Syndax Announces Plans to Advance into Phase 1b Portion of Trial Evaluating Revumenib in Relapsed or Refractory Metastatic MSS CRC

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– IDMC recommendation to advance based on favorable safety profile observed in Phase 1a portion of trial –

WALTHAM, Mass., June 6, 2024 /PRNewswire/ -- Syndax Pharmaceuticals (Nasdaq: SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today announced that it has advanced into the Phase 1b portion of its Phase 1/2 proof-of-concept trial of revumenib, the Company's highly selective, oral menin inhibitor, as a monotherapy in patients with relapsed or refractory (R/R) metastatic microsatellite stable (MSS) colorectal cancer (CRC). The Company's decision was supported by the trial's Independent Data Monitoring Committee (IDMC) following its recent pre-planned review of initial data from the Phase 1a portion of the trial.

"In our first clinical trial exploring expansion of revumenib beyond hematological malignancies, initial results from the Phase 1a portion of the trial are encouraging," said Neil Gallagher, M.D., Ph.D., President, Head of Research and Development at Syndax. "We are particularly pleased to observe a compelling safety profile consistent with our existing revumenib dataset, as well as efficacy signals that include a 33% stable disease rate at 16 weeks as a monotherapy, which compares favorably with current standard-of-care and supports advancement into the Phase 1b portion. As we continue to focus on preparations for the potential launches of revumenib and axatilimab later this year, we look forward to continuing to explore the role revumenib could play in the treatment of R/R metastatic MSS CRC."

The Phase 1/2 trial (NCT05731947) is designed to assess the safety, tolerability, and anti-tumor activity of revumenib in patients with relapsed or refractory metastatic MSS CRC. The Phase 1a dose escalation portion of the trial enrolled a total of 19 patients who had a median of four prior therapies across three dose cohorts, including 163 mg, 226 mg, and 276 mg three times a day (TID). Revumenib was well-tolerated at all dose levels tested and the safety profile was consistent with the Company's previously reported data. No Grade 3 or greater treatment-related adverse events (TRAEs) were observed and the most common TRAEs were decreased appetite, dysgeusia, nausea, and fatigue. In addition, the initial efficacy results provide early clinical support that revumenib may be able to impact disease progression in R/R patients with metastatic MSS CRC. At doses believed to achieve full target saturation, dose levels 2 and 3, 44% (4/9) of patients had stable disease at 8 weeks, and 33% (3/9) of patients had stable disease at 16 weeks. One patient with prolonged stable disease remained on study for 32 weeks. Based on the initial data, 276 mg TID was selected as the go-forward dose in the Phase 1b portion.

About Metastatic MSS CRC

Metastatic microsatellite stable (MSS) colorectal cancer (CRC) represents the second leading cause of cancer death in the U.S. with an estimated incidence in the relapsed or refractory (R/R) setting of over 55,000 patients per year. Activation of the Wnt/β-catenin signaling pathway is believed to be a key initiating step and growth driver for the majority of CRC tumors. The menin-MLL1 protein complex has been shown to regulate β-catenin activity and disrupting this complex through menin inhibition blocks growth of Wnt/β-catenin driven CRC tumors in preclinical models.

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) acute myeloid leukemia (AML). Positive topline results from the pivotal 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. Pivotal data from the AUGMENT-101 trial in R/R NPM1 AML patients are expected in the fourth quarter of 2024. Revumenib was granted Orphan Drug Designation by the FDA and European Commission for the treatment of patients with AML 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. The NDA filing for revumenib in R/R KMT2Ar acute leukemia is currently under Priority Review by the FDA under RTOR with a PDUFA action date of September 26, 2024.

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 menin inhibitor, 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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View original content:https://www.prnewswire.com/news-releases/syndax-announces-plans-to-advance-into-phase-1b-portion-of-trial-evaluating-revumenib-in-relapsed-or-refractory-metastatic-mss-crc-302165405.html

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