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Bench-to-Bedside: Phase 1 Trial Begin for a Japanese-Developed Nipah Virus Vaccine

―Moving toward human trials to combat deadly infectious disease―

＜Summary＞

On Monday, June 15, 2026, a research group led by Misako Yoneda, a Specially Appointed Professor at the Teikyo University Advanced Comprehensive Research Organization; Chieko Kai, a Specially Appointed Professor at the same institute; and Tomoko Fujiyuki, an Associate Professor at the same institute, have just launched the Phase 1 clinical trial in Belgium to evaluate the safety and immunogenicity of a vaccine against Nipah virus infection in humans.

The Nipah virus first caused an outbreak in Malaysia in 1997, and since then, outbreaks have occurred almost every year, primarily in South Asia, causing fatal encephalitis. With a case fatality rate reaching up to 90% and confirmed human-to-human transmission, it is considered a global public health threat. Furthermore, the natural host, the large fruit bat, is widely distributed throughout the world, raising concerns about the risk of further spread. However, there are currently no treatments, preventive measures, or vaccines available for Nipah virus infection.

The research group led by Professor Misako Yoneda is promoting international collaborative research aimed at the practical application of a Nipah virus vaccine using the measles virus as a vector (※1).

Having completed the manufacturing of the clinical trial vaccine formulation and the preclinical evaluation of its efficacy and safety, and having obtained approval from the Belgian regulatory authorities, they have now commenced a Phase 1 clinical trial in that country, with the first dose administered to a participant on June 15, 2026.

This clinical trial is expected to mark a major step toward the clinical application of a Japanese-developed recombinant vaccine for a deadly infectious disease for which no effective treatment currently exists.

＜Background＞

Since the Nipah virus was identified as an emerging infectious disease in 1999, outbreaks have occurred repeatedly, primarily in Bangladesh and India. The case fatality rate is extremely high, ranging from 40% to 75% (up to 90%), and human-to-human transmission has been confirmed. It has also been established that fruit bats, the natural hosts of Nipah-like viruses, are widely distributed throughout the world.

However, there are currently no effective treatments or vaccines available, and the development of a vaccine to prepare for future outbreaks is an urgent priority on the international stage. For this reason, the Nipah virus has been classified as a “priority pathogen” by the WHO and as a “Category C bioterrorism pathogen” by the Centers for Disease Control and Prevention (CDC).

The measles virus (MV) vaccine, which is widely used, is known to be an excellent live-attenuated vaccine that has demonstrated high safety and efficacy in preventing disease through many years of global use and can maintain immunity over the long term. The research group led by Professor Kai, who was the principal investigator at the time, started to modify the existing MV vaccine as a vector and developed a candidate Nipah vaccine (MV-NiV) by inserting a gene that expresses a Nipah virus antigen protein. In basic research, animal experiments using hamsters

and monkeys demonstrated that MV-NiV confers extremely high protection against Nipah virus and is safe, as it does not cause measles or shed the virus.

To advance the clinical application of MV-NiV, the research group — with the University of Tokyo, where we were affiliated at the time, serving as the lead institution — established an international collaborative research framework with the European Vaccine Initiative (EVI), Stanford University, and the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). They applied for and were selected under a CEPI (※2) call for proposals, and began practical development research in 2019. Subsequently, starting in 2023, the project was selected for funding through a call for proposals by AMED SCARDA (※3) of Japan. Teikyo University is currently leading the project.

＜Research Topic＞

This applied research project is being carried out through a collaborative effort involving more than 15 domestic and international institutions, including Teikyo University, the University of Tokyo, European Vaccine Initiative (EVI), Stanford University, Ghent University, ERINHA (※4), Harmony Clinical Research, and icddr,b.

To date, the team has completed the manufacturing of the vaccine for clinical trials and confirmed preclinically its high efficacy in preventing the onset of Nipah virus infection at a BSL-4 facility in the EU (※5). Furthermore, safety has been demonstrated in non-clinical studies in non-human primate. Subsequently, they received approval from the Belgian regulatory authorities to begin the first-in-human clinical trial.

As a result, a Phase 1 clinical trial has just started at the Center for Vaccinology of Ghent University in Belgium. The first participant received the vaccine on June 15, 2026. This trial will evaluate the safety and immunogenicity of MV-NiV.

＜Significance＞

If the safety and immunogenicity of the vaccine are confirmed in humans during this Phase 1 clinical trial, it will be possible to proceed to Phase 1 and Phase 2 clinical trials in Bangladesh, an area where Nipah virus infections are prevalent, marking a significant step toward commercialization.

This vaccine is based on previous research findings and an existing measles vaccine, and thus is expected to be highly safe and to induce strong protective immunity. Furthermore, it is anticipated that two doses will provide long-lasting (lifelong) protection.

Consequently, this holds the potential to provide vaccines that offer affordable and long-lasting immunity against neglected infectious diseases prevalent in developing countries and thus is expected to contribute directly to curbing the spread of these diseases in affected regions. In addition, this could mark the first instance of research originating in Japan being utilized globally as a practical vaccine. Therefore, it is considered to be of utmost importance in the context of global infectious disease control.

If this vaccine is established as a strategy for preventing Nipah virus infection, it is expected to directly contribute to infection control in endemic areas and help ensure the safety and security of people worldwide in the face of the threat posed by deadly viral infections.

＜Note＞

This project was launched with funding from CEPI and is currently being carried out with support from AMED SCARDA.

＜Glossary＞

※1 Virus vector vaccine. A vaccine that uses a virus as a vector, loading the antigen gene of the pathogen to be prevented onto the virus to deliver it into cells and induce its expression.

※2 CEPI (Coalition for Epidemic Preparedness Innovations). Established in January 2017. It is an international framework designed to accelerate the development of vaccines and other biological countermeasures against the threat of infectious disease outbreaks and pandemics and is funded by substantial contributions from governments around the world, including Japan.

※3 AMED SCARDA (Japan Agency for Medical Research and Development, Strategic Center of Biomedical Advanced Research and Development for Preparedness and Response). This was established in March 2022 within AMED as a framework to lead research and development activities during peacetime, with the aim of rapidly advancing vaccine development in the event of an infectious disease emergency. Currently, it is implementing projects for the research and development of vaccines, novel modalities, and therapeutics; initiatives to establish world-class research and development hubs for vaccine development; and a research and development platform for medicines to address emerging infectious disease crises.

※4 ERINHA (European Research Infrastructure on Highly Pathogenic Agents AISBL). A European research collaboration organization specializing in research on highly pathogenic pathogens. A European research infrastructure that supports the effective use of major BSL-4 facilities across Europe.

※5 BSL4 (Biosafety level 4). Pathogens such as bacteria and viruses are classified into four safety levels (Classes 1–4). BSL-4 pathogens are those for which no treatment or preventive vaccines exist. Safety management standards for laboratories and facilities handling these pathogens are also regulated in accordance with this classification. BSL-4 facilities are highly contained facilities that adhere to the highest level of safety standards and safety management systems.

【For inquiries regarding this matter】

＜Research-related matters＞
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