

Xanthus Completes Special Protocol Assessment with  
FDA for Phase 3 Registration Trial of Xanafide in Patients with  
Secondary Acute Myeloid Leukemia

CAMBRIDGE, Mass.--June 12, 2007--Xanthus Pharmaceuticals, Inc., today announced that it has reached an agreement with the U.S. Food and Drug Administration (FDA) under the FDA's Special Protocol Assessment (SPA) process for the design of its planned Phase 3 registration trial of Xanafide(R) (amonafide malate) for the treatment of patients with secondary acute myeloid leukemia (sAML). Under the SPA agreement with the FDA, a statistically significant, positive result for the Phase 3 trial would support an efficacy claim for Xanafide in secondary AML in a New Drug Application (NDA).

The Phase 3 trial is designed as an open-label, randomized, active control, multi-center study of Xanafide in combination with cytarabine compared to daunorubicin in combination with cytarabine as initial remission induction therapy for patients with secondary AML. We plan to enroll approximately 350 patients in the trial. The primary endpoint of the study will be the rate of complete remission. The study is designed to confirm the rate of complete remission previously observed in the Phase 2 single arm study that we conducted with the same dose and schedule of Xanafide with cytarabine and to show superiority to the rate of confirmed complete remissions for Xanafide in combination with cytarabine as compared to daunorubicin in combination with cytarabine. Duration of remission will be a secondary endpoint to allow for assessment of the durability of remission.

"Secondary AML is a disease with a very poor prognosis, and there is currently no therapy approved specifically for patients with secondary AML," stated Robert L. Capizzi, M.D., Senior Vice President, and Chief Medical Officer at Xanthus. "We believe Xanafide could be a breakthrough treatment for this patient population, and we are very encouraged by the safety as well as the clinical response rate seen in our recently completed multi-center Phase 2 trial."

About Xanafide(R) 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 AML has approved treatments, no therapies are approved by FDA specifically for patients with secondary AML. In both Phase 1 and Phase 2 studies conducted in patients with poor-risk AML, amonafide hydrochloride, exhibited particularly promising clinical activity in patients with secondary AML. Based on these results we began the present program. Xanafide has been granted Orphan Drug designation by the U.S. Food and Drug Administration for use in the treatment of AML.

About Xanthus Pharmaceuticals, Inc.

Xanthus Pharmaceuticals, Inc. is developing a portfolio of novel, clinical-stage, small-molecule therapeutic candidates through a management team whose accomplished track record encompasses all aspects

of drug development, from discovery through regulatory approval and commercialization. Xanthus is applying its expertise to advance its current pipeline to address significant unmet medical needs in oncology and autoimmune diseases.

Xanthus is headquartered in Cambridge, Massachusetts with an additional facility in Montreal, Quebec. More information is available at [www.xanthus.com](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 such as the studies referred to above will be indicative of results obtained in future clinical trials or warrant further clinical 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; and whether the company will have the cash resources to develop and commercialize its products. Xanthus disclaims any intention or obligation to update any forward-looking statements.

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