

Karyopharm to Present Selinexor Phase 2 SEAL Data at the American Society of Clinical Oncology 2018 Annual Meeting

A Total of Four Posters Highlighting Selinexor Data in Hematologic and Solid Tumor Malignancies Will Be Presented at the Meeting

NEWTON, Mass., May 16, 2018 (GLOBE NEWSWIRE) -- Karyopharm Therapeutics Inc. (Nasdaq:KPTI), a clinical-stage pharmaceutical company, today announced that four posters will be presented at the upcoming American Society of Clinical Oncology (ASCO) 2018 Annual Meeting taking place June 1-5, 2018 in Chicago. Among the poster presentations will be results from the Company's Phase 2 SEAL study evaluating selinexor, its lead, oral SINE compound, in patients with advanced de-differentiated liposarcoma. The remaining posters will highlight clinical and preclinical data from ongoing investigator-sponsored trials evaluating selinexor in combination with other anti-cancer agents.

"Dedifferentiated liposarcoma is a rare and aggressive form of the disease that is resistant to both standard chemotherapy and radiation, and most patients who progress following surgery ultimately succumb to this difficult to treat cancer," said Sharon Shacham, PhD, MBA, President and Chief Scientific Officer of Karyopharm. "We previously reported positive top-line data from the Phase 2 SEAL study in September 2017, including oral selinexor's demonstration of superiority over placebo for the study's primary endpoint of progression-free survival (PFS), with a hazard ratio of 0.60, representing a 40% reduction in the risk of progression or death. The Phase 3 portion of the SEAL study is currently ongoing with top-line data expected by the end of 2019. We look forward to presenting the more detailed results from the Phase 2 portion of the SEAL study at ASCO this year."

Details for the ASCO 2018 selinexor presentations are as follows:

Company-sponsored Trials

Title: [Phase 2 results of selinexor in advanced de-differentiated \(DDLs\) liposarcoma \(SEAL\) study: A phase 2/3, randomized, double blind, placebo controlled cross-over study](#)

Lead author: Mrinal Gounder, Memorial Sloan Kettering Cancer Center and Weill Cornell Medical College

Poster Board #: 257

Abstract #: 11512

Poster Discussion Session: Sarcoma

Date and Time: Saturday, June 2, 2018; 8:00 AM – 11:30 AM CT; Discussion from 3:00 PM – 4:15 PM

Location: Hall A

Investigator-sponsored Trials

Title: [Phase 1 study of selinexor plus mitoxantrone, etoposide, and cytarabine in acute myeloid leukemia](#)

Lead author: Bhavana Bhatnagar, Ohio State University Comprehensive Cancer Center

Poster Board #: 108

Abstract: 7048

Poster Session: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allograft

Date and Time: Monday, June 4, 2018; 8:00 AM – 11:30 AM CT

Location: Hall A

Title: [Phase 1b study of selinexor, a first in class selective inhibitor of nuclear export \(SINE\) compound, in combination with doxorubicin in patients \(pts\) with locally advanced or metastatic soft tissue sarcoma \(STS\)](#)

Lead author: Eoghan Ruadh Malone, Princess Margaret Cancer Centre

Poster Board #: 307

Abstract: 11562

Poster Session: Sarcoma

Date and Time: Saturday, June 2, 2018; 8:00 AM – 11:30 AM CT

Location: Hall A

Title: [Profiling the immune checkpoint pathway in acute myeloid leukemia](#)

Lead author: Paola Dama, University of Chicago

Poster Board #: 75

Abstract: 7015

Poster Discussion Session: Hematologic Malignancies – Leukemia, Myelodysplastic Syndromes, and Allograft

Date and Time: Monday, June 4, 2018; 8:00 AM – 11:30 AM CT; Discussion from 11:30 AM – 12:45 PM CT

Location: Hall A

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. To date, over 2,400 patients have been treated with selinexor. In April 2018, Karyopharm reported positive top-line data from the Phase 2b STORM study evaluating selinexor in combination with low-dose dexamethasone in patients with penta-refractory multiple myeloma. Selinexor has been granted Orphan Drug Designation in multiple myeloma and Fast Track designation for the patient population evaluated in the STORM study. Karyopharm plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) during the second half of 2018, with a request for accelerated approval for oral selinexor as a new treatment for patients with penta-refractory multiple myeloma. The Company also plans to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in early 2019 with a request for conditional approval. Selinexor is also being evaluated in several other mid- and later-phase clinical trials across multiple cancer indications, including in multiple myeloma in a pivotal, randomized Phase 3 study in combination with Velcade® (bortezomib) and low-dose dexamethasone (BOSTON) and as a potential backbone therapy in combination with approved therapies (STOMP), and in diffuse large B-cell lymphoma (SADAL), liposarcoma (SEAL), and an investigator-sponsored study in endometrial cancer (SIENDO), among others. Additional Phase 1, Phase 2 and Phase 3 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 Karyopharm's clinical development priorities for selinexor. Additional 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, which was founded by Dr. Sharon Shacham, currently has several investigational programs in clinical or preclinical development. 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 timing of submissions to regulatory authorities and the potential availability of accelerated approval pathways, the therapeutic potential of and potential clinical development plans for Karyopharm's drug candidates, especially selinexor. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from Karyopharm's current expectations. For example, there can be no guarantee that any of Karyopharm's drug candidates, including selinexor, will successfully complete necessary clinical development phases, that development of any of Karyopharm's drug candidates will continue or that any feedback from regulatory authorities will ultimately lead to the approval of selinexor or any of Karyopharm's other drug candidates. 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, including with respect to the need for additional clinical studies; 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, 2018, which was filed with the Securities and Exchange Commission (SEC) on May 10, 2018, 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, except as required by law, 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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Source: Karyopharm Therapeutics Inc.

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