Kite Completes Submission of U.S. Biologics License Application (BLA) for Axicabtagene Ciloleucel as the First CAR-T Therapy for the Treatment of Patients With Aggressive Non-Hodgkin Lymphoma (NHL)

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- Kite is Preparing for Potential Approval and Launch for Axicabtagene Ciloleucel in 2017

SANTA MONICA, Calif.--(BUSINESS WIRE)-- Kite Pharma, Inc. (Nasdaq:KITE) today announced that it has completed the rolling submission with the U.S. Food and Drug Administration (FDA) of the Biologics License Application (BLA) for axicabtagene ciloleucel (previously known as KTE-C19) as a treatment for patients with relapsed or refractory aggressive non-Hodgkin lymphoma (NHL) who are ineligible for autologous stem cell transplant (ASCT).

"Last month, we announced positive results from our ZUMA-1 pivotal trial with axicabtagene ciloleucel," said Arie Belldegrun, M.D., FACS, Chairman, President, and Chief Executive Officer of Kite. "We look forward to working closely with the FDA during the review of axicabtagene ciloleucel and the possibility of bringing this therapy to patients with aggressive NHL whose outlook is dismal with current therapy."

In December 2015 axicabtagene ciloleucel received Breakthrough Therapy Designation (BTD) by the FDA for diffuse large B-cell lymphoma (DLBCL), transformed follicular lymphoma (TFL), and primary mediastinal B-cell lymphoma (PMBCL). If approved, Kite plans to commercially launch axicabtagene ciloleucel in 2017. Kite is also planning a regulatory submission to the European Medicines Agency (EMA) for axicabtagene ciloleucel in 2017.

"The Leukemia & Lymphoma Society (LLS) applauds Kite for achieving this significant milestone and bringing this promising therapy closer to patients with lymphoma who desperately need new options," said Louis J. DeGennaro, Ph.D., LLS President and Chief Executive Officer. "LLS has supported companies that are working to dramatically change cancer treatment through the development of immunotherapy for the past two decades, and we immediately recognized the great opportunity to support Kite's CAR-T program in 2015 through our Therapy Acceleration Program ® (TAP). Partnerships created through TAP, now in its tenth year, have the potential to bring several breakthrough therapies, such as axicabtagene ciloleucel, to patients in the coming year."

The ZUMA-1 pivotal trial for axicabtagene ciloleucel for the treatment of patients with aggressive NHL was supported in part by funding from LLS' TAP.

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 and the timing and ability of 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-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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