June 5, 2017

Kite Reports 73 Percent of Patients Achieved MRD Negative Complete Remission in Updated Analysis From Phase 1 ZUMA-3 CAR-T Trial of KTE-C19 in Adult Patients With High Burden Relapsed/Refractory Acute Lymphoblastic Leukemia

- Remissions Ongoing From 2.0 to Greater than 7.4 Months
- KTE-C19 Successfully Manufactured in Six Days Across a Range of Absolute Lymphocyte and Blast Counts
- Phase 2 Initiation Planned for 2017

SANTA MONICA, Calif.--(BUSINESS WIRE)-- Kite Pharma, Inc., (Nasdaq:KITE), a leading cell therapy company, today announced that 73 percent of patients achieved complete remission, including those with incomplete or partial recovery of bone marrow, in an updated analysis of the Phase 1 ZUMA-3 trial of KTE-C19 in adults with high burden relapsed/refractory acute lymphoblastic leukemia (r/r ALL). All responders tested negative for minimal residual disease (MRD). The data were presented today in a poster session at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL and follow previously reported results from the American Society of Hematology (ASH) Annual Meeting in December 2016.

In the Phase 1 trial, 11 patients were treated with KTE-C19 at two target dose levels (2.0×10^6/kg and 1.0×10^6/kg). No dose-limiting toxicities (DLT) occurred in the trial. Both doses were tolerable and responses were achieved at each level. Ongoing complete remissions have been observed at 2.0+ to 7.4+ months.

"The majority of adult patients diagnosed with ALL will experience disease relapse and subsequently face a poor prognosis," said David Chang M.D., Ph.D., Executive Vice President, Research and Development, and Chief Medical Officer of Kite. "We are encouraged by the results from the ZUMA-3 trial to date in this extremely difficult-to-treat patient population. Before launching a pivotal Phase 2 study, we plan to optimize the cell dose of this potentially life-saving therapy for patients with significant unmet need."

Three of 11 (27 percent) patients had grade 3 or higher cytokine release syndrome (CRS) and six of 11 (55 percent) had grade 3 or higher neurologic events. These adverse events were generally reversible. As previously reported at ASH 2016, one patient experienced fatal CRS. In order to further improve the safety profile of KTE-C19, ZUMA-3 is also evaluating additional patients who will receive tocilizumab within 36 hours post-KTE-C19 infusion, and a lower dose of 0.5×10^6 CAR T cells/kg.

KTE-C19 was successfully manufactured in this multi-center trial for all patients in six days across a range of absolute lymphocyte and blast counts in a centralized and streamlined process. Responses were observed across a wide range of CD4:CD8 ratios and T-cell phenotypes.

Kite plans to initiate Phase 2 of the ZUMA-3 trial in 2017.

Poster Presentation Details

Updated results from ZUMA-3: A phase 1/2 study of KTE-C19 chimeric antigen receptor (CAR) T cell therapy in adults with high-burden relapsed/refractory acute lymphoblastic leukemia (R/R ALL)

- Abstract #3024
- Session: Poster Session: Developmental Therapeutics - Immunotherapy
- Poster Board #119
- Session Time/Location: Monday, June 5, 2017: 8:00-11:30 AM CDT, Hall A
- Presenter: Bijal D. Shah, M.D., Moffitt Cancer Center, Tampa, FL

About axicabtagene ciloleucel/KTE-C19

Kite's lead product candidate, axicabtagene ciloleucel, also known as KTE-C19, is an investigational therapy in which a patient's T cells are engineered to express a chimeric antigen receptor (CAR) to target the antigen CD19, a protein expressed on the cell surface of B-cell lymphomas and leukemias, and redirect the T cells to kill cancer cells. Axicabtagene ciloleucel has been granted Breakthrough Therapy Designation status for diffuse large B-cell lymphoma (DLBCL), transformed follicular lymphoma (TFL), and primary mediastinal B-cell lymphoma (PMBCL) by the U.S. Food and Drug Administration (FDA) and Priority Medicines (PRIME) regulatory support for DLBCL in the EU.

About Kite

Kite is a biopharmaceutical company engaged in the development of innovative cancer immunotherapies with a goal of providing rapid, long-term durable response and eliminating the burden of chronic care. The company is focused on chimeric antigen receptor (CAR) and T cell receptor (TCR) engineered cell therapies designed to empower the immune system's ability to recognize and kill tumors. Kite is based in Santa Monica, CA. For more information on Kite, 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. The press release 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 intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the timing and ability to progress the ZUMA-3 trial, including to initiate Phase 2 of the ZUMA-3 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 March 31, 2017. Any forward-looking statements that are made in this press release speak only as of the date of this press release. Kite assumes no obligation to update the 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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