Callisto Pharmaceuticals Files IND for SP-304 (Guanilib) in Chronic Constipation and Irritable Bowel Syndrome

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NEW YORK--(BUSINESS WIRE)--Callisto Pharmaceuticals, Inc. (AMEX: KAL; FWB: CA4) announced today that through its wholly-owned subsidiary, Synergy Pharmaceuticals, Inc. it filed an IND on April 2, 2008 with the FDA for SP-304 (also called Guanilib) for the treatment of chronic constipation and constipation-predominant irritable bowel syndrome.

SP-304 is an analog of uroguanylin, a natural hormone produced in the gastro-intestinal (GI) tract that is a key regulator of intestinal function. SP-304 works by activating a unique receptor, the GC-C receptor, on intestinal epithelial cells, promoting fluid and ion transport. The drug is administered orally. Nonclinical animal studies have shown SP-304 to be well tolerated. Importantly, SP-304 shows almost no absorption systemically into the body, exerting its effect locally on GC-C receptors within the gut.

“Callisto is pleased that SP-304 is moving forward on schedule into clinical studies. There is strong clinical evidence of efficacy and safety for this class of compounds and we are hopeful that this product may address the significant unmet medical need of patients suffering from chronic constipation and IBS,” said Gary S. Jacob, Ph.D., CEO of Callisto, and Chairman of Synergy Pharmaceuticals. “There are only two compounds presently in this class, our drug, and linaclotide, a drug that is currently being developed by Microbia and Forest Laboratories to treat GI disorders. We believe that SP-304 has the potential to be the best in class.”

In animal models SP-304 has been shown to produce responses supporting its potential to reduce symptoms of chronic constipation and constipation-predominant irritable bowel syndrome. Pending clearance by the FDA, Callisto intends to initiate an SP-304 Phase I clinical trial in 2Q2008 to evaluate safety, pharmacokinetic, and pharmacodynamic properties.

About Chronic Constipation

Chronic constipation is a very common gastrointestinal disorder. Up to 26 million Americans suffer from the disorder, and of this population about 5 million have a severe condition necessitating relief. The prevalence of the disorder is similar in other developed countries. Patients with chronic constipation often experience hard stools, straining during bowel movements and not enough bowel movements during the week. People with chronic constipation can experience serious discomfort which adversely affects their ability to work and their quality of life.

Irritable Bowel Syndrome

Up to one sixth of adults experience inflammatory bowel syndrome (IBS), a condition marked by disturbed bowel function and abdominal pain. IBS patients can have three different sets of symptoms; diarrhea-predominant (IBS-D), constipation-predominant (IBS-C) and mixed or alternating disorder (IBS-M). The split in prevalence between the forms is about 1/3rd each. In addition, most patients suffering from the mixed form of IBS (IBS-M) are believed to mainly have constipation. An estimated 10 M people in the US and an additional 10 M people in the EU suffer from IBS-C. IBS (all forms) accounts for 12% of adult visits to primary care physicians in the US.

About Callisto Pharmaceuticals, Inc.

Callisto is a biopharmaceutical company focused on the development of new drugs to treat various forms of gastrointestinal diseases and cancer. Callisto's drug candidates include SP-304, a proprietary drug for gastrointestinal disorders that is currently being developed by its wholly-owned subsidiary, Synergy Pharmaceuticals, as well as two anti-cancer agents. Synergy's proprietary drug SP-304 (Guanilib) is planned to begin clinical development in 2Q2008 for gastro-intestinal disorders. SP-304 is a synthetic analog of the human gastrointestinal hormone uroguanylin, and acts by activating the guanylate cyclase C (GC-C) receptor on epithelial cells of the colon. The Company's lead drug in the clinic, Atiprimod, is presently in a Phase II clinical trial in advanced carcinoid cancer, a neuroendocrine tumor, and in a Phase II extension trial in advanced carcinoid cancer patients. Callisto's second cancer drug in the clinic, L-Annamycin, is currently in a Phase I/II clinical trial in adult relapsed or refractory acute lymphocytic leukemia, and in a Phase I clinical trial in children and young adults with refractory or relapsed acute lymphocytic leukemia or acute myelogenous leukemia. Callisto has exclusive worldwide licenses from Genzyme Inc. and M.D. Anderson Cancer Center to develop, manufacture, use and sell Atiprimod and L-Annamycin, respectively. Callisto is also listed on the Frankfurt Stock Exchange under the ticker symbol CA4. 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.

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