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Kite Receives U.S. Food and Drug Administration Priority Review for Axicabtagene Ciloleucel

- First Investigational CAR-T Therapy to Demonstrate Positive Data in Aggressive Non-Hodgkin Lymphoma (NHL)
- Biologics License Application Submission Based on the Primary Analysis of the ZUMA-1 Phase 2 Trial
- Prescription Drug User Fee Act (PDUFA) Set for November 29, 2017

SANTA MONICA, Calif.--(BUSINESS WIRE)-- Kite Pharma, Inc., (Nasdaq:KITE), a leading cell therapy company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for priority review the Biologics License Application (BLA) for axicabtagene ciloleucel. The submission follows positive data demonstrated with a single infusion of axicabtagene ciloleucel in the ZUMA-1 Phase 2 trial in patients with refractory aggressive non-Hodgkin lymphoma (NHL). The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of November 29, 2017.

"Patients with refractory aggressive NHL face a dire prognosis with only a 50 percent chance of surviving six months. This underscores the urgent medical need for these patients and why every day matters, from development to manufacturing to clinical experience," said David Chang, M.D., Ph.D., Executive Vice President of Research and Development and Chief Medical Officer of Kite. "We firmly believe in the potential for axicabtagene ciloleucel to address this need and forge a new path for the future of cell therapy."

The filing acceptance is supported by data from the ZUMA-1 Phase 2 trial which met the primary endpoint of objective response rate (ORR) recorded after a single infusion of axicabtagene ciloleucel with 82 percent ($p < 0.0001$). At a median follow-up of 8.7 months, 44 percent of patients were in ongoing response, which included 39 percent of patients in complete response (CR).

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). There were three deaths throughout the course of the registrational trial not due to disease progression, of which two events, were deemed related to axicabtagene ciloleucel.

In December 2015, axicabtagene ciloleucel received Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA) for DLBCL, TFL, and PMBCL. The company expects to submit its Market Authorization Application (MAA) of axicabtagene ciloleucel with the European Medicines Agency (EMA) in the third quarter of 2017.

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: the potential of axicabtagene ciloleucel, and the ability and timing of submitting an MAA to the EMA for 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 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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