ONO PHARMACEUTICAL CO.,LTD.

July 19, 2018

Karyopharm Initiates Rolling Submission of New Drug Application to U.S. Food and Drug Administration for Selinexor as a Treatment for Patients with Penta-Refractory Multiple Myeloma

NEWTON, Mass., July 18, 2018 (GLOBE NEWSWIRE) -- Karyopharm Therapeutics Inc. (Nasdaq: KPTI), a clinical-stage pharmaceutical company, announced that the Company has initiated a rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking accelerated approval for selinexor, its novel, oral SINE compound, as a new treatment for patients with penta-refractory multiple myeloma. Patients with penta-refractory myeloma have previously received the two proteasome inhibitors (PIs), Velcade® (bortezomib) and Kyprolis® (carfilzomib), the two immunomodulatory drugs (IMiDs), Revlimid® (lenalidomide) and Pomalyst® (pomalidomide), and the anti-CD38 monoclonal antibody Darzalex® (daratumumab), and their disease is refractory to at least one PI, at least one IMiD, Darzalex and their most recent therapy. The Company expects to complete the NDA submission during the second half of 2018. Selinexor has received both Orphan Drug and Fast Track designations from the FDA for this indication.

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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