Callisto Pharmaceuticals Redirects Atiprimod Clinical Development to Treat Rheumatoid Arthritis

NEW YORK--Callisto Pharmaceuticals, Inc. (OTC BB: CLSP.OB) today announced that it is focusing further development of atiprimod on treatment of rheumatoid arthritis (RA). Atiprimod has demonstrated a favorable clinical safety profile robustly supported by earlier RA studies as well as by recent oncology trials in advanced carcinoid cancer patients, where the drug was dosed at levels and frequencies considerably higher than anticipated for use in RA. Callisto believes that atiprimod holds significant promise as a new class of orally-administered, disease-modifying agent in RA.

During my years at SmithKline Beecham where I was directly involved in atiprimod’s initial discovery and subsequent testing in numerous biological systems, I became convinced of the potential of atiprimod to treat rheumatoid arthritis, said Dr. Alison M. Badger, former Associate Director of Research at SmithKline Beecham (now Glaxo SmithKline). Based on the earlier completion of the Phase I clinical trials of atiprimod in RA patients, where no adverse side effects were observed and reports of positive effects in RA patients were noted, I became even more convinced of its potential for the therapy of this condition. I have worked toward this goal for many years and believe that this compound has real potential to relieve the suffering of RA.

Callisto has retained Glenn Cornett, MD, PhD as a strategic advisor on the repurposing of atiprimod for RA. Dr. Cornett founded and served as CEO of Navitas Pharma, who recently closed a deal with Gilead based on the repurposing of a new class of drug for pulmonary hypertension. I was impressed by atiprimod as a significant opportunity to introduce a new class of oral DMARD for RA, said Dr. Cornett. Based on early clinical data, the drug appears to hold advantages in terms of safety and speed of onset relative to other oral, disease-modifying agents for RA, and to have a broad therapeutic window.

On December 19, 2008, Callisto announced a Technology Assignment Agreement with AnorMED, a wholly-owned subsidiary of Genzyme Corporation, acquiring all rights to atiprimod in return for a cash payment of $650,000 from Callisto. Pursuant to the Technology Assignment Agreement, the earlier Amended and Restated License Agreement between Callisto and AnoMED dated December 31, 2007 was terminated. Callisto is now discussing atiprimod financing with potential investors and development partners.

Callisto also has initiated a program to preserve capital that includes 50% deferral of senior management salaries, payroll reductions through staff elimination, as well as an across-the-board salary adjustment to all employees and key consultants, resulting in an
overall 28% reduction in personnel compensation.

About Atiprimod

Originally, atiprimod was discovered in a joint research and development program between AnorMED and SmithKline Beecham (SKB). SKB took atiprimod through Phase Ib/Ia trials in RA patients, where the drug gave promising clinical results. Callisto has been developing atiprimod to treat severe late stage cancers, recently finishing a Phase II single-agent clinical trial of the drug to treat advanced carcinoid cancer patients. Atiprimod has a novel mechanism of action, and an extensive toxicology package, as well as a significant body of preclinical studies that demonstrate a novel, meaningful approach to RA. Importantly, current data suggest that the drug modulates interleukin-6 (IL-6), interleukin 1 (IL-1), tumor necrosis factor (TNF), and macrophage and osteoclast activity without being prohibitively immunosuppressive. The drug has also been demonstrated to enhance suppressor-cell activity in the immune system.

About Callisto Pharmaceuticals, Inc.

Callisto is a biopharmaceutical company focused on the development of new drugs to treat human diseases and disorders. Callisto’s drug candidates include SP-304, a proprietary drug for gastrointestinal disorders currently being developed by its majority-owned subsidiary, Synergy Pharmaceuticals, as well as two anti-cancer agents, atiprimod and L-Annamycin. Synergy's proprietary drug SP-304 to treat gastrointestinal disorders recently completed its first Phase I clinical trial in volunteers. The Company's lead drug in the clinic, atiprimod, completed a Phase II clinical trial in advanced carcinoid cancer, a neuroendocrine tumor, and is presently continuing a Phase II extension trial on advanced carcinoid cancer patients. Callisto’s second cancer drug in the clinic, L-Annamycin, is currently in a Phase I clinical trial in children and young adults with refractory or relapsed acute lymphocytic leukemia or acute myelogenous leukemia. Callisto has an exclusive worldwide license from M.D. Anderson Cancer Center to develop, manufacture, use and sell L-Annamycin. More information is available at http://www.callistopharma.com.

Forward-Looking Statements

Certain statements made in this press release are forward-looking. Such statements are indicated by words such as "expect," "should," "anticipate" and similar words indicating uncertainty in facts and figures. Although Callisto believes that the expectations reflected in such forward-looking statements are reasonable, it can give no assurance that such expectations reflected in such forward-looking statements will prove to be correct. As discussed in the Callisto Pharmaceuticals Annual Report on Form 10-K for the year ended December 31, 2007, and other periodic reports, as filed with the Securities and Exchange Commission, actual results could differ materially from those projected in the forward-looking statements as a result of the following factors, among others: uncertainties associated with product development, the risk that products that appeared promising in early clinical trials do not demonstrate efficacy in larger-scale clinical trials, the risk that Callisto will not obtain approval to market its products, the risks associated with dependence upon key personnel and the need for additional financing.

Web site: http://www.callistopharma.com