Karyopharm Initiates STOMP Clinical Trial of Oral Selinexor in Multiple Myeloma

NEWTON, Mass., Oct. 19, 2015 (GLOBE NEWSWIRE) -- Karyopharm Therapeutics Inc. (Nasdaq:KPTI), a clinical-stage pharmaceutical company, announced today the initiation of the Selinexor and Backbone Treatments of Multiple Myeloma Patients, (STOMP) study. STOMP is a multi-center, Phase 1b/2 study of selinexor and other standard therapies in patients with multiple myeloma (MM). Selinexor, the company's lead, novel, oral Selective Inhibitor of Nuclear Export/SINE™ compound, will be evaluated in combination with low-dose dexamethasone in independent cohorts with bortezomib (Velcade®), lenalidomide (Revlimid®) and pomalidomide (Pomalyst®). Selinexor and low dose dexamethasone is already being combined with carfilzomib (Kyprolis®) in an Investigator Sponsored MM Trial, where promising preliminary data were presented at the American Society of Hematology (ASH) 2014 Annual Meeting. Selinexor has received orphan drug designation from both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for MM.

"The activity demonstrated to-date in multiple myeloma with selinexor and low-dose dexamethasone, as well as the combination of selinexor and low-dose dexamethasone with carfilzomib, is encouraging and we look forward to further evaluating the activity of selinexor-based combinations in patients with multiple myeloma whose disease has relapsed following, or is refractory to, various agents," said Sharon Shacham, PhD, MBA, President and Chief Scientific Officer of Karyopharm. "Despite the availability of new therapies for multiple myeloma, nearly all patients eventually relapse and eventually succumb to this disease. We hope the selinexor/low-dose dexamethasone regimen in combination with existing therapies will improve the outcomes for these patients."

This multi-arm Phase 1b/2 study will evaluate the safety and efficacy of selinexor and low-dose dexamethasone at 60mg and 20mg, respectively, twice weekly or 80mg and 40mg, respectively, once weekly in separate combinations with either bortezomib, lenalidomide or pomalidomide. 220 patients with MM whose disease has relapsed after one or more prior therapies are expected to enroll in STOMP and overall response rate (ORR) is the primary endpoint of the study.

STOMP was designed based on both preclinical combination data as well as from Karyopharm's ongoing Phase 1/2 study of selinexor with low-dose dexamethasone in combination with the proteasome inhibitor carfilzomib in relapsed/refractory multiple myeloma. Phase 1/2 data demonstrating the activity of selinexor with low-dose dexamethasone in combination with carfilzomib were presented at ASH 2014. In this ongoing study conducted by investigators at the University of Chicago, the first three patients, all of whom had MM refractory to carfilzomib and dexamethasone, were treated with selinexor, dexamethasone and carfilzomib achieved at least partial responses. Further clinical updates from this ongoing study are expected at the ASH 2015 annual meeting.

About Selinexor

Selinexor (KPT-330) is a first-in-class, oral Selective Inhibitor of Nuclear Export / SINE™ compound. Selinexor functions by binding with and inhibiting the nuclear export protein XPO1 (also called CRM1), leading to the accumulation of tumor suppressor proteins in the cell nucleus. This reinitiates and amplifies their tumor suppressor function and is believed to lead to the selective induction of apoptosis in cancer cells, while largely sparing normal cells. Over 1,200 patients have been treated with selinexor in company and investigator-sponsored Phase 1 and Phase 2 clinical trials in advanced hematologic malignancies and solid tumors. Karyopharm has initiated four later-phase clinical trials of selinexor, including one in older patients with acute myeloid leukemia (SOPRA), one in patients with Richter's transformation (SIRRT), one in patients with diffuse large B-cell lymphoma (SADAL) and a single-arm trial of selinexor and lose-dose dexamethasone in patients with multiple myeloma (STORM). In solid tumors, Karyopharm plans to initiate a randomized, placebo-controlled Phase 2/3 trial of selinexor to treat liposarcoma during the fourth quarter of 2015. Additional Phase 1 and Phase 2 studies are ongoing or currently planned, including multiple studies in combination with one or more approved therapies in a variety of tumor types to further inform the company's clinical development priorities for selinexor. 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. Karyopharm's SINE™ compounds function by binding with and inhibiting the nuclear export protein XPO1 (or CRM1). In addition to single-agent activity against a variety of different human cancers, SINE™ compounds have also shown biological activity in models of cancer,

inflammation, autoimmune disease, certain viruses, and wound-healing. Karyopharm was founded by Dr. Sharon Shacham and is located in Newton, Massachusetts. For more information, 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, which is on file with the Securities and Exchange Commission (SEC) as of August 10, 2015, 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.

CONTACT: Justin Renz

(617) 658-0574

jrenz@karyopharm.com

Gina Nugent

(617) 460-3579

nugentcomm@aol.com

Source: Karyopharm Therapeutics
