Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Press Release

Daiichi Sankyo Submits Application for Oncolytic Virus Teserpaturev (G47Δ) for Treatment of Patients with Malignant Glioma in Japan

- NDA submission based on phase 2 trial conducted by the University of Tokyo in patients with residual or recurrent glioblastoma, an aggressive primary brain cancer
- Daiichi Sankyo and the University of Tokyo are collaboratively developing teserpaturev, which has received SAKIGAKE Designation and Orphan Drug Designation in Japan

Tokyo – (January 5, 2021) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced it has submitted a New Drug Application (NDA) to Japan's Ministry of Health, Labour and Welfare (MHLW) for teserpaturev (G47Δ), an oncolytic virus, for the treatment of patients with malignant glioma.

Gliomas are primary brain tumors classified from grade I to IV based on the level of malignancy.[1] Malignant glioma refers to grade III and grade IV tumors which are characterized by rapid progression, high rate of recurrence and poor prognosis.[2]

Daiichi Sankyo is collaboratively developing teserpaturev with Dr. Tomoki Todo, Professor at the Institute of Medical Science, University of Tokyo. The Japan NDA submission, which took place on December 28, 2020, is based on results of a single-arm phase 2 clinical trial conducted by Dr. Todo at the University of Tokyo in patients with residual or recurrent glioblastoma tumors, which met its primary endpoint for one-year survival rate.

Oncolytic viruses are genetically engineered or naturally occurring viruses that can selectively replicate in and destroy cancer cells without harming normal tissues.[3] Oncolytic viruses have also been shown to induce systemic antitumor immunity.[3]

Daiichi Sankyo will continue to work with the University of Tokyo and with regulatory authorities to safely and expeditiously develop teserpaturev as the first potential oncolytic virus therapy for patients in Japan with malignant gliomas who are in need of new treatment options.

About Teserpaturev

Teserpaturev (G47Δ; formerly DS-1647) is a genetically engineered oncolytic herpes simplex virus type 1 (HSV-1) developed by Dr. Todo and his colleagues. The first-in-human phase 1/2a trial and the investigator-initiated phase 2 clinical trial were conducted by Dr. Todo at the University of Tokyo in patients with glioblastoma. Teserpaturev has triple mutations within the viral genome that cause augmented and selective replication in cancer cells and enhanced induction of antitumor immune response while retaining the high safety features.[3] Teserpaturev is currently the first third generation oncolytic HSV-1 to be tested in humans.[3]

Teserpaturev received Orphan Drug Designation in 2017 and SAKIGAKE Designation in 2016 from the Japan MHLW for the treatment of patients with malignant glioma.

About Malignant Glioma

Gliomas, which originate in glial cells in brain tissue, represent almost 80 percent of all malignant primary brain tumors.[1] Gliomas are classified from grade I to IV based on the level of malignancy.[1] Grade III and grade IV are called malignant gliomas or high grade gliomas and are characterized by rapid progression, high rate of recurrence and poor prognosis.[2]

Primary malignant brain tumors and other central nervous system tumors are rare, but case rates vary by country and region, and related morbidity and mortality is disproportionate to incidence.[4] The number of glioma cases in Japan is estimated to be around 5,000 annually and the number of malignant glioma cases is estimated to be about 2,800 annually.[5]

There are no oncolytic viruses approved for treatment of malignant glioma or any primary brain cancer.

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] Hanif F, et al. *Asian Pac J Cancer Prev*. 2017; Jan 1;18(1): 3-9.
[2] Birk HS, et al. *CNS Oncol*. 2017; 6(1); 61–70.
[3] Fukuhara H, et al. *Cancer Sci*. 2016; (107); 1373–1379.
[4] Leece R, et al. *Neu Onc*. 2017; 19(11); 1553–1564.
[5] Brain Tumor Registry of Japan (2005-2008). *Neurol Med Chir* (Tokyo). 2017; 57(Suppl 1):9-102.