Cytokinetics Announces the Presentation of Clinical Trials Data at the 2007 Annual Meeting of the American Society of Clinical Oncology

June 4, 2007 1:34 PM EDT

SOUTH SAN FRANCISCO, CA, Jun 04, 2007 (MARKET WIRE via COMTEX News Network) -- Cytokinetics, Incorporated (NASDAQ: CYTK) announced today that data from clinical trials relating to its oncology program were presented at the 2007 Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL. Two of these abstracts relate to Phase II clinical trials evaluating ispinesib that were sponsored by GlaxoSmithKline (GSK) or the National Cancer Institute (NCI). The third abstract relates to a clinical trial sponsored by Cytokinetics evaluating SB-743921.

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.

Ispinesib

The poster entitled, "A Phase II, Open-Label Study of Ispinesib (SB-715992) in Patients with Platinum/Taxane Refractory or Resistant Relapsed Ovarian Cancer," was presented by Patricia S. Braly, Hematology & Oncology Specialists, New Orleans, LA, on Saturday, June 2, 2007. Mark S. Shahin, Abington Memorial Hospital, Abington, PA was the primary author. The primary objective of this clinical trial was to evaluate the overall response rate of patients with metastatic ovarian cancer treated with ispinesib as monotherapy. The secondary objectives were to determine the median time to radiographic response, median time to CA-125 response, median duration of radiographic response and progression-free survival. Patients in this clinical trial received ispinesib at a dose of 18 mg/m2 every 21 days. Twenty-two patients were enrolled in Stage 1 of this two-stage clinical trial. One confirmed CA-125 response was required to proceed to Stage 2. The median number of cycles was 2 (range 1-21). The best radiographic response was 1 partial response (PR) with a duration of 42 weeks and 5 patients with stable disease. None of the 22 evaluable patients had a CA-125 response and the median time to CA-125 progression was 5.3 weeks. In this clinical trial, the protocol-specific criteria to proceed to Stage 2 were not met. The most common grade 4 toxicities included neutropenia (n=11), febrile neutropenia (n=2), thrombocytopenia (n=1), and small intestine obstruction (n=1).

An abstract entitled, "University of Chicago Consortium Phase II Study of Ispinesib (SB-715992) in Patients with Advanced Renal Cell Carcinoma," by K.W. Beekman, University of Michigan, Ann Arbor, MI, was published in the ASCO 2007 Annual Meeting Proceedings and presented interim data from this clinical trial. The primary objective of this clinical trial was to assess overall response rate using the RECIST criteria. Secondary objectives included evaluating toxicities, time to progression and overall survival. In this clinical trial, 19 patients were enrolled and received a dose of ispinesib as a monotherapy at 7 mg/m2 as a one-hour infusion on days 1, 8 and 15 every 28 days with radiologic disease re-evaluation every 8 weeks. Of the 19 patients enrolled, 15 were evaluable and 4 were considered too early for assessment. Of the 15 evaluable patients included in the interim analysis, the best response observed was stable disease in 7 patients after 8 weeks. One patient experienced Grade 3 neutropenia but no other Grade 3 or 4 toxicities were deemed to be attributable to the study drug. The authors concluded that treatment with ispinesib as a monotherapy at this dose and schedule in this patient population does not appear to lead to objective responses but appears to be well-tolerated.

SB-743921

An abstract entitled, "A Phase I-II Study to Assess the Safety, Pharmacokinetics, and Potential Efficacy of Intravenous SB-743921 on Days 1 and 15 of a 28-day Cycle in Patients with Non-Hodgkin Lymphoma," by A. Goy, Hackensack University Medical Center, Hackensack, NJ, was published in the ASCO 2007 Annual Meeting Proceedings and presented interim data from this clinical trial. The primary objectives of this clinical trial are to evaluate the safety, pharmacokinetics and maximum tolerated dose (MTD) of SB-743921 without prophylactic Granulocyte colony-stimulating factor (GCSF) in patients with non-Hodgkin's lymphoma (NHL) or Hodgkin's disease. In this clinical trial, SB-743921 was given to dose-escalating cohorts of 3 patients as a 1-hour infusion every 14 days. At the time of this analysis, six NHL patients were enrolled and 5 were evaluable. Grade 3 toxicities observed were hemolytic anemia (n=1), leucopenia (n=1), thrombocytopenia (n=1) and dyspnea (n=1). The authors concluded that SB-743921 was well-tolerated without prophylactic GCSF in Cohort 1 of the Phase I portion of this clinical trial, which continues to dose-escalate.

Clinical Trials of Ispinesib

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 NCI. GSK has 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 and in non-small cell lung cancer, with the more robust clinical activity observed in a Phase II clinical trial evaluating ispinesib in the treatment of metastatic breast cancer patients that have failed treatment with taxanes and anthracyclines. GSK has informed Cytokinetics that final data are expected from the breast cancer clinical trial in the first half of 2007.

In addition, GSK has sponsored three dose-escalating Phase Ib clinical trials. Each of these clinical 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 clinical trial evaluating ispinesib in combination with capecitabine is ongoing. Final data from this trial are expected in 2007.

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 broad series of Phase I and Phase II clinical trials sponsored by GSK that have demonstrated clinical activity in the treatment of patients with metastatic breast cancer and that have shown

an acceptable tolerability profile for ispinesib in combination with standard chemotherapeutics.

The NCI has sponsored six 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 for all of these trials; patients remain on treatment in the renal cell cancer trial. Data are expected from the hepatocellular cancer, the prostate cancer, the melanoma and the renal cell cancer trials in 2007. Data from the other ispinesib clinical trials have already been reported.

The NCI has 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 have failed to respond to all standard therapies; data from this trial have already been reported. The NCI is continuing 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. Data from this trial are expected in 2007.

About SB-743921

SB-743921, Cytokinetics' second KSP inhibitor to enter clinical trials, is structurally distinct from ispinesib, Cytokinetics' most advanced drug candidate. In May 2006, GSK presented data from an 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.

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, 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 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, CK-1827452, a novel small molecule cardiac myosin activator, recently 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. 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. Ispinesib has been the subject of a broad clinical trials program comprised of nine Phase II clinical trials as well as six Phase I or Ib clinical trials. Cytokinetics plans to conduct additional clinical trials with ispinesib and is conducting a Phase I/II trial of SB-743921 in non-Hodgkin's lymphoma. Under a strategic alliance established in 2001, Cytokinetics and GlaxoSmithKline (GSK) are conducting research and development activities focused on the potential treatment of cancer. 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. GSK is expected to begin clinical trials 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 expected initiation, timing, scope and results of Cytokinetics' and its partners' research and development programs, including statements regarding initiation of clinical trials, the potential benefits of Cytokinetics' drug candidates and potential drug candidates and the enabling capabilities of Cytokinetics' biological 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 decisions by GSK or the NCI to postpone or discontinue development efforts for GSK-923295 or ispinesib, respectively; 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 delayed, Cytokinetics' drug candidates may have unexpected adverse side effects or inadequate therapeutic efficacy, and Cytokinetics may be unable to obtain and maintain patent or trade secret protection for its intellectual property; 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.