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DAIICHI SANKYO AUTHORIZES THE FIRST YESCARTA® (AXICABTAGENE CILOLEUCEL) CAR T-CELL THERAPY TREATMENT SITE IN JAPAN

-- Kite and Daiichi Sankyo to Expand YESCARTA® Collaboration in Japan --

Santa Monica, Calif. and Tokyo – December 16, 2021 – Kite, a Gilead Company, and Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that YESCARTA® (axicabtagene ciloleucel), a chimeric antigen receptor (CAR) T-cell therapy, will be available to patients with relapsed or refractory large B-cell lymphomas in Japan through the first treatment center now authorized by Daiichi Sankyo. Kite and Daiichi Sankyo will also build on the exclusive licensing deal for commercialization rights for axicabtagene ciloleucel in Japan, formalized in January 2017. Both partners are pleased to agree on a broadening of their business collaboration in Japan.

"We are pleased to bring the benefits of axicabtagene ciloleucel to eligible patients in Japan, in collaboration with Daiichi Sankyo," said Warner Biddle, Kite's Global Head of Commercial. "Japan has the second-largest number of people diagnosed with non-Hodgkin lymphoma globally[1] and we remain committed to bringing our innovative CAR T-cell therapies to additional new markets."

"We are pleased to be able to deliver axicabtagene ciloleucel, Daiichi Sankyo's first cell therapy product, to patients in Japan," said Akio Sakurai, Daiichi Sankyo Corporate Officer, Head of Sales Division. "By strengthening our collaboration with Kite, the originator of axicabtagene ciloleucel and a world leader in cell therapy, we will strive to bring this innovative therapy to as many patients as possible."

CAR T-cell therapy is a complex immunotherapy, and all hospitals must complete a rigorous training process before administering axicabtagene ciloleucel to patients. These hospitals receive specific training in handling and risk minimization procedures in order to ensure that patient safety remains a priority.

Several factors are considered when qualifying a hospital, including their specialist skills and services, geographic coverage and experience in managing other complex procedures, such as stem cell transplantation and a co-located intensive care unit.

Axicabtagene ciloleucel has been approved in Japan for treatment of patients with relapsed or refractory diffuse large B-cell lymphoma, primary mediastinal B-cell lymphoma, transformed follicular lymphoma or high-grade B-cell lymphoma. The use of axicabtagene ciloleucel is limited to patients not previously treated with a CD-19 CAR-positive T-cell infusion; patients previously treated with two or more lines of treatment including chemotherapy or an autologous stem cell transplant; and, patients ineligible for an autologous stem cell transplant. In January 2017, Daiichi Sankyo received exclusive development, manufacturing and commercialization rights for axicabtagene ciloleucel in Japan from California-based Kite, a Gilead Company.

The approval of axicabtagene ciloleucel in Japan is based on data from the global pivotal trial conducted by Kite (ZUMA-1)[2] and results of a Phase 2 study conducted by Daiichi Sankyo in Japan. In the Japanese Phase 2, open-label, single-arm study, the same dose (2.0×10^6 cells/kg) of axicabtagene ciloleucel as used in the ZUMA-1 study was administered to assess efficacy and safety in 16 Japanese patients with relapsed or refractory large B-cell lymphoma, including diffuse large B-cell lymphoma, primary mediastinal B-cell lymphoma, transformed follicular lymphoma or high-grade B-cell lymphoma. The study reached its primary endpoint, demonstrating an objective response rate (ORR) of 86.7% (95% CI: 59.5 – 98.3%).

The overall safety and tolerability profile of axicabtagene ciloleucel in the Japan trial was consistent with that observed in ZUMA-1. Dose limiting toxicity was not observed. Grade ≥3 treatment emergent adverse event occurred in all patients; most commonly neutropenia (81.3%), lymphopenia (81.3%) and thrombocytopenia (62.5%). Cytokine release syndrome (CRS), a typical CAR T-cell therapy-emergent adverse event, occurred in 13 patients (81.3%, all Grade), with Grade ≥3 CRS in one patient (6.3%). No neurological events, another CAR T-cell therapy-emergent adverse event, were observed.

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 and engineering them in the lab to express chimeric antigen receptors so that they can recognize and destroy cancer cells. The CAR T therapy is manufactured specifically for each patient and administered only once.[3]

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® is approved in the U.S. and Europe for patients with certain types of relapsed or refractory B-cell lymphoma, where it is developed, manufactured and commercialized by Kite.

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 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.

- 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).

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, with manufacturing operations in North America and Europe. Kite's singular focus is cell therapy to treat and potentially cure cancer. As the cell therapy leader, Kite has more approved CAR T indications to help more patients than any other company. For more information on Kite, please visit www.kitepharma.com.

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 Kite's ability to realize the anticipated benefits from the collaboration with Daiichi Sankyo or other investments in cell therapy; Kite's ability to initiate, progress or complete clinical trials or studies within currently anticipated timelines or at all, including those involving YESCARTA®; the possibility of unfavorable results from ongoing or additional clinical trials or studies, including those involving YESCARTA®; the risk that physicians may not see the benefits of prescribing YESCARTA®; the possibility that the treatment center may experience disruptions or difficulties in delivering YESCARTA® to patients; and any assumptions underlying any of the foregoing. These and other risks, uncertainties and factors are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, 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.*

For more information on Kite, please visit the company's website at www.kitepharma.com Follow Kite on social media on Twitter (@KitePharma) and LinkedIn.

1. Globocan 2020. Available at: https://gco.iarc.fr. Accessed November 2021.
2. Neelapu S. et al. Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma. N Engl J Med. 2017 Dec; 377(26):2531-2544.
3. Roberts Z, et al. Leukemia and Lymphoma. Volume 59, 2018 - Issue 8 Pages 1785-1796 | 23 Oct 2017.