July 31, 2017

Kite Files the Industry's First CAR-T Marketing Authorization Application in Europe for Axicabtagene Ciloleucel

- Submission Based on Primary Analysis of ZUMA-1 in Patients with Aggressive NHL
- Accelerated Assessment Granted Through Priority Medicines (PRIME) Regulatory Initiative

SANTA MONICA, Calif.--(BUSINESS WIRE)-- Kite Pharma, Inc. (Nasdaq:KITE), a leading cell therapy company, today announced that it has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for axicabtagene ciloleucel as a treatment for patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL), transformed follicular lymphoma (TFL), and primary mediastinal B-cell lymphoma (PMBCL) who are ineligible for autologous stem cell transplant. This application represents the first chimeric antigen receptor (CAR) T-cell therapy submitted to the EMA. Axicabtagene ciloleucel is currently under review by the U.S. Food and Drug Administration (FDA), and the FDA has set a Prescription Drug User Fee Act (PDUFA) action date of November 29, 2017.

The MAA for axicabtagene ciloleucel is supported by data from the ZUMA-1 trial, which met the primary endpoint of objective response rate (ORR), with 82 percent ($p < 0.0001$) of patients achieving a response after a single infusion of axicabtagene ciloleucel. 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 cytokine release syndrome and neurologic events, which were generally reversible.

"The MAA submission of axicabtagene ciloleucel marks an important global milestone in the development of engineered T cell therapy," said Arie Belldegrun, M.D., FACS, Chairman, President, and Chief Executive Officer of Kite. "We are excited to work closely with the EMA, Committee for Medicinal Products for Human Use (CHMP) and Committee for Advanced Therapies (CAT) to help bring this potentially transformative therapy to patients in the EU."

Non-Hodgkin lymphoma (NHL) is a type of blood cancer that affects around 93,000 people in Europe every year.[i] DLBCL is one of the subtypes of NHL that is aggressive or fast growing.[ii] While many patients can achieve and maintain complete remission after initial treatment, patients who experience relapse or do not respond to initial treatment historically have poor outcomes. The company estimates that approximately 7,800 patients in the EU 5 alone may benefit from CAR-T therapy.

In May 2016, the CHMP and CAT granted access to its newly established Priority Medicines (PRIME) regulatory initiative for axicabtagene ciloleucel in the treatment of patients with 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 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 to obtain EMA approval 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.

[i] Ferlay J, Steliarova-Foucher E, Lortet-Tieulent J, et al. Cancer incidence and mortality patterns in Europe: Estimates for 40 countries in 2012. *European Journal of Cancer 2013*;49:1374-1403.

[ii] Non-Hodgkin Lymphoma (NHL). "NHL Subtypes" Leukemia & Lymphoma Society. http://www.lls.org/lymphoma/non-hodgkin-lymphoma/diagnosis/nhl-subtypes [Last accessed July 20, 2017].

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