



Syndax Announces Orphan Drug Designation Granted to SNDX-5613 by European Commission for the Treatment of Acute Myeloid Leukemia

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WALTHAM, Mass., Dec. 22, 2021 /PRNewswire/ -- Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq: SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today announced that the European Commission has granted Orphan Drug Designation to SNDX-5613, the Company's highly selective oral menin inhibitor, for the treatment of acute myeloid leukemia (AML).

"Supported by a growing body of clinical data, we firmly believe that SNDX-5613 is ideally positioned to serve as a best-in-class, meaningful intervention for patients with NPM1 and MLLr acute leukemias," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "Receipt of Orphan Drug Designation from the European Commission further validates the important role that SNDX-5613 could play in the treatment of this highly underserved patient population, and we are fully committed to ensuring that it is able to reach as many of these patients as possible."

The European Commission grants Orphan Drug Designation for medicinal products intended to treat life-threatening or chronically debilitating conditions that affect fewer than five in 10,000 people in the European Union (EU) and when no satisfactory method of diagnosis, prevention, or treatment of the condition can be authorized. The designation provides certain benefits and incentives in the EU, including protocol assistance, fee reductions, and ten years of market exclusivity once the medicine is on the market.

SNDX-5613 was [previously granted](#) Orphan Drug Designation for the treatment of adult and pediatric AML by the U.S. Food and Drug Administration.

About SNDX-5613

SNDX-5613 is a potent, selective, small molecule inhibitor of the menin-MLL binding interaction that is being developed for the treatment of mixed lineage leukemia rearranged (MLLr) acute leukemias including acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML), and NPM1 mutant AML. In preclinical models of MLLr acute leukemias, SNDX-5613 demonstrated robust, dose-dependent inhibition of tumor growth, resulting in a marked survival benefit. Menin-MLL interaction inhibitors have also demonstrated robust treatment benefit in multiple preclinical models of NPM1 mutant AML, which represents the most frequent genetic abnormality in adult AML. SNDX-5613 is currently being evaluated in the Company's AUGMENT-101 Phase 1/2 open-label clinical trial for the treatment of relapsed/refractory (R/R) acute leukemias. SNDX-5613 was granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and European Commission for the treatment of patients with AML, and Fast Track designation by the U.S. FDA for the treatment of adult and pediatric patients with R/R acute leukemias harboring a mixed lineage leukemia rearranged MLLr or NPM1 mutation.

About Syndax Pharmaceuticals, Inc.

Syndax Pharmaceuticals is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. The Company's pipeline includes SNDX-5613, a highly selective inhibitor of the Menin-MLL binding interaction, axatilimab, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, and entinostat, a class I HDAC inhibitor. For more information, please visit www.syndax.com or follow the Company on Twitter and LinkedIn.

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 and fibrotic diseases. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical trials, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, the COVID-19 pandemic may disrupt our business and that of the third parties on which we depend, including delaying or otherwise disrupting our clinical trials and preclinical studies, manufacturing and supply chain, or impairing employee productivity, 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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