



Meiji Seika Pharma Co., Ltd.



KM Biologics Co., Ltd.

## NEWS RELEASE

January 27, 2025

### **Japanese Government Delivers KM Biologics' Mpox Vaccine to the Democratic Republic of the Congo**

KM Biologics Co., Ltd. (Headquarters: Kumamoto, Japan; President and Representative Director: Toshiaki Nagasato; hereinafter referred to as “KM Biologics”) and Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan; President and Representative Director: Daikichiro Kobayashi; hereinafter referred to as “Meiji Seika Pharma”), pharmaceutical companies of Meiji Holdings, are pleased to announce that 50,000 doses of the mpox vaccine LC16 KMB (LC16m8 vaccine), for which KM Biologics has received manufacturing and marketing approval, was provided free of charge to the Democratic Republic of the Congo by the Japanese government on January 25, 2025.

The mpox epidemic has been ongoing in the Democratic Republic of the Congo with large numbers of infected patients and deaths being still reported. As of November 17, 2024, the number of confirmed cases of mpox reached 9,513 (including 43 deaths) with 43,862 suspected cases (including 1,138 deaths) in the Democratic Republic of the Congo. In endemic areas of the country, the incidence is the highest in children under 15 years of age. <sup>\*1</sup>

LC16 KMB (LC16m8 vaccine) 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.” In November 2024, the vaccine was granted Emergency Use Listing (EUL)<sup>\*2</sup> by the World Health Organization (WHO), which led to its provision.

KM Biologics and Meiji Seika Pharma will now aim to obtain WHO prequalification (WHO PQ) for this vaccine. Furthermore, while continuing to work together with relevant organizations such as the WHO and the Ministry of Health, Labour and Welfare of Japan, KM Biologics and Meiji Seika Pharma will aim to eliminate serious mpox outbreaks in Africa, particularly in the Democratic Republic of the Congo and do their parts in response activities in the international public health emergency by expanding the vaccination of this vaccine in endemic areas.

\*1 Source: 2022-24 Mpox (Monkeypox) Outbreak: Global Trends, World Health Organization, Produced on 16 January 2025 ([https://worldhealthorg.shinyapps.io/mpx\\_global/](https://worldhealthorg.shinyapps.io/mpx_global/))

\*2 The WHO Emergency Use Listing (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.

Reference: World Health Organization News release (<https://www.who.int/news/item/19-11-2024-who-adds-1c16m8-mpox-vaccine-to-emergency-use-listing>)