Kite and the CIBMTR® Present Positive Findings From Real-World Use of Yescarta® (Axicabtagene Ciloleucel) in Relapsed or Refractory Large B-Cell Lymphoma

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-- Post-Marketing Study with a Larger Proportion of Older and More Difficult-to-Treat Patients Demonstrates Comparable Safety and Efficacy Data to ZUMA-1 Pivotal Trial --

-- Results Presented at the American Society of Hematology (ASH) Annual Meeting --

ORLANDO, Fla.--(BUSINESS WIRE)--Dec. 9, 2019-- Kite, a Gilead Company (Nasdaq: GILD), and the CIBMTR® (Center for International Blood and Marrow Transplant Research®), the research collaboration between the National Marrow Donor Program® (NMDP)/Be The Match® and the Medical College of Wisconsin (MCW), today announced findings from an ongoing post-marketing study evaluating the safety and efficacy of Yescarta® (axicabtagene ciloleucel) in adult patients with relapsed or refractory large B-cell lymphoma. In this analysis, efficacy and safety of Yescarta were comparable to that observed in the ZUMA-1 trial, despite a larger proportion of older, more difficult-to-treat patients in the real-world setting. The findings were presented today at the 61st American Society of Hematology (ASH) Annual Meeting & Exposition, held in Orlando from December 7–10, 2019.

“The similar efficacy and safety results seen across this post-approval analysis and the ZUMA-1 registrational trial are extremely encouraging for appropriate patients with relapsed or refractory large B-cell lymphoma who may benefit from Yescarta,” said Marcelo Pasquini, MD, MS, co-lead investigator and Senior Scientific Director of the CIBMTR; Cellular Therapy Registry Director; and Associate Professor of Medicine, Division of Hematology / Oncology at the Medical College of Wisconsin. “The comparable early outcomes, including side effects, support the potential of Yescarta in older, higher risk and more difficult-to-treat patients that physicians often see in the clinic.”

In October 2017, Yescarta became 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 (PMBCL), 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 U.S. Prescribing Information for Yescarta contains a Boxed Warning regarding the risk of cytokine release syndrome (CRS) and neurological toxicities; see below for Important Safety Information.

The post-approval study population (n=533) included a larger proportion of older patients (≥65 years; 37 percent versus 25 percent) and more patients with double and triple hit lymphoma (36 percent versus 11 percent) compared to ZUMA-1.

At follow-up of at least six months after a single infusion of Yescarta, the best objective response via investigator assessment among the 326 patients evaluable for efficacy showed an objective response rate (ORR) of 84 percent, with 66 percent of patients having achieved a complete response (CR). ORR was similar among older and younger patients (92 percent in patients ≥65 years versus 80 percent in patients <65 years). Patients ≥65 years (n=108) achieved a CR rate of 72 percent versus 62 percent in patients <65 years (n=218).

Among all patients evaluable for safety (n=533), those 65 years or older had comparable rates of CRS (Any Grade: 84 percent vs. 80 percent; Grade ≥3: 10 percent vs. 8 percent) and neurologic toxicity (Any grade: 64 percent vs. 55 percent; Grade ≥3: 22 percent vs. 19 percent) as those under 65 years. Four patients died due to CRS, four patients died from neurologic toxicity and one patient died from both CRS and neurologic toxicity. This Grade 5 AE rate of approximately 1 percent for CRS and neurologic toxicity each is comparable to ZUMA-1.

“With more than 85 centers authorized to treat patients with Yescarta, these post-approval results reinforce its potentially transformative role in third line or later relapsed or refractory large B-cell lymphoma,” said Christi Shaw, Chief Executive Officer of Kite. “The demonstrated efficacy and safety of Yescarta in the real-world setting, coupled with our industry-leading manufacturing that has delivered for thousands of patients so far, means physicians have a real opportunity to bring the potential benefits of CAR T to their patients in need.”

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.

About the CIBMTR

The CIBMTR® (Center for International Blood and Marrow Transplant Research®) is a research collaboration between the National Marrow Donor Program® (NMDP)/Be The Match® and the Medical College of Wisconsin (MCW). Through a collaboration with Be The Match BioTherapies®, a subsidiary of NMDP/Be The Match, the organizations offer end-to-end solutions for cell and gene therapy developers, including cell sourcing and collection support, clinical trial services, supply chain and logistics, manufacturing and commercialization support, and outcomes management. The CIBMTR collaborates with the global scientific community to advance hematopoietic cell transplantation (HCT) and cellular therapy worldwide to increase survival and enrich quality of life for patients. The CIBMTR has developed a dedicated cellular therapy registry which now serves as the infrastructure for the National Cancer Institute -funded Cellular Immunotherapy Data Resource (CIDR) and further expands the utilization of this

resource by the general biomedical community. The CIBMTR facilitates critical observational and interventional research through scientific and statistical expertise, a large network of transplant centers, and a unique and extensive clinical outcomes database.

For more information on the CIBMTR, please visit www.cibmtr.org.

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. There is also the risk that physicians may not see the benefits of the use of Yescarta for relapsed or refractory large B-cell lymphoma in the older and more difficult-to-treat patient population as described herein. 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 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 or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000. Follow Kite on social media on Twitter (@KitePharma) and LinkedIn.

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