Karyopharm to Present Preliminary STOMP Phase 1B Clinical Data at 2016 European Hematology Association Annual Meeting

NEWTON, Mass., May 19, 2016 (GLOBE NEWSWIRE) -- Karyopharm Therapeutics Inc. (Nasdaq:KPTI), a clinical-stage pharmaceutical company, today announced that an abstract describing preliminary activity of selinexor (KPT-330) and dexamethasone in combination with bortezomib (Velcade®), pomalidomide (Pomalyst®), or lenalidomide (Revlimid®) for the treatment of relapsed/refractory multiple myeloma (MM) (the STOMP study) has been accepted for presentation at the 21st Congress of the European Hematology Association (EHA) held June 9-12, 2016 in Copenhagen, Denmark. The abstract describes preliminary Phase 1b data in which responses were observed with selinexor, Karyopharm's first-in-class, oral Selective Inhibitor of Nuclear Export / SINE™ compound that inhibits exportin 1 (XPO1), and dexamethasone in combination with standard of care MM therapies in patients with heavily pretreated MM. Updated and detailed results from the study will be presented at the conference.

"We are very encouraged by the activity, safety and tolerability profile observed to date with selinexor and dexamethasone in combination with these backbone multiple myeloma therapies, especially in light of the extensive pretreatment history of this patient group," said Sharon Shacham, PhD, MBA, President and Chief Scientific Officer of Karyopharm. "These clinical data further support the synergistic activity of selinexor in combination with proteasome inhibitors and immunomodulatory agents, or iMiDs, which was previously demonstrated in preclinical models of multiple myeloma. This study will be informative for designing future selinexor combination studies."

Poster Presentation:

Title:

A Phase 1b/2 Study of Selinexor in Combination with Backbone Therapies for Treatment of Relapsed/Refractory Multiple

Mackbone Therapies for Treatment of Relapsed/Refractory Multiple

Myeloma

Author: Bahlis, Southern Alberta Cancer Research Institute, Calgary

Abstract/Board: P277

Session: Innovative therapies for MM 1

Date/Time: Friday, June 10, 2016 5:15-6:45 PM CET

Location: Poster Hall H

In a poster to be presented by Dr. Nizar Bahlis, Southern Alberta Cancer Research Institute and colleagues, preliminary clinical data from the ongoing Phase 1b/2 STOMP study of selinexor and dexamethasone in combination with bortezomib, pomalidomide, or lenalidomide for the treatment of relapsed/refractory MM will be described. Selinexor and dexamethasone demonstrated promising early response rates in the bortezomib and pomalidomide combination arms and summary data as of February 10, 2016 are described below.

- 10 patients (5 male/5 female, median of 8 prior regimens, median age 65 years) have been enrolled in the bortezomib combination arm. Of 7 evaluable patients, 3 achieved partial response (PR) (including patients with MM refractory to bortezomib and MM with deletion 17p), 2 achieved minor response (MR), 1 had stable disease (SD) and 1 had progressive disease (PD). Among the 10 enrolled patients, the most common adverse events were fatigue, nausea and diarrhea, which were primarily grade 1/2; five grade 3 and no grade 4 adverse events of thrombocytopenia were also reported.
- 4 patients (2 male/2 female, median of 8 prior regimens, median age 61 years) have been enrolled in the pomalidomide combination arm. Of 2 evaluable patients, 1 achieved a very good partial response (VGPR) and 1 achieved MR. Among the 4 enrolled patients, the most common adverse events were nausea and dysgeusia, which were primarily grade 1/2; one grade 4 adverse event of neutropenia was reported.

Data on additional patients and longer follow up will be presented at the conference.

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 1,500 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. Selinexor is being evaluated in several later-phase clinical trials, including one in older patients with acute myeloid leukemia (SOPRA), one in patients with diffuse large B-cell lymphoma (SADAL), one in patients with liposarcoma (SEAL) and a single-arm trial of selinexor and lose-dose dexamethasone in patients with multiple myeloma (STORM). 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 and related 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 and combination activity against a variety of human cancers, SINE™ compounds have also shown biological activity in models of neurodegeneration, 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 March 31, 2016, which was filed with the Securities and Exchange Commission (SEC) on May 9, 2016, 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

https://investors.karyopharm.com/2016-05-19-Karyopharm-to-Present-Preliminary-STOMP-Phase-1B-Clinical-Data-at-2016-European-Hematology-Association-Annual-Meeting