

Denka Applies for Approval for Marketing of the G47Δ Oncolytic Virus

Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Manabu Yamamoto; hereinafter “Denka”) hereby announces that on December 28, 2020, Daiichi Sankyo Company, Limited (hereinafter “Daiichi Sankyo”) filed an application for approval for marketing of a regenerative medicine product concerning the G47Δ oncolytic virus, for which Denka has been developing commercial pharmaceutical production technologies. After the marketing is approved by the Ministry of Health, Labour and Welfare (MHLW), it is planned for Denka to handle production of the virus.

G47Δ is an oncolytic virus for treating cancer developed by Professor Tomoki Todo (hereinafter “Professor Todo”) of the Institute of Medical Science, the University of Tokyo, by genetically modifying herpes simplex virus type-1 (HSV-1). There are high hopes for G47Δ as a completely new kind of cancer treatment, and investigator-initiated clinical trials (Phase II) to test its effectiveness against glioblastoma—a type of malignant brain tumor—ended in a favorable result, with an early efficacy stop (*). Because producing G47Δ involves manufacturing the virus itself, commercial production requires the establishment of large-scale virus production and testing methods. Because this required special techniques and experience, Professor Todo contracted with Denka to expand technologies for producing G47Δ, given that it had developed and manufactured vaccines and virus testing kit reagents for many years (including during the former Denka Seiken era.) On February 10, 2016, G47Δ was classified under the "Scheme for prompt practical use of unapproved drugs," aimed at facilitating the application of products such as medical devices, in-vitro diagnostic drugs and regenerative treatment products. Therefore, it is hoped that G47Δ will be swiftly approved as a regenerative medicine product after the application.

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 new businesses in the new field of cancer treatment. Denka is currently advancing preparations for the commercialization in Japan of the CANCERPLEX multiplex genomic panel testing system, which analyzes genetic mutations with a focus on over 400 cancer genes, including G47 Δ. Looking ahead, Denka will continue contributing to improving quality of life (QoL) for people around the world, through the development and production of products in the fields of prevention, diagnosis and treatment.

(*) Efficacy stopping is the practice of terminating a clinical drug trial early, when the efficacy (effectiveness) of the drug has been proven.

Reference:

- ” 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, Manabu Yamamoto, are committed to contributing to the sound development of the society while sincerely tackling the challenges that the society is now confronting.

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