

Denka Announces Launch of DELYTACT® (G47Δ) Oncolytic Virus

Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Toshio Imai; hereinafter, "Denka") and Dr. Tomoki Todo (hereinafter "Dr. Todo"), the professor of the Institute of Medical Science, the University of Tokyo, developed the commercial production process for DELYTACT® (G47Δ) (*1) Oncolytic Virus (generic name: Tesseraturev, hereinafter, the "Product") as a regenerative medicine product for treatment of malignant glioma. Daiichi Sankyo Company, Limited (hereinafter, "Daiichi Sankyo") commenced its domestic distribution in Japan this day. Having been contracted by Daiichi Sankyo, Denka manufactured and started to ship the Product this October. The impact on Denka's consolidated financial results for fiscal 2021 is being examined.

The Product is the oncolytic virus (G47Δ), the world's first approved oncolytic virus for treating cancer targeting malignant glioma. Since the production of the Product involves processing live viruses, it requires the establishment of large-scale virus production technology and special testing skills. Denka has demonstrated 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 commercial pharmaceutical production, thereby making a contribution to development of healthcare. Denka will fully satisfy needs of domestic medical institutions for stable product supply. It will also pursue its initiatives to establish and enhance the presence as a Contract Development and Manufacturing Organization (CDMO) mainly for viral formulations while utilizing the technology and knowhow acquired from development of the manufacturing process for the Product.

Denka will aim to be a company that is truly needed and indispensable in society, which creates a better world for all through work it can perform better than anybody, in reference to the SDGs.

(*1) G47Δ

Developed by Dr. Todo and his team. 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 highly 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 estimated to be approximately 2,800 per year.

* DELYTACT is a registered trademark of Daiichi Sankyo Company, Ltd.

Reference:

- “Denka Receives Approval for Marketing of the DELYTACT (G47Δ) Oncolytic Virus in Japan
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- “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”
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