

## Press Release

# DELYTACT® Oncolytic Virus G47Δ Approved in Japan for Treatment of Patients with Malignant Glioma

- First oncolytic virus ever approved for treatment of malignant glioma or any primary brain cancer
- Fourth innovative oncology medicine approved in Japan over the past two years for Daiichi Sankyo

**Tokyo – (June 11, 2021)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has received conditional and time-limited approval from the Japan Ministry of Health, Labour and Welfare (MHLW) for DELYTACT® (teserpaturev/G47Δ), an oncolytic virus, for the treatment of patients with malignant glioma.

DELYTACT previously received SAKIGAKE Designation and Orphan Drug Designation from the MHLW for this indication and is now the first oncolytic virus to be approved in any region of the world for treatment of malignant glioma or any type of primary brain cancer. Daiichi Sankyo has been collaboratively developing DELYTACT with Dr. Tomoki Todo of the Institute of Medical Science, The University of Tokyo, and is the Marketing Authorization Holder of DELYTACT in Japan.

The approval of DELYTACT in Japan is based on results of a single-arm phase 2 clinical trial evaluating DELYTACT in patients with residual or recurrent glioblastoma, the most common and aggressive form of malignant glioma.<sup>1</sup> The trial met its primary endpoint for one-year survival rate in an interim analysis. Results of the study will be submitted for publication by Dr. Todo.

“With the approval of DELYTACT in Japan we can now offer the first-ever oncolytic virus therapy option to patients with glioblastoma and other malignant gliomas that are not controlled with currently available treatments,” said Wataru Takasaki, PhD, Executive Officer, Head of R&D Division in Japan, Daiichi Sankyo. “DELYTACT is the fourth oncology medicine to be approved in Japan for Daiichi Sankyo over the past two years and we are grateful for the opportunity to collaborate with Dr. Todo to deliver this truly innovative treatment modality to patients and physicians in Japan.”

### About Malignant Glioma

Glioma, which originates in glial cells in brain tissue, represents almost 80 percent of all malignant primary brain tumors.<sup>2</sup> Glioma is classified from grade I to IV based on the level of malignancy.<sup>2</sup> Grade III and grade IV are called malignant glioma or high grade glioma and characterized by rapid progression, high rate of recurrence and poor prognosis.<sup>3</sup>

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.<sup>4</sup> 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.<sup>5</sup>

### **About the Phase 2 Study**

The phase 2 open-label, single-arm, non-randomized, single-center study conducted by Dr. Todo of the Institute of Medical Science, The University of Tokyo, evaluated the safety and efficacy of G47Δ (DELYTACT) in adult patients with glioblastoma who had been treated with radiotherapy and temozolomide chemotherapy and had one residual tumor or one recurrent lesion after the initial treatment.

The primary endpoint of the trial is one-year survival rate after initiation of DELYTACT therapy, analyzed using historical control. Secondary endpoints include progression-free survival, overall survival and overall response rate.

### **About DELYTACT®**

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 mutation within the viral genome that cause augmented and selective replication in cancer cells and enhanced induction of antitumor immune response while retaining high safety features.<sup>6</sup> DELYTACT is currently the first third generation oncolytic HSV-1 to be evaluated in humans.<sup>6</sup>

DELYTACT has received conditional and time-limited approval in Japan for the treatment of patients with malignant gliomas based on the phase 2 study results. Continued approval for this indication may be contingent upon verification and description of clinical benefit and safety in a post-market comparative clinical study. DELYTACT is not approved for any use outside of Japan.

### **About Daiichi Sankyo 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](http://www.daiichisankyo.com).

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### References

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  - <sup>2</sup> Hanif F et al. *Asian Pac J Cancer Prev*. 2017 Jan;18(1):3-9.
  - <sup>3</sup> Birk HS et al. *CNS Oncol* 2017 Jan;6(1):61–70.
  - <sup>4</sup> Leece et al. *Neuro Oncol* 2017 Oct 19;19(11):1553-1564.
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  - <sup>6</sup> Fukuhara H, et al. *Cancer Sci*. 2016 Oct;107(10):1373–1379.