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To Members of the Press

**Initiation of Phase III Clinical Trial of a Combination Vaccine for Six Diseases
(Pertussis, Diphtheria, Tetanus, Inactivated Polio, Hib, and Hepatitis B)**

The Research Foundation for Microbial Diseases of Osaka University (Headquarters: Suita-city, Osaka; Director General: Yoshihiro Yoneda; hereinafter “BIKEN”) and Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director, CEO: Akihisa Harada; hereinafter “Tanabe Pharma”) are jointly developing a hexavalent combination vaccine to prevent pertussis, diphtheria, tetanus, poliomyelitis (polio), Haemophilus influenzae type b (Hib) infection, and hepatitis B (BIKEN Clinical Trial Code: BK1803; Tanabe Pharma Clinical Trial Code: MT-1803). The companies are pleased to announce that the initial dose was administered on October 21 in the Phase III clinical trial (jRCT: jRCT2031260370, ClinicalTrials.gov: NCT07793513).

The investigational vaccine is a combination vaccine for six diseases that combines the active substances of an existing combination vaccine for five diseases (pertussis, diphtheria, tetanus, inactivated polio, and Hib) with the active substance of a hepatitis B vaccine. Currently, the total number of routine vaccination shots recommended by two years of age is 17 or more, and combination vaccines will reduce the number of shots and the burden on infants and guardians.

This trial will be conducted in Japan to demonstrate that the immunogenicity of the investigational vaccine is non-inferior to that of the approved combination vaccine for five diseases and hepatitis B vaccine, and to assess its safety.

The combination vaccine for six diseases was designated as a high-priority vaccine for development, and its development was requested in the Ministry of Health, Labour and Welfare notice titled “Research and Development of High-Priority Vaccines (Request for Development),” issued on June 19, 2025.

BIKEN and Tanabe Pharma will continue to work toward the early development of the combination vaccine for six diseases. They will also contribute to the prevention of a wide range of infectious diseases and to the health of people around the world through the manufacture and stable supply of vaccines and therapeutic medicines.

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About Research Foundation for Microbial Diseases of Osaka University

BIKEN is a Specialty Bio-Pharmaceutical Organization engaged in the Research, Development and Supply of Vaccines. Since its establishment in 1934, BIKEN has contributed to public health by developing, manufacturing and supplying a number of first vaccines made in Japan and providing advanced laboratory test services. Based on its mission “Protect the precious lives of people around the world through excellent vaccines.” the BIKEN will continue to pursue the advancement of advanced science and unique biotechnology toward a healthy society free from disease anxiety.

For more information, visit <https://www.biken.or.jp/en>.

About Tanabe Pharma

Tanabe Pharma Corporation is a Japan-focused, innovation-driven pharmaceutical company guided by its mission, “Creating hope for all facing illness.” Founded in 1678, the company is one of Japan's oldest pharmaceutical companies and is committed to addressing unmet medical needs through R&D, business development, and strategic partnerships with the aim of improving the lives of patients.

For more information, visit <https://www.tanabe-pharma.com/en/>.