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Kite Announces Positive Topline Primary Results of Axicabtagene Ciloleucel from First Pivotal CAR-T Trial in Patients with Aggressive Non-Hodgkin Lymphoma

- Met Primary Endpoint of Objective Response Rate ($p < 0.0001$)
- 41 Percent of Patients in Response and 36 Percent in Complete Response at Month 6
- At a Median Follow-up of 8.7 Months, Median Overall Survival Not Yet Reached
- Full Data to be Presented at American Association for Cancer Research in April 2017

SANTA MONICA, Calif.--(BUSINESS WIRE)-- Kite Pharma, Inc., (Nasdaq:KITE) today announced positive data from the primary analysis of ZUMA-1 for its lead CAR-T candidate, axicabtagene ciloleucel (previously referred to as KTE-C19), in patients with chemorefractory aggressive B-cell non-Hodgkin lymphoma (NHL). The study met the primary endpoint of objective response rate (ORR), or rates of tumor response (complete response + partial response) recorded after a single infusion of axicabtagene ciloleucel, with 82 percent ($p < 0.0001$).

These results demonstrate the treatment effect of axicabtagene ciloleucel in a patient population with multiple types of aggressive NHL, including diffuse large B-cell lymphoma (DLBCL) enrolled in Cohort 1, as well as primary mediastinal B-cell lymphoma (PMBCL) and transformed follicular lymphoma (TFL) enrolled in Cohort 2.

One hundred one patients were treated in ZUMA-1. The following table shows the ORR and rate of complete response (CR) as well as the month 6 ORR and CR:

	DLBCL (n=77)		TFL/PMBCL (n=24)		Combined (n=101)	
	ORR (%)	CR (%)	ORR (%)	CR (%)	ORR (%)	CR (%)
ORR	82	49	83	71	82	54
Month 6	36	31	54	50	41	36

Four of the 101 patients in ongoing CR did not have a month 6 tumor assessment prior to the data cut-off and are therefore categorized as non-responders for month 6 in the table above. These patients have an opportunity to be counted as a month 6 CR in a follow-up analysis, which may increase the month 6 response and month 6 CR rate.

At month 6, 41 percent of treated patients achieved a response, including 36 percent in CR. Five of the 101 patients (5 percent) continue to experience highly significant and durable partial responses (PR) with minimal abnormalities in PET scans. One of these PRs converted to a CR at month 9.

With a median follow-up of 8.7 months for this primary analysis, the median overall survival (OS) has not yet been reached. In a similar patient population, the median OS was estimated to be 6.6 months (SCHOLAR-1 study, ASCO 2016).

The most common grade 3 or higher adverse events included anemia (43 percent), neutropenia (39 percent), decreased neutrophil count (32 percent), febrile neutropenia (31 percent), decreased white blood cell count (29 percent), thrombocytopenia (24 percent), encephalopathy (21 percent) and decreased lymphocyte count (20 percent). As compared to the interim analysis, grade 3 or higher cytokine release syndrome (CRS) decreased from 18 percent to 13 percent and neurologic events decreased from 34 percent to 28 percent. There were no cases of cerebral edema.

As previously reported at the American Society of Hematology Annual Meeting in 2016, there were three deaths not due to disease progression in the study. Two events, one hemophagocytic lymphohistiocytosis and one cardiac arrest in the setting of CRS, were deemed related to axicabtagene ciloleucel. The third case, a pulmonary embolism, was deemed unrelated. Between the interim analysis that included 62 patients, and this primary analysis which now includes all 101 patients, there were no additional deaths due to adverse events.

"These results with axicabtagene ciloleucel are exceptional and suggest that more than a third of patients with refractory aggressive NHL could potentially be cured after a single infusion of axicabtagene ciloleucel," said Jeff Wiezorek, M.D., Senior Vice President of Clinical Development. "The ZUMA-1 study was built on a foundation of support and commitment from Dr. Steven Rosenberg and the National Cancer Institute and our ZUMA-1 clinical trial investigators who believed in the potential for CAR-T therapy to change the paradigm of cancer treatment."

Kite intends to seek regulatory approval of axicabtagene ciloleucel in aggressive NHL based upon the combined data from all 101 patients and plans to complete its rolling submission of the Biologics License Application (BLA) by the end of the first quarter of 2017. In addition, Kite plans to submit a marketing authorization application (MAA) for axicabtagene ciloleucel for the treatment of relapsed or refractory DLBCL, PMBCL and TFL with the European Medicines Agency (EMA) in 2017.

"We know as clinicians that patients with aggressive lymphoma who do not respond to their previous treatments have a very poor prognosis. In fact, we know from the SCHOLAR-1 study, these patients have only an eight percent chance of achieving a complete response with current therapies," said Frederick L. Locke, M.D., ZUMA-1 Co-Lead Investigator, and Director of Research for the Immune Cell Therapy Program at Moffitt Cancer Center in Tampa, Florida. "Several patients we treated at Moffitt Cancer Center experienced a rapid and durable complete response with this first-of-its kind therapy. The ZUMA-1 study results suggest that axicabtagene ciloleucel could become a new standard of care for patients with refractory aggressive lymphoma."

Sattva S. Neelapu, M.D., Department of Lymphoma/Myeloma, Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center, served as a co-lead investigator in the ZUMA-1 trial.

Full data from the primary analysis will be presented at the American Association for Cancer Research in April 2017 in Washington, D.C.

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 9:00 AM Eastern Time (6:00 AM Pacific Time) to discuss the results of this primary analysis. To access the live conference call by telephone, please dial (888) 771-4371 (U.S.) or (847) 585-4405 (International). The conference ID number for the live call is 44040763. 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 axicabtagene ciloleucel
Kite Pharma's lead product candidate, axicabtagene ciloleucel, 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 of completing a BLA submission with the FDA, completing an MAA with the EMA, obtaining regulatory approval and commercially launching axicabtagene ciloleucel. 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, 2016. 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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