



Cytokinetics Presents Clinical Data Relating to Ispinesib in Patients With Metastatic Breast Cancer at the 2009 Annual Meeting of the American Society of Clinical Oncology

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New Dosing Schedule Suggests Potential Amplified Clinical Activity of This Novel KSP Inhibitor

SOUTH SAN FRANCISCO, CA, Jun 02, 2009 (MARKET WIRE via COMTEX) -- Cytokinetics, Incorporated (NASDAQ: CYTK) announced today that a poster presentation summarizing interim data from the Phase I portion of a Phase I/II clinical trial evaluating ispinesib, a novel inhibitor of kinesin spindle protein (KSP), in patients with locally advanced or metastatic breast cancer was presented at the 2009 Annual Meeting of the American Society of Clinical Oncology (ASCO) held from May 29 - June 2, 2009 in Orlando, FL. This poster highlights the safety and tolerability of ispinesib and tumor-reductions of 30 percent in 3 patients in this ongoing Phase I/II clinical trial of ispinesib dosed on days 1 and 15 of a 28-day cycle. In this trial, ispinesib appears to demonstrate anti-cancer activity with a similar toxicity profile when compared with prior clinical trials conducted with a once every 21 days dosing schedule.

"In the ongoing Phase I portion of this Phase I/II clinical trial, we have observed signs of clinical activity for ispinesib in patients with locally advanced or metastatic breast cancer without our having yet reached the maximum-tolerated dose," stated Henry Gomez, M.D., Instituto Nacional de Enfermedades Neoplasicas, Lima, Peru. "Amplification of the anti-cancer signal on this newer dosing schedule, combined with a favorable tolerability profile, suggests the potential for this drug candidate in the treatment of metastatic breast cancer patients."

"The dosing schedule, an intravenous 1-hour infusion on days 1 and 15 of a 28-day cycle, studied in this Phase I/II clinical trial appears to be both well-tolerated and generating encouraging signs of clinical activity," stated Andrew A. Wolff, MD, FACC, Cytokinetics' Senior Vice President of Clinical Research and Development and Chief Medical Officer. "We look forward to continuing the dose-escalation of ispinesib in this trial as we explore the possible role of this novel drug candidate in patients with metastatic breast cancer."

Poster Presentation at ASCO

A poster titled, "A Phase I/II Trial of Ispinesib, a Kinesin Spindle Protein (KSP) Inhibitor, Dosed q14d in Patients with Advanced Breast Cancer Previously Untreated with Chemotherapy for Metastatic Disease or Recurrence" was presented on Monday, June 1, 2009. This poster summarized interim data from the Phase I portion of an ongoing Phase I/II clinical trial evaluating ispinesib in patients with advanced breast cancer. The primary objectives of the Phase I portion of this clinical trial are to determine the dose-limiting toxicities (DLTs) and maximum-tolerated dose 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 potential effect of ispinesib on biomarkers of cell proliferation in patients with accessible tumors. The authors concluded that one Response Evaluation Criteria in Solid Tumors (RECIST)-confirmed partial response (PR) with a duration of 6 months has been reported. Also, two additional patients had a best response of PR (unconfirmed), and 10 additional patients have had stable disease not reaching PR criteria, four of which had a duration of 4 or more months. The authors also noted that protocol-defined DLTs of Grade 3 ALT/AST increases with questionable relationship to study drug were observed in two out of seven patients treated at the 14 mg/m² dose level. The 12 mg/m² cohort has been expanded to six patients with no observed DLTs. The protocol has been amended to further evaluate the 14 mg/m² dose level.

Development Status of Ispinesib

Previously, in December 2008, at the San Antonio Breast Cancer Symposium, Cytokinetics presented interim results from the Phase I portion of its Phase I/II clinical trial of ispinesib. Interim data demonstrated that this drug candidate was well-tolerated when administered as a 1-hour intravenous infusion on days 1 and 15 of a 28-day cycle, with the most frequent adverse event being neutropenia. The best responses observed to date were investigator-reported tumor reductions of 30% or greater in the sum of the target lesion diameter, reported in 3 patients. One of these patients had an investigator-reported PR according to the RECIST. Cytokinetics continues to enroll and dose-escalate patients in the Phase I portion of this trial.

In June 2007, Cytokinetics reported final results of a Phase II clinical trial conducted by GlaxoSmithKline (GSK) designed to evaluate the safety and efficacy of ispinesib in patients with locally advanced or metastatic breast cancer whose disease had recurred or progressed despite treatment with anthracyclines and taxanes. In that trial, patients received ispinesib as monotherapy at 18 mg/m² as a 1-hour intravenous infusion every 21 days. The primary endpoint of the trial was objective response by 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 6.9 weeks to 19.1 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).

About Cytokinetics

Cytokinetics is a clinical-stage biopharmaceutical company focused on the discovery and development of novel small molecule therapeutics that modulate muscle function for the potential treatment of serious diseases and medical conditions. Cytokinetics' cardiac muscle contractility program is focused on cardiac muscle myosin, a motor protein essential to cardiac muscle contraction. Cytokinetics' lead compound from this program, CK-1827452, a novel small molecule cardiac muscle myosin activator, is in Phase II clinical trials for the treatment of heart failure. Amgen Inc. has exercised an option for an exclusive license to develop and commercialize CK-1827452 world-wide (excluding Japan), subject to Cytokinetics' development and commercialization participation rights. In mid-2009, Cytokinetics plans to initiate a Phase I clinical trial of CK-2017357, a fast skeletal

muscle troponin activator, in healthy volunteers in the United States. CK-2017357 is being developed as a potential treatment for diseases and medical conditions associated with aging, muscle wasting, and neuromuscular dysfunction. In January 2009, Cytokinetics announced the selection of a potential drug candidate directed towards smooth muscle contractility. Cytokinetics' smooth muscle myosin inhibitors have arisen from research focused towards potential treatments for diseases and conditions, such as systemic hypertension, pulmonary arterial hypertension or bronchoconstriction.

Cytokinetics' cancer development programs are focused on mitotic kinesins, a family of motor proteins essential to cell division. Cytokinetics is developing two drug candidates that have arisen from this program, ispinesib and SB-743921, each an inhibitor of kinesin spindle protein. In addition, Cytokinetics and GlaxoSmithKline are collaborating on research and development activities focused on GSK-923295, an inhibitor of centromere-associated protein E (CENP-E).

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. 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 Act's safe harbor for forward-looking statements. Examples of such statements include, but are not limited to, statements relating to Cytokinetics' and its partners' research and development activities, including the initiation, conduct, dosing and scope of clinical trials, and the results of clinical trials and the significance of such results; and the properties and potential benefits of Cytokinetics' compounds. 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 approvals for trial commencement, progression or production of Cytokinetics' compounds that could slow or prevent clinical development or 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 or conduct of clinical trials may be difficult or delayed, Cytokinetics' compounds 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's decisions with respect to the design, conduct, timing and continuation of development activities for GSK-923295; Amgen's decisions with respect to the design, conduct, timing and continuation of development activities for CK-1827452; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain the additional funding necessary to conduct development of some or all of its compounds; standards of care may change rendering Cytokinetics' compounds obsolete; others may introduce products or alternative therapies for the treatment of indications Cytokinetics' compounds may target; and risks and uncertainties relating to the timing and receipt of payments from its partners, including option fees, 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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