Kite Announces New Data Analyses for CAR T Therapy in Patients with Blood Cancers at the 2018 American Society of Clinical Oncology Meeting

June 4, 2018 9:02 AM ET

-- ZUMA-1 Data Suggest Patient Response to Yescarta® (axicabtagene ciloleucel) at Three Months May be Predictive of Longer-Term Response in Refractory B-cell Lymphoma --

-- ZUMA-3 Analysis Suggests High Complete Response Rates with KTE-C19 in Adult Patients with Relapsed or Refractory Acute Lymphoblastic Leukemia (ALL) Regardless of Prior Blinatumomab Treatment --

CHICAGO--(BUSINESS WIRE)--Jun. 4, 2018-- Kite, a Gilead Company (Nasdaq: GILD), today announced new analyses from the ZUMA chimeric antigen receptor T (CAR T) cell therapy development program that are being presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. The results include analyses of the ZUMA-1 study of Yescarta® (axicabtagene ciloleucel) in adult patients with refractory large B-cell lymphoma showing that response status may predict rates of progression-free survival (PFS) (Abstract #3003) and that treatment responses were consistent across prior lines of therapy (Abstract #3039). Additionally, an analysis of the ZUMA-3 study evaluating investigational KTE-C19 for the treatment of adult patients with relapsed or refractory acute lymphoblastic leukemia (ALL) showed that patients experienced manageable safety and encouraging efficacy irrespective of prior blinatumomab use (Abstract #7006).

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20180604005338/en/

“With the U.S. approval of Yescarta last year, we aim to transform the treatment of patients with refractory large B-cell lymphoma,” said Alessandro Riva, MD, Gilead’s Executive Vice President, Oncology Therapeutics & Head, Cell Therapy. “We are also committed to studying Yescarta and other CD19-directed CAR T therapies for people with other relapsed or refractory blood cancers. Based on the strength of the ZUMA-1 data, we are now evaluating the potential of Yescarta in the second-line treatment setting in a Phase 3 study, ZUMA-7, and we continue to evaluate KTE-C19 in Phase 1/2 studies in ALL and other hematologic cancers.”

Yescarta was the first CAR T cell therapy to be approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma.

Yescarta has a Boxed Warning in its product label and an associated Risk Evaluation and Mitigation Strategy (REMS) regarding the risks of CRS and neurologic toxicities. Please see below for Important Safety Information.

A Marketing Authorization Application (MAA) for axicabtagene ciloleucel is currently under review with the European Medicines Agency (EMA).

Ongoing Responses, Response by Prior Lines of Therapy in ZUMA-1 (Abstracts #3003 and #3039)

Long-term ZUMA-1 follow-up data have shown an overall response rate (ORR) of 83 percent (n=84/101), including 58 percent (n=59/101) of patients with a complete response at a median follow-up of 15.1 months. In this long-term follow-up, Grade 3 or higher cytokine release syndrome (CRS) and neurologic events were seen in 12 percent and 29 percent of patients, respectively.

A new analysis of ZUMA-1 suggests that response status three months after infusion of Yescarta may be predictive of longer-term disease control. Of the 42 patients with complete response and nine with partial response at three months, the

12-month PFS rates were 79 percent and 78 percent, respectively. This abstract has also been selected for inclusion in the 2018 Best of ASCO® program.

“We are encouraged by the strong long-term complete response rates in ZUMA-1, which represents a patient population that previously had few if any remaining treatment options,” said Frederick L. Locke, MD, ZUMA-1 Co-Lead Investigator and Vice Chair of the Department of Blood and Marrow Transplant and Cellular Immunotherapy at Moffitt Cancer Center in Tampa, Florida. “Importantly, this new study analysis indicates that response status at three months is potentially predictive of prolonged PFS.”

An additional ZUMA-1 analysis evaluated outcomes based on prior therapy the patients had received. The results indicate long-term clinical benefit for patients with refractory large B cell lymphoma, irrespective of the number of prior lines of therapy.

