Karyopharm’s Selinexor Receives Fast Track Designation from FDA for the Treatment of Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma

NEWTON, Mass., Nov. 07, 2018 (GLOBE NEWSWIRE) -- Karyopharm Therapeutics Inc. (Nasdaq:KPTI), a clinical-stage pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to selinexor, the Company’s first-in-class, oral SINE compound for the treatment of patients with diffuse large B-cell lymphoma (DLBCL) who have received at least two prior therapies and are not eligible for high dose chemotherapy with stem cell rescue or CAR-T therapy. Selinexor is currently being studied in the ongoing Phase 2b SADAL study in patients with relapsed or refractory DLBCL who are not eligible for stem cell transplantation for which top-line results will be presented at the upcoming American Society of Hematology (ASH) 2018 Annual Meeting.

Karyopharm previously received Fast Track Designation for selinexor as a potential new treatment for patients with penta-refractory multiple myeloma who have received at least three prior lines of therapy. In October 2018, the U.S. FDA accepted Karyopharm’s New Drug Application for selinexor seeking accelerated approval as a new treatment for patients with penta-refractory multiple myeloma. The FDA has assigned a Priority Review and given an action date of April 6, 2019 under the Prescription Drug User-Fee Act (PDUFA).

The FDA's Fast Track program facilitates the development of drugs intended to treat serious conditions and that have the potential to address unmet medical needs. A drug program with Fast Track status is afforded greater access to the FDA for the purpose of expediting the drug's development, review and potential approval. In addition, the Fast Track program allows for eligibility for Accelerated Approval and Priority Review, if relevant criteria are met, as well as for Rolling Review, which means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be submitted for review.

“The receipt of Fast Track designation from the FDA for selinexor in relapsed DLBCL underscores the great unmet medical need for this aggressive form of lymphoma,” said Sharon Shacham, PhD, MBA, Founder, President and Chief Scientific Officer of Karyopharm. “Pending positive results from the Phase 2b SADAL study, we plan to submit a second NDA to the FDA in the first half of 2019, with a request for accelerated approval, for oral selinexor as a potential new treatment for patients with relapsed or refractory DLBCL.”

About the Phase 2b SADAL Study

The multicenter, open-label Phase 2b SADAL (Selinexor Against Diffuse Aggressive Lymphoma) study is evaluating oral selinexor in patients with relapsed or refractory DLBCL who have received two to five prior therapies and who are not currently eligible for hematopoietic stem cell transplantation. In this study, approximately 125 patients will receive 60mg oral selinexor twice weekly in 4-week cycles. At least 50% of study participants must have the GCB sub-type. Objective response rate is the primary endpoint of the study, with duration of response a key secondary endpoint.

About Selinexor

Selinexor 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 2,800 patients have been treated with selinexor. In April and September 2018, Karyopharm reported positive 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’s New Drug Application (NDA) has been accepted for filing and granted Priority Review by the FDA, and oral selinexor is currently under review by the FDA as a possible 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), as a potential backbone therapy in combination with approved therapies (STOMP), 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 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 our expectations relating to submissions and to the review and potential approval of selinexor by regulatory authorities, including the anticipated timing of such submissions and actions, and the potential availability of accelerated approval pathways, the therapeutic potential of and potential clinical development plans for Karyopharm's drug candidates, especially selinexor, and the plans for commercialization. Such statements are subject to numerous important factors, risks and uncertainties, many of which are beyond Karyopharm’s control, that may cause actual events or results to differ materially from Karyopharm's current expectations. For example, there can be no guarantee that regulators will agree that selinexor qualifies for accelerated approval in the U.S. or conditional approval in the E.U. as a result of the data from the STORM study in patients with penta-refractory myeloma or the SADAL study in patients with relapsed or refractory DLBCL or that any of Karyopharm's drug candidates, including selinexor, will successfully complete necessary 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, 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 June 30, 2018, which was filed with the Securities and Exchange Commission (SEC) on August 7, 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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