

Cytokinetics Announces the Initiation of Phase I/II Clinical Trial for SB-743921

April 17, 2006 4:00 AM EDT

South San Francisco, CA, April 17, 2006 - Cytokinetics, Incorporated (Nasdaq: CYTK) today announced the initiation of a Phase I/II clinical trial of its second Kinesin Spindle Protein (KSP) inhibitor, SB-743921, in patients with non-Hodgkin's lymphoma (NHL). Cytokinetics is conducting this clinical trial in order to expand the development activities for SB-743921, based on a recently amended agreement with GlaxoSmithKline (GSK). SB-743921 is the second drug candidate in clinical development arising from a strategic collaboration between Cytokinetics and GSK to discover, develop and commercialize novel small molecule therapeutics targeting human mitotic kinesins for applications in the treatment of cancer and other diseases. GSK is conducting a broad Phase II clinical trials program for the lead drug candidate from this program, the KSP inhibitor ispinesib (SB-715992), and is evaluating SB-743921 in an ongoing Phase I trial in patients with advanced solid tumors.

This Phase I/II clinical trial is an open-label, non-randomized study to investigate the safety, tolerability, pharmacokinetic, and pharmacodynamic profile of SB-743921, administered as a one-hour infusion on days 1 and 15 of a 28 day schedule, in patients with non-Hodgkin's lymphoma. The objective of the Phase I portion of the clinical trial is to identify the maximum tolerated dose (MTD) of SB-743921 on this schedule, in patients with either Hodgkin's or non-Hodgkin's lymphoma, first without prophylactic administration of granulocyte colony stimulating factor (GCSF). If the dose-limiting toxicity determining this first MTD is neutropenia, a second MTD will be determined with SB-743921 given with prophylactic administration of GCSF. Following review of the Phase I data from this clinical trial, the optimal dose and regimen of SB-743921 (i.e., without or with prophylactic administration of GCSF) will be determined for Phase II. In Phase II, 70 NHL patients, with either aggressive or indolent disease, are planned to be treated with the objective of evaluating frequency and duration of disease response in these patients.

"We are excited about the initiation of this clinical trial in patients with non-Hodgkin's lymphoma," stated Dr. Andrew A. Wolff, Cytokinetics' Senior Vice President of Clinical Research and Development and Chief Medical Officer. "The advancement of SB-743921 into this additional Phase I/II clinical trial represents a significant step forward and is consistent with the vision of our alliance with GSK to broadly explore the role of inhibitors of KSP such as SB-743921."

About SB-743921

In September of 2005, Cytokinetics and GSK announced an amendment to their original agreement to support further expansion of the development activities for SB-743921. Under the terms of the amendment, Cytokinetics is responsible for leading and funding development activities to explore the potential application of SB-743921 for the treatment of non-Hodgkin's lymphoma, Hodgkin's lymphoma and multiple myeloma, subject to the option for GSK to resume responsibility for development and commercialization activities for SB-743921 for these indications during a defined period. Cytokinetics' development activities will be conducted in parallel with GSK's conduct of development activities for SB-743921 in other indications and for ispinesib.

In May of 2005, Cytokinetics and GSK presented interim data from an ongoing open-label, non-randomized, dose-finding Phase I clinical trial in patients with advanced solid tumors at the American Society of Clinical Oncologists (ASCO) annual meeting. Based on the interim analysis, it was determined that SB-743921 appeared to have an acceptable tolerability profile on a once every 21 day schedule. The dose-limiting toxicities reported at that time were prolonged neutropenia, febrile neutropenia (with or without infection), elevated transaminases, hyperbilirubinemia and hyponatremia. Neurotoxicities, mucositis, thrombocytopenia, alopecia and nausea/vomiting requiring pre-medication had not been observed. That trial is still ongoing at this time. SB-743921 is structurally distinct from ispinesib, Cytokinetics' most advanced drug candidate under the strategic alliance with GSK.

Background on Cytokinetics and GlaxoSmithKline Strategic Alliance

In June 2001, Cytokinetics and GSK announced that the two companies had entered into a broad strategic collaboration to discover, develop and commercialize novel small molecule therapeutics targeting mitotic kinesins for applications in the treatment of cancer and other diseases. Under the original terms of the agreement, GSK committed funding of approximately \$50 million over the minimum 5-year research term, including a \$14 million upfront cash payment and a \$14 million purchase of Cytokinetics preferred stock. In addition, GSK could make milestone payments to Cytokinetics of up to an aggregate of \$30-50 million per target for products directed to each mitotic kinesin target. GSK is responsible for worldwide development and commercialization of products arising from the collaboration. Cytokinetics will receive royalties from the sale of any resulting products. In addition, Cytokinetics retains a product-by-product option to co-fund certain development activities, thereby increasing its royalty and affording co-promotion rights in North America. During the collaboration, targets may rever to Cytokinetics for independent research and development, with GSK retaining an option to resume joint activities. In September 2005, Cytokinetics and GSK announced an amendment to their original agreement to support further expansion of the development activities for SB-743921. Based on Cytokinetics' expanded role under the amendment in the development of SB-743921 for the additional indications described above and increased royalties from GSK on net sales of products containing SB-743921 under certain scenarios.

