

Karyopharm to Present Selinexor Clinical Data at the American Society of Clinical Oncology Annual Meeting

NEWTON, Mass., May 18, 2016 (GLOBE NEWSWIRE) -- Karyopharm Therapeutics Inc. (Nasdaq:KPTI), a clinical-stage pharmaceutical company, today announced that three abstracts involving selinexor (KPT-330), the Company's lead product candidate in development for hematological malignancies and solid tumors, have been selected for two poster presentations and one poster discussion at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting taking place June 3-7 in Chicago. Updated and detailed results from these studies will be presented at the conference. The abstracts, which represent both company- and investigator-sponsored clinical studies, describe data related to selinexor, Karyopharm's first-in-class, oral Selective Inhibitor of Nuclear Export / SINE™ compound that inhibits exportin 1 (XPO1). Posters to be presented include a Phase 2 clinical update with single-agent selinexor in recurrent glioblastoma, Phase 2 study design of single-agent selinexor in advanced liposarcoma and Phase 1 data for selinexor in multiple myeloma in combination with liposomal doxorubicin and dexamethasone.

"We are encouraged by the activity observed to date with oral selinexor in solid tumors, including the single-agent data to be presented at ASCO demonstrating brain penetration, anti-cancer activity and disease control in recurrent glioblastoma," said Sharon Shacham, PhD, MBA, President and Chief Scientific Officer of Karyopharm. "We are also excited about the response rates observed to date with selinexor in combination with doxorubicin and dexamethasone in relapsed and refractory multiple myeloma."

Poster Presentations:

Title: [A phase 2 study on efficacy, safety and intratumoral pharmacokinetics of oral selinexor \(KPT-330\) in patients with recurrent glioblastoma \(GBM\)](#)
Author: Mau-Sorensen, Rigshospitalet, Copenhagen
Abstract/Board: 2077/264
Session: Central Nervous System Tumors
Date/Time: Saturday, June 4, 1:00 PM — 4:30 PM CDT

In a poster presentation, Dr. Morten Mau-Sorensen of Rigshospitalet, Copenhagen and colleagues will describe updated clinical data from Karyopharm's ongoing KING study, a Phase 2 clinical trial of single-agent selinexor in patients with recurrent glioblastoma following treatment with temozolomide and radiation. As of January 20, 2016, selinexor demonstrated anti-tumor activity with a 33% disease control rate in 27 evaluable patients with glioblastoma including 3 (11%) partial responses, 6 (22%) stable disease, and 18 (67%) progressive disease. The most common adverse events were thrombocytopenia, fatigue and anorexia, which were mostly Grade 1/2.

Title: [The Selinexor in Advanced Liposarcoma \(SEAL\) study: A phase 2/3, multicenter, randomized, double blind study of selinexor versus placebo in patients with advanced, unresectable, dedifferentiated liposarcoma \(DDLs\)](#)
Author: Gounder, Memorial Sloan Kettering Cancer Center
Abstract/Board: TPS11072/197a
Session: Sarcoma
Date/Time: Monday, June 6, 8:00 AM - 11:30 AM CDT

Dr. Mrinal Gounder of Memorial Sloan Kettering Cancer Center and colleagues will present a poster on the design of Karyopharm's SEAL study, a Phase 2/3 clinical trial evaluating the activity of single-agent selinexor in patients with advanced liposarcomas. Patients eligible for enrollment in this study will have measurable disease, radiologic evidence of progressive disease within 6 months, and have had at least one prior line of systemic therapy. Patients are being randomized to receive oral selinexor 60 mg or placebo twice weekly on a 42-day cycle until progressive disease or intolerability. Patients with progressive disease on placebo can crossover to selinexor. The primary endpoint is progression free survival and the study is powered to detect a 50% improvement with selinexor versus placebo. Patient enrollment began in January 2016 with top-line data on the Phase 2 portion of the study expected in mid-2017.

Title: [Phase I trial of the combination of selinexor \(SEL\), liposomal doxorubicin \(DOX\) and dexamethasone \(Dex\) for relapsed and refractory multiple myeloma \(RRMM\)](#)
Author: Baz, Moffitt Cancer Center
Abstract/Board: 8013/278
Session: Hematologic Malignancies—Plasma Cell Dyscrasia
Date/Time: Monday, June 6, 3:00 PM - 4:15 PM CDT

In a poster session presented by Dr. Rachid Baz of the Moffitt Cancer Center and colleagues, data from a Phase 1 study of selinexor in combination with doxorubicin and dexamethasone including safety, tolerability and preliminary responses in heavily pretreated patients with multiple myeloma will be discussed. Eligible patients had relapsed or refractory myeloma and received ≥ 2 prior therapies (median of 6 prior lines (range 2-9) including lenalidomide and a proteasome inhibitor. As of January 2016 ten patients were evaluable for response including 2 (20%) very good partial responses, 2 (20%) partial responses, 2 (20%) minor responses, 3 (30%) with stable disease and 1 (10%) with progressive disease. The most common Grade 3/4 possibly related adverse events include asymptomatic hyponatremia, anemia, thrombocytopenia, neutropenia, diarrhea and vomiting.

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 low-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.

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