Kite Announces Data From ZUMA-3 Study of KTE-C19 in Adult Patients with Relapsed or Refractory Acute Lymphoblastic Leukemia

December 11, 2017 7:31 PM ET

-- Phase 1 Data for KTE-C19 Demonstrates High Rates of Response --

-- Results Presented at the Annual Meeting of the American Society of Hematology --

ATLANTA--(BUSINESS WIRE)--Dec. 11, 2017-- Kite, a Gilead Company (Nasdaq: GILD), announced updated results from the ongoing Phase 1/2 ZUMA-3 study of KTE-C19, a CD19 chimeric antigen receptor T (CAR T) cell therapy, which is investigational for the treatment of adult patients with relapsed or refractory acute lymphoblastic leukemia (ALL). With a minimum of eight weeks of follow-up, 71 percent of ALL patients (n=17/24) who received a single infusion of KTE-C19 achieved complete tumor remission (complete remission (CR) or CR with incomplete hematological recovery). The ZUMA-3 study results were presented in an oral session at the Annual Meeting of the American Society of Hematology (ASH) in Atlanta.

This press release features multimedia. View the full release here: http://www.businesswire.com/news/home/20171211005311/en/

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

“Approximately half of new ALL cases occur in adults age 20 or older and a majority of adult ALL patients relapse and have poor subsequent outcomes,” said Bijal Shah, MD, ZUMA-3 investigator and medical oncologist, Moffitt Cancer Center, Tampa, Fla. “The deep remissions seen with these early study results offer promise that adults with this aggressive disease may benefit from personalized cell therapy with KTE-C19. Pending further clinical evaluation, this has the potential to be an advance for adults with no other treatment options.”

ZUMA-3 is an ongoing multicenter Phase 1/2 study in patients 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-C19 in this patient population.

At the time of data cutoff, 24 patients were evaluable for response. KTE-C19 demonstrated a 71 percent (n=17/24) rate of complete remission, with 100 percent of responders having no detectable minimal residual disease, including in those with high tumor burden and high risk genetic abnormalities.

In the safety analysis of 29 patients, adverse events were consistent with the known toxicities of CD19 CAR T treatment, including Grade 3 or higher cytokine release syndrome (CRS) and neurologic toxicities in 28 percent (n=8/29) and 52 percent of patients (n=15/29), respectively. Two patients receiving KTE-C19 died due to adverse events, including one patient with a cerebrovascular accident not related to KTE-C19 treatment approximately seven weeks after treatment and a previously reported patient who experienced fatal CRS.

“We believe personalized cell therapy has the potential to become a cornerstone of cancer treatment and are rapidly advancing CAR T studies in ALL and in other cancers,” said David Chang, MD, PhD, Worldwide Head of Research and Development and Chief Medical Officer at Kite. “ZUMA-3 is reflective of our continued commitment to cell therapy cancer treatment and we are pleased to see these early results for people living with ALL.”

KTE-C19 for ALL is investigational and has not been proven safe or efficacious.

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 is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California.

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 future clinical trials involving KTE-C19 may have unfavorable results. As a result, KTE-C19 may not be commercialized for ALL or other investigational indications. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties and are cautioned not to place undue reliance on these forward-looking statements. Actual results may differ materially from those currently anticipated due to a number of risks and uncertainties. Risks and uncertainties that could cause the actual results to differ from expectations contemplated by forward-looking statements include risks and uncertainties detailed from time to time in Gilead Sciences, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 as filed with the 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 and disclaim any intent to update any such forward-looking statements.

For more information on Gilead Sciences, 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.

View source version on businesswire.com: http://www.businesswire.com/news/home/20171211005311/en/

Source: Gilead Sciences

Gilead Sciences
Sung Lee, 650-524-7792
Investors
or
Nathan Kaiser, 650-522-1853
Media