GILEAD

Kite Announces Updated Data From ZUMA-3 Study of KTE-X19 in Adult Patients With Relapsed or Refractory Acute Lymphoblastic Leukemia

December 4, 2018

-- Ongoing Phase 1/2 Study Continues to Demonstrate High Rates of Response to a Single Infusion of KTE-X19 in a Patient Population with Limited Treatment Options --

-- Based on Recent Data, One Phase 3 Portfolio of KITE-2 (i.e. LNCaP) --

-- Nektar Promoted in Oral Session at the Annual Meeting of the American Society of Hematology (ASH) --

SAN DIEGO -- Kite, a Gilead Company (Nasdaq: GILT), announced updated results from ZUMA-3, a single-arm Phase 1/2 study evaluating KTE-X19 (formerly KTE-C19), an investigational CD19 chimeric antigen receptor (CAR) T cell therapy, in adult patients with relapsed or refractory acute lymphoblastic leukemia (ALL). With a median follow-up of 15.1 months (range 3.7 – 28.6 months), following a single infusion of KTE-X19, 69 percent of evaluable patients (n=36) achieved complete tumor remission, identical to complete remission (CR) or CR with incomplete blood count recovery (CBCR). The rate of serious adverse events (SAEs) in patients who achieved complete tumor remission was 10 percent. Detailed findings were presented today at the Annual Meeting of the American Society of Hematology (ASH) in San Diego, CA.

"We are encouraged by the high number of patients that achieved complete tumor remission following a single KTE-X19 infusion on this trial," said William G. Wierda, MD, PhD, Executive Medical Director and Professor, Department of Leukemia, Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center. "This early and encouraging data for ALL, where the majority of adult patients have poor response to traditional and frontline and salvage therapies, gives us optimism for improving outcomes and potentially moving chimeric T cell therapy for those affected by ALL.

"These updated results from ZUMA-3 provide continued support for the potential of our CD19 directed CAR T therapy in new types of cancers and reinforce our leadership in cell therapy," said Alessandro Riva, MD, Executive Vice President, Oncology Therapeutics and Head, Cell Therapy, Gilead Sciences. "Based on these findings, we have initiated Phase 2 of the study evaluating KTE-X19 in a larger set of adult patients with ALL who are in need of new treatment options.

KTE-X19 is an investigational agent that has not been approved for any use. Efficacy and safety have not been established.

About ALL

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

About ZUMA-3

ZUMA-3 is an ongoing, multinational, single-arm Phase 1/2 study in adult patients (≥18) 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 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 (CAR) and T cell receptor (TCR) 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 discovers and commercializes innovative medicines in areas of unmet medical need. The company discovers and commercializes innovative medicines in areas of unmet medical need. The company discovers and commercializes innovative medicines in areas of unmet medical need. The company discovers and commercializes innovative medicines in areas of unmet medical need. The company discovers and commercializes innovative medicines in areas of unmet medical need.

Forward-Looking Statement

This press release includes forward-looking statements that are subject to risks, uncertainties and other factors, including Gilead's ability to complete Phase 1/2 clinical trials evaluating KTE-X19 in the currently enrolled patient population at all sites; in addition, there is the possibility that other adverse events from ongoing and additional clinical trials involving KTE-X19. Further, it is possible that no other adverse events may occur in any previously unreported categories.

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. For more information on Gilead, please visit the company’s website at www.gilead.com. Follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.