Press Releases

January 28, 2020

European Medicines Agency Validates Kite's Marketing Application for Company's Second CAR T Cell Therapy

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

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

SANTA MONICA, Calif.--(BUSINESS WIRE)--Jan. 28, 2020-- Kite, a Gilead Company (Nasdaq: GILD), today announced that the company's Marketing Authorization Application (MAA) 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), has been fully validated and is now under evaluation by the European Medicines Agency (EMA).

The MAA is supported by data from the single arm, open-label, 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 (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.

"Relapse rates in mantle cell lymphoma remain overwhelmingly high and there is a significant need for new therapies that may improve patients' prognosis," said Ken Takeshita, MD, Kite's Global Head of Clinical Development. "The EMA validation of our marketing application brings us closer to delivering on the promise of our industry-leading cell therapy development program, with the hope that we can bring KTE-X19 to appropriate patients in Europe as quickly as possible."

Kite submitted a Biologics License Application (BLA) for KTE-X19 to the U.S. Food and Drug Administration (FDA) on December 11, 2019 for the treatment of adult patients with relapsed or refractory MCL. KTE-X19 has been granted Breakthrough Therapy Designation (BTD) by the FDA and Priority Medicines (PRIME) by the EMA.

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 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, EMA 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. 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.

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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/20200128005723/en/

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