



Syndax Announces Updated Results from Phase 2 ENCORE 601 Trial of Entinostat in Combination with KEYTRUDA® (pembrolizumab) in Non-Small Cell Lung Cancer

- *Updated biomarker analyses continue to support prior observation of enhanced clinical benefit in subpopulation of patients with elevated baseline levels of peripheral classical blood monocytes; 5.3 month PFS and 21% ORR observed in subpopulation –*
- *Company provides update on timeline for E2112 Phase 3 registration trial of entinostat plus exemestane in HR+, HER2- breast cancer -*

WALTHAM, Mass., September 24, 2018 (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 updated results from the ongoing ENCORE 601 cohort enrolling non-small cell lung cancer (NSCLC) patients previously treated with both chemotherapy and PD-(L)1 therapy. The oral presentation titled, "Efficacy/Safety of Entinostat (ENT) and Pembrolizumab (PEMBRO) in NSCLC Patients Previously Treated with Anti-PD-(L)1 Therapy", was presented by Matthew D. Hellman, M.D., study investigator and medical oncologist at Memorial Sloan Kettering Cancer Center, at the International Association for the Study of Lung Cancer (IASLC) 19th World Conference on Lung Cancer (WCLC) in Toronto, Canada. A copy of the presentation is available via the Syndax website at <http://www.syndax.com/science/publications/>.

"The observation of durable responses seen with the entinostat-pembrolizumab combination in NSCLC patients previously treated with both chemotherapy and PD-(L)1 therapy is an important result, and we look forward to more fully characterizing patient selection tools to identify those who are most likely to respond," said Peter Ordentlich, Ph.D., Syndax co-founder and Chief Scientific Officer. "The exploratory finding that baseline peripheral classical monocytes may predict clinical benefit to the combination provides an opportunity to potentially correlate a readily measurable circulating biomarker with the state of the tumor microenvironment and supports the use of this approach for patient selection in future studies."

The Company previously presented a subset of data from the first 57 patients in the Phase 2 ENCORE 601 NSCLC cohort, which enrolled patients whose disease had progressed after prior chemotherapy and anti-PD-(L)1 treatment, at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting this past June. The updated data set presented today includes data from all 76 patients who enrolled in this cohort prior to the close of enrollment in December 2017, and highlights the durability of the observed responses independent of prior treatment history or PD-(L)1 status. At the time of data cut-off, there were 7 confirmed partial responses (PRs) among the overall population of 72 efficacy-evaluable patients, for a 10% objective response rate (ORR) (95% CI: 4-19%), a median duration of response of 5.3 months, and a median progression free survival (PFS) of 2.8 months. The results did not meet the prespecified ORR endpoint. Six of the 7 responders had low or negative PD-(L)1 expression at study entry. At the time of data cut-off, 6 patients remain on study. Updated data continue to demonstrate a manageable toxicity profile for the entinostat-pembrolizumab combination, with treatment emergent adverse events observed consistent with those previously reported.



Exploratory analysis of baseline biomarkers in the fully enrolled cohort supports the previous observation from the first 57 patients that elevated pre-treatment baseline levels of peripheral classical blood monocytes (CD14+CD16-HLA-DRhi) are associated with enhanced clinical benefit to the entinostat-pembrolizumab combination. Baseline peripheral classical monocyte data were available for 65 of the 72 NSCLC patients evaluable for efficacy and were divided into a group of high baseline monocytes (“monocyte high” n = 19) and low baseline monocytes (“monocyte low” n = 46). The monocyte high subset showed an improved median PFS (5.3 months vs 2.7 months), and an enhanced ORR (21% vs 7%), with 5 of 19 (26%) patients remaining on study compared to only 1 of 46 (2%) in the monocyte low group.

“We continue to remain encouraged by the consistent observation of enhanced clinical benefit in the subgroup of patients who failed prior PD-1 treatment and had high baseline levels of classical peripheral monocytes, a population for whom novel therapies are needed,” said Briggs Morrison, M.D., Chief Executive Officer of Syndax. “We recognize the importance of identifying patients more likely to respond to treatment and believe that our updated classical monocyte dataset strengthens the rationale for further validation of this patient selection biomarker. We look forward to communicating our plans for entinostat in this indication in the fourth quarter.”

E2112 Update

Syndax also announced today that ECOG-ACRIN Cancer Research Group has informed the Company that enrollment in the ongoing E2112 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 now scheduled to close in late October. The Company will release the results of the PFS analysis following its review, and anticipates communicating this in the fourth quarter. The trial remains ongoing, with interim overall survival (OS) analyses scheduled to occur every May and November until either the appropriate number of events are achieved or definitive interim results are obtained.

About Entinostat

Entinostat is a selective, oral, once-weekly inhibitor of class 1 HDACs, currently being evaluated in a pivotal Phase 3 clinical trial (E2112) in combination with exemestane for advanced hormone receptor positive, human epidermal growth factor receptor 2 negative breast cancer, an indication for which it has been granted Breakthrough Therapy Designation by the FDA. Entinostat has also been shown to block the function of immune suppressive cells in the tumor microenvironment, and is being evaluated in combination with several approved PD-1/PD-L1 antagonists, including in ongoing Phase 2 clinical trials combining entinostat with KEYTRUDA® from Merck & Co., Inc. for non-small cell lung cancer, melanoma and colorectal cancer (ENCORE 601); with TECENTRIQ® from Genentech, Inc. for triple negative breast cancer as well as advanced hormone receptor positive, human epidermal growth factor receptor 2 negative breast cancer (ENCORE 602); and with BAVENCIO® from Pfizer Inc. and Merck KGaA, Darmstadt, Germany, for ovarian cancer (ENCORE 603).

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-L1 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 MLLr. 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 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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