Gilead and Kite Continue to Advance Next Generation Cancer Therapies at 2020 American Society of Clinical Oncology Annual Meeting

May 13, 2020

-- Nine Abstracts, Including Three Oral Presentations, Highlight Leadership in Hematologic Malignancies and Early Progress in Solid Tumors --

-- Interim Analysis from Phase 2 Study Investigating Yescarta® in Indolent Non-Hodgkin Lymphoma and New Phase 1b Data for Investigational Magrolimab Among Oral Presentations --

FOSTER CITY, Calif. & SANTA MONICA, Calif.--(BUSINESS WIRE)--May 13, 2020-- Gilead Sciences, Inc. (Nasdaq: GILD) and Kite, a Gilead Company, today announced the acceptance of nine abstracts, including three oral presentations across its immuno-oncology research and development program, during the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting being held from May 29-31, 2020. Data at ASCO include abstracts highlighting Kite’s leading cell therapy portfolio and magrolimab, an investigational anti-CD47 monoclonal antibody developed by Forty Seven, Inc., which was recently acquired by Gilead.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200513005577/en/

“Gilead has a deep commitment to innovation in oncology. Our colleagues at Kite are driving advances in cell therapy, and our growing immuno-oncology portfolio at Gilead now includes magrolimab, which has the potential to be a first-in-class anti-CD47 antibody based on its mechanism of action and emerging clinical data."

Continuing Scientific Advances in Hematologic Malignancies

Updated results from a Phase 1b study of magrolimab in patients with myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML), including highly under-served AML patients with P53 mutations, will be the focus of an oral presentation (Abstract #7507). Magrolimab has the potential to be a first-in-class anti-CD47 antibody based on its mechanism of action and emerging clinical data.

Additionally, new data building on Kite’s leadership in chimeric antigen receptor (CAR) T cell therapy include an interim analysis from the Phase 2 ZUMA-5 study evaluating an investigational use of Yescarta® (axicabtagene ciloleucel) in patients with relapsed or refractory indolent non-Hodgkin lymphoma (iNHL). These data will also be featured in an oral presentation (Abstract #8008). Yescarta has been granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA) for relapsed or refractory follicular lymphoma or marginal zone lymphoma (two subtypes of iNHL) after at least two prior systemic therapies.

“At Kite, we are committed to advancing science to bring potentially curative therapies to patients with hematologic malignancies and other cancers,” said Ken Takeda, MD, Kite’s Global Head of Clinical Development. “Our data at ASCO represent important progress as we work toward this goal.”

Early Progress with Cell Therapy in Solid Tumors

Data focused on T cell receptor (TCR) technology, a promising approach to solid tumor-directed cell therapy under investigation, also will be featured in an oral presentation. Results from a Phase 1 clinical trial conducted by the National Cancer Institute (NCI), as part of a Cooperative Research and Development Agreement (CRADA) between the Experimental Transplantation and Immunology Branch (ETIB) of the NCI and Kite, describe the safety and clinical activity of E7 TCR T cells in patients with highly refractory metastatic human papillomavirus (HPV)-16 cancers, such as vulvar, anal, head and neck, and cervical cancer (Abstract #101). Additionally, Kite has an IND for its own candidate, KITE-439, based on the NCI E7 TCR, and is currently conducting a Phase 1 study of investigational KITE-439 in patients with relapsed or refractory HPV-16-positive cancers (Abstract #TPS3149).

Accepted abstracts are as follows:

<table>
<thead>
<tr>
<th>Area of Focus</th>
<th>Presentation Number</th>
<th>Abstract Title</th>
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<tbody>
<tr>
<td>MDS and AML</td>
<td>Abstract #7507 (Oral)*</td>
<td>Tolerability and Efficacy of the First-in-Class Anti-CD47 Antibody Magrolimab Combined with Azacitidine in MDS and AML Patients: Phase 1b Results</td>
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<td>Non-Hodgkin Lymphoma</td>
<td>Abstract #8008 (Oral)*</td>
<td>Interim Analysis of ZUMA-5: A Phase 2 Study of Axicabtagene Ciloleucel (Axi-Cel) in Patients with Relapsed/Refractory Indolent Non-Hodgkin Lymphoma (R/R iNHL)</td>
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<td>Solid Tumors</td>
<td>Abstract #101 (Oral)* (NCI study: NCT02858310)</td>
<td>Safety and Clinical Activity of Gene-engineered T-Cell Therapy Targeting HPV-16 E7 for Epithelial Cancers</td>
</tr>
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Large B-cell Lymphoma
Abstract #8012 (Poster 345)*
Retreatment of Patients with Refractory Large B-cell Lymphoma with Axicabtagene Ciloleucel (Axi-Cel) in ZUMA-1

Mantle Cell Lymphoma
Abstract #3023 (Poster 87)*
Product Characteristics and Pharmacological Profile of KTE-X19 in Patients With Relapsed/Refractory Mantle Cell Lymphoma (MCL) in the Phase 2 Registrational ZUMA-2 Trial

Large B-cell Lymphoma
Abstract #3022 (Poster 86)*
Tumor Microenvironment Associated With Increased Pretreatment Density of Activated PD-1+ LAG-3+/− TIM-3− CD8+ T Cells Facilitates Clinical Response to Axicabtagene Ciloleucel (Axi-Cel) in Patients with Large B-cell Lymphoma

Trials-In-Progress

Solid Tumors
Abstract #TPS3149 (Poster 213)*
KITE-439: A Phase 1 Study of HPV16 E7 T Cell Receptor-Engineered T Cells in Patients with Relapsed/Refractory HPV16-Positive Cancers

Online Publication

Lymphoma
(Online only)
Health-Related Quality of Life Burden in Patients with Relapsed/Refractory Diffuse Large B-cell Lymphoma and Non-Hodgkin’s Lymphoma

MDS and AML
(Online only)
Pharmacokinetic-Pharmacodynamic Analysis and Receptor Occupancy Data to Support Every Other Week Maintenance Dosing of Magrolimab in Combination with Azacitidine in MDS/AML Patients

*Presentation will be made available on-demand beginning Friday, May 29 at 8:00 am ET.

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 (CRS) and neurologic toxicities, and Yescarta is approved with a risk evaluation and mitigation strategy (REMS) due to these risks; see below for Important Safety Information.

The use of Yescarta in relapsed or refractory iNHL is investigational and not approved globally. It’s efficacy and safety have not been established in this indication. Magrolimab, KTE-X19 and KITE-439 are investigational and not approved anywhere globally. Their efficacy and safety have not been established. More information about clinical trials with magrolimab, KTE-X19 and KITE-439 is available at www.clinicaltrials.gov.

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
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. 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. Fever or 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 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 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.

Gilead and Kite Forward-Looking Statements

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 studies involving Yescarta, magrolimab, KTE-X19 and KITE-439. 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, 2020, 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.