Syndax Announces PDUFA Action Date Extension for Revumenib NDA for Relapsed or Refractory KMT2Ar Acute Leukemia

July 29, 2024

– New PDUFA action date of December 26, 2024 allows FDA additional time to complete their review –

WALTHAM, Mass., July 29, 2024 /PRNewswire/ -- Syndax Pharmaceuticals (Nasdaq: SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today announced that the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) action date for the New Drug Application (NDA) for revumenib for the treatment of adults and pediatric patients with relapsed or refractory (R/R) KMT2Ar acute leukemia.

The FDA notified Syndax on July 26, 2024 that they required additional time to conduct a full review of supplemental information provided to the FDA in response to their requests. The submission of additional information to the FDA was determined to constitute a Major Amendment to the NDA and resulted in a standard three-month extension to the original PDUFA action date of September 26, 2024. No additional trials or manufacturing information have been requested by the FDA.

"Revumenib, upon approval, will be the first drug indicated to treat patients with KMT2A-rearranged acute leukemia, a population with significant unmet need," said Michael A. Metzger, Chief Executive Officer. "We are confident that the data from the AUGMENT-101 trial, as well as the additional information provided to the FDA, support approval and continue to demonstrate the meaningful benefit revumenib brings to patients with this devastating disease. We look forward to continuing our engagement with the FDA as they complete their review of the NDA by December 26, 2024."

The NDA for revumenib was granted Priority Review and is being reviewed under the FDA's Real-Time Oncology Review (RTOR) program. The FDA previously granted Breakthrough Therapy, Fast Track and Orphan Drug designations for revumenib.

About Revumenib
Revumenib is a potent, selective, small molecule inhibitor of the menin-KMT2A binding interaction that is being developed for the treatment of KMT2A-rearranged (KMT2Ar), also known as mixed lineage leukemia rearranged or MLLr, acute leukemias including ALL and AML, and mutant nucleophosmin (mNPM1) AML. Positive topline results from the Phase 2 AUGMENT-101 trial in R/R KMT2Ar acute leukemia showing the trial met its primary endpoint were presented at the 65th American Society of Hematology Annual Meeting, and data from the Phase 1 portion of AUGMENT-101 in acute leukemia was published in Nature. Revumenib was granted Orphan Drug Designation for the treatment of AML and ALL by the FDA and for the treatment of AML by the European Commission, and Fast Track designation by the FDA for the treatment of adult and pediatric patients with R/R acute leukemias harboring a KMT2A rearrangement or NPM1 mutation. Revumenib was granted Breakthrough Therapy Designation by the FDA for the treatment of adult and pediatric patients with R/R acute leukemia harboring a KMT2A rearrangement.

About the Real-Time Oncology Review Program (RTOR)

RTOR provides a more efficient review process for oncology drugs to ensure that safe and effective treatments are available to patients as early as possible, while improving review quality and engaging in early iterative communication with the applicant. Specifically, it allows for close engagement between the sponsor and the FDA throughout the submission process and it enables the FDA to review individual sections of modules of a drug application rather than requiring the submission of complete modules or a complete application prior to initiating review. Additional information about RTOR can be found at: https://www.fda.gov/about-fda/oncology-center-excellence/real-time-oncology-review-pilot-program

About Syndax

Syndax Pharmaceuticals is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. Highlights of the Company's pipeline include revumenib, a highly selective inhibitor of the menin–KMT2A binding interaction, and axatilimab, a monoclonal antibody that blocks the CSF-1 receptor. For more information, please visit www.syndax.com or follow the Company on X (formerly Twitter) and LinkedIn.

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 "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative or plural of those terms, 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, the reporting of clinical data for Syndax's product candidates, and the potential use of its 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; 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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