Kite Pharma Announces Patients With Relapsed or Refractory Acute Lymphoblastic Leukemia (ALL) Experience Positive Results After Receiving Anti-CD19 Chimeric Antigen Receptor (CAR) T Cells

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Phase 1 Clinical Trial Highlights:

- **14 of 20 pediatric or young adult patients (70%) with relapsed or refractory ALL experienced a complete response.**
- **12 of the 20 patients (60%) achieved a minimal residual disease (MRD)-negative complete response.**
- **10 of the patients who had an MRD-negative complete response subsequently underwent hematopoietic stem-cell transplantation, and all 10 remained disease free upon 10-month follow-up.**
- **The results have been published in the October 13, 2014 Issue of *The Lancet***

SANTA MONICA, Calif., Oct. 13, 2014 (GLOBE NEWSWIRE) -- Kite Pharma, Inc., (Nasdaq:KITE), a clinical-stage biopharmaceutical company focused on developing engineered autologous T cell therapy (eACT™) products for the treatment of cancer, today announced the publication in *The Lancet* of clinical results demonstrating the potential to treat relapsed or refractory acute lymphoblastic leukemia (ALL) with an anti-CD19 chimeric antigen receptor (CAR) T cell therapy. Kite's most advanced product candidate, KTE-C19, is an anti-CD19 CAR T cell therapy that involves genetically modifying a patient's T cells to express a CAR that is designed to target CD19, a protein expressed on the cell surface of B cell lymphomas and leukemias.

The findings from a Phase 1 clinical trial conducted by the Pediatric Oncology Branch of the National Cancer Institute (NCI) demonstrated that administration of anti-CD19 CAR T cells resulted in a 70% complete response rate in 20 pediatric or young adult patients with relapsed or refractory ALL. Sixty percent of the 20 patients achieved an MRD-negative complete response. Ten of the patients who had an MRD-negative complete response subsequently underwent hematopoietic stem-cell transplantation (HSCT), and all 10 remained disease free with a median follow-up of 10 months. These and other findings from the Phase 1 study are being published in an article titled, "T cells expressing CD19 chimeric antigen receptors for acute lymphoblastic leukaemia in children and young adults: a phase 1 dose-escalation trial," http://dx.doi.org/10.1016/S0140-6736(14)61403-3, which is appearing in the October 13, 2014 issue of *The Lancet*. Lead author on the article is Crystal L. Mackall, M.D., Head of Immunology Section and Chief of the Pediatric Oncology Branch at the National Cancer Institute.

Gary Schiller, M.D., F.A.C.P., Professor, Director, Hematological Malignancies/Stem Cell Transplantation Unit, David Geffen School of Medicine at UCLA, commented, "This article, the first publication of an intention-to-treat analysis from a completed clinical study of CD19-CAR therapy in pediatric and young adult patients with relapsed/refractory ALL, deepens our understanding of this important investigational approach. The results show that this treatment is feasible in many patients with ALL and can eradicate chemoresistant disease with an acceptable toxicity profile. Further, the findings demonstrate substantially higher response rates than seen in the literature for the most recently approved agent for refractory ALL. CD19-CAR therapy represents a potentially important new tool to address the urgent need for new treatment modalities in these patients."

The open-label, Phase 1 dose-escalation study enrolled patients aged 1-30 years. Prior to the study, all patients had been

heavily pretreated for their disease. Patients received a conditioning regimen of chemotherapy (cyclophosphamide and fludarabine) followed by a single infusion of one of two dose levels of anti-CD19-CAR T cells. The CAR-expressing T cells were produced from each patient's own peripheral blood mononuclear cells (PBMCs), modified using a gammaretroviral vector encoding the CAR, as well as a CD28 costimulatory moiety. After the dose-escalation phase, an expansion cohort was treated at the maximum tolerated dose. Pursuant to the study protocol, patients are continuing to be monitored.

As seen in other studies, infusion of anti-CD19 CAR T cells was associated with significant, acute toxicities, including fever, hypokalemia, and transient neurological deficits. All toxicities were fully reversible.

David Chang, M.D., Ph.D., Kite Pharma's Executive Vice President, Research and Development, and Chief Medical Officer, stated, "The findings of the study reported in the *Lancet* further support promising results with our CD19-CAR construct in other blood cancers, such as in patients with aggressive, refractory non-Hodgkin's lymphoma. Toxicities were readily managed in the *Lancet* study, and the findings provided important information on defining response rates and maximum tolerated dose, as well as affirming the feasibility of generating CD19-CAR T cells in this heavily pretreated patient population."

Kite previously announced positive results in chemotherapy-refractory diffuse large B-cell lymphoma (DLBCL) in a study conducted under the auspices of Kite and the Surgery Branch of the NCI, led by Steven A. Rosenberg, M.D., Ph.D. Kite and Dr. Rosenberg's team are collaborating under a Cooperative Research and Development Agreement (CRADA) for the research and development of eACT™-based product candidates for the treatment of multiple cancer indications.

"We are greatly encouraged by the continuing strong results from the NCI using our proprietary CD19-CAR construct in very sick patient groups," commented Arie Belldegrun, M.D., FACS, Kite's President and Chief Executive Officer. "The importance of a new approach to treating advanced cancer in the youngest patients cannot be over-emphasized."

Dr. Belldegrun continued, "As previously reported, Kite plans to file an IND this year to initiate a Phase 1-2 single-arm multicenter clinical trial of its lead CD19-CAR therapy, KTE-C19, in patients with DLBCL who have failed two or more lines of therapy. For the trial, we will manufacture product using our streamlined and rapid production process. We are excited to advance this promising therapy and anticipate initiating our first Kite-sponsored study next year."

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 eACT™ designed to restore the immune system's ability to recognize and eradicate tumors. In partnership with the NCI Surgery Branch through a Cooperative Research and Development Agreement (CRADA), Kite is advancing a pipeline of proprietary eACT™ product candidates, both CAR (chimeric antigen receptor) and TCR (T cell receptor) products, directed to a wide range of cancer indications. Kite is based in Santa Monica, CA. For more information on Kite Pharma, please visit www.kitepharma.com.

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 the ongoing and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation of our clinical trial of KTE-C19; the ability and willingness of the NCI to continue research and development activities relating to eACT™ pursuant to the CRADA; our expectations regarding the clinical effectiveness and safety of our product candidates and results of the NCI's clinical trials; our ability to manufacture our product candidates; the timing of and our ability to obtain and maintain

U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates and advancing a clinical trial of KTE-C19; and our ability to protect our proprietary technology and enforce our intellectual property rights. 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 June 30, 2014. 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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