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Takeda Pharmaceutical Company Limited has announced that the Japanese Ministry of Health, Labour and Welfare has approved the New Drug Application (NDA) for a conjugate vaccine to prevent infections caused by Haemophilus influenza type b (Hib) in children aged from 2 months to 5 years and below of age.

The vaccine was licensed from Novartis (Switzerland) in May 2009 (Novartis' product name: VAXEM Hib). The vaccine is supplied as a suspension for injection that does not require reconstitution.

The application approval is based on positive Phase 3 clinical results of a multicenter, randomized, double-blind, parallel-group, comparative study in 416 Japanese children, which evaluated the safety and immunogenicity of this vaccine compared to a Hib vaccine licensed in Japan.

Hib frequently inhabits the nasopharynx (nose and throat) of individuals and can spread to other parts of the body, causing life threatening illness such as meningitis, pneumonia, or sepsis, particularly in young children. Hib meningitis can be fatal or result in long term disability, but can be prevented through immunization.

"The approval of this NDA will provide parents in Japan with an important option to help protect their children against illnesses caused by Hib," said Hitoshi Oinuma, Head of Takeda's Japan Vaccine Business Unit. "Takeda will continue to focus efforts on advancing public health in Japan and across the globe through the development of high quality vaccines that prevent disease and save lives."