Karyopharm Announces Open Enrollment At Participating Hospitals In Europe For A Phase 3 Maintenance Study Evaluating Selinexor In Patients With Endometrial Cancer After Combination Chemotherapy

NEWTON, Mass., May 26, 2021 /PRNewswire/ -- Karyopharm Therapeutics Inc. (Nasdaq: KPTI), a commercial-stage pharmaceutical company pioneering novel cancer therapies, today announced that enrollment for its Phase 3 maintenance study evaluating selinexor in patients with endometrial cancer after combination chemotherapy is now recruiting eligible patients at participating hospitals in Belgium, Czech Republic, Germany, Italy, and Spain with Greece starting in the coming weeks. Full study details can be found at Karyopharm.com/clinicaltrials.

The KCP-330-024/ENGOT-EN5/SIENDO study is an ongoing multicenter, blinded, placebo-controlled, randomized Phase 3 study evaluating the efficacy and safety for front-line maintenance therapy with selinexor in patients with advanced or recurrent endometrial cancer. Participants with primary stage IV or recurrent disease who had a partial or complete response after a single line of at least 12 weeks of standard taxane-platinum combination chemotherapy are randomized in a 2:1 manner to receive either maintenance therapy of 80mg of selinexor taken once per week or placebo, until disease progression. The study is expected to enroll approximately 248 participants at study sites across the United States, Canada, Israel and Europe. The primary endpoint in the study is progression free survival with the goal of the study demonstrating a hazard ratio of 0.6.

"While selinexor has been most extensively studied in patients with hematologic malignancies, there is increasing evidence that selinexor may also play an important role in the treatment of a variety of solid tumors, including patients with endometrial cancer," said Sharon Shacham, PhD, MBA, Chief Scientific Officer of Karyopharm. "As there are currently no approved drugs in the U.S. or Europe to treat patients with endometrial cancer in the maintenance setting following chemotherapy, the SIENDO study has the potential to help meaningfully advance the treatment paradigm for patients in need of new options for advanced or recurrent endometrial cancer."

About Endometrial Cancer

Endometrial cancer, more commonly known as uterine cancer, is the most common cancer of the female reproductive system, with more than 130,000 new cases and 30,000 deaths in Europe in 2020.1 Endometrial cancer is typically treated by one or a combination of treatments, including surgery, radiation therapy, and systemic treatments using medications. Combinations of these cancer treatments are often recommended, but they depend on the stage and characteristics of the cancer.

About Karyopharm

Karyopharm Therapeutics Inc. (Nasdaq: KPTI) is a commercial-stage pharmaceutical company pioneering novel cancer therapies and dedicated to the discovery, development, and commercialization of first-in-class drugs directed against nuclear export for the treatment of cancer and other diseases. Karyopharm's Selective Inhibitor of Nuclear Export (SINE) compounds function by binding with and inhibiting the nuclear export protein XPO1. Karyopharm's lead compound, XPOVIO® (selinexor), is approved in the U.S. in multiple hematologic malignancy indications, including in combination with Velcade® (bortezomib) and dexamethasone for the treatment of adult patients with multiple myeloma after at least one prior therapy, in combination with dexamethasone for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma. NEXPOVIO® (selinexor) has also been granted conditional marketing authorization by the European Commission in combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. 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 Karyopharm's expectations relating to selinexor to treat patients with solid tumors and the therapeutic potential of and clinical development plans for selinexor. 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 any positive developments in the development of selinexor 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 risk that the COVID-19 pandemic could interrupt or delay ongoing or planned clinical trials; the ability to retain regulatory approval of selinexor; results of clinical trials; the content and timing of regulatory decisions, including with respect to the need for additional clinical studies; and Karyopharm's ability to enroll patients in its clinical trials. 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, 2021, which was filed with the Securities and Exchange Commission (SEC) on May 4, 2021, 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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¹World Health Organization; Globocan 2020 ; https://gco.iarc.fr/today/data/factsheets/cancers/24-Corpus-uteri-fact-sheet.pdf

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https://investors.karyopharm.com/2021-05-26-Karyopharm-Announces-Open-Enrollment-At-Participating-Hospitals-In-Europe-For-A-Phase-3-Maintenance-Study-Evaluating-Selinexor-In-Patients-With-Endometrial-Cancer-After-Combination-Chemotherapy