Kite to Present New Data From Leading Cell Therapy Portfolio at ASCO 2019

May 15, 2019

-- New Safety Data Involving Steroid Use and New Subpopulation Analyses from Pivotal ZUMA-1 Trial to Provide Greater Understanding of Yescarta® in Patients with Relapsed or Refractory Large B-cell Lymphoma --

-- End of Phase 1 Results from ZUMA-3 Evaluating KTE-X19 in Adults with Relapsed or Refractory Acute Lymphoblastic Leukemia to be Presented --

SANTA MONICA, Calif.--(BUSINESS WIRE)--May 15, 2019-- Kite, a Gilead Company (Nasdaq: GILD), today announced that new data from its cell therapy programs will be presented at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO) being held in Chicago from May 31 – June 4, 2019. Six abstracts highlighting updated Yescarta® (axicabtagene ciloleucel) efficacy and safety results, and ongoing research from the company's chimeric antigen receptor T (CAR T) cell therapy development program in hematologic malignancies will be presented at the meeting.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20190515005176/en/

"Our CAR T research program is progressing at a rapid pace and we are excited to share the latest data at ASCO," said John McHutchison, AO, MD, Chief Scientific Officer and Head of Research and Development, Gilead Sciences. "Our data at this year's meeting will include new analyses from the pivotal ZUMA-1 trial of Yescarta, early results from a novel approach to improve the Yescarta safety profile and results from the ZUMA-3 trial of our investigational CAR T therapy KTE-X19 in adults with acute lymphoblastic leukemia. These findings will help physicians better assess the potential role of CAR T in patients with high unmet need and continue to build upon our understanding of cell therapy."

Data from the ZUMA CAR T cell therapy development program to be presented at the meeting include new results evaluating earlier steroid use on the rates of adverse events in patients with relapsed or refractory large B-cell lymphoma treated with Yescarta, as well as a separate subpopulation analysis of efficacy and safety results in refractory large B-cell lymphoma patients over the age of 65 in the ZUMA-1 trial. End of Phase 1 data from the ZUMA-3 trial of investigational KTE-X19 in adult patients with relapsed or refractory acute lymphoblastic leukemia (ALL) will also be presented.

Details on Kite cell therapy data to be presented at the meeting include:

Area of Focus, Presentation Number and Date/Time (CDT)	**Abstract Title**
Presentations	
Acute Lymphoblastic Leukemia Abstract #7006 (Oral) *Saturday, June 1* *(5:00-5:12 pm)*	End of Phase 1 Results of ZUMA-3, a Phase 1/2 Study of KTE-X19, Anti-CD19 Chimeric Antigen Receptor T Cell Therapy, in Adult Patients with Relapsed/Refractory Acute Lymphoblastic Leukemia
Large B-Cell Lymphoma Abstract #7555 (Poster) *Monday, June 3* *(8:00-11:00 am)*	Outcomes of Patients ≥ 65 Years of Age in ZUMA-1, a Pivotal Phase 1/2 Study of Axicabtagene Ciloleucel in Refractory Large B-Cell Lymphoma
Large B-Cell Lymphoma Abstract #7558 (Poster) *Monday, June 3* *(8:00-11:00 am)*	Preliminary Results of Earlier Steroid Use with Axicabtagene Ciloleucel in Patients with Relapsed/Refractory Large B-Cell Lymphoma

Large B-Cell Lymphoma Abstract #7545 (Poster) *Monday, June 3* *(8:00-11:00 am)*	Hematopoietic Recovery and Immune Reconstitution After Axicabtagene Ciloleucel Chimeric Antigen Receptor T Cell Therapy in Patients with Relapsed/Refractory Large B-cell Lymphoma

Trials-In-Progress

Chronic Lymphocytic Leukemia Abstract #TPS7566 (Poster) *Monday, June 3* *(8:00-11:00 am)*	ZUMA-8: A Phase 1/2 Multicenter Study Evaluating KTE-X19 in Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia
Large B-Cell Lymphoma Abstract #TPS7574 (Poster) *Monday, June 3* *(8:00-11:00 am)*	ZUMA-12: A Phase 2 Multicenter Study of Axicabtagene Ciloleucel as a First-Line Therapy in Patients with High-Risk Large B-Cell Lymphoma

For more information, including a complete list of abstract titles at the meeting, please visit: https://meetinglibrary.asco.org/.

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.

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

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 ongoing and additional clinical trials involving Yescarta or KTE-X19. 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.

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

Yescarta is a registered trademark 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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