Kite Pharma Presents Phase 1 Results From ZUMA-1 at the 57th American Society of Hematology (ASH) Annual Meeting

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SANTA MONICA, Calif., Dec. 7, 2015 (GLOBE NEWSWIRE) -- Kite Pharma, Inc. (Nasdaq:KITE) today announced clinical results and biomarker data for the phase 1 portion of Kite's ZUMA-1 trial of KTE-C19 in patients with refractory, 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) 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 Pharma's Executive Vice President, Research and Development, and Chief Medical Officer, commented, "We are encouraged by these early clinical findings from our first company-sponsored, multi-center clinical trial in this highly refractory patient population. The overall safety, efficacy, and biomarker data were generally consistent with previously published data from the National Cancer Institute (NCI) and supported advancing ZUMA-1 to the pivotal phase. We look forward to providing interim data from the pivotal phase 2 portion of the study in 2016."

A summary of the ZUMA-1 Poster Presentations at ASH:

"Phase 1 Clinical Results of the ZUMA-1 (KTE-C19-101) Study: A Phase 1-2 Multi-Center Study Evaluating the Safety and Efficacy of Anti-CD19 CAR T Cells (KTE-C19) in Subjects with Refractory Aggressive Non-Hodgkin Lymphoma (NHL)." Abstract #3991; Presenter: Frederick Locke M.D., Moffitt Cancer Center; Monday, December 7, 2015: 6:00-8:00pm Eastern.

- Phase 1 of the ZUMA-1 study treated a total of 7 patients with refractory, aggressive diffuse large B cell lymphoma (DLBCL)
  - KTE-C19 was administered at a target dose of 2 x 10^6 (minimum 1 x 10^6) anti-CD19 CAR T cells/kg body weight after a fixed-dose conditioning chemotherapy regimen
- KTE-C19 was successfully manufactured for all leukapheresed subjects
- KTE-C19 related adverse events consisted predominantly of cytokine release syndrome (CRS) and neurotoxicity, which were self-limited and generally reversible
  - One subject experienced dose-limiting toxicities of grade 4 encephalopathy and CRS, and grade 5 intracranial hemorrhage. The grade 5 event was deemed unrelated to KTE-C19 per the study investigator
- Four complete remissions (CRs) and one partial remission (PR) were observed, representing an overall objective response rate of 71% (5/7)
  - All CRs were observed at one month
  - Three subjects had ongoing CRs at three months.

"Phase 1 Biomarker Analysis of the ZUMA-1 (KTE-C19-101) Study: A Phase 1-2 Multi-Center Study Evaluating the Safety and Efficacy of Anti-CD19 CAR T Cells (KTE-C19) in Subjects with Refractory Aggressive Non-Hodgkin Lymphoma (NHL)." Abstract number #2730; Presenter: Sattva S. Neelapu, M.D., The University of Texas MD Anderson Cancer Center; Sunday, December 6, 2015: 6:00-8:00pm Eastern.

- *In vitro* and *in vivo* characteristics of KTE-C19 from 7 subjects in the Phase 1 portion of ZUMA-1 study were evaluated by flow cytometry, co-culture, and a panel of cytokines, chemokines and immune effector related markers
- KTE-C19 contains naïve and central memory T cells. CAR T cells peaked within 2 weeks post infusion and were detectable at 1-3+ months post-infusion
- Select homeostatic, pro-inflammatory/regulatory cytokines, tumor homing chemokines and effector molecules peaked within 1-2 weeks post-infusion and generally decreased within 3 weeks
- The overall product characteristics and pharmacodynamic profile of KTE-C19 in ZUMA-1 phase 1 subjects were consistent with what has been observed with anti-CD19 CAR T cell therapy in the ongoing NCI study.

About Kite's ZUMA Clinical Programs

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	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

About Kite Pharma

Kite Pharma, Inc., is a clinical-stage biopharmaceutical company engaged in the development of novel cancer immunotherapy products, with a primary focus on engineered autologous cell therapy (eACT™) designed to restore the immune system's ability to recognize and eradicate tumors. Kite is based in Santa Monica, CA. For more information on Kite Pharma, please visit www.kitepharma.com. Sign up to follow @KitePharma on Twitter at www.twitter.com/kitepharma.

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 success and timing of ZUMA-1, including obtaining and reporting results from the trial. 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 its Form 10-Q for the quarter ended September 30, 2015. 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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