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Syndax Pharmaceuticals Announces Collaboration with the National Cancer Institute to Develop Entinostat and SNDX-6352 for the Treatment of Cancer

WALTHAM, Mass., Dec. 14, 2016 (GLOBE NEWSWIRE) -- Syndax Pharmaceuticals, Inc. ("Syndax," or "we") (Nasdaq:SNDX), a clinical stage biopharmaceutical company focused on developing entinostat and SNDX-6352 in multiple cancer indications, today announced that it has entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), part of the National Institutes of Health, for intramural preclinical and clinical research. As part of the CRADA, Syndax will collaborate with the Laboratory of Tumor Immunology and Biology at the NCI to evaluate the therapeutic benefit of entinostat, an oral, Class 1 selective small molecule histone deacetylase (HDAC) inhibitor in development for the treatment for multiple cancers, and SNDX-6352, a humanized IgG4 monoclonal antibody with high affinity against colony-stimulating factor 1 receptor (CSF-1R) in development as a treatment of neoplastic diseases. This CRADA complements the existing CRADA in place with the NCI's Cancer Therapy Evaluation Program to evaluate entinostat in clinical trials.

All preclinical and clinical studies conducted under this new CRADA will be led by Jeffrey Schlom, Ph.D., Chief of the Laboratory of Tumor Immunology and Biology at the NCI's Center for Cancer Research, and in collaboration with James Gulley, M.D., Ph.D., Chief of the Genitourinary Malignancies Branch at the NCI's Center for Cancer Research. The terms of the CRADA allow for *in vitro* and *in vivo* testing of entinostat and SNDX-6352 as single agents and as combination therapies for the treatment of cancer. Based on the results of these studies, the NCI and Syndax may also conduct clinical studies with entinostat and SNDX-6352 alone or in combination with each other. Additionally, entinostat and SNDX-6352 may be combined with other therapeutic regimens such as chemotherapy, small molecule targeted therapeutics, monoclonal antibodies, radiation, immunotherapy-enhancing molecules including checkpoint inhibitors, cancer vaccines and NK cell-based approaches.

"We are excited by this collaboration with the NCI's Center for Cancer Research, as it will allow us to leverage the expertise of Dr. Schlom and his team to enhance our ongoing efforts to identify the most promising potential applications of entinostat and SNDX-6352," said Briggs W. Morrison, M.D., Chief Executive Officer at Syndax. "In preclinical models, entinostat inhibits regulatory T cells and myeloid-derived suppressor cells, while SNDX-6352 down regulates tumor promoting macrophages. In turn, this leads to the targeting of what are believed to be some of the most critical pathways by which tumors mediate immunosuppression in the tumor microenvironment. We look forward to sharing our progress on this important collaborative research and to further partner with the NCI."

About Syndax Pharmaceuticals, Inc.

Syndax is a clinical stage biopharmaceutical company focused on developing an innovative pipeline of combination therapies in multiple cancer indications. 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. Syndax is developing entinostat, which has direct effects on both cancer cells and immune regulatory cells, and SNDX-6352, an anti-CSF-1R monoclonal antibody, to enhance the body's immune response on tumors that have shown sensitivity to immunotherapy. Entinostat is being evaluated as a combination therapeutic in Phase 1b/2 clinical trials with Merck & Co., Inc. for non-small cell lung cancer and melanoma; with Genentech, Inc. for TNBC; and with Pfizer Inc. and Merck KGaA, Darmstadt, Germany, for ovarian cancer. 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. For more information on Syndax, please visit www.syndax.com.

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 SNDX-6352 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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