

## Kite Pharma Presents Results of Multi-Center Pivotal ZUMA-1 Trial of Axicabtagene Ciloleucel (KTE-C19) in Aggressive Non-Hodgkin Lymphoma as Late-Breaking Abstract at Annual Meeting of American Society of Hematology

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- 76 Percent of Patients with Diffuse Large B-Cell Lymphoma Achieved Objective Response ( $p < 0.0001$ ) and 47 Percent Complete Remissions (CR) at Pre-specified Interim Analysis
- Grade  $\geq 3$  Cytokine Release Syndrome (CRS) and Neurologic Events (NE) Observed in 13 Percent and 29 Percent, Respectively
- Total of 111 Patients Enrolled and 101 Patients Treated Across More than 20 Sites in US and Israel

SANTA MONICA, Calif.--(BUSINESS WIRE)-- Kite Pharma, Inc. (Nasdaq:[KITE](#)) presented results from the ZUMA-1 trial of axicabtagene ciloleucel (KTE-C19) in patients with chemorefractory aggressive non-Hodgkin lymphoma (NHL) in two oral presentations at the American Society of Hematology (ASH) 58<sup>th</sup> Annual Meeting in San Diego, California.

ZUMA-1 enrolled 111 patients with diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL), or transformed follicular lymphoma (TFL). Patients were required to have chemorefractory disease, defined as progressive or stable disease as best response to last line of therapy, or disease progression  $\leq 12$  months after autologous stem cell transplant. Manufacturing was successful for 110 patients, and 101 patients were treated. The pre-specified interim analysis was triggered when 51 patients with DLBCL had a minimum of three months of follow-up. At the time of interim analysis, 11 patients with PMBCL/TFL had been followed for three months. An additional 31 patients with one month of follow-up were included in the late breaker presentation.

"The vast majority of patients enrolled in ZUMA-1 are unable to undergo autologous stem cell transplant due to chemorefractory disease. This group has a dire need for more effective therapies," said Jeff Wiezorek, M.D., Senior Vice President of Clinical Development. "We are encouraged by the high rate of complete remissions in this group and look forward to presenting longer follow-up at the primary analysis in the first quarter 2017. We are grateful to the patients and investigators who have made this important study possible."

ZUMA-1 met the primary endpoint of objective response rate (ORR),  $p < 0.0001$ . Response rates by disease subtype are shown in the table below. Responses were observed across key subgroups, including 75 percent CR in patients who relapsed in  $\leq 12$  months after autologous stem cell transplant and 47 percent CR in patients refractory to second line or later chemotherapy. At the month three assessment, 39 percent of patients were in CR.

### **Best Overall Response in Patients with $\geq 3$ Month Follow-up**

<b>Subgroup</b>	<b>N</b>	<b>ORR</b>	<b>CR</b>
DLBCL	51	76%	47%
TFL / PMBCL	11	91%	73%
<b>Total</b>	<b>62</b>	<b>79%</b>	<b>52%</b>

In 93 patients with a minimum one month follow-up, the most common grade 3 or higher adverse events included neutropenia (63 percent), anemia (42 percent), leukopenia (40 percent), febrile neutropenia (29 percent), thrombocytopenia (26 percent), encephalopathy (19 percent), hypophosphatemia (17 percent), and decreased lymphocyte count (17 percent). Grade 3 or higher CRS and NE were observed in 13 percent and 29 percent of patients, respectively. Three patients died from treatment-emergent adverse events (hemophagocytic lymphohistiocytosis, cardiac arrest in the setting of CRS and pulmonary embolism). There were no cases of cerebral edema.

The primary analysis of ZUMA-1 will include a minimum of 6 months of follow-up. Kite intends to seek regulatory

approval of axicabtagene ciloleucel in refractory aggressive NHL and plans to complete its rolling submission of the Biologics License Application (BLA) in the first quarter of 2017.

The late-breaker abstract (LBA-6), "KTE-C19 (anti-CD19 CAR T Cells) Induces Complete Remissions in Patients with Refractory Diffuse Large B-Cell Lymphoma (DLBCL): Results from the Pivotal Phase 2 ZUMA-1," was presented by Sattva S. Neelapu, M.D., Associate Professor, Deputy Department Chair ad interim, Department of Lymphoma/Myeloma, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX. <https://ash.confex.com/ash/2016/webprogram/Paper98715.html>

### **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 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](http://www.kitepharma.com). Sign up to follow @KitePharma on Twitter at [www.twitter.com/kitepharma](https://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 ability and timing of obtaining axicabtagene ciloleucel (KTE-C19) data, completing a BLA submission with the FDA, 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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