

## Xanthus Presents at ASCO: Phase 1 Data Shows Significant Activity of Amonafide in Combination With ara-C for Treatment of Poor Risk AML

ORLANDO, Fla. and CAMBRIDGE, Mass., May 17 /PRNewswire/ -- Xanthus Life Sciences today announced the presentation of data from a Phase 1 study of Amonafide (now called Xanafide(TM)) in combination with cytosine arabinoside (ara-C) at the 41st Annual Meeting of the American Society of Clinical Oncology (ASCO). In the study, the combination demonstrated promising activity in patients with poor-risk acute myeloid leukemia (AML).

"Based on the strength of these Phase 1 data, where 38% of the patients went into complete remission, we believe that the Xanafide combination may be an excellent therapeutic candidate for traditionally difficult-to-treat cases of AML," said Robert L. Capizzi, M.D., Xanthus' Chief Medical Officer. "Currently, there are no approved therapies specifically indicated for secondary AML, and following treatment with the regimens that are used today, response rates are low and of brief duration. Xanthus has discussed the results of this Phase 1 study with the FDA, and we plan to initiate a Phase 2 clinical study using Xanafide and ara-C for patients with secondary AML later this year."

### About the study

In the Phase 1 study, 26 patients with AML (secondary AML, i.e., patients with antecedent MDS, myeloproliferative disorder or prior leukemogenic therapy; relapsed de novo AML; and CML in blast crisis) received one of 3 fixed daily doses of Amonafide (600, 700 or 800 mg/m<sup>2</sup>/d) for five days in combination with a standard daily dose of ara-C (200 mg/m<sup>2</sup>/day) as a continuous infusion for 7 days. The maximum tolerated dose of Amonafide was 700 mg/m<sup>2</sup>/d. Among all patients, the clinical response rate was 46% (12/26), with 38% (10/26) achieving complete remission and two patients achieving near-complete remission. The median duration of remission was five months, with two patients remaining disease-free for >29 months and >5 years following post remission therapy. Five early deaths occurred during the study. Overall, Amonafide exhibited an acceptable safety profile in this patient group. Details of the study are included in the ASCO abstract titled, "Phase I study of amonafide + cytosine arabinoside (AraC) in patients with poor-risk acute myeloid leukemia (AML)". The study was presented by the principal investigator, Stephen L. Allen, M.D. of North Shore University Hospital - NYU School of Medicine, Manhasset, New York, in an ASCO Poster Session on May 17, 2005.

### About Xanafide

Xanthus utilized its expertise in chemistry to develop a new salt form of the anticancer compound amonafide, an ATP-independent topoisomerase 2 inhibitor originally developed at Knoll Pharmaceuticals. The Company expects that its new salt form, Xanafide, will have advantages over amonafide in terms of manufacturing yield, solubility, and bioavailability in oral formulations. The original formulation of Xanafide,

amonafide, was administered to over 1000 patients in clinical studies carried out by Knoll and the NCI.

## About Xanthus

Xanthus is an oncology drug development company. Xanthus' small molecule candidates are Xanafide, Symadex(TM) and Clomet(TM) which are advancing in clinical and preclinical development for multiple cancer indications. Each of these product candidates was in-licensed based on significant clinical and, or preclinical data supporting safety and activity. Xanthus also has proprietary technology to individualize patient dosing, which it believes may help improve the performance of certain drugs in development, and facilitate the life cycle management of certain marketed products, without limiting patient populations or markets.

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 Life Sciences

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