News Release

VLP Therapeutics Japan, Inc.

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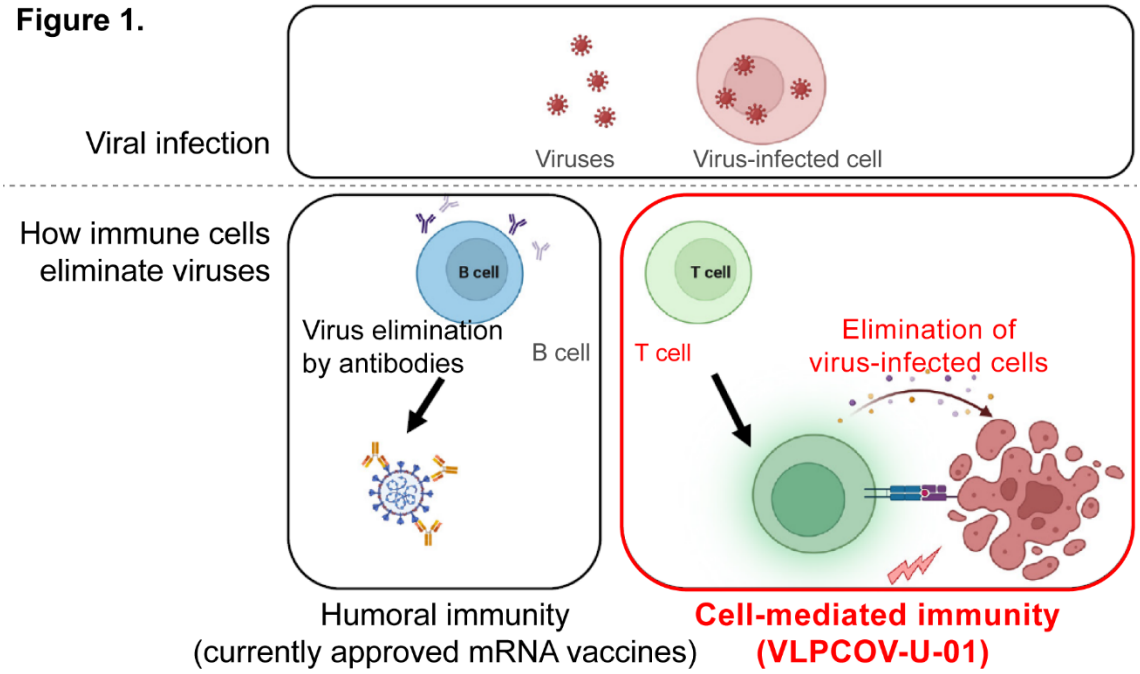
VLP Therapeutics Japan initiates Phase 1 clinical trial of T-cell inducing COVID-19 vaccine: advancing the development of a universal vaccine against multiple SARS-CoV-2 variants

VLP Therapeutics Japan, Inc. (VLPT Japan), a Tokyo-based biotech company, announced on March 31 the initiation of a Phase 1 clinical trial in Japan for its COVID-19 vaccine (VLPCOV-U-01). VLPCOV-U-01 is a novel T-cell inducing mRNA vaccine designed to prevent the onset and progression of COVID-19.

Currently approved mRNA vaccines are based on **humoral immunity**, which induces neutralizing antibodies that bind to and inactivate the virus (Figure 1). These vaccines express the viral spike protein in the body and use it as an antigen to elicit neutralizing antibodies. However, because the virus repeatedly acquires mutations that alter the structure of the spike protein, neutralizing antibodies induced by prior vaccination may no longer effectively recognize it, leading to diminished effectiveness.

In contrast, VLPCOV-U-01 is based on **cell-mediated immunity**, which eliminates virus-infected cells (Figure 1). By incorporating T-cell epitopes derived not only from the spike protein but also from non-spike regions as vaccine antigens, VLPCOV-U-01 is designed to induce cytotoxic T lymphocytes (killer T-cells) that attack infected cells, thereby facilitating viral clearance. The vaccine is also engineered to cover HLA types found in more than 95% of the Japanese population. A key feature of this T-cell inducing vaccine is its targeting of epitopes derived from conserved (less mutation-prone) regions of the structural proteins across viral strains. This design may be effective not only against currently circulating strains, but also against emerging variants, supporting its potential as a universal vaccine.

Figure 1.



This clinical trial (jRCT2051250250) will evaluate the safety and tolerability of VLPCOV-U-01 in healthy adults who have completed a primary COVID-19 vaccination series and subsequently received an Omicron-adapted booster. The study is a dose-escalation, randomized, placebo-controlled, observer-blind trial conducted at a medical institution in Japan.

VLPT Japan has been advancing research and development of COVID-19 vaccines in collaboration with multiple domestic institutions, leveraging its proprietary replicon (self-amplifying RNA) platform technologies. Building on the progress and clinical findings achieved to date, this trial is being conducted with support from the Japan Agency for Medical Research and Development (AMED) and its Strategic Center of Biomedical Advanced Research and Development (SCARDA | Vaccine and new modality research and development project). Through this research, VLPT Japan aims to develop a “universal vaccine” against multiple SARS-CoV-2 variants.

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About VLPT Japan: VLP Therapeutics Japan, Inc. (VLPT Japan), founded in 2020 by Dr. Wataru Akahata originally as a wholly owned subsidiary of US-based VLP Therapeutics, Inc., is a Tokyo-based biotech company. VLPT Japan is currently engaged in research and development of prophylactic vaccines against infectious diseases, including COVID-19, influenza, and dengue. The COVID-19 project is funded by the Japan Agency for Medical Research and Development (AMED), the AMED Strategic Center of Biomedical Advanced Research and Development (SCARDA), and the Japanese Ministry of Health, Labour and Welfare.