# Cytokinetics Announces Clinical Trials Data Presented at the 2008 Annual Meeting of the American Society of Clinical Oncology

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**Company Provides Updates on Progress of Clinical Trials With Ispinesib and SB-743921**

SOUTH SAN FRANCISCO, CA, Jun 03, 2008 (MARKET WIRE via COMTEX News Network) -- Cytokinetics, Incorporated (NASDAQ: CYTK) announced today that three abstracts summarizing data from clinical trials relating to its oncology programs were presented at the 2008 Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL. Two of these abstracts related to clinical trials evaluating ispinesib, one trial sponsored by Cytokinetics and the other by the National Cancer Institute (NCI). The third abstract related to a clinical trial sponsored by Cytokinetics evaluating SB-743921. Ispinesib and SB-743921 are 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 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.

The oral presentation entitled, "Pediatric Phase I Trial and Pharmacokinetic (PK) study of ispinesib (SB-715992): A Children's Oncology Group Phase I Consortium Study," was presented by Susan Blaney, M.D., Texas Children's Cancer Center at Baylor College of Medicine, Houston, Texas. The primary objectives of this clinical trial were to determine the maximum tolerated dose (MTD) and recommended Phase II dose of ispinesib as a 1-hour infusion administered weekly for 3 weeks on a 28-day schedule in children with refractory solid tumors. Additional objectives were to define and describe the toxicities of ispinesib administered on this schedule and to characterize the pharmacokinetics of ispinesib in children with refractory cancer. Of the 24 patients enrolled in this clinical trial, 18 were evaluable for toxicity and 23 were evaluable for a response. The authors concluded that the MTD on this schedule for this patient population was 9 mg/m2. In this clinical trial, the dose-limiting toxicities (DLTs) observed were neutropenia (n=3), hyperbilirubinemia (n=1) and elevated ALT (n=1). The best response observed was stable disease at 7 courses. Three patients experienced stable disease for longer than 3 courses of therapy. The authors concluded that ispinesib was well-tolerated in pediatric patients, with neutropenia and hepatotoxicity representing the most commonly observed DLTs.

A poster presentation entitled, "A Phase I-II Open-Label Trial of Ispinesib on an Alternate Dosing Schedule in Chemotherapy-Naive Patients with Locally Advanced or Metastatic Breast Cancer (MBC)," was presented by Manuel Philco, MD, Hospital Nacional Alberto Sabogal Sologuren, in Lima, Peru. The primary objectives of the Phase I portion of this clinical trial are to determine the DLTs and MTD and to assess the safety and tolerability of ispinesib administered as a 1-hour intravenous infusion on days 1 and 15 of a 28-day cycle. The secondary objectives are to characterize the pharmacokinetics of ispinesib on this schedule and to evaluate the effect of ispinesib on biomarkers of cell proliferation in patients with accessible tumors. At the interim analysis point, 6 patients had been enrolled at 2 dose levels, 10 mg/m2 and 12 mg/m2, and had completed at least 1 cycle. The authors concluded that preliminary data suggests that ispinesib is well-tolerated when dosed on days 1 and 15 every 28 days at doses up to 12 mg/m2. In addition, this schedule's dose density at 12 mg/m2 (0.86 mg/m2/day) is equivalent to the dose density of the MTD of 18 mg/m2 given on the once every 21-day schedule used in prior Phase II clinical trials for ispinesib. The most common toxicity in this clinical trial observed to date has been neutropenia. No neuropathy, alopecia or Grade 2 or higher gastrointestinal toxicity has been observed. Dose escalation in this clinical trial is ongoing.

