Syndax Announces NCI and FDA Reach Agreement on a Special Protocol Assessment (SPA) for the Phase 3 Trial of Entinostat in Patients with Advanced ER+ Breast Cancer

WALTHAM, Mass., Feb. 13, 2014 — Syndax Pharmaceuticals, Inc., today announced that the Division of Cancer Treatment and Diagnosis (DCTD) of the National Cancer Institute (NCI) has reached a special protocol assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) for the planned pivotal Phase 3 trial of entinostat in patients with advanced breast cancer. The Phase 3 trial, expected to begin in the first half of this year, is intended to evaluate entinostat in combination with exemestane in postmenopausal patients with advanced estrogen receptor-positive (ER+) breast cancer who have progressed on a non-steroidal aromatase inhibitor. The study is being conducted by the ECOG-ACRIN Cancer Research Group under the sponsorship of the DCTD. DCTD, NCI is sponsoring the trial as part of the development of entinostat under a Cooperative Research and Development Agreement between NCI and Syndax.

“This agreement between the NCI and FDA clearly defines our path to submission of entinostat for FDA approval in patients with ER+ advanced breast cancer if our pivotal Phase 3 trial is successful,” said Arlene M. Morris, Syndax’s chief executive officer. “We’ve worked closely with the NCI and ECOG-ACRIN to design this Phase 3 trial, and we’re pleased that FDA has agreed with the overall design and proposed data analysis, particularly the use of two primary endpoints allowing for either progression-free survival (PFS) or overall survival (OS) as a basis for submitting an NDA, if data are positive.”

A SPA agreement is an affirmation from the FDA that a planned Phase 3 trial's design, clinical endpoints and statistical analyses are suitable for support of regulatory approval and acceptance of the proposed efficacy claim after the trial has concluded and if the data fit the prospectively defined success criteria. The SPA is not binding on FDA if new scientific or public health concerns arise prior to approval of an entinostat NDA.

About Syndax Pharmaceuticals

Syndax is developing entinostat for the treatment of patients with therapy-resistant cancers. Entinostat is designed to prolong the effectiveness of current cancer treatments through an epigenetic mechanism and has been designated a Breakthrough Therapy by the FDA when used in combination with exemestane in ER+ metastatic breast cancer. The company holds worldwide rights to entinostat, an oral, selective HDAC inhibitor that is expected to be evaluated

in combination with exemestane in a pivotal Phase 3 clinical study for the treatment of ER+ metastatic breast cancer.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements contained in this press release include statements about the timing and design of the Phase 3 trial, and the FDA approval process. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" 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 not guarantees of future performance and involve a number of unknown risks, assumptions, uncertainties and factors that are beyond Syndax's control. All forward-looking statements are based on Syndax's expectations and assumptions as of the date of this press release. Actual results may differ materially from these forward-looking statements. Except as required by law, Syndax expressly disclaims any responsibility to update any forward-looking statement contained herein, whether as a result of new information, future events or otherwise.