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Kite Announces Initiation of Axicabtagene Ciloleucel CAR-T Clinical Program in the European Union

- First Patient Dosed in Safety Expansion Cohort of ZUMA-1 in the European Union (EU)
- Axicabtagene Ciloleucel Being Developed Under Priority Medicines (PRIME) Designation in the EU
- Marketing Authorization Application to the European Medicines Agency for Axicabtagene Ciloleucel Submitted in July 2017

SANTA MONICA, Calif.--(BUSINESS WIRE)-- Kite Pharma, Inc., (Nasdaq:KITE), a leading cell therapy company, today announced that patients in the European Union (EU) are now being treated with its lead investigational candidate, axicabtagene ciloleucel, in the safety expansion cohort of ZUMA-1 (ClinicalTrials.gov, NCT: 02348216). Kite is currently enrolling adult patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL), and transformed follicular lymphoma (TFL) at multiple EU medical centers. Kite filed a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for axicabtagene ciloleucel in July 2017, the first CAR-T application in Europe.

"This important milestone underscores our commitment to providing a potentially curative therapy to patients with serious blood cancers worldwide," said David Chang, M.D., Ph.D., Executive Vice President of Research and Development and Chief Medical Officer of Kite. "Our CAR-T expertise established in the United States will be key as we expand our global footprint this year."

The first patient treated in the safety expansion cohort was at the Academic Medical Center (AMC) in Amsterdam by Professor Dr. Marie José Kersten. Additional patients are expected to be treated in multiple clinical sites across Europe in 2017.

"We are encouraged by the promising results observed in ZUMA-1 in the United States and are excited to be one of the first medical centers to bring this novel treatment modality to the EU," said Professor Dr. Marie José Kersten, Principal Investigator and Head of the Department of Hematology of the AMC in Amsterdam. "As a lymphoma specialist, I am gratified that we can now offer this potentially transformative therapy to patients with refractory, aggressive NHL who previously had no other therapeutic options."

Kite has been granted access to Priority Medicines (PRIME) regulatory support in the EU for treatment of refractory DLBCL. Access to the PRIME initiative is granted by the EMA to support the development and accelerate the review of new therapies to treat patients with a high unmet need.

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 is currently under review by the U.S. Food and Drug Administration (FDA) for aggressive non-Hodgkin lymphoma and was granted Breakthrough Therapy Designation status for diffuse large B-cell lymphoma (DLBCL), transformed follicular lymphoma (TFL), and primary mediastinal B-cell lymphoma (PMBCL).

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, with EU locations in London and Amsterdam. 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 ability and timing of advancing axicabtagene ciloleucel in the EU and additional countries. 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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