Karyopharm Announces Results of Clinical Studies Investigating Selinexor in Multiple Myeloma and Diffuse Large B-Cell Lymphoma to be Presented at the American Society of Hematology 2018 Annual Meeting

-- Top-line Results from Phase 2b SADAL Study in DLBCL to be Presented --
-- Additional Results from the Pivotal Phase 2b STORM Study in Penta-Refractory Multiple Myeloma and Updated Phase 1b/2 STOMP Data in Relapsed or Refractory Multiple Myeloma to be Highlighted in Oral Presentations --

NEWTON, Mass., Nov. 01, 2018 (GLOBE NEWSWIRE) -- Karyopharm Therapeutics Inc. (Nasdaq:KPTI), a clinical-stage pharmaceutical company, today announced that ten abstracts have been selected for presentation, including three oral presentations, at the upcoming American Society of Hematology (ASH) 2018 Annual Meeting being held December 1-4, 2018 in San Diego. Four key abstracts to be presented at the meeting will feature clinical data for selinexor, the Company's first in class, oral SINE compound, from Karyopharm-sponsored trials. The presentations will include: top-line results from the Phase 2b SADAL study in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), additional data from the pivotal Phase 2b STORM study in patients with penta-refractory multiple myeloma, and updated data from the Darzalex® (daratumumab) and Pomalyst® (pomalidomide) arms of the Phase 1b/2 STOMP study of selinexor in combination with backbone therapies for the treatment of patients with relapsed or refractory multiple myeloma.

"With ten abstracts to be presented at this year's ASH meeting, we believe the depth and breadth of the selinexor clinical data is highly compelling," said Sharon Shacham, PhD, MBA, Founder, President and Chief Scientific Officer of Karyopharm. "We look forward to the presentation of top-line results from the fully enrolled SADAL study in DLBCL. These data, if positive, could support our second planned New Drug Application in the first half of 2019, with a request for accelerated approval for selinexor as a new treatment for patients with relapsed or refractory DLBCL. In the previously reported interim analysis for the Phase 2b SADAL study, single-agent oral selinexor demonstrated activity and independently-confirmed durable responses in patients with heavily pretreated DLBCL, and these responses correlated to improved overall survival. We are delighted that data from the selected research abstracts will be shared with the medical community at ASH this year."

In addition to top-line data from the SADAL study, this year's ASH meeting will also feature updated data from the STORM study in an oral presentation. As part of this presentation, data from an independent database of patients with heavily pretreated myeloma will also be presented, further underscoring how poor the prognosis is for patients with penta-refractory multiple myeloma. In October 2018, the U.S. FDA accepted Karyopharm's New Drug Application for selinexor seeking accelerated approval as a new treatment for patients with penta-refractory multiple myeloma. The FDA has assigned a Priority Review and given an action date of April 6, 2019 under the Prescription Drug User-Fee Act (PDUFA).

Other key abstracts at the meeting include data from two arms of the Phase 1b/2 STOMP study. There will be an oral presentation with updated data from the arm evaluating selinexor in combination with Darzalex® and low-dose dexamethasone (SDd). In previously reported data, the once weekly SDd combination without a proteasome inhibitor or immunomodulatory drug demonstrated high response rates in the patient population as a doublet regimen. Finally, a poster presentation will highlight updated data from the arm evaluating selinexor in combination with Pomalyst® and low-dose dexamethasone (SPd). In data reported previously from these arms, selinexor demonstrated evidence of synergistic anti-myeloma activity when combined with these standard approved therapies.

Details for the ASH 2018 presentations are as follows:

Oral Presentations – Company-Sponsored Trials

Title:Results of the Pivotal STORM Study (Part 2) in Penta-Refractory Multiple Myeloma (MM): Deep and Durable Responses with Oral Selinexor Plus Low Dose Dexamethasone in Patients with Penta-Refractory MM
Presenter:Ajai Chari, Icahn School of Medicine at Mount Sinai, New York, New York
Abstract Number/Publication ID: 598
Session: 653. Myeloma: Therapy, excluding Transplantation: Antibodies and Targeted Therapies
Date and Time:Monday, December 3, 2018; 7:45 AM PT
Location:San Diego Convention Center, Room 6F

Title:Deep and Durable Responses with Selinexor, Daratumumab, and Dexamethasone (SDd) in Patients with Multiple Myeloma (MM) Previously Exposed to Proteasome Inhibitors and Immunomodulatory Drugs: Results of Phase 1b Study of SDd
Presenter:Cristina Gasparetto, Duke University Cancer Center, Durham, North Carolina
Abstract Number/Publication ID: 599

Session: 653. Myeloma: Therapy, excluding Transplantation: Antibodies and Targeted Therapies
Date and Time:Monday, December 3, 2018; 8:00 AM PT
Location:San Diego Convention Center, Room 6F

