Passion for Innovation.
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Daiichi-Sankyo

Press Release

Daiichi Sankyo Launches DELYTACT® Oncolytic Virus G47Δ in Japan

Tokyo – (November 1, 2021) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has launched DELYTACT® (teserpaturev/G47Δ)[*1], an oncolytic virus developed by the company in collaboration with Professor Tomoki Todo (hereinafter, Dr. Todo) of the Institute of Medical Science, The University of Tokyo.

DELYTACT® received conditional and time-limited marketing approval in Japan as a regenerative medical product for treatment of malignant glioma in June 2021 based on results from a Japanese phase 2 clinical trial (investigator-initiated trial) in patients with glioblastoma[*2] (a type of malignant glioma[*3]) conducted by Dr. Todo.

For the time being, DELYTACT® will be commercially available only at hospitals that served as trial sites. Daiichi Sankyo will establish a stable supply system of the medicine as soon as possible.

Daiichi Sankyo is pleased to offer DELYTACT® as a new option for the treatment of malignant glioma and to contribute to the high unmet medical needs of patients suffering from this brain cancer.

Brief description of DELYTACT®

Brand Name	DELYTACT®
Non-proprietary Name	Teserpaturev
Indication or Performance	Malignant glioma
Dosage and Administration or Method of Use	The usual adult dosage is 1 mL (1×10^9 PFU) of DELYTACT® administered intratumorally. In principle, the first and second doses are separated by 5 to 14 days, and each of the third and subsequent doses is separated from the previous dose by 4 weeks. Up to 6 doses may be administered.
Approval Conditions and Time Limit	Approval Conditions 1. The applicant is required to ensure that the product is used by a neurosurgeon with sufficient knowledge and experience in treatment of malignant glioma and neurosurgical procedures who has been adequately informed of clinical study results and adverse events of the product in an environment that ensures appropriate actions such as monitoring with laboratory tests and management. 2. The applicant is required to conduct a post-marketing approval condition evaluation in all patients treated with the product until a

	marketing approval application is submitted again after the conditional time-limited authorization 3. The applicant is required to ensure that the product is used in compliance with Provisions for Type 1 Use authorized under the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Act) (Act No. 97 of 2003) through necessary actions such as dissemination of the provisions for use of genetically modified living organisms. Time limit 7 years
NHI drug price (yen)	1,431,918 per 1-mL vial
Date of approval for marketing	June 11, 2021
Date of listing on the NHI Drug Tariff	August 12, 2021
Date of launch	November 1, 2021
Marketing authorization holder	Daiichi Sankyo Company, Limited

*1 DELYTACT® (teserpaturev/G47Δ) is a genetically engineered oncolytic herpes simplex virus type 1 (HSV-1) developed by Dr. Todo and his colleagues. DELYTACT® has triple mutations within the viral genome that cause augmented and selective replication in cancer cells (third generation oncolytic HSV-1).

*2 Glioblastoma is highly malignant glioma (grade IV) and found in approximately 60% to 70% of patients with malignant glioma.

*3 Of glioma which is a primary brain tumor that originates in glial cells of a supporting tissue for neurons, highly malignant grade III and IV tumors are defined as malignant glioma, which is estimated to affect approximately 2,800 persons in Japan annually.

Daiichi Sankyo in Oncology

The oncology portfolio of Daiichi Sankyo is powered by our team of world-class scientists that push beyond traditional thinking to create transformative medicines for people with cancer. Anchored by our DXd antibody drug conjugate (ADC) technology, our 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 the U.S. We also work alongside leading academic and business collaborators to further advance the understanding of cancer as Daiichi Sankyo builds towards our ambitious goal of becoming a global leader in oncology by 2025.

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.

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