A poster entitled, "A Phase I-II trial of the Kinesin Spindle Protein (KSP) Inhibitor SB-743921 on Days 1 and 15 Every 28 Days in Non-Hodgkin or Hodgkin Lymphoma," was presented. The lead author for this poster was Owen A. O'Connor, MD, PhD, Columbia Medical Center, New York, NY. The primary objectives of the Phase I portion of this clinical trial are to determine the DLTs and MTD and to assess the safety and tolerability of SB-743921 administered as a 1-hour intravenous infusion on days 1 and 15 of a 28-day cycle, first without and then the prophylactic administration of granulocyte colony-stimulating factor (G-CSF). The secondary objectives are to characterize the pharmacokinetics of SB-743921 administered on this schedule and to evaluate the effect of SB-743921 on biomarkers of cell proliferation in patients with accessible tumors. At the interim analysis point, 42 patients had been enrolled and 39 patients were treated. Of the treated patients, 39 were evaluable for safety and 28 were evaluable for efficacy. The authors concluded that the pattern of neutropenia onset and recovery support a dosing schedule for SB-743921 of days 1 and 15 of a 28-day cycle. The MTD of SB-743921 was 6 mg/m2 when given days 1 and 15 every 28 days without G-CSF support. This represents a greater dose density (0.43 mg/m2/day) than on the previously studied schedule; i.e., 4 mg/m2 once every 21 days (0.19 mg/m2/day). The only DLT observed without G-CSF was neutropenia; therefore further dose escalation with empiric, prophylactic G-CSF is ongoing and the trial is currently enrolling at 8 mg/m2. The declines from baseline seen in neutrophil counts on day 8 and 22 without G-CSF were not observed with 6 mg/m2 plus G-CSF suggesting further dose escalation with G-CSF may be possible. Grade 3 and 4 toxicities other than neutropenia were uncommon, in particular there was no evidence of neuropathy or alopecia. To date, one objective partial response has been observed at the MTD in Hodgkin Lymphoma.

About Ispinesib

In June 2007, Cytokinetics reported final results of a Phase II clinical trial conducted by GSK designed to evaluate the safety and efficacy of ispinesib in the second- or third-line treatment of patients with locally advanced or metastatic breast cancer whose disease had recurred or progressed despite treatment with anthracyclines and taxanes. In this trial, patients received ispinesib monotherapy at 18 mg/m2 as a 1-hour intravenous infusion every 21 days. The primary endpoint of the trial was objective response by the Response Evaluation Criteria in Solid Tumors (RECIST). Partial responses, observed in 4 of 45 evaluable patients, were confirmed by independent radiology review and were seen in liver, lung and lymph node metastases. The duration of these responses, also independently reviewed, ranged from 7.1 weeks to 30.0 weeks. The median time to progression in the treated population was 5.9 weeks. The adverse events were manageable, predictable and consistent with those seen in the Phase I trials of ispinesib. The most common grade 3/4 adverse events observed in the 50 patients evaluable for safety were neutropenia (21 patients), febrile neutropenia (4 patients) and neutropenic sepsis (1 patient).

Ispinesib has been the subject of a broad Phase II clinical trials program under the sponsorship of GSK and is also being developed in collaboration with the National Cancer Institute (NCI). GSK sponsored three Phase II clinical trials, one evaluating ispinesib as second- or third-line treatment for patients with locally advanced or metastatic breast cancer, one evaluating ispinesib as second-line treatment for patients with non-small cell lung cancer, and one evaluating ispinesib as second-line treatment for patients with advanced ovarian cancer. Enrollment in all of these studies has been closed. To date, clinical activity with ispinesib has been observed in breast cancer as well as in ovarian and non-small cell lung cancer, with the most robust clinical activity observed in a Phase II clinical trial evaluating ispinesib in the treatment of patients with locally advanced or metastatic breast cancer that failed to respond or recurred after treatment with taxanes and anthracyclines.

In addition, GSK sponsored three dose-escalating Phase Ib clinical trials. Each of these trials was designed to evaluate the safety, tolerability and pharmacokinetics of ispinesib in combination with a leading anti-cancer therapeutic, one in combination with carboplatin, the second in combination with capecitabine and the third in combination with docetaxel. The Phase Ib clinical trials of ispinesib in combination with carboplatin and docetaxel were completed in 2006 and demonstrated that ispinesib has an acceptable tolerability profile in combination with these standard chemotherapeutic agents. The clinical trial evaluating ispinesib in combination with capecitabine is closed to enrollment. Final data from this trial are expected in 2008.

