Kite Announces Initial Results From a Phase 1 Study of T Cell Receptor (TCR) Cell Therapy in HPV-16-Positive Solid Tumors

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– National Cancer Institute (NCI) Study Shows Investigational TCR Therapy Induces Response in Patients with Epithelial Cancers –

– Data at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting Support Development of KITE-439 for HPV-Associated Solid Tumors –

CHICAGO--(BUSINESS WIRE)--Jun. 4, 2018-- Kite, a Gilead Company (Nasdaq: GILD), today announced results from an ongoing Phase 1 study conducted by the National Cancer Institute (NCI) showing that clinical responses were observed with investigational T cell receptor (TCR) cell therapy targeting human papillomavirus type 16 (HPV-16) E7 in solid tumor cancers caused by HPV. These findings were presented today in a poster session at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago (Abstract #3043).

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20180604005335/en/

TCR therapy is a type of personalized immunotherapy designed to activate the immune system's ability to recognize and target specific tumors. TCR therapy involves engineering an individual’s own T cells to express naturally occurring receptors that can recognize specific tumor antigens. Epithelial cancers caused by HPV, including cervical, head and neck, anal and genital cancers, contain a protein called E7 inside tumor cells. Patients with these tumors whose cancers have relapsed and/or are refractory to standard therapy are currently incurable.

In this study, eight patients with metastatic HPV-16 cancers received a single infusion of gene-engineered E7 T cells at one of three dose levels. Patients had received between three and seven prior lines of systemic cancer therapy. In the initial six patients, the E7 TCR was expressed by 90-99 percent of the infused T cells, and E7 T cells were detectable in the peripheral blood six weeks following treatment. The study is ongoing.

Partial responses (Response Evaluation Criteria in Solid Tumors (RECIST); RECIST 1.1) were observed in three out of the seven evaluable patients and another two patients had stable disease. To date, the responses have lasted as long as nine months and have occurred in patients with vulvar, oropharyngeal and anal cancer. Two of these patients had been previously treated with anti-PD1 checkpoint blockade.

“Metastatic HPV-cancers are incurable and poorly addressed by standard therapies,” said Christian S. Hinrichs, MD, Lasker Clinical Research Scholar at the Center for Cancer Research’s Experimental Transplantation and Immunology Branch (ETIB) at the NCI and lead study investigator. “The early results from this Phase 1 trial support the continued evaluation of TCR therapy in HPV-associated cancers.”

No dose-limiting toxicity occurred. The most common grade 3 or higher adverse events were anemia, lymphopenia, leukopenia and neutropenia, each of which occurred in all seven evaluable patients.

The trial is part of a Cooperative Research and Development Agreement (CRADA) between the ETIB of the NCI and Kite to further the research and clinical development of TCR product candidates for the treatment of HPV-associated cancers. Patients interested in enrolling in the 16-C-0154 clinical trial can call the National Cancer Institute’s toll-free number 1-800-4-Cancer (1-800-422-6237) (TTY: 1-800-332-8615) or visit https://trials.cancer.gov.

HPV has a causal role in nearly all cervical cancers, and in many head and neck and anogenital malignancies. HPV-16 is the most commonly found strain in these cancers. More than 33,000 cases of HPV-associated cancers are diagnosed each year in the U.S. and more than 10,000 deaths are attributed to the disease, according to the Centers for Disease Control and

Prevention. Current therapies for HPV-associated tumors have low response rates and poor response duration.

“Findings from this Phase 1 study validate the E7 protein as a viral target for TCR therapy,” said Alessandro Riva, MD, Gilead’s Executive Vice President, Oncology Therapeutics & Head, Cell Therapy. “We plan to submit an IND for our TCR candidate, KITE-439, for HPV-16 E7 solid tumors by the end of the year, and we continue to explore other potential TCR therapy candidates for a variety of cancers in partnership with the NCI.”

KITE-439 is investigational and has not been proven safe or efficacious.

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 additional clinical trials involving KITE-439 for the treatment of HPV-16 E7 solid tumors or other HPV-associated cancers. In addition, Kite may be unable to submit the IND for KITE-439 in the currently anticipated timelines or at all. 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, 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.

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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