Kite and Kiniksa Pharmaceuticals Announce Clinical Collaboration Evaluating Investigational Combination of Yescarta® and Mavrilimumab in Relapsed or Refractory Large B-Cell Lymphoma

December 11, 2019

-- Phase 2 study will Examine the Effect of Mavrilimumab on the Clinical Profile of Yescarta --

SANTA MONICA, Calif., & HAMILTON, Bermuda--(BUSINESS WIRE)--Dec. 11, 2019-- Kite, a Gilead Company (Nasdaq: GILD), and Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) ("Kiniksa") announced today that the companies have entered into a clinical collaboration to conduct a Phase 2, multicenter study of mavrilimumab, an investigational fully human monoclonal antibody that targets granulocyte macrophage colony stimulating factor receptor alpha (GM-CSFRα), in combination with Yescarta® (axicabtagene ciloleucel) in patients with relapsed or refractory large B-cell lymphoma. The objective of the study is to determine the effect of mavrilimumab on the safety of Yescarta. Kite will be the sponsor of this study and will be responsible for its conduct.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20191211005149/en/

"We were excited to present data from several abstracts at the recent ASH meeting that build upon our understanding of the efficacy and safety profile of Yescarta and we are committed to the exploration of new approaches and treatment combinations that further optimize outcomes for patients," said Christi Shaw, Chief Executive Officer of Kite. "We look forward to working with Kiniksa to learn more about the potential impact of GM-CSFRα inhibition with mavrilimumab."

"The clinical collaboration with Kite furthers Kiniksa's goal to develop life-changing medicines for patients with significant unmet medical need," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "We believe the potential for GM-CSFRα inhibition to advance the clinical profile for CAR T cell therapy speaks to the potential broad utility of mavrilimumab."

Treatment related induction of GM-CSF has been identified through clinical, translational and preclinical studies as a potential key signal associated with side effects of chimeric antigen receptor T (CAR T) cell therapy. Preclinical evidence shows the potential for interruption of GM-CSF signaling to disrupt CAR T cell mediated inflammation without disrupting anti-tumor efficacy.

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.

Mavrilimumab, alone or in combination with other therapies such as Yescarta, is investigational and has not been approved by the FDA or any regulatory authority for any uses. Efficacy and safety have not been established.

About Mavrilimumab

Mavrilimumab is an investigational fully-human monoclonal antibody that is designed to antagonize GM-CSF signaling by binding to the alpha subunit of the GM-CSF receptor. Kiniksa is developing mavrilimumab for the potential treatment of giant cell arteritis (GCA), a chronic inflammatory disease of medium to large arteries.

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 Kiniksa

Kiniksa is a biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need. Kiniksa has a pipeline of product candidates across various stages of

development, focused on autoinflammatory and autoimmune conditions. For more information, please visit www.kiniksa.com.

Gilead 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 parties' ability to complete the Phase 2 clinical trial evaluating the combination of Yescarta and mavrilimumab in the currently anticipated timelines, or at all. In addition, there is the possibility of unfavorable results from other ongoing and additional clinical trials involving this combination and Yescarta. 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.

Kiniksa Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these identifying words. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, statements regarding: our collaboration with Kite; the Phase 2 clinical trial evaluating the combination of Yescarta and mavrilimumab; proposed indications for the investigation of mavrilimumab, including in a combination with Yescarta; the potential for mavrilimumab with respect to CAR T cell mediated inflammation and otherwise; and plans and timing to report or present clinical trial and other data with respect to mavrilimumab.

These forward-looking statements are based on management's current plans, estimates or expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including without limitation, the following: potential delays or difficulty in enrollment of patients in, and activation of sites for, clinical trials with mavrilimumab (including the Phase 2 clinical trial evaluating the combination of Yescarta and mavrilimumab, collectively the "clinical trials"); potential complications in coordinating among requirements, regulations and guidelines of regulatory authorities across a number of jurisdictions for the clinical trials; potential amendments to the clinical trial protocols; potential delays or difficulty in completing the clinical trials, including as a result of clinical trial design; potential undesirable side effects caused by mavrilimumab, including in combination with Yescarta; the potential inability to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities or otherwise producing negative, inconclusive or commercially uncompetitive results from the clinical trials; potential for changes between final data and any preliminary and interim "top-line" data we or the parties may announce; impact of additional data from the parties, us, Kite or other companies, including from other ongoing clinical trials involving this combination and Yescarta; the potential inability to replicate in later clinical trials positive results from earlier pre-clinical and clinical trials; our reliance on certain third parties as the sole manufacturer and source of supply of the drug substance and drug products used in mavrilimumab; and our reliance on third parties to conduct the clinical trials, including the Phase 2 clinical trial in collaboration with Kite.

These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission ("SEC") on November 5, 2019 and our other reports subsequently filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's plans, estimates, or expectations as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

*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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