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. Cytokinetics plans to conduct, at its expense, a focused development program for ispinesib in breast cancer specifically designed to supplement the Phase I and Phase II clinical trials sponsored by GSK that demonstrated clinical activity in the treatment of patients with metastatic breast cancer and an acceptable tolerability profile for ispinesib in combination with capecitabine. The objective of Cytokinetics' on-going Phase I/II clinical of ispinesib is to evaluate the possibility that ispinesib administered as monotherapy on days 1 and 15 of a 28-day cycle may demonstrate an amplified signal of clinical activity in chemotherapy-naive breast cancer patients.

The NCI sponsored additional Phase II clinical trials, one evaluating the potential efficacy of ispinesib in the second-line treatment of patients with colorectal cancer, one in the first-line treatment of patients with hepatocellular cancer, one in the first-line treatment of patients with melanoma, one in the first- or second-line treatment of patients with head and neck cancers, one in the second-line treatment of patients with hormone-refractory prostate cancer, and one in the second-line treatment of patients with renal cell cancer. Enrollment has been closed and data have been reported for all of these trials.

The NCI completed patient treatment in a Phase I clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of ispinesib on an alternative dosing schedule in patients with advanced solid tumors that failed to respond to all standard therapies. Data from this trial have been reported. The NCI has completed patient enrollment in a Phase I clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of ispinesib on an alternative dosing schedule in patients with relapsed or refractory acute leukemia, chronic myelogenous leukemia in blast crisis or advanced myelodysplastic syndromes.

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. In May 2006 at the ASCO annual meeting, GSK presented data from an open-label, non-randomized, dose-finding Phase I clinical trial in patients with advanced solid tumors at. The authors concluded that SB-743921 appeared to have an acceptable tolerability profile on a once-every-21-day schedule. 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.

In April 2006, Cytokinetics announced the initiation of a Phase I/II clinical trial of SB-743921 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, pharmacodynamics and pharmacokinetic 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 MTD of SB-743921 administered on this schedule in patients with Hodgkin and non-Hodgkin lymphoma.

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. The November 2006 amendment superseded a September 2005 amendment to the collaboration and license agreement, which specifically related to SB-743921. 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 providing Cytokinetics an opportunity to increase its potential royalties and obtain co-promotion rights for the applicable products 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 activities are primarily directed to advancing multiple drug candidates through clinical trials with the objective of determining the intended pharmacodynamic effect or effects in two principal diseases: 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. are performing joint research focused on identifying and characterizing activators of cardiac myosin as back-up and follow-on potential drug candidates to CK-1827452. Amgen has obtained an option for an exclusive license to develop and commercialize CK-1827452, subject to Cytokinetics' development and commercial participation rights. 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 clinical activity for ispinesib has been observed in Phase II monotherapy clinical trials in breast cancer, ovarian cancer and non-small cell lung cancer and recently initiated an additional Phase I/II clinical trial of ispinesib as monotherapy as a first-line treatment in chemotherapy-naive patients with locally advanced or metastatic breast cancer on a more

dose-dense schedule than previously studied Cytokinetics is also conducting a Phase I/II trial of SB-743921 on a similar more dose-dense schedule in non-Hodgkin and Hodgkin lymphomas. GSK has obtained an option for the joint development and commercialization of ispinesib and SB-743921. 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. In April 2008, Cytokinetics announced the selection of a potential drug candidate directed towards skeletal muscle contractility which may be developed as a potential treatment for skeletal muscle weakness associated with neuromuscular diseases or other conditions. All of these drug candidates and potential 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 and other diseases. 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 Cytokinetics' and its partners' research and development activities, including the design, focus, scope and results of clinical trials and the expected availability and planned presentations of data from clinical trials; the potential benefits of Cytokinetics' drug candidates and potential drug candidates; 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 or production of Cytokinetics' drug candidates that could slow or prevent clinical development, product approval, 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 delayed, Cytokinetics' drug candidates may have 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 or maintain patent or trade secret protection for its intellectual property; GSK may decide to postpone or discontinue development activities for GSK-923295, Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing necessary to conduct development of its products, standards of care may change, others may introduce products or alternative therapies for the treatment of indications Cytokinetics' drug candidates and potential drug candidates may target, and risks and uncertainties relating to the timing and receipt of payments from our partners, including milestones and royalties on future potential product sales under Cytokinetics' collaboration agreements with such partners. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission.

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