Gilead to Present Latest Scientific Research in Hematologic Malignancies and Solid Tumors at ASH 2018

November 1, 2018 9:02 AM ET

-- Data Reinforce Breadth of Cell Therapy Portfolio and Commitment to Continued Innovation for People with Advanced Cancers --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Nov. 1, 2018-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced data from its oncology and cell therapy research programs will be presented at the 60th American Society of Hematology (ASH) Annual Meeting & Exposition, in San Diego from December 1 – 4, 2018. Twelve abstracts will be presented, including data highlighting Gilead's broad cell therapy pipeline in hematologic malignancies and solid tumors.

Notable data to be presented at the meeting include new analyses from the ZUMA chimeric antigen receptor T (CAR T) cell therapy development program, including long-term data from the Yescarta® (axicabtagene ciloleucel) ZUMA-1 trial showing efficacy and safety results with a minimum follow-up of two years in certain patients with refractory large B-cell lymphoma, and updates to the ZUMA-3 study evaluating investigational KTE-X19 (formerly KTE-C19) in adult patients with relapsed or refractory acute lymphoblastic leukemia (ALL). Data from two trials as part of Cooperative Research and Development Agreements (CRADAs) between the Experimental Transplantation and Immunology Branch (ETIB) of the National Cancer Institute (NCI) Center for Cancer Research and Kite, a Gilead Company, to further the research and clinical development of cell therapies, including a T cell receptor (TCR) product candidate for the treatment of HPV-associated solid tumors, will also be presented in oral sessions.

"At Gilead and Kite, we are proud to be leading the field of cell therapy with our research and development efforts on behalf of patients," said Alessandro Riva, MD, Gilead's Executive Vice President, Oncology Therapeutics & Head, Cell Therapy. "We look forward to sharing data at ASH that highlight the long-term treatment observed with Yescarta in refractory large B-cell lymphoma, as well as the potential of our pipeline of investigational cell therapies in treating other advanced cancers."

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, 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.

Key presentations at ASH will include:

Area of Focus, Presentation Number and Date/Time (PST)	**Abstract Title**
Cell Therapy Presentations	
Large B-Cell Lymphoma	
Abstract #2967 (Poster) *Sunday, Dec 2 (6:00-8:00 pm)*	2-Year Follow-Up and High-Risk Subset Analysis of ZUMA-1, the Pivotal Study of Axicabtagene Ciloleucel (Axi-Cel) in Patients With Refractory Large B Cell Lymphoma
Solid Tumors	
Abstract #492 (Oral)	Regression of Epithelial Cancers Following T Cell Receptor Gene Therapy Targeting Human Papillomavirus-16 E7

Sunday, Dec 2 (5:45 pm) Large B-Cell Lymphoma	
Abstract #678 (Oral)	Analysis of CAR-T and Immune Cells within the Tumor Micro-Environment of Diffuse Large B-Cell Lymphoma Post CAR-T Treatment By Multiplex Immunofluorescence
Monday, Dec 3 (11:45 am) Large B-Cell Lymphoma	
Abstract #697 (Oral)	Low Levels of Neurologic Toxicity with Retained Anti-Lymphoma Activity in a Phase I Clinical Trial of T Cells Expressing a Novel Anti-CD19 CAR
Monday, Dec 3 (10:30 am) ALL	
Abstract #897 (Oral)	Updated Phase 1 Results of ZUMA-3: KTE-C19, an Anti-CD19 Chimeric Antigen Receptor T Cell Therapy, in Adult Patients With Relapsed/Refractory Acute Lymphoblastic Leukemia
Monday, Dec 3 (5:00 pm) Large B-Cell Lymphoma	
Abstract #4192 (Poster)	End of Phase 1 Results From ZUMA-6: Axicabtagene Ciloleucel (Axi-Cel) in Combination With Atezolizumab for the Treatment of Patients With Refractory Diffuse Large B Cell Lymphoma
Monday, Dec 3 (6:00-8:00 pm) Large B-Cell Lymphoma	
Abstract #4779 (Poster)	Cost-Effectiveness of Axicabtagene Ciloleucel for Relapsed or Refractory Diffuse Large B-Cell Lymphoma in Italy
Monday, Dec 3 (6:00-8:00 pm) Large B-Cell Lymphoma	
Abstract #4795 (Poster)	Comparing Survival for Different CAR Ts: Need for Addressing Bias Due to Differences in the Pre-Infusion Period
Monday, Dec 3 (6:00-8:00 pm)	

Additional Key Hematology Presentations

CLL/FL	
Abstract #2302 (Poster)	Real-World Clinical Management of Patients Treated with Idelalisib in France: A Study of 529 Cases of Chronic Lymphocytic Leukemia (CLL) and Follicular Lymphoma (FL)
Saturday, Dec 1 (6:15-8:15 pm) CLL	
Abstract #3135 (Poster)	Updated Preliminary Results of a Phase 1b Dose Escalation and Dose Expansion Study of Tirabrutinib Alone or in Combination with Idelalisib or Entospletinib in Patients with Previously Treated Chronic Lymphocytic Leukemia
Sunday, Dec 2 (6:00-8:00 pm) CLL/FL	
Abstract #3149 (Poster)	Survival Outcomes Following Idelalisib Interruption in the Treatment of Relapsed or Refractory Indolent Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia
Sunday, Dec 2 (6:00-8:00 pm)	

