Karyopharm Announces Initiation of Phase 2 Study of Selinexor (KPT-330) in Patients with Hormone Refractory Prostate Cancer (SHIP Study)

NATICK, Mass., June 9, 2014 (GLOBE NEWSWIRE) -- Karyopharm Therapeutics Inc. (Nasdaq:KPTI), a clinical-stage pharmaceutical company focused on the discovery and development of novel first-in-class drugs directed against nuclear transport targets for the treatment of cancer and other major diseases, today announced the initiation of a Phase 2 trial of its novel, oral Selective Inhibitor of Nuclear Export (SINE) compound Selinexor (KPT-330) in patients with metastatic hormone-refractory prostate cancer (HRPC). The study, referred to as the SHIP (Selinexor in Hormone Refractory Indications in Prostate Cancer) study, is led by Drs. Christopher J. Logothetis and John Araujo of the M.D. Anderson Cancer Center at the University of Texas in Houston and is being funded in part by a grant from the Prostate Cancer Foundation.

"We recently presented data at ASCO showing an 88% disease control rate, meaning stable disease or better, in eight evaluable patients with heavily pretreated prostate cancer," stated Dr. Sharon Shacham, Karyopharm's Founder, President and CSO. "These patients were treated in our Phase 1 clinical trial of Selinexor in advanced or metastatic solid tumors. All had progressive disease upon entering the study and had exhausted available therapies including taxane-based chemotherapy, and many had received newer agents such as enzalutamide and/or abiraterone. As a result of this encouraging data, we have initiated the SHIP Study, a Phase 2 study to further evaluate Selinexor's potential in patients with treatment-resistant prostate cancer."

Approximately 50 qualifying patients with metastatic HRPC following at least one of the recently approved agents (enzalutamide, abiraterone or radium 223) will receive 50 mg/m2 of Selinexor orally twice per week over each 28-day cycle. The primary goal of the study is to determine the disease control rate assessed according to RECIST criteria and the prevention of new bone lesions. The secondary goal of the study is to evaluate the prostate-specific antigen (PSA) response relative to baseline. A full description of the study is available at www.clinicaltrials.gov (NCT02146833).

"Patients with hormone refractory prostate cancer have very limited options, particularly after their disease progresses on chemotherapy," commented Dr. Logothetis. "However, we are encouraged by Selinexor's disease control rate in the prostate cancer patients with significant bone disease in the ongoing phase 1 study, as well as its single-agent activity against a variety of both localized and disseminated prostate cancer in preclinical mouse models. We look forward to assessing the treatment potential of Selinexor in this patient population where there is a high unmet need for further therapy to control their disease and to prolong their lives."

About Prostate Cancer

Approximately one in every seven men in North America will be diagnosed with prostate cancer during his lifetime, according to the American Cancer Society. In men, it is the most common malignancy other than skin malignancies, and the second most common cause of cancer death in North American males. Worldwide, prostate cancer ranks third in cancer incidence and sixth in cancer mortality among men. Despite the recent approvals of novel agents, the American Cancer Society estimates that over 29,000 men in the United States will die of prostate cancer in 2014, indicating the clear medical need for additional novel therapies.

About Selinexor

Selinexor (KPT-330) is a first-in-class, oral Selective Inhibitor of Nuclear Export (SINE) compound. Selinexor functions by binding with the nuclear export protein XPO1 (also called CRM1), leading to the accumulation of tumor suppressor proteins in the cell nucleus, which subsequently reinitiates and amplifies their tumor suppressor function. This is believed to lead to the selective induction of apoptosis in cancer cells, while largely sparing normal cells. To date, over 300 patients have been treated with Selinexor in Phase 1 and Phase 2 clinical trials in advanced hematologic malignancies and solid tumors. Additional Phase 1 and Phase 2 studies are ongoing or currently planned and three registration-directed clinical trials in hematological indications are expected to begin enrollment during 2014. The latest clinical trial information for Selinexor is available at www.clinicaltrials.gov.

About Karyopharm Therapeutics

Karyopharm Therapeutics Inc. (Nasdaq:KPTI) is a clinical-stage pharmaceutical company focused on the discovery and development of novel first-in-class drugs directed against nuclear transport targets for the

treatment of cancer and other major diseases. SINE compounds have shown biological activity in models of cancer, autoimmune disease, certain viruses, and wound-healing. Karyopharm was founded by Dr. Sharon Shacham and is located in Natick, Massachusetts. For more information about Karyopharm, please visit www.karyopharm.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the therapeutic potential of and potential clinical development plans for Karyopharm's drug candidates, including the timing of initiation of certain trials and of the reporting of data from such trials. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the company's current expectations. For example, there can be no guarantee that any of Karyopharm's SINE compounds, including Selinexor (KPT-330), or any other drug candidate that Karyopharm is developing will successfully complete necessary preclinical and clinical development phases or that development of any of Karyopharm's drug candidates will continue. Further, there can be no guarantee that any positive developments in Karyopharm's drug candidate portfolio will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other factors, including the following: Karyopharm's results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. Food and Drug Administration and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; Karyopharm's ability to obtain and maintain requisite regulatory approvals and to enroll patients in its clinical trials; unplanned cash requirements and expenditures; development of drug candidates by Karyopharm's competitors for diseases in which Karyopharm is currently developing its drug candidates; and Karyopharm's ability to obtain, maintain and enforce patent and other intellectual property protection for any drug candidates it is developing. These and other risks are described under the caption "Risk Factors" in Karyopharm's Annual Report on Form 10-K for the year ended December 31, 2013, which is on file with the Securities and Exchange Commission (SEC), and in other filings that Karyopharm may make with the SEC in the future. Any forward-looking statements contained in this press release speak only as of the date hereof, and Karyopharm expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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