Rates of Response with Prior Blinatumomab Treatment in ZUMA-3 (Abstract #7006)

Phase 1 data for KTE-C19, an investigational CD19 CAR T cell therapy, presented at the 2017 Annual Meeting of the American Society of Hematology (ASH) demonstrated high rates of complete response in adult patients with relapsed or refractory acute lymphoblastic leukemia (ALL). A new analysis of data from the ZUMA-3 study shows patients responded to KTE-C19 regardless of prior treatment with blinatumomab, an FDA-approved treatment for relapsed or refractory ALL. After eight or more weeks of follow-up, 63 percent (n=5/8) of patients with prior blinatumomab treatment and 80 percent (n=8/10) of patients without prior blinatumomab treatment had achieved a complete response or complete response with incomplete hematological recovery. Overall, 94 percent (n=17/18) of patients had minimal residual disease (MRD)-negative remission. KTE-C19 was also manufactured successfully in both groups, with similar product characteristics in terms of CD4/CD8 ratio and other measures.

“As a CD19/CD3 bispecific T cell antibody, the possible impact of prior blinatumomab use on the efficacy of KTE-C19 – a CD19-directed CAR T therapy – was an important question for exploration,” said Bijal Shah, MD, ZUMA-3 investigator and medical oncologist, Moffitt Cancer Center. “We observed that prior blinatumomab use did not affect the manufacturing of efficacious product, and that high response rates were seen regardless of previous treatment with blinatumomab.”

Grade 3 or higher CRS was seen in 27 percent of patients with prior blinatumomab and in 17 percent of patients without prior blinatumomab. Grade 3 or higher neurologic events were seen in 36 percent of patients with prior blinatumomab and 67 percent of patients without prior blinatumomab. A greater number of subjects in the blinatumomab-naïve group received the higher 1×10^6 cells/kg dose.

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

U.S. Important Safety Information for Yescarta

BOXED WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITIES

- **Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving Yescarta®. Do not administer Yescarta® to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.**
- **Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving Yescarta®, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with Yescarta®. Provide supportive care and/or corticosteroids as needed.**
- **Yescarta® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Yescarta® REMS.**

CYTOKINE RELEASE SYNDROME (CRS): CRS occurred in 94% of patients, including 13% with ≥ Grade 3. Among patients who died after receiving Yescarta®, 4 had ongoing CRS at death. The median time to onset was 2 days (range: 1-12 days) and median duration was 7 days (range: 2-58 days). Key manifestations include fever (78%), hypotension (41%), tachycardia (28%), hypoxia (22%), and chills (20%). Serious events that may be associated with CRS include cardiac arrhythmias (including atrial fibrillation and ventricular tachycardia), cardiac arrest, cardiac failure, renal insufficiency, capillary leak syndrome, hypotension, hypoxia, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome. Ensure that 2 doses of tocilizumab are available prior to infusion of Yescarta®. Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for 4 weeks after infusion. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. At the first sign of CRS, institute treatment with supportive care, tocilizumab or tocilizumab and corticosteroids as indicated.

NEUROLOGIC TOXICITIES: Neurologic toxicities occurred in 87% of patients. Ninety-eight percent of all neurologic toxicities occurred within the first 8 weeks, with a median time to onset of 4 days (range: 1-43 days) and a median duration of 17 days. Grade 3 or higher occurred in 31% of patients. The most common neurologic toxicities included encephalopathy (57%), headache (44%), tremor (31%), dizziness (21%), aphasia (18%), delirium (17%), insomnia (9%) and anxiety (9%). Prolonged encephalopathy lasting up to 173 days was noted. Serious events including leukoencephalopathy and seizures occurred with Yescarta®. Fatal and serious cases of cerebral edema have occurred in patients treated with Yescarta®. Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of neurologic toxicities. Monitor patients for signs or symptoms of neurologic toxicities for 4 weeks after infusion and treat promptly.

