

# U.S. FDA Division of Hematology Products Lifts Partial Clinical Hold on Karyopharm's Selinexor Clinical Trials

## **Recruitment Resumes Across All Selinexor Trials in Hematological Malignancies Timelines for Ongoing and Planned Studies Expected to Remain Materially Unchanged**

NEWTON, Mass., March 30, 2017 (GLOBE NEWSWIRE) -- Karyopharm Therapeutics Inc. (Nasdaq:KPTI), a clinical-stage pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) Division of Hematology Products has lifted the partial clinical hold placed on the clinical trials for selinexor (KPT-330), enabling patient enrollment and dosing of new patients in the Company's clinical trials of selinexor in hematological malignancies. The partial clinical hold was not the result of any patient death or any change in the safety profile of selinexor. Enrollment may now resume in all selinexor studies in hematologic malignancies, including the STORM study in refractory multiple myeloma, the SADAL study in relapsed/refractory diffuse large B-cell lymphoma (DLBCL), and the STOMP study of selinexor and backbone therapies in multiple myeloma. In addition, Investigator Sponsored Trials in hematologic malignancies with selinexor may resume accruing patients.

Michael G. Kauffman, MD, PhD, Chief Executive Officer of Karyopharm, stated, "The Karyopharm team worked diligently to update and submit the required documents to the FDA, which allowed the hematology division to expeditiously remove the partial clinical hold. We anticipate that the solid tumor divisions will follow suit shortly. Patient enrollment is again underway in our hematologic oncology studies. Our previously disclosed enrollment rates and timelines for both ongoing and planned trials are not expected to be materially impacted."

### 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 1,900 patients have been treated with selinexor and it is currently being evaluated in several mid- and later-phase clinical trials across multiple cancer indications, including in multiple myeloma in combination with low-dose dexamethasone (STORM) and backbone therapies (STOMP), and in diffuse large B-cell lymphoma (SADAL), and liposarcoma (SEAL), among others. Karyopharm plans to initiate a pivotal randomized Phase 3 study of selinexor in combination with bortezomib (Velcade®) and low-dose dexamethasone (BOSTON) in patients with multiple myeloma in early 2017. 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 the Company's clinical development priorities for selinexor. Additional clinical trial information for selinexor is available at [www.clinicaltrials.gov](http://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](http://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 anticipated impact of the partial clinical hold, the potential timing for the removal of the partial clinical hold by the solid tumor divisions of the FDA, therapeutic potential of and potential clinical development plans for Karyopharm's drug candidates, including the timing of initiation of and enrollment in certain 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 the FDA will release the partial clinical hold in a timely manner or at all, any of Karyopharm's SINE™ compounds, including selinexor (KPT-330), 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 FDA 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 Annual Report on Form 10-K for the year ended December 31, 2016, which was filed with the Securities and Exchange Commission (SEC) on March 16, 2017, 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.

Velcade® is a registered trademark of Takeda Pharmaceutical Company Limited

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