

News Release

March 28, 2024

Press Release

The Research Foundation for Microbial Diseases of Osaka University

Marketing Authorization Application of Intranasal Influenza Vaccine (BK1304)

The Research Foundation for Microbial Diseases of Osaka University (Headquarters: Suita City, Osaka; Director General: Yoshihiro Yoneda; hereinafter, “BIKEN”) announced that it submitted an application for marketing authorization of intranasal influenza vaccine (BIKEN Clinical Trial Code: BK1304; hereinafter, “this vaccine”) to the Ministry of Health, Labour and Welfare (MHLW) today.

This vaccine has been jointly developed with Toko Yakuhin Kogyo Co., Ltd. (Headquarters: Osaka City, Osaka; President: Taizo Kamishita) in response to the request for high-priority vaccine development (Notification No. 1216-1 of the Tuberculosis and Infectious Disease Control Division, Health Service Bureau, MHLW).

The application for marketing authorization is based on the results of clinical studies (in subjects aged 13 to under 65 years) conducted in Japan. The conventional injection-type influenza hemagglutinin (HA) vaccines use spike proteins on the viral surface (HA proteins) as antigens, and are inoculated subcutaneously to induce antibodies primarily in the blood to prevent exacerbation after influenza virus infection. In contrast, this vaccine uses the whole inactivated virus particles as antigens, and is sprayed into the nasal cavity to induce antibodies on the mucosal tissues to help prevent the onset of influenza.

In addition, by using the dosing system comprising a special base and a nasal device instead of the conventional syringe, this vaccine enables delivery of the appropriate dose to the target site of the nasal cavity, which is thereby alleviating the pain and anxiety experienced by the vaccine recipients.

The influenza HA vaccines are used for a wide range of age groups from children to the elderly, with 25 to 30 million mL used every year.*

*According to the “Supply of seasonal influenza vaccines for 2023/24” by the MHLW.

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News Release

◆ About The Research Foundation for Microbial Diseases of Osaka University (BIKEN)

The BIKEN Foundation is engaged in the research, development, and supply of vaccines and provides advanced laboratory test services. As a pioneer of university ventures, the BIKEN Foundation has contributed to public health since its establishment in 1934 based on its mission “Protect the precious lives of people around the world through excellent vaccines.” Toward a healthy society, the BIKEN Foundation will continue to pursue achievements with its proprietary research and development expertise and biotechnologies to meet society’s expectations.

<https://www.biken.or.jp/>

◆ About Toko Yakuhin Kogyo Co., Ltd.

Toko Yakuhin Kogyo Co., Ltd. (Headquarters: Osaka City, Osaka) was established in 1971.

The company has gained numerous patents based on its unique drug formulation technology in Japan as well as overseas, and has provided various pharmaceutical products using their unique technology. In recent years, the company has particularly been focusing on mucosal absorption, and its intranasal formulation using a special dosing system to spray gel base is attracting the attention of several researchers and pharmaceutical companies.

<https://www.toko-yakuhin.co.jp/>
