ONO PHARMACEUTICAL CO.,LTD.

April 12, 2018

Karyopharm's Selinexor Receives Fast Track Designation from FDA for the Treatment of Patients with Penta-Refractory Multiple Myeloma

NEWTON, Mass., April 10, 2018 (GLOBE NEWSWIRE) -- Karyopharm Therapeutics Inc. (Nasdaq: KPTI), a clinical-stage pharmaceutical company, announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the Company's lead, oral Selective Inhibitor of Nuclear Export (SINE) compound selinexor for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy. The FDA's statement, consistent with the design of Karyopharm's Phase 2b STORM study, noted that the three prior lines of therapy include regimens comprised of an alkylating agent, a glucocorticoid, Velcade® (bortezomib), Kyprolis® (carfilzomib), Revlimid® (lenalidomide), Pomalyst® (pomalidomide) and Darzalex® (daratumumab). In addition, the patient's disease must be refractory to at least one proteasome inhibitor (Velcade or Kyprolis), one immunomodulatory agent (Revlimid or Pomalyst), glucocorticoids and to Darzalex, as well as to the most recent therapy. The Company expects to report top-line data from the STORM study at the end of April 2018.

In October 2017, Ono Pharmaceutical Co., Ltd. concluded an exclusive license agreement with Karyopharm Therapeutics Inc. for the development and commercialization of Selinexor, their first-in-class oral XPO1 (Exportin 1) inhibitor, and KPT-8602, a second-generation oral XPO1 inhibitor, for all oncology indications exclusively in Japan, South Korea, Taiwan, Hong Kong and ASEAN countries.

Please click here for the press release distributed by BMS.

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