About Ispinesib

Ispinesib is a novel small molecule inhibitor of Kinesin Spindle Protein (KSP), a mitotic kinesin protein essential for proper cell division. Ispinesib is the first drug candidate in clinical development that has arisen from a broad strategic collaboration between Cytokinetics and GlaxoSmithKline (GSK) to discover, develop and commercialize novel small molecule therapeutics targeting human mitotic kinesins for applications in the treatment of cancer and other diseases. GSK is conducting a broad clinical trials program for ispinesib designed to study the drug candidate in multiple tumor types, combination regimens and dosing schedules. GSK is currently evaluating ispinesib in two Phase II clinical trials being conducted in patients with each of ovarian and breast cancers and two Phase Ib clinical trials designed to evaluate ispinesib in combination with each of carboplatin and capecitabine. Interim data from the ongoing breast cancer clinical trial and data from the platinum-refractory and the platinum-sensitive treatment arms of the non-small cell lung cancer clinical trial were announced recently. Interim data from the ongoing breast cancer such so the san Antonio Breast Cancer Symposium in San Antonio, Texas. In this Phase II clinical trial enrolling patients with advanced breast cancer, the best overall responses observed with ispinesib administered as monotherapy have been partial responses in three of thirty-three evaluable patients to date. In the platinum-refractory treatment arm of a Phase II clinical trial enrolling patients (N=20) with a median TTP was six weeks). In the platinum-sensitive treatment arm of this Phase II clinical trial.

overall response observed with ispinesib administered as monotherapy has been disease stabilization in 50% of evaluable patients (N=20) with a median time to progression (TTP) of 17 weeks (overall median TTP was six weeks). In addition to the ongoing studies being conducted by GSK, the National Cancer Institute (NCI) continues five other Phase II clinical trials evaluating ispinesib in other tumor types, including melanoma, head and neck, hepatocellular, colorectal and prostate cancers. In addition, the NCI plans to conduct one additional Phase II clinical trial in patients with renal cell carcinoma. The NCI is also conducting two other Phase I clinical trials evaluating an alternative schedule of ispinesib in leukemia and advanced solid tumors.

About Cytokinetics

Cytokinetics is a leading biopharmaceutical company focused on the discovery, development and commercialization of novel small molecule drugs that specifically target the cytoskeleton. The cytoskeleton is a complex biological infrastructure that plays a fundamental role within every human cell. Cytokinetics' focus on the cytoskeleton enables it to develop novel and potentially safer and more effective classes of drugs directed at treatments for cancer, cardiovascular disease and other diseases. Cytokinetics has developed a cell biology driven approach and proprietary technologies to evaluate the function of many interacting proteins in the complex environment of the intact human cell. Cytokinetics employs the PUMA(TM) system and Cytometrix(TM) technologies to enable early identification and automated prioritization of compounds that are highly selective for their intended protein targets without other cellular effects, and may therefore be less likely to give rise to clinical side effects. Cytokinetics and GlaxoSmithKline (GSK) have entered into a strategic alliance to discover, develop and commercialize small molecule therapeutics targeting human mitotic kinesins for applications in the treatment of cancer and other diseases. Ispinesib, SB-743921 and GSK-923295 are being developed under the strategic alliance with GSK. GSK is conducting Phase II and Ib clinical trials for ispinesib (SB-715992) and GSK and Cytokinetics are each conducting a Phase I clinical trial for SB-743921. Cytokinetics is conducting a Phase I clinical trial with CK-1827452, a novel small molecule cardiac myosin activator, for the intravenous treatment of chard myosin activator, for the intravenous treatment of chard myosin activator, for the intravenous Additional information about Cytokinetics can be obtained at www.cytokinetics.com.

This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 and it is the Company's intent that such statements be protected by the safe harbor created thereby. Examples of such statements include, but are not limited to, statements relating to the future initiation and expected focus of clinical trials by the National Cancer Institute, statements relating to the potential clinical trials under the amendment of our strategic collaboration with GlaxoSmithKline, and statements relating to the potential benefits of the Company's drug candidate and potential drug candidates and of our proprietary technologies. Such statements are based on management's current expectations, but actual results may differ materially due to various factors. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of the Company's drug candidates that could slow or prevent product approval or market acceptance (including the risk that uncertainty of patent protection for the Company's intellectual property or trade secrets, the Company's ability to obtain additional financing if necessary and unanticipated research and development and other costs). For further information regarding these and other risks related to the Company's business, investors should consult the Company's filings with the Securities and Exchange Commission. Cytokinetics does not undertake any obligation to update forward-looking statements.