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DENKI KAGAKU KOGYO KABUSHIKI KAISHA (Denka)
DENKA SEIKEN Co., Ltd.

DENKA SEIKEN Initiates the Development of Large-Scale Production Methods for the "G47Δ" Oncolytic Virus

DENKI KAGAKU KOGYO KABUSHIKI KAISHA (headquarters: Chuo-ku, Tokyo; president: Shinsuke Yoshitaka; hereafter "Denka") hereby announces that DENKA SEIKEN Co., Ltd. (headquarters: Chuo-ku, Tokyo; president: Tetsuro Maeda; hereafter "DENKA SEIKEN"), one of its core Group companies, initiated the development of a method for large-scale production of a cancer treatment biological drug using the "G47Δ" virus. DENKA SEIKEN was commissioned to implement this development project by Dr. Tomoki Todo, a professor at the Institute of Medical Science of the University of Tokyo, who has been spearheading R&D on oncolytic virotherapy[1] using G47Δ.[2]

Developed under a new concept, the G47Δ employs HSV-1, a genetically modified herpes virus, and the biological drug is expected to represent an epoch-making advance as a cancer treatment that leverages the properties of viruses. 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 January 2015. The commercialization of G47Δ as an anticancer drug will require large-scale manufacturing facilities and established testing methods.[5] Moreover, the production of such a biological drug requires the application of highly specialized techniques and expertise for manufacturing drug preparations with the live G47Δ virus. Backed by its longstanding track record in the development and manufacture of vaccines and virus diagnostic reagents, DENKA SEIKEN was chosen to undertake this development project based on its technological strength and command of the knowledge necessary to commercialize G47Δ.

G47Δ 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 humanity's 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. In one instance, a clinical trial spearheaded by a major U.S.-based pharmaceutical company has completed Phase III trials, and plans call for commercialization in the near future.
2. G47Δ(Delta): Developed by Dr. Tomoki Todo, a professor at the Institute of Medical Science of the University of Tokyo, G47Δ is an oncolytic virus based on herpes simplex virus type-1 (HSV-1), a third-generation genetically-modified HSV-1. 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. The investigator-initiated clinical trial: A clinical trial 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. Large-scale manufacturing facilities and established testing methods: Unlike other pharmaceutical products made using mainly chemical processes, biological drugs, including vaccines and antibody drugs, are manufactured through such processes as cell culture and virus growth and the purification technology of such culture. Because of that, the successful production of these drugs requires specialized facilities as well as sufficient expertise. Moreover, since methods for testing interim and finished products differ from methods used to test other types of pharmaceutical products, the design and implementation of appropriate testing procedures requires extensive experience in the field. Thus, DENKA SEIKEN was commissioned to develop a method for large-scale production of G47Δ toward the commercialization, as it has gained a wealth of know-how in producing biological drug through the manufacture of vaccines and virus diagnostic reagents.