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Kite Pharma Announces Positive Topline KTE-C19 Data from ZUMA-1 Pivotal Trial in Patients with Aggressive Non-Hodgkin Lymphoma (NHL)

Study Met Primary Endpoint of Objective Response Rate (p < 0.0001) at Interim Analysis

First Multicenter Pivotal Trial of CAR-T Therapy to Report Positive Outcome

Company Plans to Present Additional Data at Upcoming Scientific Meeting

SANTA MONICA, Calif.--(BUSINESS WIRE)-- Kite Pharma, Inc., (Nasdaq:KITE) today announced positive topline results from a pre-planned interim analysis of ZUMA-1 for its lead product candidate, KTE-C19, in patients with chemorefractory diffuse large B-cell lymphoma (DLBCL). KTE-C19 met the primary endpoint of objective response rate (ORR), p < 0.0001, with ORR of 76 percent, including 47 percent complete remissions (CR).

ZUMA-1 enrolled patients with chemorefractory aggressive NHL into two cohorts. Cohort 1 included patients with DLBCL, and Cohort 2 enrolled patients with transformed follicular lymphoma (TFL) and primary mediastinal B-cell lymphoma (PMBCL). Kite's intent is to seek regulatory approval of KTE-C19 in DLBCL, TFL and PMBCL based upon the combined data of both cohorts.

The interim analysis of ZUMA-1 evaluated the ORR in the first 51 patients in Cohort 1 with at least three months of follow-up. This analysis also included an additional 11 patients in Cohort 2. The table below summarizes the response rates from this interim analysis together with the previously reported results from the Phase 1 portion of ZUMA-1 (Neelapu ASCO 2016).

	ZUMA-1 Phase 1		ZUMA-1 Phase 2					
	DLBCL (n=7)		DLBCL (n=51)		TFL/PMBCL (n=11)		Combined (n=62)	
	ORR (%)	CR (%)	ORR (%)	CR (%)	ORR (%)	CR (%)	ORR (%)	CR (%)
ORR	71	57	76	47	91	73	79	52
Month 3	43	43	39	33	64	64	44	39
Months 6 and 9	43	43	Data Pending					

Across the combined 62 patients, the most common grade 3 or higher adverse events included neutropenia (66 percent), anemia (40 percent), febrile neutropenia (29 percent), thrombocytopenia (29 percent), and encephalopathy (26 percent). Grade 3 or higher cytokine release syndrome (CRS) and neurological toxicity was observed in 18 percent and 34 percent of patients, respectively. Two patients died from KTE-C19 related adverse events (hemophagocytic lymphohistiocytosis and cardiac arrest in the setting of CRS).

The Phase 2 interim outcomes in ZUMA-1 are largely consistent with results from the Phase 1 portion of the study and the National Cancer Institute (NCI) study based on the same CAR construct, a low-dose cyclophosphamide-fludaribine conditioning regimen, and Kite's proprietary manufacturing process (Kochenderfer ASCO 2016).

"ZUMA-1 enrolled patients with chemorefractory aggressive NHL, a disease that is very difficult to treat. The combined CR rate of 39 percent at three months is very exciting as it represents nearly a five-fold increase from the CR rate of 8 percent seen in the SCHOLAR-1 study in a similar patient population," said Jeff Wiezorek, M.D., Senior Vice President of Clinical Development. "ZUMA-1 is the largest CAR-T study reported in NHL. We were able to manufacture KTE-C19 for 99 percent of patients enrolled in the study, and successfully handle the study logistics and adverse event management at over 20 sites, most of which had no prior experience in CAR-T therapy."

Additional data from this interim analysis will be submitted for presentation at an upcoming scientific meeting. The primary analysis of 101 patients with chemorefractory aggressive NHL (DLBCL, TFL and PMBCL) will include approximately six months of follow-up and is expected in the first quarter of 2017.

"We are grateful to the study participants and investigators who have made this important research possible. What started at the NCI over a decade ago with the pioneering work of Steven A. Rosenberg, M.D., Ph.D., has evolved into a technology that has the potential to fundamentally change the outlook of patients with cancer. For patients with aggressive NHL, every day matters and a new treatment option like KTE-C19 is desperately needed," said Arie Belldegrun, M.D., FACS, Chairman, President and Chief Executive Officer of Kite. "I am proud of what we have achieved to date and excited to apply our advanced learnings from ZUMA-1 to our ongoing clinical development programs to bring continued innovation to patients and the scientific community at large."

ZUMA-1 is supported in part by funding from The Leukemia & Lymphoma Society (LLS) Therapy Acceleration Program®.

Conference Call and Webcast Details

Kite will host a live conference call and webcast today at 4:30PM Eastern Time (1:30PM Pacific Time) to discuss the results of this interim analysis. To access the live conference call by telephone, please dial (877) 301-8565 (U.S.) or (678) 562-4240 (International). The conference ID number for the live call is 88811489. The webcast will be made available on the Company's website at www.kitepharma.com under the Investors tab in the Events and Presentations section. Following the live audio webcast, a replay will be available on the Company's website for approximately 30 days.

About KTE-C19

Kite Pharma's lead product candidate, 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. KTE-C19 has been granted Breakthrough Therapy Designation status for DLBCL, TFL, and PMBCL by the U.S. Food and Drug Administration and Priority Medicines (PRIME) regulatory support for DLBCL in the EU.

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: expectations regarding the clinical effectiveness and safety of KTE-C19 and timing of the primary analysis of ZUMA-1. 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, 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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