



April 11, 2022

Marketing Authorization Application of Pertussis, Diphtheria, Tetanus, Inactivated Polio and Hib Combined Vaccine (BK1310/MT-2355)

The Research Foundation for Microbial Diseases of Osaka University (Headquarters: Suita City, Osaka; Director General: Koichi Yamanishi; hereafter, "BIKEN") and Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Hiroaki Ueno; hereafter, "MTPC") announced that BIKEN submitted today to the Ministry of Health, Labour and Welfare an application for marketing authorization of combination vaccine (BIKEN Clinical Trial Code: BK1310, MTPC Clinical Trial Code: MT -2355) for prophylaxis of pertussis, diphtheria, tetanus, acute poliomyelitis (polio) and Haemophilus influenzae type b (Hib), which they have jointly developed.

This vaccine combines TETRABIK (Adsorbed Diphtheria-purified Pertussis-tetanus-inactivated polio [Sabin strain] Combined Vaccine) with Hib vaccine. The combination vaccine for five diseases has been selected as one of the vaccines with high development priority according to the "National Immunization Plan" stipulated in 2014. At present, the total number of shots of routine vaccinations required by two years old is twenty or more, and combination vaccines will reduce the number of shots and the burden on infants and quardians.

BIKEN and MTPC will continue to contribute to the prevention of various infectious diseases and the health of people around the world through the manufacture and stable supply of vaccines and therapeutic drugs.

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◆Please refer to the following URL for the infections to be prevented with pertussis, diphtheria, tetanus, inactivated polio and Hib combined Vaccine.
https://www.cdc.gov/vaccines/parents/diseases/index.html

♦ Research Foundation for Microbial Diseases of Osaka University

The 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. https://www.biken.or.jp/english

♦ About Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma Corporation (MTPC), the pharma arm of Mitsubishi Chemical Holdings Group (MCHC Group), is one of the oldest pharmaceutical companies in the world, founded in 1678, and focusing on ethical pharmaceuticals. MTPC is headquartered in Doshomachi, Osaka, the birthplace of Japan's pharmaceutical industry. The MCHC Group has positioned Health Care as its strategic focus in its management policy, "Forging the future". MTPC set the MISSION of "Creating hope for all facing illness". To that end, MTPC is prioritizing work on "precision medicine" to provide drugs with high treatment satisfaction by identifying patient populations with high potential for efficacy and safety, focusing on the disease areas of central nervous system and immuno-inflammation. In addition, MTPC is working to develop "around the pill solutions" to address specific patient concerns based on therapeutic medicine, including prevention of diseases, pre-symptomatic disease care, prevention of aggravation and prognosis. For more information, go to https://www.mt-pharma.co.jp/e/