

NEWS RELEASE

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KM Biologics is Selected Through an Open Call for Conducting the “Large-scale Vaccine Clinical Study Project” by the Ministry of Health, Labour and Welfare

KM Biologics Co.,Ltd. (Headquarters: Kumamoto, Japan; President and Representative Director: Toshiaki Nagasato; hereinafter, “KM Biologics”), a pharmaceutical company under Meiji Holdings, is pleased to announce that we have been selected as a business operator for conducting the “Large-scale Vaccine Clinical Study Project” (hereinafter, “this Project”) sponsored by the Ministry of Health, Labour and Welfare (MHLW).

This Project aims to support domestic pharmaceutical companies undertaking the challenge of developing vaccines against priority infectious diseases with potential for future pandemics, particularly by allowing them to accumulate experience and knowledge in conducting large-scale clinical studies to verify vaccine efficacy. This will facilitate prompt development of vaccines in Japan when the next pandemic occurs.

Using the subsidy given by the MHLW for the open call of this Project, through which we have been selected, KM Biologics will work on developing the KD-382*¹ vaccine to prevent dengue virus infections*².

KD-382 is a live-attenuated tetravalent dengue vaccine expected to be effective against all four serotypes with a single dose. Currently, KD-382 is undergoing a phase II clinical study in adults and children in countries experiencing dengue epidemics, funded by the grant obtained in December 2022 for a under “Vaccine/New Modality Research and Development Project” from the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA). We plan to utilize the subsidy from this Project to conduct a phase III clinical study of the vaccine.

As a Meiji Group company, KM Biologics will continue to protect people from vaccine-preventable infectious diseases, thus contributing to healthier and prosperous future.

*1 KD-382 is a live attenuated tetravalent dengue vaccine that is expected to be effective against all four serotypes with a single dose. As a live attenuated virus vaccine is expected to induce both neutralizing antibodies and cellular immunity, similar to natural infection, the long-term persistence of neutralizing antibodies and low probability of disease enhancement due to antibody-dependent enhancement (ADE) can be expected.

*2 Dengue virus is a mosquito-borne virus belonging to the Flaviviridae family and causes dengue fever, dengue hemorrhagic fever, and dengue shock syndrome in humans. Four serotypes, ranging from type 1 to type 4, are involved in human epidemics. Dengue is endemic in more than 120 countries in tropical and subtropical regions. Approximately 50% of the world's population, or 3.9 billion people, are at risk of infection, and approximately 100 million people become infected each year. It was estimated that in 2010, 390 million people were infected, and 96 million people required hospitalization and other treatments. In addition, 500,000 people require hospitalization owing to severe illness every year because of dengue fever or dengue hemorrhagic fever, and the annual mortality rate is estimated to be 2.5% (12,500 people) (WHO report).

[Contact for inquiries]
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