Research and development of universal sarbecovirus vaccine

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The available COVID-19 vaccine has a low neutralizing antibody titer against the Omicron strain after the second immunization, and it has been clarified that a third booster immunization is required to establish a sufficient neutralizing antibody to protect infection. Therefore, it is unclear whether the current vaccine is effective against new variant of concern that will appear in the future.

In this study, we will design an antigen that induces robust immune response against various variants in sarbecoviruses and that can induce a neutralizing antibody titer equal to or higher than that of available vaccines by a novel technology. And we will produce a recombinant protein antigen by using the BEVS technology and mixing it with an adjuvant that has proved safety and efficiency in clinical trials.

1. Antigen design research (2022)

Research on antigen design has already started in October 2021. Among them, we have been identified antigen candidates that can induce neutralizing antibody titer against pseudoviruses

which are expressing the spike protein from wide range of VOC strains of various SARS-CoV-2 and SARS coronavirus. During the fiscal year of 2022, we will conduct study for optimization of design to improve universality of neutralizing antibody titer induced by vaccination.

2. Non-clinical and clinical trials (2023-2025)

The vaccine will be containing the designed antigen and squalene-based adjuvant. The safety and efficacy of the vaccine will be evaluated by the GLP and immunogenicity studies. We will carry out the Ph1/2 study as a vaccine against the existing coronavirus at the time of study. The vaccinated sera obtained at this time are stored, and the neutralizing antibody titer against the new variant virus will be evaluated at the time of the expected pandemic. The goal is to start clinical trials in Japan during the fiscal year of 2023 and complete the phase 2 clinical trials in Japan during the fiscal year of 2025. After the clinical trials in Japan, global study will be conducted.

・ Expected results

It is expected to develop a vaccine that can rapidly establish a sufficient neutralizing antibody titer against a new pandemic caused by a novel SARS-CoV-2 mutant virus or a subgenus sarbecovirus in the future. By using robust recombinant protein expressing technology, it is expected that a rapid supply system will be constructed even when a new pandemic occurs, and that it will contribute to the prevention of the spread of infection.