European CHMP Adopts Positive Opinion for Kite's KTE-X19 for the Treatment of Relapsed or Refractory Mantle Cell Lymphoma

October 16, 2020

-- If Approved, KTE-X19 will be an Important New Advance for this Disease with a Poor Prognosis --

-- Kite would Become the First Company with Multiple Approved CAR T Therapies in Europe --

SANTA MONICA, Calif.--(BUSINESS WIRE)--Oct. 16, 2020-- Kite, a Gilead Company (Nasdaq: GILD), today announced that the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion on the company's Marketing Authorization Application for KTE-X19, a chimeric antigen receptor (CAR) T cell therapy, as a potential treatment for adult patients with relapsed or refractory mantle cell lymphoma after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor. The CHMP opinion recommends conditional authorization, an early access pathway for medicines that show promising therapeutic effects, but for which comprehensive data are not available. The CHMP recommendation was based on the positive benefit-risk for KTE-X19 as demonstrated from the safety and efficacy results of the ZUMA-2 trial.

Mantle cell lymphoma is a rare form of non-Hodgkin lymphoma that arises from cells originating in the "mantle zone" of the lymph node and predominantly affects men over the age of 60. Patients with relapsed or refractory mantle cell lymphoma after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) have a poor prognosis, with a median overall survival of 6 to 10 months. In Europe, it is estimated that at least 7,400 people are diagnosed with mantle cell lymphoma each year.

"This opinion is an important milestone for patients in Europe living with relapsed or refractory mantle cell lymphoma," said Ken Takeshita, MD, Kite's Global Head of Clinical Development. "Kite is committed to bringing the promise of CAR T cell therapy to patients with hematological cancers and, pending approval by European Commission, we hope to bring this innovative treatment option forward for patients in Europe as quickly as possible."

KTE-X19 is an autologous, anti-CD19 CAR T cell therapy, an individualized method of treatment that harnesses the body's own immune system to target cancer cells. KTE-X19 uses the XLP™ manufacturing process that includes T cell enrichment, a necessary step in certain B cell malignancies in which circulating lymphoblasts are a common feature. In recognition of its potential to benefit patients with significant unmet medical need, KTE-X19 was granted Priority Medicines (PRIME) designation by the EMA.

In Europe, KTE-X19 is not yet approved and remains investigational with its efficacy and safety not established. The European Commission will now review the CHMP recommendation and the final decision on the Marketing Authorization is expected in the coming months.

Conditional marketing authorization in Europe is initially valid for one year but can be extended or converted into an unconditional marketing authorization after the submission and assessment of additional confirmatory data. Conditional approval is granted to a medicinal product that fulfils an unmet medical need where the benefit of immediate availability outweighs the risk of less comprehensive data than normally required. It requires additional monitoring and post-marketing data before full approval is granted.

About ZUMA 2

The Marketing Authorization Application of KTE-X19 is supported by data from the ongoing, multinational, single arm, Phase 2, open-label ZUMA-2 pivotal trial. The study enrolled 74 adult patients with relapsed or refractory mantle cell lymphoma who had previously received anthracycline- or bendamustine-containing chemotherapy, an anti-CD20 antibody therapy and a Bruton tyrosine kinase inhibitor (ibrutinib or acalabrutinib). The primary endpoint was objective response rate per the Lugano Classification (2014), defined as the combined rate of complete response and partial responses as assessed by an Independent Radiologic Review Committee. KTE-X19 was manufactured for 71 patients and administered to 68 patients.

About Kite

Kite, a Gilead Company, is a biopharmaceutical company based in Santa Monica, California, with commercial manufacturing operations in North America and Europe. 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 physicians and patients may not see the potential benefits of KTE-X19 therapy and the possibility of unfavorable results from other ongoing and additional clinical studies involving KTE-X19 for the treatment of adult patients with relapsed or refractory mantle cell lymphoma and other potential indications. There is also the risk that the European Commission may not approve KTE-X19 for the treatment of relapsed or refractory mantle cell lymphoma in the anticipated timelines or at all, and the marketing approval, if granted, may have significant limitations on its use. 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 June 30, 2020, 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.

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

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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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