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Kite Presents Ongoing Response Rate in Plenary Session from its Pivotal CAR-T Trial of Axicabtagene Ciloleucel in Patients with Aggressive Non-Hodgkin Lymphoma at the 2017 American Association of Cancer Research Annual Meeting

- 44 Percent in Ongoing Response, Including 39 Percent in Complete Response (CR) with a Median Follow-up of 8.7 Months
- Median Duration of Response for CR Not Yet Reached
- Second Plenary Presentation Identified Biomarkers Associated with Response and Adverse Events

SANTA MONICA, Calif.--(BUSINESS WIRE)-- Kite Pharma, Inc., (Nasdaq:KITE) today announced two plenary presentations of positive data from the primary analysis of ZUMA-1 for its lead CAR-T candidate, axicabtagene ciloleucel, in patients with refractory aggressive B-cell non-Hodgkin lymphoma (NHL) at the 2017 American Association of Cancer Research Annual Meeting in Washington, D.C. Both presentations were given by Frederick L. Locke, M.D., the ZUMA-1 Co-Lead Investigator, and Director of Research for the Immune Cell Therapy Program at Moffitt Cancer Center in Tampa, Florida.

The study met the primary endpoint of objective response rate (ORR) recorded after a single infusion of axicabtagene ciloleucel, with 82 percent ($p < 0.0001$). These results demonstrate the treatment effect of axicabtagene ciloleucel in diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL) and transformed follicular lymphoma (TFL), which are types of aggressive NHL.

ZUMA-1 enrolled 111 patients of whom 101 were successfully treated with axicabtagene ciloleucel. ZUMA-1 patients were heavily pretreated and representative of those in the SCHOLAR-1 pooled analysis of refractory aggressive NHL. The key ZUMA-1 patient characteristics are below:

- Stage III/IV disease (85 percent)
- Refractory to chemotherapy, no prior autologous stem cell transplant (ASCT) (79 percent)
- Relapsed within 12 months of ASCT (21 percent)
- Received three or more lines of prior therapy (69 percent)
- Refractory to two consecutive lines of prior therapy (54 percent)

The following table shows response data including the month 6 ORR and CR as well as ongoing response rates at the primary analysis data cut-off.

	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
Ongoing	36	31	67	63	44	39

ORR was generally consistent in key subgroups. ORR in patients who are refractory to second or greater line of therapy was 83 percent and 76 percent in patients who relapsed within 12 month of ASCT.

With a median follow-up of 8.7 months, the median overall survival (OS) has not yet been reached. The overall duration of response (DOR) was 8.2 months and has not yet been reached for patients with a CR. In the SCHOLAR-1 pooled analysis, the median OS was estimated to be 6.6 months with only 8 percent achieving CR with currently available therapies.

As previously reported, 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 three deaths throughout the course of the trial not due to disease progression. Two events, one hemophagocytic lymphohistiocytosis (HLH) and one cardiac arrest in the setting of CRS, were deemed related to axicabtagene ciloleucel. The third case, a pulmonary embolism, was deemed unrelated. There were no cases of cerebral edema.

The accompanying plenary presentation reviewed the product characteristics and biomarker analysis from ZUMA-1. Axicabtagene ciloleucel was successfully manufactured (99 percent) from heavily pretreated patients with a broad range of baseline T cell numbers. Objective responses were observed across a wide range of product CD4:CD8 ratios, and were associated with higher levels of anti-CD19 CAR T cells in the blood. Immune signatures of CRS and neurological events were identified.

"We are excited to present the data from the primary analysis of ZUMA-1 at AACR. Close to half of patients treated remained in response, which represents a remarkable result in this heavily treated population with refractory aggressive NHL who previously faced a dismal outlook," said Jeff Wiezorek, M.D., Senior Vice President of Clinical Development. "We believe the rates of CRS and neurologic events decreased over the course of the study as clinicians gained experience in the management of adverse events. Biomarker analysis advances our understanding of product characteristics and immune signatures associated with clinical outcomes and provides us further opportunity to potentially improve the safety profile."

Kite recently announced completion of its rolling submission of the Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA). 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.

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.

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

About axicabtagene ciloleucel

Kite'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: expectations regarding the clinical effectiveness and safety of axicabtagene ciloleucel, the ability to use biomarker analysis to improve the safety profile, the ability of obtaining regulatory approval and commercially launching axicabtagene ciloleucel, and the timing and ability to submit an MAA for axicabtagene ciloleucel with the EMA. 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-K for the year ended December 31, 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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