July 21, 2016
Denka Company Limited
Denka Seiken Co., Ltd.

Denka Seiken to Establish a Production Facility for the G47Δ Oncolytic Virus

Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Shinsuke Yoshitaka; hereinafter "Denka") hereby announces that Denka Seiken Co., Ltd. (headquarters: Chuo-ku, Tokyo; president: Tetsuro Maeda; hereinafter "Denka Seiken"), one of its core Group companies, has decided to construct its first production facility for a virus-based anticancer drug for use in oncolytic virotherapy[1] that uses G47Δ.[2]

As announced on May 12, 2015, Denka Seiken has been commissioned to develop a method for the large-scale production of G47Δ by Dr. Tomoki Todo, a professor at the Institute of Medical Science of the University of Tokyo. With the completion of the facility scheduled for September 2017, Denka Seiken will bring it online after obtaining approval from Japan's Ministry of Health, Labour and Welfare (hereinafter "MHLW") with regard to the manufacture and sales of this drug.

In addition, this facility construction project was designated by Niigata Prefecture as a subsidized project.

Developed under a new concept, the G47Δ employs a genetically-modified herpes simplex virus type-1, and the biological drug incorporating it is expected to represent an epoch-making advance as a cancer treatment that leverages the properties of the virus. To test its effectiveness against glioblastoma,[3] a type of malignant brain tumor, an investigator-initiated clinical trial[4] (Phase II) has been under way since 2015. On February 10, 2016, the G47Δ was classified under the category of "regenerative, cellular therapy and gene therapy products," a group of pharmaceuticals subject to the "Scheme for prompt practical use of unapproved drugs[5] aimed at facilitating the application of innovative medical products and devices. Because of this, Denka Seiken expects that the G47Δ will be approved before so long.

In line with the Denka100 management plan growth strategies, Denka is focusing its management resources on growth drivers and the development of next-generation products. As the healthcare field has been identified as one of the Denka Group's growth drivers, Denka Seiken is playing an ever greater role in this field.

G47 Delta is much anticipated as a pioneering solution that is blazing a new path in the field of oncolytic virotherapy. Looking ahead, the Denka Group will strive to commercialize this drug at the earliest possible date, thereby helping advance the medical field and promote wellbeing.

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Notes:

1. Oncolytic virotherapy: A novel treatment modality using viruses to remedy cancers by leveraging an inherent property of viruses to destroy infected cells. Applying gene modification technologies, this treatment method uses viruses designed to replicate selectively in cancer cells. Currently, R&D projects focusing on this mechanism of action are under way in countries around the world. Recently, a biological cancer treatment drug developed by a major U.S.-based pharmaceutical company was released in European markets and the United States.

2. G47Δ(Delta): Developed by Dr. Tomoki Todo, a professor at the Institute of Medical Science of the University of Tokyo, G47Δ is a herpes simplex virus type-1 (HSV-1), a third-generation genetically-modified oncolytic virus. Since 2009, clinical studies against glioblastoma have been carried out at the University of Tokyo. In 2013, clinical studies against prostatic cancer and olfactory neuroblastoma were initiated. In January 2015, an investigator-initiated Phase II clinical trial was launched against glioblastoma.

3. Glioblastoma: A type of malignant brain tumor, glioblastoma is deemed difficult to treat through conventional treatment methods, with the patient's average life expectancy being approximately one year from the time of diagnosis. In cases where a tumor recurs after surgery, the patient has very few options for treatment. G47Δ is expected to become a life-saving solution for such patients as it treats cancer with mechanisms that are different from conventional remedies.

4. Investigator-initiated clinical trials: Clinical trials initiated by physicians. The 2003 revision of Japan's Pharmaceutical Affairs Act allows this type of clinical trial. Prior to the revision, clinical trials were initiated only upon the submission of applications by pharmaceutical companies intending to acquire marketing authorization from the government, while physicians collaborated with them to collect required clinical data. All trials from the non-clinical phase to the current Phase II trials undertaken to develop G47Δ have been spearheaded by physicians.

5. The "Scheme for prompt practical use of unapproved drugs": Led by MHLW, the scheme identifies innovative but unapproved drugs that meet prescribed criteria as drug candidates eligible to be prioritized in an examination process and prior consultations with relevant authorities. By identifying promising drug candidates from the early stage of development, the scheme is expected to accelerate the commercialization of such drugs and thereby help Japan be in the vanguard of cutting-edge medical technologies.