



Karyopharm Announces Results of Clinical Studies Investigating Selinexor to be Presented at the European Hematology Association 2019 Annual Meeting

May 16, 2019

-- Oral Presentation Highlighting Updated Data from the Phase 1b/2 STOMP Study Arm Evaluating Selinexor and Dexamethasone in Combination with Darzalex® in Patients with Relapsed or Refractory Multiple Myeloma --

-- Two Posters Highlighting Updated Data from the STOMP Arms Evaluating Selinexor and Dexamethasone in Combination with Kyprolis® or Pomalyst® --

NEWTON, Mass., May 16, 2019 (GLOBE NEWSWIRE) -- Karyopharm Therapeutics Inc. (Nasdaq:KPTI), a clinical-stage pharmaceutical company, today announced that five abstracts relating to selinexor, the Company's first in class, oral SINE compound, will be presented at the upcoming European Hematology Association (EHA) 2019 Annual Meeting taking place June 13-16, 2019 in Amsterdam. The first abstract, which was selected for an oral presentation, will highlight updated data from the Phase 1b/2 STOMP study arm evaluating selinexor and dexamethasone in combination with Darzalex (daratumumab) in patients with relapsed or refractory multiple myeloma. Two abstracts selected for poster presentations will feature new and updated data, respectively, from the STOMP arms evaluating selinexor and dexamethasone in combination with Kyprolis (carfilzomib) or Pomalyst (pomalidomide) in patients with relapsed or refractory multiple myeloma.

Two additional abstracts will also be presented regarding selinexor in acute myeloid leukemia (AML). One is an oral presentation which describes data from a Phase 2 study evaluating selinexor in combination with cytarabine and idarubicin in patients with relapsed or refractory AML, and the other is a poster that summarizes clinical data from the Phase 2 SOPRA study evaluating single-agent selinexor in patients with relapsed or refractory AML. As reported previously by Karyopharm in 2017, the SOPRA study did not meet its pre-specified primary endpoint.

"The Phase 1b/2 STOMP study continues to generate encouraging efficacy and safety data from multiple ongoing arms evaluating once weekly oral selinexor and dexamethasone in combination with the standard approved myeloma therapies," said Sharon Shacham, PhD, MBA, President and Chief Scientific Officer of Karyopharm. "Of note, at EHA this year, we will be presenting new data from the STOMP arm evaluating selinexor and dexamethasone in combination with the proteasome inhibitor Kyprolis as well as updated data from both the Darzalex and Pomalyst arms. There remains a growing need for new therapies, especially ones with novel mechanisms, for myeloma patients whose disease progresses despite treatment with currently available combination regimens. As such, the aim of the STOMP study is to establish that selinexor holds the potential to be a safe and effective backbone combination therapy option for patients with multiple myeloma."

Updated STOMP data from what appears in the abstracts will be presented at this meeting.

Details for the EHA 2019 presentations are as follows:

Oral Presentations

Title: Safety and Efficacy of combination of Selinexor, Daratumumab, and Dexamethasone (SDd) in Patients with Multiple Myeloma (MM) Previously Exposed to Proteasome Inhibitors and Immunomodulatory Drugs

Lead author: Cristina Gasparetto, Duke University Cancer Center

Abstract #: S1606

Session: Myeloma and other monoclonal gammopathies – Clinical

Date and Time: Sunday, June 16, 2019; 09:00 – 09:15 CEST

Location: Auditorium

Title: A Phase 2 Study of Selinexor Plus Cytarabine and Idarubicin in Patients with Relapsed/Refractory Acute Myeloid Leukemia (AML)

Lead author: Walter Fiedler, Hubertus Wald University Cancer Center Hamburg

Abstract #: S880

Session: Acute myeloid leukemia – Clinical

Date and Time: Saturday, June 15, 2019; 17:00 – 17:15 CEST

Location: Elicium 2

Poster Presentations

Title: Selinexor, Pomalidomide, and Dexamethasone (SPd) in Patients with Relapsed or Refractory Multiple Myeloma (RRMM)

Lead author: Christina Chen, Princess Margaret Cancer Center

Abstract #: PF587

Session: Myeloma and other monoclonal gammopathies – Clinical

Date and Time: Friday, June 14, 2019; 17:30 – 19:00 CEST

Location: Poster Area

Title: A Randomized, Open-Label, Phase II Study of Selinexor Versus Physician's Choice (PC) In Older Patients with Relapsed or Refractory Acute Myeloid Leukemia (AML)

Lead author: Kendra Sweet, Moffitt Cancer Center

Abstract #: PF261

Session: Acute myeloid leukemia – Clinical

Date and Time: Friday, June 14, 2019; 17:30 – 19:00 CEST

Location: Poster Area

Title: A Phase 1b/2 Study of Selinexor, Carfilzomib, and Dexamethasone (SKd) in Relapsed/ Refractory Multiple Myeloma (RRMM)

Lead author: Cristina Gasparetto, Duke University Cancer Center

Abstract #: PS1414

Session: Myeloma and other monoclonal gammopathies – Clinical

Date and Time: Saturday, June 15, 2019; 17:30 – 19:00 CEST

Location: Poster Area

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. In 2018, Karyopharm reported positive data from the Phase 2b STORM study evaluating selinexor in combination with low-dose dexamethasone in patients with triple class refractory multiple myeloma who have been previously exposed to all five of the most commonly prescribed anti-myeloma therapies currently available. 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 triple class refractory multiple myeloma. The Company has also submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) with a request for conditional approval. Selinexor is also being studied in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). In 2018, Karyopharm reported positive top-line results from the Phase 2b SADAL study evaluating selinexor in patients with relapsed or refractory DLBCL after at least two prior multi-agent therapies and who are ineligible for transplantation, including high dose chemotherapy with stem cell rescue. Selinexor has received Fast Track designation from the FDA for the patient population evaluated in the SADAL study. 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 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 to, and 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 our clinical data, including the data from the STORM study in patients with triple class 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 March 31, 2019, which was filed with the Securities and Exchange Commission (SEC) on May 9, 2019, 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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