



## **Syndax Announces Dosing of First Patient in Pivotal Trial of Entinostat for the Treatment of Advanced or Recurrent Breast Cancer in Japan by Partner Kyowa Hakko Kirin**

*- Enrollment of First Patient Triggers \$5 Million Milestone Payment to Syndax -*

WALTHAM, Mass., October [5], 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 Kyowa Hakko Kirin Co., Ltd (Kyowa Hakko Kirin), its Japan and Korea sublicensee, has now dosed the first patient in a randomized, double-blind, placebo-controlled, pivotal Phase 2 trial of entinostat (designated KHK2375 by Kyowa Hakko Kirin), Syndax's oral Class-I histone deacetylase inhibitor, in combination with exemestane versus exemestane plus placebo in Japanese patients with advanced or recurrent hormone receptor-positive (HR+), human epidermal growth factor receptor two-negative (HER2-) breast cancer. Enrollment of the first patient in this trial triggers a \$5 million milestone payment to Syndax from Kyowa Hakko Kirin.

"Dosing of the first patient in this pivotal trial marks another important milestone in the entinostat development program," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "We are nearing completion of enrollment of our Phase 3 trial, E2112, comparing entinostat plus exemestane to exemestane monotherapy in advanced HR+, HER2- breast cancer. We currently anticipate completion of enrollment in this Phase 3 trial, and release of the progression free survival analysis to be available in the first half of 2018. Through our partnership with Kyowa Hakko Kirin, we are also working to make this promising breast cancer therapy available to patients globally."

The Phase 2 trial is expected to enroll approximately 124 patients in Japan. The primary endpoint of the trial will be progression free survival, with secondary endpoints including overall survival, overall response rate, and safety.

In January 2015, Syndax announced completion of a license agreement with Kyowa Hakko Kirin for the exclusive rights to develop and commercialize entinostat in Japan and Korea.

### **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 Phase 1 clinical trials and is expected to be developed to treat a variety of cancers.

### **About Kyowa Kirin**

Kyowa Hakko Kirin Co., Ltd. is a research-based life sciences company, with special strengths in biotechnologies. In the core therapeutic areas of oncology, nephrology and immunology/allergy, Kyowa Hakko Kirin leverages leading-edge biotechnologies centered on antibody technologies, to continually discover innovative new drugs and to develop and market those drugs world-wide. In this way, the company is working to realize its vision of becoming a Japan-based global specialty pharmaceutical company that contributes to the health and wellbeing of people around the world. You can learn more about the business at: [www.kyowa-kirin.com](http://www.kyowa-kirin.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 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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