

Cytokinetics Announces Non-Clinical Data Relating to GSK-923295 Presented at the 2009 Annual Meeting of the American Society of Clinical Oncology

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Preclinical Data Highlights Potential Application for Novel Mechanism Drug Candidate in Pediatric Cancers

SOUTH SAN FRANCISCO, CA, Jun 01, 2009 (MARKETWIRE via COMTEX) -- Cytokinetics, Incorporated (NASDAQ: CYTK) announced today that a poster presentation summarizing non-clinical data for GSK-923295, a novel inhibitor of centromere-associated protein E (CENP-E), 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. The poster summarizes an evaluation of GSK-923295 in pediatric preclinical cancer xenograft models and highlights possible opportunities for exploration of this novel mechanism in pediatric cancers.

"These data relating to GSK-923295 are encouraging for the future potential of this novel mechanism in the treatment of pediatric patients with certain cancers," stated David J. Morgans, Jr., PhD, Cytokinetics' Executive Vice President, Preclinical Research and Development. "The findings in these preclinical models point to areas for possible exploration in further human clinical testing following the completion of the ongoing Phase I clinical trial designed to explore the safety and tolerability profile of GSK-923295 in adult cancer patients."

Moderated Poster Discussion at ASCO

A poster titled, "Pediatric Preclinical Testing Program (PPTP) Testing of the CENP-E Inhibitor: GSK923295A" was presented on Monday, June 1, 2009 and moderated by Malcolm A. Smith, MD, PhD, Associate Branch Chief for Pediatric Oncology, Cancer Therapy Evaluation Program, National Cancer Institute, Bethesda, MD. This poster summarized preclinical testing of GSK-923295, an inhibitor of CENP-E, in pediatric preclinical xenograft models. The authors concluded that GSK-923295 potently inhibited growth of the PPTP cell lines, with a complete cytotoxic effect most obvious for the acute lymphoblastic leukemia (ALL) cell lines. GSK-923295 showed high level in vivo activity against many of the PPTP xenografts across multiple tumor histologies, with the most consistent activity noted in the Ewing sarcoma and rhabdoid tumor panels. The pattern of response to GSK-923295 showes similarity to that observed in the kinesin spindle protein (KSP) inhibitor ispinesib. The observed high level of activity for GSK-923295 in pediatric xenograft models will need to be evaluated in the context of systemic exposures achieved in the xenograft models and those achievable in humans at tolerable doses. GSK-923295 is currently the subject of an ongoing Phase I clinical trial in adult patients with solid tumors. Pediatric clinical evaluation is planned following completion of this Phase I clinical trial.

Development Status of GSK-923295

In October 2008, GlaxoSmithKline (GSK) reported interim data from a Phase I dose-escalation and pharmacokinetic study of GSK-923295 in adult patients with solid tumors. The primary objective of this trial is to determine the maximum-tolerated dose (MTD), dose-limiting toxicity (DLT), safety and pharmacokinetics of GSK-923295 in advanced, refractory solid tumors. In this clinical trial, the authors concluded that GSK-923295 was well-tolerated at doses evaluated to date, which ranged from 10-105 mg/m2. Of the adverse events observed, nausea and fatigue (all less than or equal to grade 2) were the most frequent non-hematological toxicities, and anemia (all less than or equal to grade 2) was the most frequent hematological toxicity. In addition, no neurotoxicity was observed. The MTD had not been reached but one DLT was observed in the form of reversible aspartate aminotransferase (AST) elevation. Finally, the authors concluded that the plasma pharmacokinetics of GSK-923295 observed were dose-proportional and exhibited low intra-patient and modest inter-patient variability.

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 nanounced 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 conducting 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.

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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 and scope of clinical trials, and the results of preclinical studies and 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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SOURCE: Cytokinetics, Inc.