U.S. FDA Grants Priority Review for Kite's KTE-X19 Biologics License Application (BLA) in Relapsed or Refractory Mantle Cell Lymphoma

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-- If Approved, Kite Could be First Company with Multiple Commercialized CAR T Therapies --

SANTA MONICA, Calif.--(BUSINESS WIRE)--Feb. 10, 2020-- Kite, a Gilead Company (Nasdaq: GILD), today announced that the U.S. Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) and granted Priority Review designation for KTE-X19, an investigational chimeric antigen receptor (CAR) T cell therapy for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

The BLA is supported by data from the single arm, open-label, Phase 2 ZUMA-2 trial, which showed that 93 percent of patients responded to a single infusion of KTE-X19, including 67 percent of patients achieving a complete response, as assessed by an Independent Radiologic Review Committee (IRRC; median follow-up of 12.3 months). 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 during an oral session at the 61st American Society of Hematology (ASH) Annual Meeting & Exposition in Orlando.

"Despite recent advances, patients with relapsed/refractory mantle cell lymphoma currently face a significant lack of effective treatment options once their disease no longer responds to currently available therapy," said Ken Takeshita, MD, Kite's Global Head of Clinical Development. "Based on the encouraging results for KTE-X19, we are eager to continue discussions with the FDA on how to bring this innovative treatment to these patients who may benefit from CAR T therapy."

The Prescription Drug User Fee Act (PDUFA), or target action date, is August 10, 2020. The European Medicines Agency (EMA) recently validated the Marketing Authorization Application for KTE-X19 in the European Union. KTE-X19 has been granted Breakthrough Therapy Designation (BTD) by the FDA and Priority Medicines (PRIME) designation by the EMA for relapsed or refractory MCL.

KTE-X19 is investigational and not yet approved in any country globally. Its efficacy and safety have not been established. A final decision by the FDA is anticipated by August. 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 in which circulating lymphoblasts are a common feature. 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 the European Commission may not approve KTE-X19 for the treatment of adult patients with relapsed or refractory MCL in the anticipated timelines or at all, and any marketing approvals, if granted, may have significant limitations on its use. 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/20200210005203/en/

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