Kite Pharma Initiates Rolling Submission of U.S. Biologics License Application (BLA) for KTE-C19, its Investigational anti-CD19 CAR-T Therapy, for the Treatment of Patients with Relapsed/Refractory Aggressive B-cell Non-Hodgkin Lymphoma (NHL)

December 4, 2016

First CAR-T Therapy BLA Filing Initiated with the U.S. Food and Drug Administration

Company Expects to Complete BLA Submission by the end of Q1 2017

United States Adopted Name, or USAN, for KTE-C19 will be axicabtagene ciloleucel

SANTA MONICA, Calif.--(BUSINESS WIRE)-- Kite Pharma, Inc. (Nasdaq:KITE) today announced that it has initiated the rolling submission with the U.S. Food and Drug Administration (FDA) of the Biologics License Application (BLA) for KTE-C19 as a treatment for patients with relapsed/refractory aggressive B-cell non-Hodgkin lymphoma (NHL) who are ineligible for autologous stem cell transplant (ASCT). The pivotal ZUMA-1 study supporting this submission enrolled patients with chemorefractory diffuse large B-cell lymphoma (DLBCL), transformed follicular lymphoma (TFL), and primary mediastinal B-cell lymphoma (PMBCL), three subtypes of aggressive NHL. The company expects to complete its BLA submission by the end of the first quarter of 2017.

"I am both proud and appreciative of the Kite team and our clinical investigators, who have helped to make this key milestone possible," said Arie Belldegrun, M.D., FACS, Chairman, President, and Chief Executive Officer of Kite. "This is an important first step toward Kite's biggest goal - bringing to market a potentially life-saving treatment for patients suffering from aggressive NHL."

Kite also announced that the United States Adopted Name, or USAN, for KTE-C19 will be axicabtagene ciloleucel.

Axicabtagene ciloleucel (KTE-C19) received Breakthrough Therapy Designation (BTD) by the FDA in December 2015. If approved, Kite plans to commercially launch KTE-C19 in 2017. Kite is also planning a regulatory submission to the European Medicines Agency (EMA) for axicabtagene ciloleucel in 2017. Kite was granted access to Priority Medicines (PRIME) regulatory support in 2016 by the EMA for axicabtagene ciloleucel (KTE-C19) for the treatment of refractory DLBCL.

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. 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 ability and timing of obtaining axicabtagene ciloleucel (KTE-C19) data, completing a BLA submission with the FDA, obtaining regulatory approval, commercially launching axicabtagene ciloleucel, and seeking marketing approval 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-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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