Press Release

Company name: DAIICHI SANKYO COMPANY, LIMITED
Representative: Sunao Manabe, Representative Director, President and COO
(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

Oncolytic Virus G47Δ (DS-1647) designated as Orphan Drug under Orphan Drug/Medical Device Designation System

TOKYO, Japan (July 11, 2017) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that the oncolytic virus G47Δ[*1] (DS-1647), which the company is jointly developing with Dr. Tomoki Todo, Professor at the Institute of Medical Science, the University of Tokyo (hereafter, Professor Todo), has been designated as an orphan drug for the treatment of malignant glioma[*2] under the Orphan Drug/Medical Device Designation System[*3] by the Ministry of Health, Labour and Welfare.

G47Δ, created by Professor Todo and his colleagues, is currently being developed as a treatment for several cancers, including malignant glioma. Using G47Δ, Professor Todo is currently conducting a GCP based phase 2 investigator initiated clinical trial targeting malignant glioma. In collaboration with Professor Todo, Daiichi Sankyo submitted G47Δ (DS-1647) for review under the SAKIGAKE Designation System[*4], receiving the designation on February 10, 2016. With this additional designation as an orphan drug, Daiichi Sankyo, together with Professor Todo, will strive to provide malignant glioma patients and medical personnel with the new treatment as quickly as possible.

[*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 therapy using G47Δ has shown excellent safety and efficacy in non-clinical and clinical studies.

[*2]Malignant Glioma

Glioma is a primary brain tumor arising from glial cells, the supporting tissue of neurons, and is classified from grade I to IV based on histopathological findings. The number of domestic glioma cases is estimated to be around 5,000 annually. Among them, grade III (such as anaplastic astrocytoma or anaplastic oligodendroglioma) and grade IV (glioblastoma) are called malignant glioma, and the number of cases is estimated to be about 3,500 annually. Malignant gliomas progress rapidly, and show a high rate of recurrence and a poor prognosis.

[*3]Orphan Drug/Medical Device Designation System

Drugs and medical devices can be designated as orphan drugs or orphan medical devices in Japan based on Article 77-2 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics, if they are intended for the use in diseases with less than 50,000 patients in Japan and if there is a high medical need. They are designated by the Minister of Health, Labour and Welfare based on the opinion of the Pharmaceutical Affairs and Food Sanitation Council. This system was created to supply safe and quality drugs and medical devices as swiftly as possible to those patients for whom research and development have not sufficiently progressed, despite high medical needs, due to the rarity of the disease. Governmental support, such as tax incentives and reexamination period extensions, is also provided.

[*4]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 for an 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 relatively early stage of development and are given priority for clinical trial consultation and review by the Pharmaceuticals and Medical Devices Agency. The system is currently being carried out on a trial basis.