

Xanthus Meets Milestone in Phase 2 Clinical Study of Xanafide for Treatment of Secondary AML

CAMBRIDGE, Mass., June 5 /PRNewswire/ -- Xanthus Pharmaceuticals, Inc., a privately-held oncology drug development company, today announced the completion of a planned interim analysis of its Phase 2 study of Xanafide(TM) (amonafide malate) for the treatment of patients with secondary acute myeloid leukemia (AML).

The planned interim efficacy analysis was conducted on data from the first 26 patients enrolled in the trial. In addition, an independent Data Safety Monitoring Board (DSMB) has reviewed the current safety and efficacy data and has recommended continuation of the trial under the current protocol.

"The completion of this planned interim efficacy analysis and the DSMB review are an important milestone in our Xanafide development program, as we continue enrolling patients and move forward to complete this Phase 2 study. While it is too early to draw any firm conclusions, we were pleased with the interim results of this Phase 2 study, both in terms of safety as well as the clinical response rate," said Richard T. Dean, Ph.D., Chief Executive Officer at Xanthus.

About the Xanafide(TM) Phase 2 study

The Phase 2 study is being conducted at multiple centers in North America and is expected to enroll up to 80 patients with secondary AML (patients with antecedent myelodysplastic syndrome or prior exposure to leukemogenic therapy). In this study, patients receive a daily dose of Xanafide for five days in combination with a standard dose of ara-C as a continuous infusion for 7 days. The primary endpoint of the study is the rate of complete remission, and secondary endpoints include duration of remission and overall survival.

Xanthus also announced today that data from Phase 1 studies of Xanafide were presented at the 42nd Annual Meeting of the American Society of Clinical Oncology (ASCO). The data were from a retrospective review of the activity of Xanafide, both as a monotherapy and in combination with ara-C, specifically in patients with secondary AML in the Phase 1 studies. In both the monotherapy and combination regimens Xanafide was found to be active. These results formed the basis of Xanthus' ongoing Phase 2 trial. The details of the data can be found in ASCO abstract # 6584 titled, "Clinical and Cytogenetic Responses to Amonafide in Secondary Acute Myeloid Leukemia (AML)".

About Xanafide(TM) and Secondary AML

Xanafide (amonafide malate) is an ATP-independent topoisomerase 2 inhibitor that the Company is developing for the treatment of secondary acute myeloid leukemia (AML) and related disorders. Secondary AML patients have had either antecedent myelodysplastic syndrome or prior exposure to leukemogenic therapy and represent a poor prognosis population. While de novo AML is currently treated by approved drugs for this first-line indication, no effective therapies are approved specifically for patients with secondary AML. In a Phase 1 study conducted in patients with poor-risk AML, amonafide and ara-C exhibited particularly promising clinical activity in patients with secondary AML and in some cases, resulted in complete or near-complete remissions.

About Xanthus Pharmaceuticals, Inc.

Xanthus Pharmaceuticals, Inc. is developing a portfolio of novel, clinical-stage, small-molecule oncology candidates through a management team whose accomplished track record encompasses all aspects of drug development, from discovery through regulatory approval and commercialization. The Company is applying its expertise both to advance its current pipeline and expand it into indications of unmet medical need beyond oncology.

Xanthus is headquartered in Cambridge, Massachusetts with an additional facility in Montreal, Quebec. More information is available at <http://www.xanthus.com>.

This press release contains forward-looking statements concerning Xanthus that involve a number of risks and uncertainties. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words, "believes," "anticipates," "plans," "expects," "estimates," "intends," "should," "could," "will," "may," and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause Xanthus' actual results to differ materially from those indicated by such forward-looking statements, including risks as to whether results obtained in early clinical studies or in preclinical studies such as the studies referred to above will be indicative of results obtained in future clinical trials or warrant additional trials; whether products based on Xanthus' technology will advance through the clinical trial process and receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether the company will have the cash resources to develop and commercialize its products; and whether the patent and patent applications owned or licensed by Xanthus will protect the Company's technology and

prevent others from infringing it. Xanthus disclaims any intention or obligation to update any forward-looking statements.

SOURCE Xanthus Pharmaceuticals, Inc.

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