Kite Pharma Presents Updated Phase 1 Results from ZUMA-1 at the American Association of Cancer Research (AACR) Annual Meeting

April 19, 2016 5:09 PM ET

SANTA MONICA, Calif., April 19, 2016 (GLOBE NEWSWIRE) -- Kite Pharma, Inc. (Nasdaq:KITE) ("Kite") today announced updated clinical results from the phase 1 portion of Kite's ZUMA-1 trial of its lead product candidate, KTE-C19, in patients with chemorefractory, aggressive non-Hodgkin lymphoma (NHL). KTE-C19 is an investigational therapy in which a patient's T cells are genetically modified to express a chimeric antigen receptor (CAR) that is designed to target the antigen CD19, a protein expressed on the cell surface of B cell lymphomas and leukemias.

David Chang, M.D., Ph.D., Kite's Executive Vice President, Research and Development, and Chief Medical Officer, commented, "Today's report affirms the early safety and efficacy profile of KTE-C19 in chemorefractory, aggressive NHL. We are encouraged by the ongoing complete remissions in patients with significant unmet need for new therapies. We remain on track to provide interim data from the pivotal phase 2 portion of the study later this year and to submit the KTE-C19 registration filing to the U.S. Food and Drug Administration (FDA) by the end of 2016."

"The data reported today are important because refractory DLBCL is incurable. Median survival for these patients is short and there is no standard therapy," noted Ronald Levy, M.D., Robert K. Summy and Helen K. Summy Professor of Medicine and Director of the Lymphoma Program at Stanford University School of Medicine and Associate Director of Translational Science for the Stanford Cancer Institute. "A rate of complete response and durability of response in the ranges of those reported today would be of profound clinical importance if replicated in the phase 2 portion of the ZUMA-1 study. Adoptive transfer of engineered T cells has the potential to become standard of care for patients with refractory NHL in the near future."

Updated Phase 1 Results from ZUMA-1: A Phase 1-2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-C19 (Anti-CD19 CAR T Cells) in Subjects with Refractory Aggressive Non-Hodgkin Lymphoma (NHL)

Session: Early Clinical Trials Evaluating Cell-based, Checkpoint Inhibitors, and Novel Immunotherapeutics; Abstract Number: CT135; Presenter: Armin Ghobadi, M.D., Washington University, St. Louis, MO

- Phase 1 of ZUMA-1 treated a total of 7 patients with chemorefractory, diffuse large B cell lymphoma (DLBCL)
- KTE-C19 related adverse events consisted predominantly of cytokine release syndrome (CRS) and neurotoxicity which were generally reversible
    - Grade 3 or higher CRS was observed in 14% and neurotoxicity in 57%; all were reversible except in one patient with dose-limiting toxicity
- KTE-C19 achieved rapid and durable responses in patients with chemorefractory disease (objective response rate 71%, complete response rate 57%)
- Ongoing complete response (CR) observed in 3 of 7 patients. One ongoing CR as of 9-month study follow-up and 2 ongoing CRs as of 6-month study follow-up.

In addition, two posters on KTE-C19 engineered cell manufacturing and characteristics were presented at AACR on April 18, 2016.

Manufacturing and Characterization of KTE-C19 in a Multicenter Trial of Patients with Refractory Aggressive Non-Hodgkin Lymphoma (NHL) (ZUMA-1)

Session: Adoptive Cell Therapy; Abstract Number: 2308; Presenter: John Rossi, M.S., Kite Pharma

- The optimized GMP-manufacturing process generated anti-CD19 CAR T cells rapidly and without the need for pre-selection of a defined composition of T cells
- Biologically active anti-CD19 CAR T cells were manufactured for all patients enrolled in the multicenter phase 1

ZUMA-1 trial.

Comparative Evaluation of Peripheral Blood T Cells and Resultant Engineered Anti-CD19 CAR T Cell Products from Relapsed/Refractory Non-Hodgkin's Lymphoma (NHL) Patients

Session: Adoptive Cell Therapy; Abstract Number: 2305; Presenter: Timothy J. Langer, Kite Pharma

- CAR T cells were successfully manufactured for all patients enrolled in the study at the National Cancer Institute, Surgery Branch
- CAR T cell products were composed of both CD4+ and CD8+ T cells with a less differentiated phenotype than the starting leukapheresis products
- CAR T cells were polyfunctional and produced a wide range of immune homeostatic, modulating and effector cytokines/chemokines in response to antigen-positive target cells.

About Kite's ZUMA Clinical Programs for KTE-C19

KTE-C19 is an investigational therapy in which a patient's T cells are genetically modified to express a CAR that is designed to target the antigen CD19, a protein expressed on the cell surface of B cell lymphomas and leukemias. Kite is currently enrolling four pivotal studies (also known as ZUMA studies) for KTE-C19 in patients with various B cell malignancies. The U.S. Food and Drug Administration has granted Breakthrough Therapy Designation status to KTE-C19 for the treatment of patients with refractory DLBCL, primary mediastinal B cell lymphoma, and transformed follicular lymphoma. KTE-C19 has also secured Orphan Drug Designation in the U.S. for DLBCL and in the EU for various hematological indications.

Study	Phase	Indication	Status
ZUMA-1 NCT02348216	Phase 2 Pivotal (N=112)	Refractory DLBCL, PMBCL, TFL	Phase 2 enrolling
ZUMA-2 NCT02601313	Phase 2 Pivotal (N=70)	Relapsed/refractory MCL	Phase 2 enrolling
ZUMA-3 NCT02614066	Phase 1/2 Pivotal (N=75)	Relapsed/refractory Adult ALL	Phase 1/2 enrolling
ZUMA-4 NCT02625480	Phase 1/2 Pivotal (N=75)	Relapsed/refractory Pediatric ALL	Phase 1/2 enrolling

DLBCL = diffuse large B cell lymphoma

PMBCL = primary mediastinal B cell lymphoma

TFL = transformed follicular lymphoma

MCL = mantle cell lymphoma

ALL = acute lymphoblastic leukemia

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current

expectations concerning, among other things: the ability and timing of obtaining interim KTE-C19 data and submitting a registration filing to the FDA by the end of 2016, and the ability to advance multiple clinical trials of KTE-C19. Various factors may cause differences between Kite's expectations and actual results as discussed in greater detail in Kite's filings with the Securities and Exchange Commission, including without limitation in Kite's Annual Report on Form 10-K filed with the SEC on February 29, 2016. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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