Kite Announces End of Phase 1 ZUMA-3 Results for KTE-X19 in Adult Patients with Relapsed or Refractory Acute Lymphoblastic Leukemia

June 1, 2019

-- Data Show High Rates of Response to Single Infusion of KTE-X19 --

-- Phase 2 Portion of ZUMA-3 is Ongoing and Includes Dosing and Revised Safety Management Protocol Studied in Phase 1 --

CHICAGO--(BUSINESS WIRE)--Jun. 1, 2019-- Kite, a Gilead Company (Nasdaq: GILD), today announced results from the completed Phase 1 of the ZUMA-3 study evaluating KTE-X19, an investigational CD19 chimeric antigen receptor T (CAR T) cell therapy. ZUMA-3 is a single-arm Phase 1/2 study in adult patients with relapsed or refractory acute lymphoblastic leukemia (ALL). The results provide guidance on dosing and safety management for KTE-X19 to inform the ongoing Phase 2 study. The data were presented during an oral session at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, May 31 – June 4 (Abstract #7006).

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20190601005017/en/

By the end of Phase 1, 45 patients received KTE-X19 at one of three different doses levels [2 x 10^6 cells/kg (n=6), 1 x 10^6 cells/kg (n=23), or 0.5 x 10^6 cells/kg (n=16)]. Patients enrolled in this study were primary refractory or relapsed/refractory after at least two prior lines of therapy. Of 41 patients who were evaluable for efficacy after a minimum two months of follow-up (median follow-up of 16 months), 68 percent achieved complete response (CR) or CR with incomplete hematological recovery (CRi) and 100 percent of responders had undetectable minimal residual disease (MRD). Of the 23 patients treated with the dose level that will be used in the ongoing Phase 2 study (1 x 10^6 cells/kg), 19 were evaluable for efficacy. At the time of data cut-off (median duration of remission = 12.9 months), 16 (84 percent) patients achieved CR or CRi, and 12 patients (75 percent) were in ongoing response.

No dose-limiting toxicities (DLTs) were identified. Grade ≥3 cytokine release syndrome (CRS) events and neurologic events occurred in 29 percent and 38 percent of all patients, respectively. As previously reported, two patients experienced KTE-X19–related Grade 5 adverse events (AEs) during the study; one developed stroke in the context of CRS and neurologic events, and one experienced multiorgan failure secondary to CRS. Among patients receiving 1 x 10^6 cell/kg (n=23), 26 percent experienced Grade ≥3 CRS, and 43 percent experienced Grade ≥3 neurologic events.

A revised AE management protocol was implemented in nine patients treated with 1 x 10^6 cells/kg of KTE-X19 during the study. In this revised protocol, corticosteroids were initiated at onset of Grade ≥2 neurologic events (versus previous onset of Grade 3) and tocilizumab was only given for management of toxicities in the context of CRS (versus prophylactic administration in Cohort 2). Of those patients, two (22 percent) had Grade 3 CRS and one (11 percent) had Grade 3 neurologic events. There were no Grade 4/5 events.

"Adults with relapsed or refractory ALL represent an extremely difficult-to-treat patient population," said Bijal Shah, MD, ZUMA-3 investigator and medical oncologist, Moffitt Cancer Center, Tampa, Florida. "We’re encouraged by the high response rates in this study, as well as the reduced incidence and severity of CRS and neurologic events that were observed following implementation of the revised safety management protocol. We are now evaluating the use of KTE-X19 at the selected dose with this safety management protocol in the ongoing ZUMA-3 Phase 2 study."

"The completion of the Phase 1 portion of the ZUMA-3 trial is an important milestone for our second investigational CAR T cell therapy," said John McHutchison, AO, MD, Chief Scientific Officer, Head of Research and Development, Gilead. "We are pleased with the high response rates observed with KTE-X19 in this trial, and the progress of our broader effort aimed to further improve the benefit/risk profile of CAR T therapy through the investigation of novel safety management approaches."

This abstract has also been selected to be included in the 2019 Best of ASCO® program, which will be held this summer following the ASCO Annual Meeting.

KTE-X19 is an investigational therapy that has not been approved by the U.S. Food and Drug Administration (FDA) or any regulatory authority for any uses. Efficacy and safety have not been established.

About ALL

ALL is an aggressive type of blood cancer which can also involve the lymph nodes, spleen, liver, central nervous system and other organs.

About ZUMA-3

ZUMA-3 is an ongoing multicenter, registrational Phase 1/2 study in adult patients (≥18 years old) with ALL whose disease is refractory to or has relapsed following standard chemotherapy or hematopoietic stem cell transplantation. The objectives of the study are to evaluate the safety and efficacy of KTE-X19 in this patient population.

About KTE-X19

KTE-X19 is an investigational CD19 CAR T cell therapy. KTE-X19 has the same construct as axicabtagene ciloleucel; however, the manufacturing process for KTE-X19 differs from that of axicabtagene ciloleucel and includes the enrichment of lymphocytes. Lymphocyte enrichment is necessary in certain B-cell malignancies for which KTE-X19 is under investigation. 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 Kite’s ability to complete Phase 2 of the ZUMA-3 study of KTE-X19 in adult patients with relapsed or refractory acute lymphoblastic leukemia in the currently anticipated timelines, or at all. In addition, there is the possibility of unfavorable results from other ongoing and additional clinical trials involving KTE-X19. Further, Kite may be unable to obtain regulatory approval for KTE-X19 from the FDA or other regulatory authorities. 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 March 31, 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.

For more information on Kite, please visit the company’s website at www.kitepharma.com. Learn more about Gilead at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3470

View source version on businesswire.com: https://www.businesswire.com/news/home/20190601005017/en/

Source: Kite, a Gilead Company

Sung Lee, Investors
(650) 524-7792

Nathan Kaiser, Media
(650) 522-1853