Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Press Release

YESCARTA® Approved in Japan for Treatment of Patients with Relapsed/Refractory Large B-Cell Lymphomas

- Approval based on phase 2 study conducted in Japan and previous pivotal trial data
- Daiichi Sankyo has exclusive rights to YESCARTA in Japan

Tokyo – (January 22, 2021) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced the Japan Ministry of Health, Labour and Welfare (MHLW) has approved YESCARTA® (axicabtagene ciloleucel), a chimeric antigen receptor (CAR) T-cell therapy, for the treatment of adult patients with certain relapsed/refractory large B-cell lymphomas.

YESCARTA has been approved in Japan for treatment of patients with relapsed/refractory diffuse large B-cell lymphoma, primary mediastinal B-cell lymphoma, transformed follicular lymphoma or high-grade B cell lymphoma. The use of YESCARTA 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 not eligible for an autologous stem cell transplant. In January 2017, Daiichi Sankyo received exclusive development, manufacturing and commercialization rights for YESCARTA in Japan from California-based Kite, a Gilead Company.

The approval of YESCARTA in Japan is based on data from the global pivotal trial conducted by Kite (ZUMA-1) 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 cell/kg) of YESCARTA 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. An objective response rate, the primary endpoint of the study, was 86.7% (95% CI: 59.5 – 98.3%).

“With the approval of YESCARTA in Japan, we now can offer this innovative one-time cell-based immune therapy to patients in Japan who need new options for B-cell lymphomas that continue to progress on currently available treatments,” said Wataru Takasaki, PhD, Executive Officer, Head of R&D Division in Japan, Daiichi Sankyo. “We are grateful to have the opportunity to collaborate with Japanese government agencies and Kite, as well as the trial investigators and patients, all of whom have contributed to this significant treatment advancement in Japan.”

The overall safety and tolerability profile of YESCARTA 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 1 patient (6.3%). Whereas neurological event, another typical CAR T cell therapy-emergent adverse event, was not observed.

About B-Cell Lymphomas

The majority of patients with diffuse large b-cell lymphoma achieve complete and sustained remission on initial treatment (chemotherapy plus targeted therapy).[1] However, diffuse large b-cell lymphoma is an aggressive lymphoma and approximately 40 percent of patients experience relapse or resistance to initial treatment.[1] Patients who progress on subsequent chemotherapy and/or stem cell transplant continue to face a poor prognosis.[1]

New and novel treatments such as CAR T-cell therapies are providing additional options for some patients with relapsed/refractory diffuse large b-cell lymphoma after other treatments, including autologous hematopoietic stem cell transplant, have been tried.[2]

About the Japan Phase 2 Study

The phase 2 multicenter, open-label, single-arm study evaluated efficacy and safety of YESCARTA in Japanese patients with several aggressive types of large B-cell lymphoma that is refractory or relapsed following one or more lines of standard treatment including drug therapy or autologous hematopoietic stem cell transplant. The study enrolled patients with diffuse large B-cell lymphoma, primary mediastinal B-cell lymphoma, transformed follicular lymphoma and high-grade B cell lymphoma.

The primary efficacy endpoint is investigator-assessed objective response rate. Secondary efficacy endpoints include centrally evaluated objective response rate, duration of response, progression-free survival and overall survival. The study also measured safety and pharmacokinetics. For more information, visit ClinicalTrials.jp.

About YESCARTA®

YESCARTA is a CAR T-cell therapy directed against CD19 (a cell membrane protein), which harnesses a patient's own immune system to fight cancer. YESCARTA 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]

YESCARTA 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 commercialized by Kite.

About Daiichi Sankyo Cancer Enterprise

The mission of Daiichi Sankyo Cancer Enterprise is to leverage our world-class, innovative science and push beyond traditional thinking to create meaningful treatments for patients with cancer. We are dedicated to transforming science into value for patients, and this sense of obligation informs everything we do. Anchored by our DXd antibody drug conjugate (ADC) technology, our powerful research engines include biologics, medicinal chemistry, modality and other research laboratories in Japan, and Plexxikon Inc., our small molecule structure-guided R&D center in Berkeley, CA. For more information, please visit: www.DSCancerEnterprise.com.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical therapies to improve standards of care and address diversified, unmet medical needs of people globally by leveraging our world-class science and technology. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for cardiovascular diseases, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo is primarily focused on providing novel therapies in oncology, as well as other research areas centered around rare diseases and immune disorders. For more information, please visit: www.daiichisankyo.com.

Media Contacts:

Global:
Jennifer Brennan
Daiichi Sankyo, Inc.
jbrennan2@dsi.com
+1 908 992 6631 (office)
+1 908 900 3183 (mobile)

Japan:
Masashi Kawase
Daiichi Sankyo Co., Ltd.
kawase.masashi.a2@daiichisankyo.co.jp
+81 3 6225 1126 (office)

Investor Relations Contact:
DaiichiSankyoIR@daiichisankyo.co.jp

References:

[1] Skrabek P, et al. *Curr Oncol*. 2019 Aug; 26(4): 253–265.
[2] American Cancer Society. Non-Hodgkin Lymphoma. 2018.
[3] Roberts Z, et al. Leukemia and Lymphoma. 2018(59): 1785-1796