News Release

VLP Therapeutics, Inc.

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VLP Therapeutics makes dengue vaccine that induces antibodies, reduces replication in monkeys: Taking a step closer to next-gen dengue vaccine [*Journal of Virology*]

VLP Therapeutics, Inc. (VLPT) researchers and their colleagues at Nagasaki University and the National Institute of Infectious Diseases in Japan have demonstrated that immunization of monkeys with a tetravalent dengue virus-like particle-based (DENVLP) vaccine induces high levels of neutralizing antibodies and reduces the severity of infection for all four dengue serotypes. The researchers also found that the DENVLP vaccination did not generate antibody-dependent enhancement (ADE) response — a major hindrance in the development of dengue vaccines —for any of the four dengue serotypes at physiological serum concentrations. VLPT designed and developed this vaccine using its VLP platform technologies.

A paper reporting these findings was published online in the *Journal of Virology* on April 22, 2024. This research was conducted with support from the Global Health Innovative Technology Fund (G2016-109).

“In light of the levels of IgG and neutralizing antibodies induced with doses as low as 0.5μg (0.125μg x 4 dengue serotypes), we believe that this is a promising dengue vaccine candidate,” says **Dr. Wataru Akahata**, CEO and founder of VLPT. “Based on these outcomes we plan to proceed to the initial stage of clinical trials, and the preparations are well underway.”

- **Title:** A Tetravalent Dengue Virus-like Particle Vaccine Induces High levels of Neutralizing Antibodies and Reduces Dengue Replication in Non-Human Primates
- **Journal:** *Journal of Virology*（American Society for Microbiology）
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Abstract of the paper: Dengue virus (DENV) represents a significant global health burden, with 50% of the world's population at risk of infection, and there is an urgent need for next-generation vaccines. Virus-like particle (VLP)-based vaccines, which mimic the antigenic structure of the virus but lack the viral genome, are an attractive approach. Here we describe a dengue VLP (DENVLP) vaccine which generates a neutralizing antibody response against all four DENV serotypes in 100% of immunized non-human primates for up to one year. Additionally, DENVLP vaccination produced no ADE response against any of four DENV serotypes in vitro. DENVLP vaccination reduces viral replication in a non-human primate challenge model. We also show that transfer of purified IgG from immunized monkeys into immunodeficient mice protects against subsequent lethal dengue virus challenge, indicating a humoral mechanism of protection. These results indicate that this DENVLP vaccine is immunogenic and can be considered for clinical evaluation.

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About VLP Therapeutics: VLP Therapeutics, Inc. (VLPT), co-founded in 2013 by Drs. Wataru Akahata, Ryuji Ueno, and Sachiko Kuno, is a Maryland, US-based biotech company with a mission to address unmet medical needs worldwide and expand the frontiers of vaccine treatment. VLPT is currently engaged in research and development of a cancer treatment vaccine as well as prophylactic vaccines against infectious diseases including malaria and dengue.

About VLP Therapeutics 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) and the Japanese Ministry of Health, Labour and Welfare.