**CONTACTS:**

Jacquie Ross, Investors
investor_relations@gilead.com

Anna Padula, Kite Media
apadula@kitepharma.com

Koji Ogiwara
Daiichi Sankyo Co., Ltd.
ogiwara.koji.ay@daiichisankyo.co.jp

# YESCARTA® NOW APPROVED IN JAPAN FOR INITIAL TREATMENT OF RELAPSED/REFRACTORY LARGE B-CELL LYMPHOMA

- ***Based on Landmark ZUMA-7 Study, Patients with LBCL Treated with Yescarta in Second-Line Achieved Four-Fold Greater Improvement in Event-Free Survival of 8.3 Months vs. Two Months for Standard of Care (SOC)***

- ***In ZUMA-7, Patients Treated with Yescarta Were 2.5 Times More Likely than SOC to be Alive at Two Years Without Disease Progression or Need for Additional Treatments –***

**SANTA MONICA, Calif. & Tokyo --(BUSINESS WIRE)**-- Kite Pharma, Inc., a Gilead Company, (hereafter, Kite) (NASDAQ: GILD) and Daiichi Sankyo Co., Ltd. (hereafter, Daiichi Sankyo) (TSE: 4568) today jointly announced that the Japan Ministry of Health, Labour and Welfare (MHLW) has approved Yescarta (axicabtagene ciloleucel), a chimeric antigen receptor (CAR) T-cell therapy, for the initial treatment of patients with relapsed/refractory large B-cell lymphoma ( R/R LBCL): diffuse large B-cell lymphoma, primary mediastinal large B-cell lymphoma, transformed follicular lymphoma, and high-grade B-cell lymphoma. Yescarta should be used only in patients who have not received prior transfusion of CAR T-cells targeted at CD19 antigen.

The Standard of Care (SOC) to treat LBCL patients has historically been a multi-step process that starts with chemoimmunotherapy, followed by high-dose chemotherapy (HDT) and then ends with a stem cell transplant (ASCT). Although approximately 60% of newly diagnosed LBCL patients will respond to the initial treatment with chemotherapy, 40% will relapse or will not respond and need second-line treatment. Yescarta is now approved for the initial treatment of R/R LBCL patients in Japan.

“We are very proud of this additional Yescarta approval in Japan,” said Christi Shaw, CEO of Kite. “As Japan has the second-largest number of people diagnosed with non-Hodgkin lymphoma globally, this approval marks an important step in bringing this innovative therapy earlier to more patients.”

“We are glad to have achieved this important milestone in order to provide an innovative treatment option to more patients with large B-cell lymphoma in Japan,” said Wataru Takasaki, PhD, Executive Officer, Head of R&D Division in Japan, Daiichi Sankyo. “It also further demonstrates the expertise of our Daiichi Sankyo R&D organization as we had successfully expanded the indication for this CAR-T modality.”

The approval of Yescarta for the initial treatment of R/R LBCL patients in Japan is based on clinical data, including the results of the global pivotal trial conducted by Kite (ZUMA-7). ZUMA-7 is the largest and longest trial of a CAR T-cell therapy versus SOC in this patient population. Results from the study demonstrated that at a median follow-up of two years, Yescarta-treated patients had a four-fold greater improvement in the primary endpoint of event-free survival (EFS; hazard ratio 0.40; 95% CI: 0.31-0.51, P<0.0001) over the current SOC (8.3 months vs 2.0 months). Additionally, Yescarta demonstrated a 2.5 fold increase in patients who were alive at two years without disease progression or need for additional cancer treatment vs SOC (41% v 16%).

This indication was first approved by the U.S. FDA in April 2022 followed by the European Commission in October 2022.

On December 7, 2022, Daiichi Sankyo and Kite jointly announced that the Marketing Authorization for Yescarta will be transferred to Gilead Sciences K.K., the Japan subsidiary of Gilead Sciences, Inc., in 2023. The Kite Cell Therapy Business Unit at Gilead Sciences K.K. will manage the sales and promotion activities of the product in Japan after the Marketing Authorization transfer.

