Karyopharm Therapeutics Announces Initiation of an Investigator Sponsored Phase 1 Dose Escalation Study of Its Lead Drug Candidate Selinexor (KPT-330) in Singapore

NATICK, Mass., Feb. 27, 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 1 study of oral Selinexor in Asian patients with advanced or metastatic solid tumors. Selinexor (KPT-330), is a first-in-class, oral Selective Inhibitors of Nuclear Export (SINE) compound that covalently inhibits exportin-1 (XPO1/CRM1), which leads to the accumulation of tumor suppressor proteins in the cell nucleus and the selective induction of apoptosis in cancer cells. This study is designed to determine the recommended Phase 2 dose and assess the safety and preliminary evidence of anti-cancer activity in Asian patients. The study is being conducted by Drs. David Tan and Goh Boon Cher at the National University Cancer Institute, Singapore (NCIS)/National University Hospital (NUH) in Singapore. Dr. Tan is a consultant medical oncologist at the Department of Haematology-Oncology and Assistant Professor at the Yong Loo Lin School of Medicine, National University of Singapore (NUS). Dr. Goh is Head of the Department of Haematology-Oncology and Deputy Director of the Cancer Science Institute of Singapore at the National University of Singapore.

Karyopharm's founder, president and Chief Scientific Officer Dr. Sharon Shacham commented, "This Phase 1 study in Asian patients will allow us to assess the tolerability and anti-tumor activity of Selinexor in patients with diverse tumor types that are under-represented in our current North American and European studies. We are particularly interested in the effects of Selinexor in malignancies such as gastric and hepatocellular carcinoma, which are poorly treated with available agents."

Dr. Tan stated, "I am very excited about bringing Selinexor into Asia for the treatment of patients with diverse solid tumors. Oral Selinexor represents a novel approach to the treatment of cancer, and could have broad anti-tumor activity. Although many of the tumors we see in Asia are similar to those in the rest of the world, we have a significant burden of difficult-to-treat cancers in need of novel therapies. I look forward to the results of Selinexor in our patients, and to further studies in Asia."

This Phase I dose escalation study will use a starting dose of 40mg/m2 orally twice each week. Selinexor is currently being evaluated in an ongoing Phase 1 dose escalation study in patients with advanced or metastatic solid tumors in North America and Europe at a dose of 85mg/m2 orally twice each week. Patients receive general supportive care, including appetite stimulating agents, in addition to oral Selinexor.

Conference Call Details

Karyopharm also announced that it will host a conference call on Wednesday, March 5, 2014, at 8:00 a.m. Eastern Time to review Karyopharm's 2013 financial results and provide an update on its development programs.

To access the live conference call via phone, please dial (855) 437-4406 from the United States and Canada or (484) 756-4292 internationally. The conference ID is 6470393.

To access the live and subsequently archived audio webcast, visit the Investors section of the Karyopharm website at www.karyopharm.com.

About Selinexor

Selinexor (KPT-330) is a first-in-class, oral Selective Inhibitor of Nuclear Export (SINE) compound that is undergoing Phase 1 studies in patients with advanced hematologic malignancies (NCT01607892), solid tumors (NCT01607905), and sarcomas (NCT01896505). 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.

About Karyopharm

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. Karyopharm's SINE compounds function by binding with the XPO1, which prevents the export of various proteins out of the nucleus. 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.

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 SINE compounds, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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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