

For Immediate Release

Company name: DAIICHI SANKYO COMPANY, LIMITED
Representative: Joji Nakayama, Representative Director, President and CEO
(Code no.: 4568, First Section, Tokyo Stock Exchange)
Please address inquiries to Noriaki Ishida, Executive Officer,
Vice President, Corporate Communications Department
Telephone: +81-3-6225-1126
<http://www.daiichisankyo.com>

Daiichi Sankyo Joint Development Product Designated Under “SAKIGAKE Designation System”

TOKYO, Japan (February 10, 2016) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that the oncolytic virus (G47Δ^{*1}), for which the company jointly applied with Dr. Tomoki Todo, a professor at the Institute of Medical Science, the University of Tokyo (hereafter, Professor Todo), has been designated under the SAKIGAKE Designation System^{*2} for medical equipment and in vitro diagnostic pharmaceuticals and regenerative medicine products, which was launched this year.

Professor Todo initiated the GCP based second-phase G47Δ clinical trial targeting glioblastoma^{*3} in 2015. G47Δ has performed well in the trial, and non-clinical as well as clinical studies for other cancers are also ongoing. Based on data obtained thus far, it has also been suggested that there is a possibility of expanding the indication of G47Δ to other cancers. Daiichi Sankyo intends to collaborate with Professor Todo on the further development of this oncolytic virus therapy.

Daiichi Sankyo remains committed to meeting the needs of more patients and medical professionals through drug development and contributing to medical care by providing new treatment options.

***1 Characteristics of cancer therapy using G47Δ**

G47Δ is a triple-mutated, replication-conditional herpes simplex virus type 1 (the third generation oncolytic herpes simplex virus type 1), designed to replicate only in cancer cells. The use of this new cancer treatment method may fundamentally alter the strategy of cancer treatment. Whereas several oncolytic virus therapies are currently being developed, this oncolytic virus therapy has shown excellent safety and efficacy in non-clinical and clinical studies.

***2 SAKIGAKE Designation System**

SAKIGAKE Designation System is a core policy of the “Strategy of SAKIGAKE” (compiled by the Ministry of Health, Labour and Welfare in June, 2014) aimed at early introduction of innovative medicines, medical devices, etc. that are initially developed in Japan. The system’s objective is to designate drugs with prominent effectiveness against serious and life-threatening diseases in order to make them available to patients in Japan ahead of the rest of the world. Drugs are designated at a comparatively early stage of development and are given priority for clinical trial consultation and review. The system is being carried out on a trial basis this year.

***3 Targeted disease**

Glioma is a primary brain tumor arising from glia cells that consist the supporting tissue for nerve cells, and the mechanism of its generation is yet unknown. In the aforementioned clinical trial undertaken by Professor Todo, glioblastoma, the most malignant form of glioma, is the targeted disease. It is estimated that about 1,000 patients annually in Japan newly acquire glioblastoma. When subjected to a standard therapy, glioblastoma shows a high rate of recurrence and an extremely poor prognosis. Since most patients die within five years from diagnoses, and there are no established treatments that can cause cure, an effective treatment for this cancer is a highly unmet medical need.