Xanthus Presents Symadex Phase 1 Results at American Society of Clinical Oncology Meeting

CAMBRIDGE, Mass., June 5 /PRNewswire/ -- Xanthus Pharmaceuticals, Inc., a privately-held oncology drug development company, today announced the presentation of data from a Phase 1 clinical trial of Symadex(TM) (C-1311) at the 42nd Annual Meeting of the American Society of Clinical Oncology (ASCO). Symadex is currently being studied in two Phase 2 trials in patients with metastatic colorectal cancer and metastatic breast cancer.

The Phase 1 results were presented by study investigator Dr. Nicolas Isambert, of the Centre G-F Leclerc, Dijon, France in a poster titled, "Evaluation of the safety of C-1311 administered in a Phase 1 dose escalation trial as a weekly infusion for three consecutive weeks in patients with advanced solid tumors" (abstract number 6029). In the Phase 1 study, Symadex was well tolerated in patients with advanced solid tumors and the recommended dose of 480 mg/m2 yielded a predictable safety profile.

"Meeting our Phase 1 safety endpoint is an important milestone that supports our continued advancement of Symadex in clinical trials for patients with advanced malignancies," stated Richard T. Dean, Ph.D., Chief Executive Officer at Xanthus.

"In our ongoing studies, Symadex continues to be a promising candidate for both cancer and autoimmune disease," stated Robert L. Capizzi, M.D., Chief Medical Officer at Xanthus. "Bioavailability merits further investigation as oral delivery could greatly improve dosing convenience for patients." Dr. Capizzi continued by stating that, "More recently, our research on Symadex has yielded new evidence suggesting that Symadex may be a targeted kinase inhibitor, a very exciting finding that we are investigating preclinically."

About the Phase 1 Trial

The Phase 1 trial was a dose escalation study that enrolled 22 patients with advanced solid tumors. The primary goal of the study was to determine the optimal dosing schedule to be used in Phase 2. Patients received weekly intravenous infusions of Symadex for three weeks, followed by a week of rest. The dose increased as each patient was added until dose limiting toxicity was reached (640 mg/m2/week) at which point additional patients were treated at the recommended dose of 480 mg/m2/week. Six patients were treated at 480 mg/m2/week in an extension study in which one of the first two doses was given orally.
Symadex exhibited a predictable tolerability profile, with reported adverse events including transient neutropenia, nausea, asthenia, vomiting and diarrhea. Two serious adverse events were reported, both consisting of post-infusion fever without evidence of infection, resolving within 24 hours. No cardiac events were reported.

Researchers published the results from a second Phase 1 study with Symadex in the ASCO 2006 Book of Abstracts that support the safety and tolerability of Symadex when dosed as a one hour infusion, every three weeks. The lead investigator on the study was Dr. Anne Thomas, and the abstract titled, "Evaluation of the safety of C-1311 administered in a Phase 1 dose-escalation trial as a 1-hour infusion once every 3 weeks in patients with advanced solid tumors" is referenced as number 12005.

About Symadex(TM)

Symadex (formerly C-1311) is a next-generation investigational anticancer compound that is part of a new series of agents, the imidazoacridinones, which have shown a potentially novel, targeted mechanism of action in preclinical studies. Additionally, in preclinical studies, Symadex has shown evidence of oral activity. The Company intends to test Symadex in multiple tumor indications. Xanthus is also exploring the use of Symadex for the treatment of a number of autoimmune diseases, such as Multiple Sclerosis, where early preclinical data has shown encouraging signs of activity. Xanthus licensed intellectual property related to Symadex from BTG International, Ltd.

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.

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