October 17, 2017

Syndax Expands Pipeline with Exclusive Worldwide License to Allergan's Portfolio of Menin-MLL Inhibitors

- Compounds Provide Novel Therapeutic Approach for the Potential Treatment of Defined Genetic Subtype of Pediatric and Adult Acute Leukemias -

WALTHAM, Mass., Oct. 17, 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 that it has entered into an exclusive worldwide license agreement with Vitae Pharmaceuticals, Inc., a subsidiary of Allergan plc, for a portfolio of preclinical, orally-available small molecule inhibitors of the interaction of Menin with the Mixed Lineage Leukemia ("MLL") protein. These compounds have potential application in the treatment of a genetically-defined subset of acute leukemias with chromosomal rearrangements in the MLL gene ("MLL-r"). Syndax expects to initiate clinical studies in 2019.

"This agreement represents another strategic addition to our pipeline that we believe will enhance the long-term value of Syndax," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "Syndax is well positioned to develop this unique product portfolio which holds the potential to significantly change the treatment paradigm for acute leukemic patients harboring MLL translocations, a disease that may meet the guidelines for orphan designation."

"The Menin-MLL-r interaction is thought to play a central role in the pathology of acute leukemia patients with MLL translocations, a patient population routinely identified in clinical practice today," said Michael L. Meyers, M.D., Ph.D., Chief Medical Officer of Syndax. "While intensive chemotherapy regimens are often employed in these patients, the 5-year survival rate remains significantly below 50% due to the lack of effective treatment options. We believe that this portfolio of compounds holds the potential to serve as an effective oral therapeutic option for pediatric and adult patients with MLL-r-driven leukemias."

Under the terms of the license agreement, Syndax will make a one-time upfront payment to Allergan and will be responsible for development, manufacturing and global commercialization of the portfolio. Allergan will receive development and commercial stage milestones and tiered royalties on net sales of commercialized products.

About MLL Rearranged (MLL-r) Leukemias

Rearrangements of the MLL gene occur in 70-80% of infant acute leukemias and up to 10% of adult acute leukemias and are associated with a poor prognosis, with less than 40% of infants with MLL-r surviving past 5 years. The protein products of MLL gene rearrangements require interaction with a protein called Menin in order to drive leukemic cancer growth. Disruption of the Menin-MLL-r interaction has been shown to halt the growth of MLL-r leukemic cells. MLL-r leukemias are routinely diagnosed through currently available genetic screening techniques in leukemic cells, but there are currently no approved therapies indicated for MLL-r leukemias.

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 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, the potential use of the acquired compounds to treat pediatric and adult patients with MLL-r driven leukemias, the timing of the clinical development of the acquired compounds, the amount of cash, cash equivalents and marketable securities needed to fund payment obligations and development efforts and Syndax's potential payment of upfront and milestone payments and royalties. 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.

Investor Contact

Melissa Forst
Argot Partners
melissa@argotpartners.com
Tel 212.600.1902

Media Contact
Eliza Schleifstein
Argot Partners
eliza@argotpartners.com
Tel 973.361.1546

SNDX-G

View original content:http://www.prnewswire.com/news-releases/syndax-expands-pipeline-with-exclusive-worldwide-license-to-allergans-portfolio-of-menin-mll-inhibitors-300537812.html

SOURCE Syndax Pharmaceuticals, Inc.