrollment ongoing in Stage 2, along with biomarker analysis-

-ENCORE 601 now enrolling expanded cohorts of melanoma and NSCLC patients progressed on or after anti-PD1 therapies, after meeting pre-specified efficacy hurdles-

WALTHAM, Mass., May 17, 2017 (GLOBE NEWSWIRE) -- 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 melanoma cohort of the ongoing Phase 2 ENCORE 601 trial of entinostat in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy, which will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting being held June 2-6, 2017 in Chicago, Illinois.

The Company recently reported that the first cohort of 13 melanoma patients who had progressed on or after prior immune checkpoint inhibitor therapy in ENCORE 601 met the pre-specified objective response criteria, with a minimum of 2 patients demonstrating a confirmed or unconfirmed objective response, to advance into the second stage of the trial. Data from the first cohort of patients indicate that 4 patients achieved an objective response (ORR) by irRECIST criteria (3 patients had a confirmed response; 1 patient had an unconfirmed response; 31% ORR, 95% CI: 9 — 61%). Of the 4 responders, 2 patients had stable disease (SD) and 2 patients had progressive disease (PD) as best response to their prior anti-PD-1 therapy prior to progressing, with a median duration on prior anti-PD-1 therapy of 4.9 months (range 2.7-12.5). Three patients remain on treatment, without progression, as of the data cutoff, 1 with a partial response (PR), and 2 with SD.

"This is important data showing that with the addition of entinostat, meaningful responses can occur in patients who have progressed on an anti-PD-1 or anti-PD-1/anti-CTLA-4 regimen. This is an area of very high unmet medical need," noted Jedd D. Wolchok, M.D., Ph.D., Chief of Melanoma and Immunotherapeutics Service at Memorial Sloan Kettering Cancer Center, and member of the Syndax Scientific Advisory Board.

ENCORE 601 (NCT02437136) is a Phase 1b/2 trial evaluating the efficacy and safety of entinostat in combination with KEYTRUDA in melanoma patients whose disease had progressed despite prior treatment with anti-PD-1/PD-L1 therapies. Responses were seen both in patients who had, as well as those who had not, received prior treatment with YERVOY® (ipilimumab) in combination with an anti-PD-1 therapy, either (OPDIVO® (nivolumab) or KEYTRUDA). Of note, 1 patient with a confirmed PR converted from a PD-L1 negative, non-inflamed gene signature in a pre-treatment tumor biopsy to PD-L1 positive, inflamed gene signature post-treatment with the entinostat-KEYTRUDA combination. Correlative analyses of peripheral blood and tumor tissue biomarkers across the entire patient cohort are ongoing. The combination of entinostat and KEYTRUDA also appears to have a manageable toxicity profile, with 8 patients having a treatment emergent adverse event with severity of Grade ≥ 3, and with 1 patient discontinuing treatment due to an adverse event (transaminitis that was deemed to be likely related to KEYTRUDA).

"Treatment options for advanced or metastatic melanoma have greatly improved with the recent regulatory approvals of several immunotherapies, including the anti-PD-1 inhibitor KEYTRUDA. However, viable treatment options for melanoma patients progressing on anti-PD-1 therapy, with or without prior YERVOY, remain an area of unmet need, as a majority of patients will progress on or following treatment with these agents. We look forward to results from the expansion cohort of 21 additional patients, enrollment of which is expected to complete in the third quarter," said Briggs Morrison, M.D., Chief Executive Officer of Syndax. "The early efficacy signal we have observed in both melanoma and NSCLC suggests that entinostat may re-sensitize a broad range of tumors after they have progressed on prior treatment with immune checkpoint therapies, and adds to the rationale supporting our trials in CRC, TNBC, and ovarian cancer."

Baseline demographic data in the first cohort of 13 melanoma patients included: Median age of 62; ECOG status of 0 (62% of patients) or 1 (38% of patients), PD-L1 expression negative (31%) or positive (46%) with 23% not evaluable; visceral metastases (46%); all patients had disease progression on or after prior treatment with a PD-1 antagonist, either KEYTRUDA therapy (54%) or OPDIVO therapy (46%); prior YERVOY therapy (62%); and prior B-Raf inhibitor therapy (15%).

The data announced today will be presented as part of a poster presentation at the upcoming ASCO meeting:

Title: ENCORE 601: A phase II study of entinostat (ENT) in combination with pembrolizumab (PEMBRO) in patients with melanoma
First Author: Melissa Lynne Johnson, M.D., Sarah Cannon Research Institute
Abstract Number: 9529
Poster Session: Melanoma/Skin Cancers
Poster Board: 137
Date and Time: Saturday, June 3, 2017, 1:15-4:45 PM CT

In addition to the melanoma cohort, ENCORE 601 is evaluating the safety, tolerability and efficacy of entinostat given in combination with KEYTRUDA in three additional cohorts: 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); and microsatellite stable colorectal cancer who have not previously been treated with a PD-1 antagonist (cohort 4). As previously announced, cohort 2 has met the pre-specified objective response threshold to advance into the second stage of the Phase 2 trial and enrollment has been reopened. A decision on whether to advance cohort 1 is expected this quarter.

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.

Trademarks

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. Kenilworth, NJ, USA.

YERVOY® is a registered trademark of Bristol-Myers Squibb Company

OPDIVO® is a registered trademark of Bristol-Myers Squibb

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