

Denka Receives Approval for Marketing of the DELYTACT (G47Δ) Oncolytic Virus in Japan ～Worlds' First Oncolytic Virus against Malignant Glioma～

Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Toshio Imai; hereinafter, "Denka") announces that Daiichi Sankyo Company, Limited received a conditional and fixed-term approval, for the marketing of DELYTACT (G47Δ) (*1) Oncolytic Virus (Generic name: Teseptaturev, hereinafter, the "Product") as a regenerative medicine product for the purpose of treating malignant glioma (*2). Denka has been developing commercial pharmaceutical production technologies for the Product with Professor Tomoki Todo (hereinafter "Professor Todo") of the Institute of Medical Science, the University of Tokyo. Denka plans to manufacture the Product at its Gosen Site (Gosen City, Niigata Prefecture) pursuant to an outsourcing agreement made with Daiichi Sankyo Company, Limited.

The Product is based on the oncolytic virus developed by Professor Todo with the use of genetically modified herpes simplex virus type 1 (HSV-1). The approval makes the Product the world's first approved oncolytic virus against malignant glioma. Because the production of the Product involves the manufacture of viruses, commercial production requires the establishment of large-scale virus production technology and special testing skills. Denka is well-positioned to demonstrate the technologies and expertise it has cultivated over many years through the development and production of vaccines and reagents for virus testing. Denka will provide an additional option for the treatment of malignant glioma, one of the critical unmet medical needs (medical needs for which there are no effective treatments) through production for practical use, thereby making a contribution to patients.

Denka began developing a manufacturing process of the Product in 2015 to facilitate production of the innovative oncolytic virus geared to practical application, and with an investment of approximately 2.0 billion yen, moved forward with the construction of a building and introduction of facilities required for the manufacture of oncolytic viruses at its Gosen Site. By establishing a manufacturing process required for commercial production following the completion of the building in October 10, 2017, Denka is now able to provide the drug in quantities required by medical institutions in Japan. The impact on Denka's consolidated financial results for fiscal 2021 is being examined carefully.

Under its Denka Value-Up management plan, Denka has positioned the healthcare domain as a key area. In addition to producing influenza vaccines, viral antigen rapid diagnosis kits and other products in the area of infectious diseases, Denka is now working to develop businesses in the new field of cancer treatment. Going forward, Denka, while keeping the SDGs in mind as guidance, will continue to contribute to improving quality of life for people around the world through the development and production of products in the areas of prevention, diagnosis and treatment. Through these efforts, it will seek to create a company that is genuinely needed by society.

(*¹) G47Δ

Created by Professor Todo and others, the G47Δ is a propagative genetically modified herpes simplex virus type 1 (third-generation herpes simplex virus type 1 for cancer treatment) featuring artificial triple mutations designed to achieve replications through cancer cells alone.

(*²) Malignant glioma

Refers to very malignant grade III and IV gliomas among primary brain tumors that occur in glial cells, which support the function of nerve cells. The number of cases in Japan is expected to be approximately 2,800 per year.

* DELYTACT is a registered trademark of Daiichi Sankyo Company, Limited

Reference:

- ” Denka Applies for Approval for Marketing of the G47 Δ Oncolytic Virus” January 5, 2021
https://www.denka.co.jp/eng/storage/news/pdf/320/20210105_denka_g47_en.pdf
- ” Denka Seiken Completes Its Production Facility for the G47 Δ Oncolytic Virus” October 6, 2017
https://www.denka.co.jp/eng/storage/news/pdf/178/20171010_g47completion_en.pdf
- ” Denka Seiken to Establish a Production Facility for the G47 Δ Oncolytic Virus” July 21, 2016
https://www.denka.co.jp/eng/storage/news/pdf/145/20160721g47_e.pdf
- “DENKA SEIKEN Initiates the Development of Large-Scale Production Methods for the “G47 Δ” Oncolytic Virus” May 12, 2015
https://www.denka.co.jp/eng/storage/news/pdf/96/20150512_G47%CE%94_e.pdf

About Denka

Denka is a chemical manufacturer headquartered in Chuo-ku, Tokyo. The company specializes in developing business activities on a global scale across a wide range of fields, from inorganic and organic chemicals, to electronic materials and pharmaceuticals. Founded in 1915, Denka has steadily continued to develop and manufacture products that contribute to the development of society by fully utilizing its unique concepts and technological capabilities. Upholding its corporate slogan, “Possibility of chemistry” the company and its president, Toshio Imai, are committed to contributing to the sound development of the society while sincerely tackling the challenges that the society is now confronting.

For more information, please visit: <https://www.denka.co.jp/eng/>

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