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Syndax Pharmaceuticals Announces Clinical Collaboration to Evaluate Entinostat in Combination with anti-PD-L1 Cancer Immunotherapy in Breast Cancer

-Phase Ib/II trial will assess the efficacy, safety, and pharmacokinetics of immunotherapy combination in HR+, HER2- metastatic breast cancer-

WALTHAM, Mass., Jan. 10, 2018 /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 a new clinical collaboration with Genentech, a member of the Roche Group. As part of the collaboration, the two companies will evaluate the combination of Syndax's entinostat, an oral, small molecule, class I HDAC inhibitor, and Genentech's programmed cell death ligand 1 (PD-L1) blocking antibody, atezolizumab (TECENTRIQ[®]), in patients with second-line hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+, HER2-) metastatic breast cancer.

The planned Phase Ib/II, open-label, multicenter, randomized trial will enroll patients with metastatic HR+, HER2- breast cancer who have experienced disease progression during or following first-line therapy. Genentech will be responsible for conducting the trial. The trial will be conducted as part of MORPHEUS, Roche's novel cancer immunotherapy development platform. MORPHEUS is a Phase Ib/II adaptive platform to develop combinations of cancer immunotherapies more rapidly and efficiently.

"This collaboration represents further validation of the ongoing interest to test the potential ability of Syndax's entinostat to enhance the effectiveness of an immuno-oncology therapy in an area of unmet medical need," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "While checkpoint inhibitors have shown initial promise in triple-negative breast cancer, there is a clear need to augment the effectiveness of such therapies in the setting of HR+, HER2- breast cancer."

In August 2015, Syndax announced a separate collaboration with Genentech for ENCORE 602, a Phase Ib/II trial to examine the safety, tolerability and clinical activity of entinostat in combination with TECENTRIQ in triple-negative breast cancer. ENCORE 602 is expected to complete enrollment in the Phase II portion of the trial in the first half of 2018.

Financial and other terms of the agreement were not disclosed.

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.

TECENTRIQ[®] (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

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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