CLL

Abstract #4428 (Poster) *Monday, Dec 3 (6:00-8:00 pm)*	Results From a Prospective Real World Study Show Strong Efficacy of Idelalisib in CLL, Including High-Risk CLL, and Provide Evidence That PJP Prophylaxis Positively Impacts On Overall Survival

For more information, including a complete list of abstract titles at the meeting, please visit: http://www.hematology.org/Annual-Meeting/3225.aspx.

Zydelig® (idelalisib) is approved in the U.S. for the treatment of relapsed follicular lymphoma (FL) or small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies, and relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate due to other comorbidities. Accelerated approval was granted for FL based on overall response rate. An improvement in patient survival or disease-related symptoms has not been established. Zydelig is not indicated or recommended for first-line treatment of any patient or in combination with bendamustine and/or rituximab for the treatment of FL. The Zydelig U.S. Prescribing Information has a BOXED WARNING for the risks of fatal and serious toxicities: hepatic, severe diarrhea, colitis, pneumonitis, infections, and intestinal perforation; see below for Important Safety Information.

KTE-X19, the combination of axicabtagene ciloleucel with atezolizumab, and tirabrutinib alone or in combination with idelalisib or entospletinib are investigational and are not approved globally; the safety and efficacy have not 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.

Please see accompanying full Prescribing Information, including **BOXED WARNING** and Medication Guide.

U.S. Important Safety Information for Zydelig

BOXED WARNING: FATAL AND SERIOUS TOXICITIES: HEPATIC, SEVERE DIARRHEA, COLITIS, PNEUMONITIS, INFECTIONS, AND INTESTINAL PERFORATION

- **Fatal and/or serious hepatotoxicity occurred in 16% to 18% of Zydelig®-treated patients. Monitor hepatic function prior to and during treatment. Interrupt and then reduce or discontinue Zydelig®.**
- **Fatal and/or serious and severe diarrhea or colitis occurred in 14% to 20% of Zydelig-treated patients. Monitor for the development of severe diarrhea or colitis. Interrupt and then reduce or discontinue Zydelig®.**
- **Fatal and/or serious pneumonitis occurred in 4% of Zydelig®-treated patients. Monitor for pulmonary symptoms and bilateral interstitial infiltrates. Interrupt or discontinue Zydelig®.**
- **Fatal and/or serious infections occurred in 21% to 48% of Zydelig-treated patients. Monitor for signs and symptoms of infection. Interrupt Zydelig® if infection is suspected.**
- **Fatal and serious intestinal perforation can occur in Zydelig-treated patients. Discontinue Zydelig® if intestinal perforation is suspected.**

Contraindications

- **History of serious allergic reactions,** including anaphylaxis and toxic epidermal necrolysis (TEN).

Warnings and Precautions

- **Hepatotoxicity:** Fatal and/or serious hepatotoxicity occurred in 18% of patients treated with Zydelig® monotherapy and 16% of patients treated with Zydelig® in combination with rituximab or with unapproved combination therapies. Findings were generally observed within the first 12 weeks of treatment and reversed with dose interruption. Upon rechallenge at a lower dose, ALT/AST elevations recurred in 26% of patients. In all patients, monitor ALT/AST every 2 weeks for the first 3 months, every 4 weeks for the next 3 months, and every 1 to 3 months thereafter. If ALT/AST is >3x upper limit of normal (ULN), monitor for liver toxicity weekly. If ALT/AST is >5x ULN, withhold Zydelig® and monitor ALT/AST and total bilirubin weekly until resolved. Discontinue ZYDELIG for recurrent hepatotoxicity. Avoid concurrent use with other hepatotoxic drugs.
- **Severe diarrhea or colitis:** Severe diarrhea or colitis (Grade ≥3) occurred in 14% of patients treated with Zydelig® monotherapy and 20% of patients treated with Zydelig® in combination with rituximab or with unapproved combination therapies. Grade 3+ diarrhea can occur at any time and responds poorly to antimotility agents. Avoid concurrent use with other drugs that cause diarrhea.
- **Pneumonitis:** Fatal and serious pneumonitis occurred in 4% of patients treated with Zydelig® compared to 1% on the comparator arms in randomized clinical trials of combination therapies. Time to onset of pneumonitis ranged from <1 to 15 months. Clinical manifestations included interstitial infiltrates and organizing pneumonia. Monitor patients on Zydelig® for pulmonary symptoms. In patients presenting with pulmonary symptoms such as cough, dyspnea, hypoxia, interstitial infiltrates on radiologic exam, or oxygen saturation decline by ≥5%, interrupt

ZYDELIG until the etiology has been determined. If symptomatic pneumonitis or organizing pneumonia is diagnosed, initiate appropriate treatment with corticosteroids and permanently discontinue Zydelig®.

