# Kite Presents Positive Results From Pivotal ZUMA-2 Trial in Relapsed or Refractory Mantle Cell Lymphoma

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***-- 93 Percent of Patients Treated with Investigational KTE-X19 Achieved Response, Including 67 Percent with a Complete Response --***

***-- Findings Support Regulatory Filings for Kite's Second CAR T Cell Therapy --***

***-- Data Presented at American Society of Hematology (ASH) Annual Meeting --***

ORLANDO, Fla.--(BUSINESS WIRE)--Dec. 9, 2019-- Kite, a Gilead Company (Nasdaq: GILD), today announced primary results from ZUMA-2, a global, multicenter, single-arm, open-label Phase 2 study of KTE-X19, an investigational CD19 chimeric antigen receptor (CAR) T cell therapy, in adult patients with relapsed or refractory mantle cell lymphoma (MCL). After a single infusion of KTE-X19, the best objective response via independent radiologic central review (n=60 evaluable for efficacy analysis) was 93 percent, with 67 percent of patients having achieved a complete response. These findings were presented today at the 61st American Society of Hematology (ASH) Annual Meeting & Exposition, in Orlando from December 7–10, 2019.

"There is a significant need for novel treatment options for patients with MCL, especially those whose disease has progressed following several lines of previous therapy," said Michael Wang, MD, ZUMA-2 Lead Investigator and Professor, Department of Lymphoma and Myeloma, Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center. "The impressive response rates observed with KTE-X19 support its potential as the first cell therapy for people living with MCL."

With a median follow-up of 12.3 months (range: 7.0 to 32.3 months) at the time of data cutoff, 57 percent of patients remained in an ongoing response. Of the first 28 patients treated (minimum follow-up of 24 months), 43 percent were alive and remained in continued remission without additional therapy. The 12-month estimates of progression-free survival (PFS) and overall survival (OS) were 61 percent and 83 percent, respectively. Median duration of response, PFS and OS were not yet reached.

Among the 68 patients evaluable for safety, cytokine release syndrome (CRS) and neurologic events were observed in 91 percent and 63 percent of patients, respectively. Grade 3 or higher CRS and neurologic events were seen in 15 percent and 31 percent of patients, respectively. No Grade 5 CRS or neurologic events occurred.

"Today's results represent a significant milestone for Kite and for the MCL community," said Christi Shaw, Chief Executive Officer of Kite. "With KTE-X19, we have the opportunity to deliver on the promise of our industry-leading cell therapy development program with a second CAR T therapy, and the first ever for patients with relapsed or refractory MCL. We look forward to progressing KTE-X19 with the FDA and other regulatory authorities to bring it to patients as quickly as possible."

Based on the results of the trial, Kite plans to submit a Biologics License Application (BLA) for KTE-X19 to the U.S. Food and Drug Administration (FDA) by the end of this year and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in the first quarter of 2020. KTE-X19 has been granted Breakthrough Therapy Designation (BTD) by the FDA and Priority Medicines (PRIME) by the EMA for relapsed or refractory MCL based on interim data from ZUMA-2.

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 Independent Radiology Review Committee.

Secondary endpoints include duration of response, best objective 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 possibility of unfavorable results from other ongoing and additional clinical trials involving KTE-X19. There is also the possibility that Kite may be unable to file a Biologics License Application to the FDA or a marketing authorization application to the EMA for KTE-X19 in the anticipated timelines, or at all. Further, it is possible that Kite may make a strategic decision to discontinue development of KTE-X19, and as a result, KTE-X19 may never be successfully commercialized. 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.*

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Source: Kite, a Gilead Company

Greg Mann, Investors
(424) 322-1795

Nathan Kaiser, Media
(650) 522-1853