YESCARTA® REMS: Because of the risk of CRS and neurologic toxicities, Yescarta® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Yescarta® REMS. The required components of the Yescarta® REMS are: Healthcare facilities that dispense and administer Yescarta® must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of 2 doses of tocilizumab are available for each patient for infusion within 2 hours after Yescarta® infusion, if needed for treatment of CRS. Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense or administer Yescarta® are trained about the management of CRS and neurologic toxicities. Further information is available at www.YESCARTAREMS.com or 1-844-454-KITE (5483).

HYPERSENSITIVITY REACTIONS: Allergic reactions may occur. Serious hypersensitivity reactions including anaphylaxis may be due to dimethyl sulfoxide (DMSO) or residual gentamicin in Yescarta®.

SERIOUS INFECTIONS: Severe or life-threatening infections occurred. Infections (all grades) occurred in 38% of patients, and in 23% with ≥ Grade 3. Grade 3 or higher infections with an unspecified pathogen occurred in 16% of patients, bacterial infections in 9%, and viral infections in 4%. Yescarta® should not be administered to patients with clinically significant active systemic infections. Monitor patients for signs and symptoms of infection before and after Yescarta® infusion and treat appropriately. Administer prophylactic anti-microbials according to local guidelines. Febrile neutropenia was observed in 36% of patients and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad spectrum antibiotics, fluids and other supportive care as medically indicated. Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure and death, can occur in patients treated with drugs directed against B cells. Perform screening for HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing.

PROLONGED CYTOPENIAS: Patients may exhibit cytopenias for several weeks following lymphodepleting chemotherapy and Yescarta® infusion. Grade 3 or higher cytopenias not resolved by Day 30 following Yescarta® infusion occurred in 28% of patients and included thrombocytopenia (18%), neutropenia (15%), and anemia (3%). Monitor blood counts after Yescarta® infusion.

HYPOGAMMAGLOBULINEMIA: B-cell aplasia and hypogammaglobulinemia can occur. Hypogammaglobulinemia occurred in 15% of patients. Monitor immunoglobulin levels after treatment and manage using infection precautions, antibiotic prophylaxis and immunoglobulin replacement. The safety of immunization with live viral vaccines during or following Yescarta® treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during Yescarta® treatment, and until immune recovery following treatment.

SECONDARY MALIGNANCIES: Patients may develop secondary malignancies. Monitor life-long for secondary malignancies. In the event that a secondary malignancy occurs, contact Kite at 1-844-454-KITE (5483) to obtain instructions on patient samples to collect for testing.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES: Due to the potential for neurologic events, including altered mental status or seizures, patients are at risk for altered or decreased consciousness or coordination in the 8 weeks following Yescarta® infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥ 20%) include CRS, fever, hypotension, encephalopathy, tachycardia, fatigue, headache, decreased appetite, chills, diarrhea, febrile neutropenia, infections-pathogen unspecified, nausea, hypoxia, tremor, cough, vomiting, dizziness, constipation, and cardiac arrhythmias.

Please see accompanying full Prescribing Information, including **BOXED WARNING** and Medication Guide.

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 the Phase 3 study of Yescarta for the treatment of relapsed or refractory large B-cell lymphoma (ZUMA-7) and the Phase 1/2 studies of KTE-C19 for the treatment of acute lymphoblastic leukemia and other hematologic cancers in the currently anticipated timelines, or at all. In addition, there is the possibility of unfavorable results from additional clinical trials involving Yescarta and KTE-C19. Further, Kite may be unable to obtain regulatory approval for axicabtagene ciloleucel from the European Commission 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, 2018, 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.

*US Prescribing Information for Yescarta, including **BOXED WARNING** and Medication Guide, is available at www.kitepharma.com and www.gilead.com.*

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 1-650-574-3000.

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