Oral Presentations – Investigator-Sponsored Trials

Title:Selinexor, a First-in-Class XPO1 Inhibitor, Is Efficacious and Tolerable in Patients with Myelodysplastic Syndromes Refractory to Hypomethylating Agents
Presenter:Virginia M. Klimek, Memorial Sloan Kettering Cancer Center, New York, New York
Abstract Number/Publication ID: 233
Session: 637. Myelodysplastic Syndromes—Clinical Studies: Novel Therapeutics I
Date and Time:Saturday, December 1, 2018; 5:00 PM PT
Location: Manchester Grand Hyatt San Diego, Grand Hall A

Poster Presentations – Company-Sponsored Trials

Title: Single Agent Oral Selinexor Demonstrates Deep and Durable Responses in Relapsed/Refractory Diffuse Large B-Cell Lymphoma (DLBCL) in Both GCB and Non-GCB Subtypes: The Phase 2b SADAL Study
Presenter: Marie Maerevoet, Institute Jules Bordet, Brussels, Belgium
Abstract Number/Publication ID: 1677
Session: 626. Aggressive Lymphoma (Diffuse Large B-Cell and Other Aggressive B-Cell Non-Hodgkin Lymphomas)—Results from Prospective Clinical Trials: Poster I
Date and Time:Saturday, December 1, 2018; 6:15-8:15 PM PT
Location:San Diego Convention Center, Hall GH

Title:Selinexor Plus Pomalidomide and Low Dose Dexamethasone (SPd) in Patients with Relapsed or Refractory Multiple Myeloma
Presenter:Christine Chen, Princess Margaret Cancer Center, Toronto, Ontario
Abstract Number/Publication ID: 1993
Session: 653. Myeloma: Therapy, excluding Transplantation: Poster I
Date and Time:Saturday, December 1, 2018; 6:15-8:15 PM PT
Location:San Diego Convention Center, Hall GH

Poster Presentations – Investigator-Sponsored Trials

Title:Phase I Study of the Selinexor in Relapsed/Refractory Childhood Acute Leukemia
Presenter:Andrew E. Place, Dana-Farber Cancer Institute and Boston Children's Hospital, Boston, Massachusetts
Abstract Number/Publication ID: 1405
Session: 613. Acute Myeloid Leukemia: Clinical Studies: Poster I
Date and Time:Saturday, December 1, 2018; 6:15 PM PT
Location:San Diego Convention Center, Hall GH

Title:E2F1 Is a Biomarker of Selinexor Resistance in Relapsed/Refractory Multiple Myeloma Patients
Presenter:Alessandro Lagana, Icahn School of Medicine at Mount Sinai, New York, New York
Abstract Number/Publication ID: 3216
Session: 652. Myeloma: Pathophysiology and Pre-Clinical Studies, excluding Therapy: Poster II
Date and Time:Sunday, December 2, 2018; 6:00-8:00 PM PT
Location:San Diego Convention Center, Hall GH

Title:Final results from a phase I trial combining selinexor with high-dose cytarabine (HiDAC) and mitoxantrone (Mito) for remission induction in acute myeloid leukemia (AML)
Presenter:Hongtao Liu and Amy Wang, University of Chicago Medicine, Chicago, Illinois
Abstract Number/Publication ID: 4073
Session: 616. Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation: Poster III
Date and Time:Monday, December 3, 2018; 6:00-8:00 PM PT
Location:San Diego Convention Center, Hall GH

Title:NAMPT inhibitor KPT-9274 selectively targets self-renewal capacity in acute myeloid leukemia
Presenter:Shaneice Mitchell, Ohio State University College of Medicine, Columbus, Ohio
Abstract Number/Publication ID: 3931
Session: 604. Molecular Pharmacology and Drug Resistance in Myeloid Diseases: Poster III
Date and Time:Monday, December 3, 2018; 6:00-8:00 PM PT
Location:San Diego Convention Center, Hall GH

Title:Inhibition of Nicotinamide Phosphoribosyltransferase (NAMPT) Activity Selectively Targets Human Acute Myeloid Leukemia Stem Cells

Presenter:Amit Subedi, Princess Margaret Cancer Centre, University Health Network, Toronto, Ontario
Abstract Number/Publication ID: 3932
Session: 604. Molecular Pharmacology and Drug Resistance in Myeloid Diseases
Date and Time: Monday, December 3, 2018; 6:00-8:00 PM PT
Location: San Diego Convention Center, Hall GH

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. To date, over 2,600 patients have been treated with selinexor. In April and September 2018, Karyopharm reported positive data from the Phase 2b STORM study evaluating selinexor in combination with low-dose dexamethasone in patients with penta-refractory multiple myeloma. 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 penta-refractory multiple myeloma. The Company also plans to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in early 2019 with a request for conditional approval. 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 diffuse large B-cell lymphoma (SADAL), 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 and to 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 the data from the STORM study in patients with penta-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 June 30, 2018, which was filed with the Securities and Exchange Commission (SEC) on August 7, 2018, 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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