Karyopharm Receives FDA Fast Track Designation for Selinexor for the Treatment of Myelofibrosis

– Regulatory Designation Includes Primary Myelofibrosis, Post-Essential Thrombocythemia Myelofibrosis and Post-Polycythemia Vera Myelofibrosis –

– Pivotal Phase 3 Study of Selinexor and Ruxolitinib in Treatment-Naïve Myelofibrosis Initiated in June 2023 –

NEWTON, Mass., July 17, 2023 /PRNewswire/ -- Karyopharm Therapeutics Inc. (Nasdaq: KPTI), a commercial-stage pharmaceutical company pioneering novel cancer therapies, today announced that the United States Food and Drug Administration (FDA) has granted Fast Track Designation to the development program of selinexor for the treatment of patients with myelofibrosis, including primary myelofibrosis, post-essential thrombocythemia myelofibrosis, and post-polycythemia vera myelofibrosis.

"Fast Track Designation for selinexor highlights its potential to address the unmet medical need in myelofibrosis, an important acknowledgement as we continue our pivotal Phase 3 study," said Reshma Rangwala, MD, PhD, Chief Medical Officer of Karyopharm. "Selinexor's unique mechanism of action, XPO1 inhibition, is a novel and potentially fundamental mechanism in myelofibrosis. We have been highly encouraged by the efficacy and safety data observed to date [in our Phase 1 study] with selinexor in combination with ruxolitinib in patients with treatment-naïve myelofibrosis and believe selinexor has the potential to shift the treatment paradigm. We look forward to continued interaction with the FDA as we advance the development of this promising treatment for patients in need."

In June 2023, Karyopharm initiated a pivotal Phase 3 clinical trial (XPORT-MF-034) (NCT04562389) to assess the efficacy and safety of once-weekly selinexor 60 mg in combination with ruxolitinib in JAKi-naïve patients with myelofibrosis. Updated data from the Phase 1 study were presented at the American Association for Cancer Research Annual Meeting 2023, American Society of Clinical Oncology 2023 and European Hematology Association 2023, which showed rapid, deep and sustained spleen responses and robust symptom improvement in patients treated with selinexor 60 mg in combination with ruxolitinib as of the April 10, 2023 cut-off date. Top-line data from the Phase 3 study is expected in 2025. The Company plans to expand its clinical development program in myelofibrosis by investigating selinexor in other JAKi-naïve settings, such as novel combinations, to benefit the greatest number of patients.

Fast Track Designation is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. Features of Fast Track Designation include frequent interactions with the FDA review team, and if relevant criteria are met, eligibility for Priority Review and Rolling Review.

Further information about the Phase 3 study can be found at www.clinicaltrials.gov.

About Karyopharm Therapeutics
Karyopharm Therapeutics Inc. (Nasdaq: KPTI) is a commercial-stage pharmaceutical company pioneering novel cancer therapies. Since its founding, Karyopharm has been an industry leader in oral Selective Inhibitor of Nuclear Export (SINE) compound technology, which was developed to address a fundamental mechanism of oncogenesis: nuclear export dysregulation. Karyopharm's lead SINE compound and first-in-class, oral exportin 1 (XPO1) inhibitor, XPOVIO® (selinexor), is approved in the U.S. and marketed by the Company in three oncology indications and has received regulatory approvals in various indications in a growing number of ex-U.S. territories and countries, including Europe and the United Kingdom (as NEXPOVIO®) and China. Karyopharm has a focused pipeline targeting multiple high unmet need cancer indications, including in multiple myeloma, endometrial cancer, myelodysplastic neoplasms and myelofibrosis. For more information about our people, science and pipeline, please visit www.karyopharm.com, and follow us on Twitter at @Karyopharm and LinkedIn.

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 ability of selinexor to treat patients with myelofibrosis; and expectations related to the clinical development of selinexor and potential regulatory submissions of 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 Karyopharm will successfully commercialize XPOVIO or that any of Karyopharm's drug candidates, including selinexor and eltanexor, 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 the development or commercialization of 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: the adoption of XPOVIO in the commercial marketplace, the timing and costs involved in commercializing XPOVIO or any of Karyopharm's drug candidates that receive regulatory approval; the ability to obtain and retain regulatory approval of XPOVIO or any of Karyopharm's drug candidates that receive regulatory approval; 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; the ability of Karyopharm or its third party collaborators or successors in interest to fully perform their respective obligations under the applicable agreement and the potential future financial implications of such agreement; Karyopharm's ability to enroll patients in its clinical trials; unplanned cash requirements and expenditures; development or regulatory approval of drug candidates by Karyopharm's competitors for products or product candidates in which Karyopharm is currently commercializing or developing; the direct or indirect impact of the COVID-19 pandemic or any future pandemic on Karyopharm's business, results of operations and financial condition; and Karyopharm's ability to obtain, maintain and enforce patent and other intellectual property protection for any of its products or product candidates. 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, 2023, which was filed with the Securities and Exchange Commission (SEC) on May 4, 2023, 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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