- **Infections:** Fatal and/or serious infections occurred in 21% of patients treated with Zydelig® monotherapy and 48% of patients treated with Zydelig® in combination with rituximab or with unapproved combination therapies. The most common infections were pneumonia, sepsis, and febrile neutropenia. Treat infections prior to initiation of Zydelig® therapy and interrupt Zydelig® for Grade 3 or higher infection. Serious or fatal *Pneumocystis jirovecii* pneumonia (PJP) or cytomegalovirus (CMV) occurred in <1% of patients treated with Zydelig®. Provide PJP prophylaxis during treatment with ZYDELIG. Interrupt Zydelig® in patients with suspected PJP infection of any grade, and permanently discontinue Zydelig® if PJP infection of any grade is confirmed. Regular clinical and laboratory monitoring for CMV infection is recommended in patients with a history of CMV infection or positive CMV serology at the start of treatment with Zydelig®. Interrupt Zydelig in the setting of positive CMV PCR or antigen test until the viremia has resolved. If Zydelig is subsequently resumed, patients should be monitored (by PCR or antigen test) for CMV reactivation at least monthly.
- **Intestinal perforation:** Advise patients to promptly report any new or worsening abdominal pain, chills, fever, nausea, or vomiting.
- **Severe cutaneous reactions:** Fatal cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have occurred. If suspected, interrupt Zydelig® until the etiology of the reaction has been determined. If SJS or TEN is confirmed, discontinue Zydelig®. Other severe or life-threatening (Grade ≥3) cutaneous reactions have been reported. Monitor patients for the development of severe cutaneous reactions and discontinue Zydelig®.
- **Anaphylaxis:** Serious allergic reactions, including anaphylaxis, have been reported. Discontinue Zydelig® permanently and institute appropriate supportive measures if a reaction occurs.
- **Neutropenia:** Treatment-emergent Grade 3-4 neutropenia occurred in 25% of patients treated with monotherapy and 58% of patients treated with Zydelig® in combination with rituximab or with unapproved combination therapies. Monitor blood counts at least every 2 weeks for the first 6 months, and at least weekly in patients while neutrophil counts are less than 1.0 Gi/L.
- **Embryo-fetal toxicity:** Zydelig® may cause fetal harm. Women who are or become pregnant while taking Zydelig® should be apprised of the potential hazard to the fetus. Advise women to avoid pregnancy while taking Zydelig® and to use effective contraception during and at least 1 month after treatment with Zydelig®.

Adverse Reactions

- **Most common adverse reactions** in patients treated with Zydelig® in combination trials (incidence ≥30%, all grades) were diarrhea, pneumonia, pyrexia, fatigue, rash, cough, and nausea; and in the monotherapy trial (incidence ≥20%, all grades) were diarrhea, fatigue, nausea, cough, pyrexia, abdominal pain, pneumonia, and rash.
- **Most frequent serious adverse reactions (SAR)** in clinical studies in combination with rituximab were pneumonia (23%), diarrhea (10%), pyrexia (9%), sepsis (8%) and febrile neutropenia (5%); SAR were reported in 59% of patients, and 17% discontinued therapy due to adverse reactions. Most frequent SAR in clinical studies when used alone were pneumonia (15%), diarrhea (11%), and pyrexia (9%); SAR were reported in 50% of patients, and 53% discontinued due to adverse reactions.
- **Most common lab abnormalities** include neutropenia, ALT elevations, and AST elevations.

Drug Interactions

- **CYP3A inducers:** Avoid coadministration with strong CYP3A inducers.
- **CYP3A inhibitors:** Avoid coadministration with strong CYP3A inhibitors. If unable to use alternative drugs, monitor patients more frequently for Zydelig® adverse reactions.
- **CYP3A substrates:** Avoid coadministration with sensitive CYP3A substrates.

Dosage and Administration

- **Adult starting dose:** One 150 mg tablet twice daily, swallowed whole with or without food. Continue treatment until disease progression or unacceptable toxicity. The safe dosing regimen for patients who require treatment longer than several months is unknown.
- **Dose modification:** Consult the Zydelig® full Prescribing Information for dose modification and monitoring recommendations for the following specific toxicities: pneumonitis, ALT/AST elevations, bilirubin elevations, diarrhea, neutropenia, thrombocytopenia, and infections. For other severe or life-threatening toxicities, withhold Zydelig® until toxicity is resolved and reduce the dose to 100 mg twice daily upon resuming treatment. If severe or life-threatening toxicities recur upon rechallenge, Zydelig® should be permanently discontinued.

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 and Zydelig. 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 June 30, 2018, 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. U.S. Prescribing Information for Zydelig, including **BOXED WARNING**, is available at www.gilead.com.*

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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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