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Kite Wins ‘Clinical Trial Result of the Year' for its Pivotal CAR-T Trial of Axicabtagene Ciloleucel in Patients with Aggressive Non-Hodgkin Lymphoma at the 2017 Clinical and Research Excellence Awards

SANTA MONICA, Calif.--(BUSINESS WIRE)-- Kite Pharma, Inc., (Nasdaq:KITE) today announced that it won the Clinical Trial Result of the Year award for ZUMA-1, its pivotal CAR-T trial of axicabtagene ciloleucel, in patients with refractory aggressive B-cell non-Hodgkin lymphoma (NHL) at the Clinical and Research Excellence (CARE) Awards. The award recognizes clinical achievements in the pharmaceutical industry and contribution to the advancement of therapies for unmet medical needs.

"This award is an important acknowledgement of the ZUMA-1 trial, the first multicenter CAR-T therapy trial in aggressive NHL, and the potential of CAR-T therapy to significantly transform the treatment of cancer," said Arie Belldegrun, M.D., FACS, Chairman, President and Chief Executive Officer of Kite. "We thank the Kite research and development team for their dedication and congratulate them on this well-deserved recognition for their central role in advancing the development of this potentially paradigm changing treatment."

The study 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). These results from 101 patients demonstrate the treatment effect of axicabtagene ciloleucel in diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL) and transformed follicular lymphoma (TFL), which are types of aggressive NHL.

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). As compared to the interim analysis, grade 3 or higher cytokine release syndrome (CRS) decreased from 18 percent to 13 percent and neurologic events decreased from 34 percent to 28 percent. There were three deaths throughout the course of the trial not due to disease progression, of which two events, were deemed related to axicabtagene ciloleucel. There were no cases of cerebral edema.

Full data from the primary analysis of ZUMA-1 were most recently presented at the 2017 American Association of Cancer Research Annual Meeting in Washington, D.C. in April. In December 2015, axicabtagene ciloleucel received Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA) for DLBCL, TFL, and PMBCL. Kite completed its submission of a Biologics License Application (BLA) for axicabtagene ciloleucel with the FDA in March 2017 and, if approved, plans to commercially launch axicabtagene ciloleucel in 2017.

The awards, presented by Informa's Pharma Intelligence, were announced at a ceremony in Boston on April 5, 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: 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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