

March 25, 2021

To the Press

## **KM Biologics Announces Phase I Clinical Study Results of a Live Attenuated Tetravalent Dengue Vaccine (KD-382)**

KM Biologics Co., Ltd. (Headquarters: Kumamoto, Japan; CEO: Toshiaki Nagasato) announced the results of the Phase I clinical study (hereinafter the “Study”) of a live attenuated tetravalent vaccine, KD-382\*<sup>1</sup> (hereinafter, the “KD-382 vaccine”), to prevent dengue\*<sup>2</sup>.

This study was conducted to evaluate the safety and immunogenicity of the KD-382 vaccine in 60 healthy adults in Australia, which is a non-dengue endemic country, by administering the KD-382 vaccine subcutaneously once or twice with a 4-week interval.

The results show that the KD-382 vaccine is safe and well-tolerated by healthy adults. Moreover, KD-382 showed 100% seroconversion at an early stage and elicited long-lasting and neutralizing antibody response for all 4 serotypes in most subjects over a 1-year follow-up, despite the single-dose administration.

Based on the supporting results indicating the KD-382 vaccine as very promising, we will proceed with preparations for Phase II clinical studies of the KD-382 vaccine in dengue-endemic countries to maximize the value of the vaccine and address the unmet medical needs of people at risk of dengue worldwide.

\*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).

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