

# Cytokinetics Announces Presentation of Clinical Trial Data Regarding SB-743921 at the 2007 Annual Meeting of American Society of Hematology

December 10, 2007 5:09 PM EST

## Clinical Data Support New Dosing Schedule for SB-743921 and Potential in Hematological Cancers

SOUTH SAN FRANCISCO, CA, Dec 10, 2007 (MARKET WIRE via COMTEX News Network) -- Cytokinetics, Incorporated (NASDAQ: CYTK) announced today that a poster summarizing interim data from a Phase I/II clinical trial evaluating SB-743921 in patients with non-Hodgkin's lymphoma (NHL) and Hodgkin's disease was presented at the 2007 Annual Meeting of the American Society of Hematology (ASH) in Atlanta, Georgia. SB-743921 is a novel, small molecule inhibitor of kinesin spindle protein (KSP), a mitotic kinesin essential for proper cell division, being developed by Cytokinetics under a collaboration and license agreement with GlaxoSmithKline.

#### Poster Presentation at ASH

A poster entitled, "A Phase I-II Study to Determine the Safety, Pharmacokinetics and Potential Efficacy of the Kinesin Spindle Protein (KSP) Inhibitor SB-743921 on Days 1 and 15 of a 28 Day Schedule in Patients with Non-Hodgkin's or Hodgkin's Lymphoma" was presented by Owen O'Connor, M.D., Columbia University Medical Center, on Sunday, December 9, 2007. The primary objectives of the Phase I portion of this clinical trial are to assess the safety and tolerability and to determine the dose-limiting toxicities (DLT) and maximum tolerated dose (MTD) of SB-743921 administered as a 1-hour intravenous infusion on day 1 and day 15 of a 28-day cycle, first without, and then with, prophylactic granulocyte-colony stimulating factor (GCSF). Secondary objectives of the Phase I portion of the trial are to evaluate the pharmacokinetic and pharmacodynamic profile of SB-743921 administered on this schedule. The primary objective of the Phase II portion of the trial is to evaluate the frequency of disease response based on independent image assessments at every second cycle according to the International Workshop Criteria for Non-Hodgkin's Lymphoma.

The authors concluded that SB-743921 is well-tolerated without prophylactic GCSF in doses less than 6 mg/m2 when given on day 1 and day 15 of a 28-day schedule. To date, the best response observed has been a partial response in a patient with Hodgkin's disease out of 23 patients evaluable for efficacy. In this interim analysis, grade 3 or 4 neutropenia was the most common toxicity reported and grade 3 or 4 non-hematological toxicities have been rare. In particular, there has been no evidence of neuropathy. To fully address the identification of the DLT and the MTD in the absence of primary GCSF support, the 6 mg/m2 cohort will be expanded to include up to six additional evaluable patients prior to a final decision on further dose escalation beyond 7 mg/m2 without primary GCSF prophylactic support. Efficacy signals in both NHL and Hodgkin's disease will be explored in Phase II once the MTDs, one with and one without primary GCSF prophylaxis, are determined.

"We are pleased with the results observed to date in this clinical trial and look forward to further investigation of SB-743921," stated Andrew A. Wolff, M.D., F.A.C.C., Cytokinetics' Senior Vice President of Clinical Research and Development and Chief Medical Officer. "We have increased the dose density beyond that previously achieved with this drug candidate in the first-in-humans clinical trial, while maintaining acceptable tolerability in these patients. We believe this increase in dose density on this alternative dosing schedule may lead to enhanced efficacy for SB-743921."

#### About SB-743921

SB-743921, Cytokinetics' second KSP inhibitor to enter clinical trials, is structurally distinct from ispinesib, Cytokinetics' most advanced anti-cancer drug candidate. At the American Society of Clinical Oncology (ASCO) annual meeting in May 2006, GlaxoSmithKline (GSK) presented data from an open-label, non-randomized, dose-finding, first-in-humans Phase I clinical trial of SB-743921in patients with advanced solid tumors. The authors concluded that SB-743921 appeared to have an acceptable tolerability profile on a once-every-21-day schedule. The MTD in the first-in-humans trial was 4 mg/m2 every 21 days, although dosing reached 8 mg/m2. The DLTs 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 were not observed.

Under a November 2006 amendment to its collaboration and license agreement with GSK, Cytokinetics assumed responsibility for the costs and activities associated with the continued development of the KSP inhibitors ispinesib and SB-743921, subject to GSK's option to resume responsibility for some or all development and commercialization activities associated with each of these novel drug candidates. The November 2006 amendment superseded a September 2005 amendment to the collaboration and license agreement, which specifically related to SB-743921. In April 2006, in connection with an expanded development program for SB-743921, Cytokinetics announced the initiation of its Phase I/II clinical trial of SB-743921 in patients with NHL and Hodgkin's disease.

