

November 20, 2024

KM Biologics Receives WHO Emergency Use Listing for its Mpox Vaccine

KM Biologics Co., Ltd. (Headquarters: Kumamoto, Japan; President and Representative Director: Toshiaki Nagasato; hereinafter referred to as “KM Biologics”), a pharmaceutical company of Meiji Holdings, is pleased to announce that its mpox vaccine, the Freeze-dried Smallpox Vaccine Prepared in Cell Culture LC16 ‘KMB’, was granted Emergency Use Listing (EUL) by the World Health Organization (WHO) on November 19, 2024.

The WHO EUL is a procedure in response to a public health emergency of international concern for assessing the safety, efficacy, and quality of unlicensed medical products, such as vaccines, based on the existing clinical data and listing them to expedite their availability for emergency use worldwide, including developing countries. Once a vaccine is granted EUL, it allows global organizations that support vaccine distribution to procure and deliver the vaccine to the countries in need.

The Freeze-dried Smallpox Vaccine Prepared in Cell Culture LC16 ‘KMB’ is a live attenuated vaccine that can provide sufficient protection after a single dose and be administered to people of all ages, including infants. In Japan, the vaccine received manufacturing and marketing approval for pharmaceutical products in 1980 for an indication of “prevention against smallpox.” In August 2022, the vaccine was approved for an additional indication of “prevention against mpox.”

KM Biologics will now aim to obtain WHO prequalification (WHO PQ) for this vaccine in collaboration with Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan; President and Representative Director: Daikichiro Kobayashi), another pharmaceutical company of Meiji Holdings. Furthermore, concerning the ongoing mpox outbreaks in Africa, particularly in the Democratic Republic of the Congo, KM Biologics will work together with relevant organizations such as the WHO and the Ministry of Health, Labor and Welfare of Japan to do its part in response activities in the international public health emergency as a pharmaceutical company with an mpox vaccine that can be administered to children, including infants.