

# Cytokinetics Announces Clinical Trials Data to be Presented at the 2006 Annual Meeting of The American Society of Clinical Oncology

# April 25, 2006 4:00 AM EDT

South San Francisco, CA, April 24, 2006 - Cytokinetics, Incorporated (Nasdaq: CYTK) announced today that five abstracts summarizing data from clinical trials conducted by GlaxoSmithKline (GSK) or the National Cancer Institute (NCI) evaluating ispinesib (SB-715992) or SB-743921 will be presented at the 2006 Annual Meeting of the American Society of Clinical Oncology (ASCO) in Atlanta, Georgia.

Ispinesib and SB-743921 are both novel, chemically-distinct, small molecule inhibitors of kinesin spindle protein (KSP), a mitotic kinesin essential for proper cell division. Both drug candidates have arisen from a broad 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.

# **Oral and Poster Presentations of Abstracts at ASCO**

The following abstracts will be presented at ASCO and will be available through the ASCO website (www.asco.org):

# **Oral Presentation:**

Abstract #2000: Phase I Study to Determine Tolerability and Pharmacokinetics (PK) of SB-743921, a Novel Kinesin Spindle Protein (KSP) Inhibitor. (Oral presentation by Kyle D. Holen, University of Wisconsin Comprehensive Cancer Center, Madison, WI, on Saturday, June 3, 2006, Inhibition of Checkpoints, Cell Cycle Progression and Mitosis; Bldg B, Level 5, Thomas B. Murphy Ballroom 3, 4:30 PM – 6:00 PM).

# **Poster Presentations:**

Abstract #2026: A Phase I Dose Escalation Trial of Ispinesib (SB-715992) Administered Days 1-3 of a 21-day Cycle in Patients with Advanced Solid Tumors. (Poster discussion by Elizabeth I. Heath, Karmanos Cancer Institute, on Sunday, June 4, 2006, Developmental Therapeutics: Cytotoxic Chemotherapy; Bldg A, Level 3, Room A311, 2:00 PM – 6:00 PM).

Abstract #2027: Phase I Study of Ispinesib in Combination with Carboplatin in Patients with Advanced Solid Tumors. (Poster discussion by Suzanne F. Jones, Sarah Cannon Research Institute, Nashville, TN, on Sunday, June 4, 2006, Developmental Therapeutics: Cytotoxic Chemotherapy; Bldg A, Level 3, Room A311, 2:00 PM – 6:00 PM).

Abstract #3595: A Randomized Phase II Non-Comparative Study of Ispinesib Given Weekly or Every Three Weeks in Metastatic Colorectal Cancer. A California Cancer Consortium Study (CCC-P). (General poster session presentation by Arthur B, El-Khoueiry, USC Norris Comprehensive Cancer Center, on Saturday, June 3, 2006, Gastrointestinal (Colorectal) Cancer, Bldg B, Level 1, Hall B5, 8:00 AM – 12:00 PM).

# Abstract:

A Phase II Study of SB-715992 (Ispinesib) in Patients with Recurrent and/or Metastatic Head and Neck Squamous Cell Carcinoma (RMHNSC). Abstract will be published in the ASCO 2006 Annual Meeting Proceedings.

#### 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 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 this 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. In the 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 3 of 33 evaluable patients to date. These 3 patients had maximum decrease in tumor size ranging from 46% to 68% with the duration of response ranging from 7.1 weeks to 13.4 weeks. The overall response rate in this clinical trial for all 33 evaluable patients was 9% with an overall median time to progression of 5.7 weeks. In the platinum-refractory treatment arm of a Phase II clinical trial enrolling patients with non-small cell lung cancer, the best overall response observed with ispinesib administered as monotherapy was disease stabilization in 25% of evaluable patients (N=20) with a median time to progression (TTP) of 12 weeks (overall median TTP was 6 weeks). In the platinum-sensitive treatment arm of this Phase II clinical trial, the best overall response observed with ispinesib administered as monotherapy was disease stabilization in 50% of evaluable patients (N=20) with a median TTP of 17 weeks (overall median TTP was 6 weeks). For both clinical trials, the adverse events were manageable, predictable, and consistent with the Phase I experience. The most common adverse event was Grade 4 neutropenia. In addition to the ongoing studies being conducted by GSK, the National Cancer Institute (NCI) is sponsoring 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 an 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 SB-743921

SB-743921, Cytokinetics' second KSP inhibitor to enter clinical trials under the strategic alliance with GSK, is structurally distinct from ispinesib, Cytokinetics' most advanced drug candidate. In May of 2005, 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 ASCO annual meeting. Based on the interim review, 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.

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 (NHL), 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 April of 2006, Cytokinetics announced the initiation of a Phase I/II clinical trial of SB-743921 in patients with NHL, in connection with an expanded development program for SB-743921. 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, and to assess the potential efficacy of the maximum tolerated dose of SB-743921 administered on this schedule in patients with NHL.

### **About Cytokinetics**

Cytokinetics is a 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 its PUMATM system and CytometrixTM 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-715992), 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, GSK is conducting a Phase I /II trial of SB-743921 in NHL. Cytokinetics is conducting a Phase I clinical trial for SB-743921, and Cytokinetics is company's expertise in cytoskeletal pharmacology. Cytokinetics is conducting a Phase I clinical trial with CK- 1827452, a novel small molecule cardiac myosin activator, for the intravenous treatment of heart failure and also has selected CK-1827452 as a potential drug candidate for the treatment of chronic heart failure via oral administration. 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 expected initiation, timing, scope and results of Cytokinetics' and its partners' clinical development and research programs, including statements regarding upcoming presentations of clinical trial results and abstracts, initiation of clinical trials, the potential benefits of our drug candidates and potential drug candidates and the enabling capabilities 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 decisions by GSK or the NCI to postpone or discontinue development efforts for one or more compounds difficulties or delays in patient enrollment for clinical trials, unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates, and other potential difficulties or delays in development, product approval, production and marketing of Cytokinetics' drug candidates that could slow or prevent clinical development, product approval or market acceptance (including the risks relating to uncertainty of patent protection for Cytokinetics' intellectual property or trade secrets, Cytokinetics' ability to obtain additional financing if necessary and unanticipated research and development and research), the conduct of activities and continued funding under Cytokinetics' collaborations and the implementation and maintenance of procedures, policies, resources and infrastructure relating to compliance with new or changing laws, regulations and practices. For furt