PRESS RELEASE

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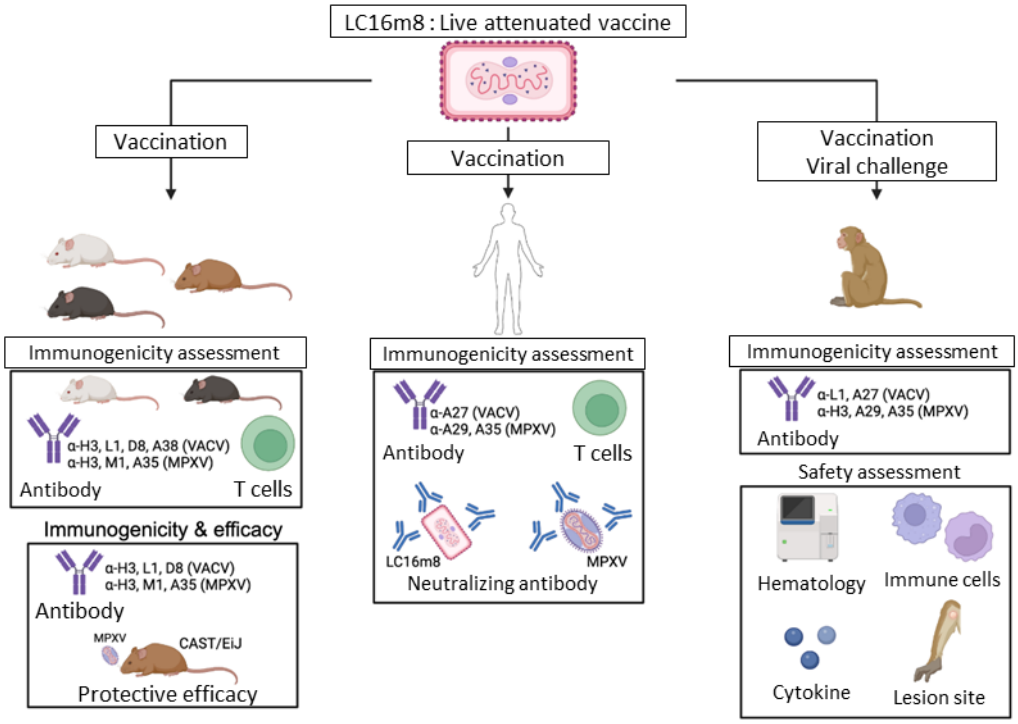
Immunological Insights into Japan's LC16m8 Vaccine Against Mpox

First Comprehensive Analysis of Immune Responses Induced by LC16m8 Vaccination

Key points

- The Japanese-developed attenuated smallpox vaccine LC16m8 has been shown to elicit strong immune responses and provide protective effects against mpox infection in animal models.
- Human samples demonstrated the induction of neutralizing antibodies effective against multiple mpox virus clades.
- These findings provide a solid scientific basis for the global deployment of LC16m8 as a safe and effective vaccine option in response to the ongoing mpox pandemic.



LC16m8 Vaccine Induces Immune Responses Against Diverse Mpox Virus Strains

LC16m8 induced strong antibody responses and cellular immunity in multiple mouse strains, and conferred protection against mpox virus infection. In humans, vaccinated individuals were confirmed to have developed neutralizing antibodies effective against various mpox virus strains.

Overview

A research group led by Associate Professor Kouji Kobiyama and Professor Ken Ishii at the Institute of Medical Science, The University of Tokyo, has conducted a comprehensive analysis of the immunological effects of the Japan-developed mpox vaccine "LC16m8," which has been approved by the World Health Organization (WHO). The findings demonstrate, for the first time, both the safety and efficacy of this vaccine in a comprehensive manner, and were published in an international scientific journal.

These results suggest that the LC16m8 vaccine is effective against the mpox virus Clade Ib, which prompted WHO to declare a renewed Public Health Emergency of International Concern (PHEIC) in 2024. The vaccine is also expected to serve as a core platform technology for vaccine development, evaluation, and therapeutic research in response to the anticipated spread of the virus, particularly in African countries.

