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Press Release

Daiichi Sankyo Submits Application for CAR T Therapy Axicabtagene Ciloleucel for Treatment of Patients with Certain Relapsed/Refractory B-cell Lymphomas in Japan

- NDA submission based on previous pivotal trial data and a phase 2 study in Japan in patients with certain relapsed/refractory B-cell lymphomas
- Daiichi Sankyo has exclusive rights to axicabtagene ciloleucel in Japan, where it has received Orphan Drug Designation

Tokyo and Basking Ridge, NJ – March 30, 2020 – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has submitted a New Drug Application (NDA) to Japan's Ministry of Health, Labour and Welfare (MHLW) for chimeric antigen receptor (CAR) T cell therapy axicabtagene ciloleucel for the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma and related lymphomas.

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 Japan NDA submission is based on previous pivotal trial data conducted globally by Kite for axicabtagene ciloleucel in addition to results from a phase 2 bridging study conducted by Daiichi Sankyo in Japan. Both trials included patients with four aggressive types of relapsed/refractory B-cell lymphomas including diffuse large B cell lymphoma (DLBCL); primary mediastinal B-cell lymphoma (PMBCL); transformed follicular lymphoma (TFL); and high-grade B cell lymphoma. The Japanese trial met its primary endpoint for objective response rate, and data will be presented at an upcoming medical meeting.

"We are pleased to confirm submission of the NDA for axicabtagene ciloleucel following positive topline results from the phase 2 bridging study in Japan," said Wataru Takasaki, PhD, Corporate Officer, Head of Oncology Function and Head of R&D Division in Japan, Daiichi Sankyo. "We will continue to work with regulatory authorities to develop this important new cell therapy for eligible patients in Japan who need additional treatment options for relapsed or refractory DLBCL and related lymphomas."

About Axicabtagene Ciloleucel

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 B-cell lymphoma. Axicabtagene ciloleucel received

Orphan Drug Designation from the Japan Ministry of Health, Labour and Welfare (MHLW) in 2018 for the treatment of DLBCL, PMBCL, TFL and high-grade B-cell lymphoma.

Axicabtagene ciloleucel is approved in the U.S. and Europe for patients with certain types of relapsed or refractory B-cell lymphoma based on the results of the pivotal ZUMA-1 study.

Unmet Treatment Need in NHL/B-Cell Lymphoma

There were an estimated 509,000 new cases and about 248,000 deaths globally from non-Hodgkin lymphoma (NHL) in 2018.[1] In Japan, there were nearly 21,000 new cases of NHL reported in 2012.[2]

About 85 percent of NHLs are B-cell lymphomas. DLBCL is the most commonly diagnosed NHL, representing about one in five cases.[3] Treatment advances have led to improved outcomes for patients with certain types of NHL, but relapsed or refractory disease has remained a significant treatment challenge.[4] DLBCL is considered an aggressive form of the disease; however, the majority of DLBCL patients do achieve complete and sustained remission on initial treatment (chemotherapy plus targeted therapy).[5] Approximately 40 percent of patients experience relapse or resistance and may subsequently receive additional chemotherapy and/or stem cell transplant (ASCT) if eligible; those who are ineligible for ASCT or who relapse after transplantation have a poor prognosis.[5]

New and novel treatments such as CAR T cell therapies are providing additional options for some patients with relapsed/refractory DLBCL after two or more lines of treatments have been tried.[6]

About the Japan Phase 2 Study

The phase 2 multicenter, open-label, single-arm study was planned to evaluate efficacy and safety of axicabtagene ciloleucel 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 stem cell transplant (ASCT). The study enrolled patients with DLBCL, PMBCL, TFL and high-grade B cell lymphoma.

The primary efficacy endpoint is investigator-assessed objective response rate (ORR). Secondary efficacy endpoints include centrally evaluated ORR, duration of response, progression-free survival and overall survival. The study will also measure safety and pharmacokinetics. Enrollment has completed and the study is ongoing at several institutions in Japan. For more information, visit ClinicalTrials.jp.

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.

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