Kite's manufacturing facility in El Segundo, California, U.S., has been approved by Japanese regulatory authorities to commence manufacturing Yescarta for the Japan market in 2023.

**About Zuma-7**
ZUMA-7 is an ongoing, randomized, open-label, global, multicenter (US, Australia, Canada, Europe, Israel) Phase 3 study of 359 patients at 77 centers, evaluating the safety and efficacy of a single-infusion of Yescarta versus current SOC for second-line therapy (platinum-based salvage combination chemotherapy regimen followed by high-dose chemotherapy and autologous stem cell transplant in those who respond to salvage chemotherapy) in adult patients with relapsed or refractory LBCL within 12 months of first-line therapy. The primary endpoint is event free survival (EFS). Key secondary endpoints include objective response rate (ORR) and overall survival (OS). Additional secondary endpoints include patient reported outcomes and safety.

**About YESCARTA®**
Yescarta (axicabtagene ciloleucel) is a CAR T-cell therapy directed against CD19 (a cell membrane protein), which harnesses a patient's own immune system to fight cancer. Axicabtagene ciloleucel is made by removing a patient's T cells from their blood and engineering them in the lab to express chimeric antigen receptors so that they can recognize and destroy cancer cells when they are infused back to the patient's body. The CAR T-cell therapy is manufactured specifically for each patient and administered only once. Axicabtagene ciloleucel received Orphan Drug Designation from the Japan MHLW in 2018 for the treatment of diffuse large B-cell lymphoma, primary mediastinal B-cell lymphoma, transformed follicular lymphoma and high-grade B-cell lymphoma. Yescarta was approved in Japan for the treatment of patients with relapsed or refractory large B-cell lymphomas, a type of non-Hodgkin lymphoma, in January 2021.

Please see full U.S. Prescribing Information, including **BOXED WARNING** and Medication Guide.
Yescarta® is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:

- Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy. (1.1)
- 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.

Limitations of Use: Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma. (1.1)

- Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). (1.2)

For the full European Prescribing Information, please visit: : https://www.ema.europa.eu/en/medicines/human/EPAR/yescarta.

**About Daiichi Sankyo**
Daiichi Sankyo is dedicated to creating new modalities and innovative medicines by leveraging our world-class science and technology for our purpose "to contribute to the enrichment of quality of life around the world." In addition to our current portfolio of medicines for cancer and cardiovascular disease, Daiichi Sankyo is primarily focused on developing novel therapies for people with cancer as well as other diseases with high unmet medical needs. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation to realize our 2030 Vision to become an "Innovative Global Healthcare Company Contributing to the Sustainable Development of Society." For more information, please visit: www.daiichisankyo.com.

**About Kite**
Kite, a Gilead Company, is a global biopharmaceutical company based in Santa Monica, California, focused on cell therapy to treat and potentially cure cancer. As the global cell therapy leader, Kite has treated more patients with CAR T-cell therapy than any other company. Kite has the largest in-house cell therapy manufacturing network in the world, spanning process development, vector manufacturing, clinical trial production and commercial product manufacturing. For more information on Kite, please visit www.kitepharma.com.

**About Gilead Sciences**
Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California. Gilead Sciences acquired Kite in 2017.

**Gilead 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 ability of the companies to consummate the transactions contemplated under and as a result of the revised arrangement in a timely manner or at all, including the transfer of the Marketing Authorization for Yescarta in Japan to Gilead Sciences K.K. and the manufacture and supply of Yescarta in Japan; the risk that Gilead and Kite may not realize the anticipated benefits of the revised arrangement with Daiichi Sankyo; difficulties or unanticipated expenses in connection with implementing the revised arrangement; the potential effect on Gilead and Kite's earnings; and any assumptions underlying any of the foregoing. These and other risks, uncertainties and other factors are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, as filed with the U.S. Securities and Exchange Commission. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The reader is cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and is cautioned not to place undue reliance on these forward-

looking statements. All forward-looking statements are based on information currently available to Gilead and Kite, and Gilead and Kite assume no obligation and disclaim any intent 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 .*