Kite and Humanigen Announce Clinical Collaboration to Evaluate Investigational Combination of Yescarta® (Axicabtagene Ciloleucel) with Lenzilumab in Relapsed/Refractory Diffuse Large B-Cell Lymphoma

May 31, 2019

-- Phase 1/2 Multi-Center Clinical Trial to Begin Enrolling in Q4 2019 --

SANTA MONICA, Calif. & BURLINGAME, Calif.--(BUSINESS WIRE)--May 31, 2019-- Kite, a Gilead Company (Nasdaq: GILD), and Humanigen, Inc. (HGEN)announced today the formation of a clinical collaboration to conduct a Phase 1/2 study of lenzilumab, an investigational anti-GM-CSF monoclonal antibody, with Yescarta® (axicabtagene ciloleucel) in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). The objective of this study is to determine the effect of lenzilumab on the safety of Yescarta. Kite will act as 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/20190531005070/en/

GM-CSF has been identified, through clinical correlative analysis and preclinical modeling, as a potential key signal in the inflammatory cascade triggering toxicities associated with chimeric antigen receptor T (CAR T) cell therapy.[1] Toxicities associated with CAR T therapy include neurologic toxicity and cytokine release syndrome (CRS). Emerging pre-clinical evidence suggests that lenzilumab inhibition of GM-CSF may have the potential to disrupt CAR T cell mediated inflammation without disrupting CAR T cell anti-tumor efficacy.

“CAR T therapy represents a significant advance in the way relapsed or refractory large B-cell lymphoma is treated,” said John McHutchison, AO, MD, Chief Scientific Officer, Head of Research and Development, Gilead. “As leaders in cell therapy, we are committed to pursuing a number of clinical and preclinical strategies aimed at further improving the efficacy and safety of CAR T therapy. We look forward to this clinical collaboration with Humanigen and to evaluating the combination of lenzilumab and Yescarta in our clinical trial.”

“Humanigen has pioneered the approach to neutralizing GM-CSF to improve CAR T,” said Cameron Durrant, MD, Chief Executive Officer, Humanigen. “This collaboration with Kite will help validate the work Humanigen has done in understanding the pathophysiology of the inflammatory cascade as well as the potential role GM-CSF plays in influencing CAR T cell treatment outcomes.”

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 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.

Lenzilumab, 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 yet been established.

Stifel, Nicolaus & Company, Incorporated acted as exclusive financial advisor to Humanigen in this transaction.

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 Humanigen, Inc.

Humanigen, Inc. is developing its portfolio of Humaneered® monoclonal antibodies to address cutting-edge CAR-T optimization and the need for new oncology drugs that provide safer, better, and more effective cancer therapies. Derived from the company's Humaneered® platform, lenzilumab, ifabotuzumab, and HGEN005 are monoclonal antibodies with first-in-class mechanisms. Lenzilumab, which neutralizes human GM-CSF, is in development as a potential biologic therapy to make CAR-T therapy safer and more effective, as well as a potential treatment for hematologic cancers. Ifabotuzumab, which targets the Eph type-A receptor 3 (EphA3), is being explored as a potential treatment for a range of solid tumors, as well as a backbone for a novel CAR-T construct, and a bispecific antibody platform. HGEN005 which selectively targets the eosinophil receptor EMR1 is being explored as a potential treatment for a range of eosinophilic diseases including eosinophilic leukemia both as an optimized naked antibody and as the backbone for a novel CAR-T construct. For more information, visit www.humanigen.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 Kite's ability to complete the Phase 1/2 study of Yescarta in combination with lenzilumab in patients with relapsed or refractory DLBCL in the currently anticipated timelines, or at all. In addition, there is the possibility of unfavorable results from clinical trials involving this combination, Yescarta and other investigational CAR T therapies. Further, it is possible that the parties may make a strategic decision to discontinue development of the investigational combination of Yescarta and lenzilumab. 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.

Humanigen Forward-Looking Statement

This release contains forward-looking statements. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct and you should be aware that actual events or results may differ materially from those contained in the forward-looking statements. Words such as "will," "expect," "intend," "plan," "potential," "possible," "goals," "accelerate," "continue," and similar expressions identify forward-looking statements, including, without limitation, statements regarding our expectations for future development of lenzilumab to help CAR-T therapy reach its full potential. Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, the risks inherent in Black Horse Capital and its affiliates owning more than 50% of our outstanding common stock, including their ability to control the company; our lack of profitability and need for additional capital to operate our business as a going concern; the uncertainties inherent in the development and launch of any new pharmaceutical product; the outcome of pending or future litigation; and the various risks and uncertainties described in the "Risk Factors" sections and elsewhere in the Company's periodic and other filings with the Securities and Exchange Commission.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You should not place undue reliance on any forward-looking statements, which speak only as of the date of this release. We undertake no obligation to revise or update any forward-looking statements made in this press release to reflect events or circumstances after the date hereof or to reflect new information or the occurrence of unanticipated events, except as required by law.

*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.

1. Sterner, R., Sakemura, R., Cox, M., Yang, N., Khadka, R., Forsman, C.,... Kenderian, S. (2019). GM-CSF inhibition reduces cytokine release syndrome and neuroinflammation but enhances CAR-T cell function in xenografts. Blood : the official journal of the American Society of Hematology, 133:697-709. doi: https://doi.org/10.1182/blood-2018-10-881722

View source version on businesswire.com: https://www.businesswire.com/news/home/20190531005070/en/

Source: Kite, a Gilead Company

Kite, A Gilead Company,Contacts:
Sung Lee, Investors
(650) 524-7792

Shant Salakian, Media
(424) 384-1841

Humanigen Contacts:
Al Palombo, Investors
(650) 243-3181
ir@humanigen.com

Chris Bowe, Media
(646) 662-7628
cbowe@humanigen.com