Meiji Seika Pharma Co., Ltd.

KM Biologics Co., Ltd.

NEWS RELEASE

September 1, 2025

KM Biologics and Meiji Seika Pharma Announce Initiation of Phase II Clinical Trial for Live, Attenuated, Tetravalent Dengue Vaccine (KD-382)

KM Biologics Co., Ltd. (Headquarters: Kumamoto, Japan; CEO: Hirotada Takahashi; hereinafter referred to as "KM Biologics") and Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan; COO: Toshiaki Nagasato; hereinafter referred to as "Meiji Seika Pharma") announced that they have initiated the Phase II clinical study of a live, attenuated, tetravalent dengue vaccine, KD-382,[*1] in adults and children.

<Overview of the Phase II clinical study>

Objective	To evaluate the safety and immunogenicity of KD-382 in healthy adults aged 18 to 64 years and healthy children aged 2 to 17 years (with adjusted dose)
Target number of subjects	680 (healthy adults: 200; healthy children: 480)
Study design	Multicenter, double-blind, randomized, placebo-controlled, parallel-group, age de-escalation, dose-escalation study (open-label only for the pediatric sentinel cohort)
Vaccination method	Single subcutaneous injection of either high dose vaccine, standard dose vaccine, or placebo
Country	Thailand (TCTR20241231011) *Dengue non-endemic countries (currently being determined) will be added in the future

Dengue virus, a mosquito-borne virus belonging to the Flaviviridae family, causes dengue fever, dengue hemorrhagic fever, and dengue shock syndrome in humans. Four serotypes, types 1 to 4, are involved in human epidemics. Dengue is endemic in more than 120 countries in the tropical and subtropical regions. Approximately 50% of the world's population (approximately 3.9 billion people) is at risk of infection, and approximately 100 to 400 million people become infected each year.

KD-382 is a live, attenuated, tetravalent dengue vaccine that is expected to be effective against all four serotypes with a single dose. The Phase I clinical study of KD-382 conducted in Australia has demonstrated satisfactory safety, tolerability, and immunogenicity.[*2]

KM Biologics and Meiji Seika Pharma will contribute to a healthy and prosperous future by protecting people from infectious diseases that can be prevented using vaccines.

This clinical study is conducted with the support of and subsidies from the “Program on R&D of new generation vaccine including new modality application” of the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response, Japan Agency for Medical Research and Development (AMED SCARDA) adopted in December 2022 (JP223fa827007).

*1 KD-382 is not a recombinant (chimeric) vaccine, and it contains full components (structural + non-structural proteins) derived from attenuated strains of all four serotypes. As it is expected to induce both humoral (neutralizing antibodies) and cellular immunity, similar to natural infection, long-term efficacy and low probability of disease exacerbation due to antibody-dependent enhancement can be expected.

*2 News Release dated March 25, 2021