Study of modernization of manufacturing and quality control method of smallpox vaccine

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KM Biologics Co., Ltd. (KMB) has the approval of smallpox vaccine LC16 ”KMB” for "prevention of smallpox and mpox". Since rabbit kidney cells are used, production depends on the supply of SPF rabbits, and production flexibility is low. The vaccine production is exposed to risks such as quality fluctuations and adventitious agents. Many quality tests are performed to minimize these risks. Many man-hours are required for manufacturing. There is also a problem from the viewpoint of animal welfare.

This study changes the viral culture substrate to continuous cell line and reviews quality control system to improve the production flexibility for the case of emergency, minimize risk of stable supply, save the number of workers, and 3Rs. KMB has experience in the development of cell culture derived vaccines such as Japanese encephalitis vaccine and maintains various knowledge, abilities, and human resources. Kumamoto University (KU) concluded a comprehensive cooperation agreement in February 2022, promoting vaccine development and new modality research with KMB. In April 2022, vaccine development research center attached to the Kumamoto University Life Sciences Research Department was established to strengthen cooperation with companies. Already, the virus culture optimization has already been conducted by Prof. Misumi of KU, and those know-how can be applied to the study. In addition, there is a world-class research platform for the development of chronic kidney disease therapy in the laboratory of Prof. Kai of KU. They can perform functional analysis at one cell level that makes up 25 the kidney and have already set up a functional analysis. They can analyze the proliferation of vaccine virus strains in any cell and screen useful stocks.

After establishing the cell line, manufacturing method, we will conduct manufacturing a prototype vaccine, non-clinical efficacy and safety studies and Phase 1/2 studies for tolerability, immunogenicity, and dose finding of the vaccine candidate. Depending on the progress, we will consider collaboration with the National Institute of Infectious Diseases, the National Center for Global Health and Medicine, and flagship/synergy bases etc.

Through the studies, we will establish modernized manufacturing process and vaccine candidate for the late phase clinical trials. We will aim to acquire the approval using acquiring data such as late phase clinical studies separately, to construct the systems to provide 40 to 50 million doses in an emergency. It also contributes to the accumulation of vaccine development knowledge and scheme development, and human resource development through organic community comprehensive collaboration with academia.