Kite Submits Biologics License Application to U.S. Food and Drug Administration for Company's Second CAR T Cell Therapy

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-- Investigational KTE-X19 To Be First Chimeric Antigen Receptor (CAR) T Cell Therapy for Mantle Cell Lymphoma if Approved --

-- Filing for Kite's Second CAR T Therapy Marks Potential Expansion of Company's Cell Therapy Portfolio --

SANTA MONICA, Calif.--(BUSINESS WIRE)--Dec. 11, 2019-- Kite, a Gilead Company (Nasdaq: GILD), today announced that it has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for the investigational chimeric antigen receptor (CAR) T cell therapy, KTE-X19, for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

The BLA submission is based on data from the Phase 2 ZUMA-2 trial, which demonstrated an overall response rate of 93 percent, including 67 percent with complete response, as assessed by an Independent Radiologic Review Committee (IRRC) following a single infusion of KTE-X19. In the safety analysis, Grade 3 or higher cytokine release syndrome (CRS) and neurologic events were seen in 15 percent and 31 percent of patients, respectively. No Grade 5 CRS or neurologic events occurred. Detailed findings from this trial were recently presented at the 61st American Society of Hematology (ASH) Annual Meeting & Exposition in Orlando.

"There remains a significant need for new treatments for patients with relapsed/refractory MCL despite recent advances, so this regulatory filing is an especially important milestone for the MCL community," said Ken Takeshita, MD, Kite's Global Head of Clinical Development. "We look forward to working with the FDA to bring KTE-X19 to appropriate patients as quickly as possible and continuing to deliver on the promise of our industry-leading cell therapy development program with a second CAR T therapy."

Kite plans to submit a Marketing Authorization Application for KTE-X19 in the European Union in early 2020. KTE-X19 has been granted Breakthrough Therapy Designation (BTD) by the FDA and Priority Medicines (PRIME) by the European Medicines Agency (EMA) for relapsed or refractory MCL.

KTE-X19 is investigational and not approved anywhere globally. Its efficacy and safety have not been established. More information about clinical trials with KTE-X19 is available at www.clinicaltrials.gov.

About MCL

MCL is a rare form of non-Hodgkin lymphoma (NHL) that arises from cells originating in the "mantle zone" of the lymph node and typically affects men over the age of 60.

About ZUMA-2

ZUMA-2 is a single-arm, multicenter, open-label Phase 2 study involving 74 enrolled/leukapheresed adult patients (≥18 years old) with MCL whose disease is refractory to or has relapsed following up to five prior lines of therapy, including anthracycline or bendamustine-containing chemotherapy, anti-CD20 monoclonal antibody therapy and the BTK inhibitors ibrutinib or acalabrutinib. The objectives of the study are to evaluate the efficacy (60 patients) and safety (68 patients) after a single infusion of KTE-X19 in this patient population. The primary endpoint for the study is objective response rate (ORR). ORR in this trial is defined as the combined rate of complete responses and partial responses as assessed by an IRRC.

Secondary endpoints include duration of response, progression-free survival, overall survival, incidence of adverse events, incidence of anti-CD19 CAR antibodies, levels of anti-CD19 CAR T cells in blood, levels of cytokines in serum, and changes over time in the EQ-5D scale score and visual analogue scale score. The study is ongoing.

About KTE-X19

KTE-X19 is an investigational, autologous, anti-CD19 CAR T cell therapy. KTE-X19 uses the XLP ™ manufacturing process that includes T-cell selection and lymphocyte enrichment. Lymphocyte enrichment is a necessary step in certain B-cell malignancies with evidence of circulating lymphoblasts. KTE-X19 is currently in Phase 1/2 trials in acute lymphoblastic leukemia (ALL), mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL).

About Kite

Kite, a Gilead Company, is a biopharmaceutical company based in Santa Monica, California. Kite is engaged in the development of innovative cancer immunotherapies. The company is focused on chimeric antigen receptor and T cell receptor engineered cell therapies. For more information on Kite, please visit www.kitepharma.com.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California. For more information on Gilead Sciences, please visit the company's website at www.gilead.com.

Forward-Looking Statement

This press release includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the risk that FDA and other regulatory agencies may not approve KTE-X19 for the treatment of adult patients with relapsed or refractory MCL, and any marketing approvals, if granted, may have significant limitations on its use. In addition, Kite may not

be able to submit the Marketing Authorization Application for KTE-X19 to the European Union in the currently anticipated timeline, or at all. There is also the possibility of unfavorable results from other ongoing and additional clinical trials involving KTE-X19. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead and Kite, and Gilead and Kite assume no obligation to update any such forward-looking statements.

XLP is a trademark of Gilead Sciences, Inc., or its related companies.

For more information on Kite, please visit the company's website at www.kitepharma.com or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000. Follow Kite on social media on Twitter (@KitePharma) and LinkedIn.

View source version on businesswire.com: https://www.businesswire.com/news/home/20191211005861/en/

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