Background on Cytokinetics and GlaxoSmithKline Strategic Alliance

In June 2001, Cytokinetics and GSK entered into a broad strategic alliance to discover, develop and commercialize novel small molecule therapeutics targeting mitotic kinesins for applications in the treatment of cancer and other diseases. The strategic alliance has generated three drug candidates in clinical development, ispinesib and SB-743921, both inhibitors of KSP, and GSK-923295, an inhibitor of centromere-associated protein E (CENP-E). In June 2007, Cytokinetics announced a further one-year extension of the strategic alliance's research term, which began in June 2001, to continue activities focused towards translational research directed to CENP-E. Under a November 2006 amendment to its collaboration and license agreement with GSK, Cytokinetics assumed responsibility for the costs and activities associated with the continued development of ispinesib and SB-743921, subject to GSK's option to resume responsibility for some or all development and commercialization activities associated with each of these novel drug candidates, exercisable during a defined period. GSK-923295, now in a Phase I clinical trial in advanced cancers, is being developed under the strategic alliance by GSK. Cytokinetics will receive royalties from the sale of any products arising from the strategic alliance that GSK progresses to commercialization. For products that GSK progresses in development, Cytokinetics retains a product-by-product option to co-fund certain later-stage development activities, thereby potentially increasing its royalties and affording co-promotion rights in North America.

#### **About Cytokinetics**

Cytokinetics is a biopharmaceutical company focused on the discovery, development and commercialization of novel small molecule drugs that may address areas of significant unmet clinical needs. Cytokinetics' development efforts are directed to advancing multiple drug candidates through clinical trials to demonstrate proof-of-concept in humans, specifically in the areas of heart failure and cancer. Cytokinetics' cardiovascular disease program is focused to cardiac myosin, a motor protein essential to cardiac muscle contraction. Cytokinetics' lead compound from this program, CK-1827452, a novel small molecule cardiac myosin activator, entered Phase II clinical trials for the treatment of heart failure in 2007. Under a strategic alliance established in 2006, Cytokinetics and Amgen Inc. plan to conduct research with activators of cardiac myosin in order to identify potential treatments for patients with heart failure. Amgen has obtained an option for the joint development and commercialization of CK-1827452 exercisable during a defined period, the ending of which is dependent on Cytokinetics' conduct of further clinical trials of CK-1827452. Cytokinetics' cancer program is focused on mitotic kinesins, a family of motor proteins essential to cell division. Under a strategic alliance established in 2001, Cytokinetics and GlaxoSmithKline (GSK) are conducting research and development activities focused on the potential treatment of cancer. Cytokinetics is developing two novel drug candidates that have arisen from this program, ispinesib and SB-743921, each a novel inhibitor of kinesin spindle protein (KSP), a mitotic kinesin. Cytokinetics believes that ispinesib has demonstrated clinical activity in Phase II monotherapy clinical trials in breast cancer, ovarian cancer and non-small cell lung cancer and plans to conduct additional clinical trials with ispinesib. Cytokinetics is also conducting a Phase I/II trial of SB-743921 in non-Hodgkin's lymphoma. GSK has obtained an option for the joint development and commercialization of ispinesib and SB-743921, exercisable during a defined period. Cytokinetics and GSK are conducting collaborative research activities directed to the mitotic kinesin centromere-associated protein E (CENP-E). GSK-923295, a CENP-E inhibitor, is being developed under the strategic alliance by GSK, subject to Cytokinetics' option to co-fund certain later-stage development activities and to co-promote any resulting approved drug in North America. GSK began a Phase I clinical trial with GSK-923295 in 2007. All of these drug candidates have arisen from Cytokinetics' research activities and are directed towards 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 and cardiovascular disease. 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 (the "Act"). Cytokinetics

disclaims any intent or obligation to update these forward-looking statements, and claims the protection of the Safe Harbor for forward-looking statements contained in the Act. Examples of such statements include, but are not limited to, statements relating to the initiation, conduct, scope and results of Cytokinetics' and its partners' planned research and development activities, including that increased dose density on alternative dosing schedules for SB-743921 may lead to enhanced efficacy; the potential benefits of Cytokinetics' drug candidates and potential drug candidates, including SB-743921's potential as a treatment for hematological cancers; Cytokinetics' receipt of royalties under its collaboration with GSK; and the enabling capabilities of Cytokinetics' cytoskeletal focus. Such statements are based on management's current expectations, but actual results may differ materially due to various risks and uncertainties, including, but not limited to, potential difficulties or delays in the development, testing, regulatory approval, production and marketing of Cytokinetics' drug candidates that could slow or prevent clinical development, product approval or market acceptance, including risks that current and past results of clinical trials or preclinical studies may not be indicative of future clinical trials results, patient enrollment for clinical trials may be difficult or take longer than anticipated, Cytokinetics' drug candidates may have unexpected adverse side effects or inadequate therapeutic efficacy, the U.S. Food and Drug Administration or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials, and Cytokinetics may be unable to obtain and maintain patent or trade secret protection for its intellectual property; potential decisions by GSK to postpone or discontinue development efforts for GSK-923295; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing if necessary; standards of care may change or others may introduce products or alternative therapies for the treatment of indications Cytokinetics' drug candidates and potential drug candidates currently or potentially target; and risks and uncertainties relating to the timing and receipt of funds under Cytokinetics' collaborations. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission.

### Contacts:

Scott R. Jordan (Media)
Director, Corporate Development
(650) 624-3000

Christopher S. Keenan (Investors) Director, Investor Relations (650) 624-3000

SOURCE: Cytokinetics, Inc.