Denka

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Denka to Sign a Licensing Contract That Allows It to Exclusively Use AMED's Norovirus-Related Research Findings

Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Manabu Yamamoto; hereinafter "Denka") hereby announces that the Company has signed a licensing contract granting it rights for the exclusive use¹ of results of the "norovirus vaccine seeds" developed under the auspices of Japan Agency for Medical Research and Development (president: Makoto Suematsu; hereinafter "AMED") as part of the Research Program on Emerging and Re-emerging Infectious Diseases. The contract was signed by Denka and Dr. Kazuhiko Katayama, professor at Kitasato University's Kitasato Institute for Life Sciences and the representative researcher of the AMED-sponsored project that resulted in the creation of the aforementioned results. More specifically, the contract will allow Denka to utilize hybridomas² that produce monoclonal antibodies³ for specifically detecting norovirus VLPs⁴ (virus-like particles)as well as recombinant baculovirus-seed virus capable of producing the norovirus VLPs.

Every winter, the outbreak of norovirus infections poses a significant threat to the public health and economy worldwide. Because of this, the development of vaccines to prevent norovirus infection and serious symptoms is desired. To meet social needs for such solutions, Icon Genetics GmbH, a Group subsidiary in Germany, is engaged in the development of norovirus vaccines that employ VLPs as antigens, taking advantage of its proprietary magnICON®,⁵ a technological platform capable of producing high molecular proteins through the use of plant-based genetic modification technology.

Since norovirus has a variety of genotypes, the antigenicity of norovirus varies widely by individual genotype. In order to develop norovirus vaccines, it is therefore essential to identify antigens and antibodies suited to the genotype of norovirus that is expected to proliferate in the upcoming season. The aforementioned contract will grant Denka rights to use monoclonal antibodies for specifically detecting various norovirus VLPs of distinct genotypes. Accordingly, Denka will be better positioned to handle the quality management of polyvalent vaccines, including controlling the vaccine mix, carrying out quality control of VLPs being mixed and testing resulting vaccines. The contract is expected to empower Denka to develop vaccines in a timely way that exactly targets the genotype of norovirus prevalent at any given time.

In addition, Denka Seiken Co., Ltd., another Group company, is marketing rapid diagnostic test kits for detecting norovirus antigens. The signing of this contract will also help Denka Seiken improve the performance of these test kits.

Looking ahead, the Denka Group will strive to deliver solutions for various issues society is now confronting and, to this end, utilize the aforementioned contract to step up its product development efforts. Notes:

- 1. Even after the signing of this contract, nationally-founded research institutes are allowed to utilize these items for the purpose of the national assay of biomedical products and performing academic research.
- 2. Hybridoma: An infinite proliferating cell line that produces antibodies. A hybridoma is produced via a cell fusion that brings together antibody-producing cells collected from an animal immunized with an antigen and a cell line with infinite proliferative properties. A large quantity of monoclonal antibodies can be produced through the cultivation of monoclonal antibodies obtained from a single hybridoma.
- 3. Monoclonal antibodies: Whereas ordinary antibodies (polyclonal antibodies) are prepared using the serum of animals immunized with antigens and are therefore mixtures of various antibody species produced by multiple antibody-producing cells, monoclonal antibodies are homogeneous, consisting of a single type of antibody as they are produced using a single type of antibody-producing cell. In general, antigens have a complex structure, and different types of antibodies are made targeting multiple antibodies targeting various antigenic sites). Polyclonal antibodies are mixtures of multiple antibodies targeting various antigenic sites. In contrast, monoclonal antibodies possess completely identical antigen specificity (antibody property of reacting to a specific antigenic site). Norovirus is classified into various genotypes, and some of its antigenic sites are specific amongst certain genotypes. Thus, monoclonal antibodies with identical antigen specificity will enable genotype-specific control.
- 4. Virus-like particles: Hollow particles that are similar in shape and antigenicity to viruses while possessing no genes or potential for infection.
- 5. magnICON®: A technology for producing high molecular proteins such as antibodies and vaccine antigens using plant-based genetic modification technology. magnICON® is also an innovative platform that enables the mass manufacturing of high molecular proteins safely, at a lower cost and in a shorter period than possible using traditional microbiological, insect or mammalian cell cultures.

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