Background

Mpox virus was first identified in Denmark in 1958, and human infection was first confirmed in the Democratic Republic of the Congo (then Zaire) in 1970. The virus continues to circulate in Central and West Africa. In 2022, cases were reported in over 100 countries, leading the WHO to declare a PHEIC. Although the PHEIC declaration ended in May 2023, the emergence and rapid spread of the new Clade Ib strain led to a second PHEIC declaration in August 2024. From January 1, 2022, to January 31, 2025, the WHO reported over 130,000 cases.

Mpox virus belongs to the Orthopoxvirus genus of the Poxviridae family, the same as variola virus (smallpox virus), and smallpox vaccines are believed to be effective against mpox. In fact, Japan's LC16m8 strain—a vaccinia virus strain originally developed for smallpox—was approved in August 2022 for use against mpox.

Details of the Study

Using mouse models, non-human primates, and human clinical samples, the study closely examined the immune responses induced by the LC16m8 vaccine against mpox virus. The research revealed that broad antibody responses and long-lasting T-cell-mediated immunity were induced.

First, immunological evaluations were conducted using three mouse strains (BALB/c, C57BL6/J, CAST/EiJ). Mpox virus-specific antibodies were induced in all strains. In the highly mpox-susceptible CAST/EiJ strain, LC16m8 was shown to confer direct protective effects for the first time (see Figure 1).

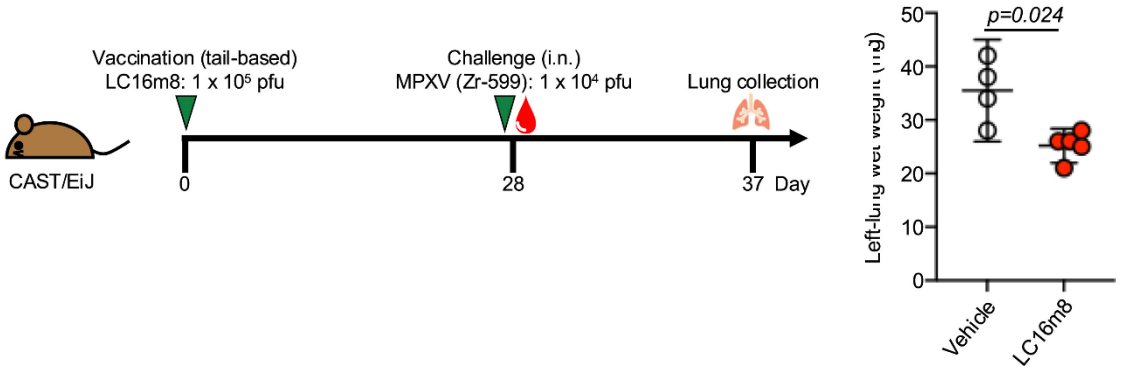


Figure 1. Preventive Effect of LC16m8 Vaccination Against Infection

Next, evaluations using cynomolgus monkeys confirmed the safety of LC16m8 and the induction of mpox virus antigen-specific antibodies following vaccination.

Finally, comparing human samples collected before and after LC16m8 vaccination confirmed the induction of antibodies against mpox virus antigens, and the generation of neutralizing antibodies against multiple clades (Ia, IIa, IIb). Antibody responses to Clade Ib—the current focus of the PHEIC—were also observed in vaccinated mice, non-human primates, and human clinical samples.

These findings demonstrate that LC16m8 induces broad antibody responses across multiple genetic clades (Ia, Ib, IIa, IIb), suggesting its promise as a future countermeasure against potential virus mutations and global outbreaks.

Paper information

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Terminology

(1) LC16m8: An attenuated smallpox vaccine strain developed in Japan and approved in 1975 for smallpox and in 2022 for mpox. Derived from the Lister strain and attenuated through cold-passaging, it features a deletion in the B5 gene.

(2) Mpox (MPOX): Formerly known as monkeypox, an infection caused by the monkeypox virus (MPXV), belonging to the Orthopoxvirus genus. Main symptoms include fever, lymphadenopathy, and characteristic rashes. Since 2022, the disease has spread globally. The virus is classified into four genetic clades: Ia, Ib, IIa, and IIb. Clades Ia and Ib are associated with higher mortality and are prevalent in parts of Africa.

(3) Clade: A group of organisms derived from a common ancestor. Mpox virus clades differ in pathogenicity and geographic distribution.

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