



Kite to Present New Data From Industry-leading Cell Therapy Portfolio at ASH 2019

November 6, 2019

-- **Survival Data at Three Years in ZUMA-1 and Results from Study Cohort Evaluating Safety and Efficacy of Earlier Steroid Use with Yescarta® (axicabtagene ciloleucel) in Large B-cell Lymphoma to be Presented --**

-- **Eight Abstracts, Including Five Oral Presentations, Highlight Latest Advances in CAR T Cell Therapy --**

SANTA MONICA, Calif.--(BUSINESS WIRE)--Nov. 6, 2019-- Kite, a Gilead Company (Nasdaq: GILD), today announced the acceptance of eight abstracts, including five oral presentations, for Yescarta® (axicabtagene ciloleucel) and other ongoing research from the company's chimeric antigen receptor (CAR) T cell therapy development program, at the 61st American Society of Hematology (ASH) Annual Meeting & Exposition, in Orlando from December 7–10, 2019.

Data from Kite's CAR T cell therapy development program to be presented at the meeting include survival data at three years from the pivotal ZUMA-1 trial of Yescarta in patients with refractory large B-cell lymphoma to be highlighted in the ZUMA-1 mechanism of relapse presentation below (Abstract #203), as well as primary results from a cohort investigating the effect of earlier steroid use with Yescarta on the rates of cytokine release syndrome and neurologic events (Abstract #243). Real-world data on Yescarta, including an analysis of post-marketing outcomes for Yescarta in large B-cell lymphoma (Abstract #764), as well as the primary analysis for the ZUMA-2 study evaluating investigational KTE-X19 in relapsed or refractory mantle cell lymphoma (Abstract #754), will also be presented.

"As we continue to lead the field in cell therapy, this year's ASH Annual Meeting will be a seminal one for Kite," said Christi Shaw, Chief Executive Officer of Kite. "We are excited to share three-year survival data, insights into potential adverse event management and findings from other studies that help further the understanding of Yescarta and cell therapy as we aim to bring this potentially life-saving treatment approach to as many appropriate people with blood cancers as possible."

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, and 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. The Yescarta U.S. Prescribing Information has a BOXED WARNING for the risks of cytokine release syndrome and neurologic toxicities; see below for Important Safety Information.

Dates and times for presentations are as follows:

Area of Focus, Presentation Number and Date/Time (ET)	Abstract Title
Presentations	
Large B-cell Lymphoma Abstract #203 (Oral) Saturday, Dec 7 (1:00 pm)	CD19-Loss with Preservation of Other B-Cell Lineage Features with Large B-Cell Lymphoma Who Relapsed Post-Axi-Cel
Large B-cell Lymphoma Abstract #243 (Oral) Saturday, Dec 7 (2:30 pm)	Earlier Steroid Use with Axicabtagene Ciloleucel (Axi-Cel) in Patients with Relapsed/Refractory Large B-Cell Lymphoma
Large B-cell Lymphoma Abstract #793 (Oral) Monday, Dec 9 (2:45 pm)	Medicare Patients Receiving Chimeric Antigen Receptor T Cell Therapy for Non-Hodgkin Lymphoma: A First Real-world Look at Patient Characteristics, Healthcare Utilization and Costs
Large B-cell Lymphoma Abstract #764 (Oral) Monday, Dec 9 (3:00 pm)	Outcomes of Post-marketing Use of an Anti-CD19 CAR T Cell Therapy, Axicabtagene Ciloleucel (Axi-Cel), for the Treatment of Large B-Cell Lymphoma in the United States
Mantle Cell Lymphoma Abstract #754 (Oral) Monday, Dec 9 (3:30 pm)	KTE-X19, an Anti-CD19 CAR T Cell Therapy, in Patients with Relapsed/Refractory Mantle Cell Lymphoma: Results of the Phase 2 ZUMA-2 Study
Large B-cell Lymphoma Abstract #4095 (Poster) Monday, Dec 9 (6:00-8:00 pm)	A Comparison of Two-year Outcomes in ZUMA-1 (Axicabtagene Ciloleucel) and SCHOLAR-1 in Patients with Refractory Large B-Cell Lymphoma

Trials-In-Progress

Large B-cell Lymphoma
Abstract #4084 (Poster)
Monday, Dec 9 (6:00-8:00 pm)

ZUMA-11: A Phase 1/2 Multicenter Study of Axicabtagene Ciloleuce (Axi-Cel) + Utomilumab in Patients with Refractory Large B-Cell Lymphoma

Large B-cell Lymphoma
Abstract #4093 (Poster)
Monday, Dec 9 (6:00-8:00 pm)

A Phase 2, Open-label, Multicenter Study Evaluating the Safety and Efficacy of Axicabtagene Ciloleuce in Combination with Either Rituximab or Lenalidomide in Patients with Refractory Large B-Cell Lymphoma (ZUMA-14)

For more information, including a complete list of abstract titles at the meeting, please visit: <https://ash.confex.com/ash/2019/webprogram/start.html>.

The use of Yescarta with utomilumab, rituximab, or lenalidomide is investigational and not approved globally. Efficacy and safety of these potential combinations have not been established. KTE-X19 is investigational and not approved anywhere globally. Its efficacy and safety have not been established. More information about clinical trials with KTE-X19 is available at www.clinicaltrials.gov.

About KTE-X19

KTE-X19 is an investigational, autologous, anti-CD19 CAR T cell therapy. KTE-X19 uses the XLP™ manufacturing process that includes T-cell selection and lymphocyte enrichment. Lymphocyte enrichment is a necessary step in certain B-cell malignancies with evidence of circulating lymphoblasts. KTE-X19 is currently in Phase 1/2 trials in acute lymphoblastic leukemia (ALL), mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL).

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.

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 the possibility of unfavorable results from other ongoing and additional clinical trials involving Yescarta or KTE-X19. Further, it is possible that Kite may make a strategic decision to discontinue development of KTE-X19, and as a result, KTE-X19 may never be successfully commercialized. 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 September 30, 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.

*U.S. Prescribing Information for Yescarta, including **BOXED WARNING**, is available at www.kitepharma.com and www.gilead.com.*

Yescarta, Axi-Cel and XLP are trademarks of Gilead Sciences, Inc., or its related companies.

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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Source: Kite, a Gilead Company

Greg Mann, Investors
(424) 322-1795

Nathan Kaiser, Media
(650) 522-1853