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First-ever WHO prequalification for China vaccine firm

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Singapore: PATH, a global health nonprofit organization, and China National Biotec Group, a leading vaccine manufacturer in China, has achieved prequalification by World Health Organization (WHO) for a vaccine to protect children against Japanese encephalitis (JE).

The SA 14-14-2 live, attenuated JE vaccine is the first JE vaccine to be prequalified for use in children by WHO. This milestone also marks the first time a Chinese vaccine manufacturer has achieved WHO prequalification. The vaccine is manufactured by Chengdu Institute of Biological Products, a subsidiary of CNBG.

With funding from the Bill & Melinda Gates Foundation, PATH led a series of pivotal clinical trials to establish the immunogenicity and safety of the vaccine in at-risk children and provided technical and financial support to help CDIBP meet the international manufacturing standards required for WHO prequalification.

Ã?Â¢Ã¢â??Â¬Ã â??This milestone brings the world within reach of an audacious goal: the elimination of a devastating disease through expanded access to an affordable and lifesaving vaccine,Ã?Â¢Ã¢â??Â¬Ã?Â• said Mr Steve Davis, PATH president and CEO. Ã?Â¢Ã¢â??Â¬Ã â??Our groundbreaking collaboration with leading Chinese partners also helped lay the foundation for reshaping global vaccine supply, pricing, and accessibility through increased competition. This milestone signals China's rising importance as a global supplier of high-quality vaccines for the most vulnerable children in the world.Ã?Â¢Ã¢â??Â¬Ã?Â•

WHO prequalification is a critical step in expanding access to this lifesaving vaccine. The WHO decision allows United Nations' procurement agencies to purchase the vaccine and serves as an endorsement of quality for countries interested in adopting it. Prequalification also opens the door for the vaccine's inclusion in the GAVI Alliance portfolio and for essential vaccine financing for low-resource countries.

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More than four billion people live in JE-endemic regions in South East Asia and the Western Pacific. JE is carried by mosquitoes and causes a viral brain infection. It is the leading cause of viral neurological disease and disability in Asia, with nearly 70,000 cases and an estimated 10,000 to 15,000 deaths reported each year.

However, because of limited surveillance and complexities in diagnosis, these figures likely underestimate JE's impact. Children who survive JE are often left with severe neurological damage. Ã?Â¢Ã¢â??Â¬Ã â??We have reached two major milestones today. In addition to achieving WHO prequalification of our JE vaccine, we are proud to be the first Chinese manufacturer to produce a WHO-prequalified vaccine,Ã?Â¢Ã¢â??Â¬Ã?Â• said Dr YANG Xiaoming, CEO of CNBG.

Ã?Â¢Ã¢â??Â¬Ã â??As one of the largest vaccine manufacturers in the world, we take our mission of providing safe, effective, and affordable vaccines very seriously. With PATH's support and WHO's prequalification, we're proud to bring China onto the global stage as an important vaccine supplier serving GAVI-eligible countries.Ã?Â¢Ã¢â??Â¬Ã?Â• Over the past decade, PATH has led a cross-sector collaboration with CNBG, CDIBP, and other global partners to pave the way for the prequalified JE vaccineÃ?Â¢Ã¢â??Â¬Ã¢â?¬Â•improving surveillance systems to better understand the disease burden; identifying the existing SA 14-14-2 live, attenuated JE vaccine and working to scale it up; collaborating on clinical trials; and helping countries plan for vaccine introduction.

PATH worked with CDIBP to construct a new manufacturing facility that would meet rigorous international standards for vaccine quality and good manufacturing practices while ensuring adequate supply. PATH also negotiated with CDIBP to establish an affordable public-sector price and supported vaccination campaigns in 11 countries outside of China that have already licensed or registered the vaccine for use ahead of WHO prequalification. Those campaigns have reached more than 200 million people to date.

Ã?Â¢Ã¢â??Â¬Ã â??Today's prequalification means that all communities in JE regions will have access to a safe, affordable vaccine,Ã?Â¢Ã¢â??Â¬Ã?Â• said Dr. Kathleen Neuzil, director of PATH's Vaccine Access and Delivery Global Program. Ã?Â¢Ã¢â??Â¬Ã â??We'll now work with our global health and in-country partners to accelerate the delivery of this vaccine to children in low-resource settings who are most vulnerable to the disease and its severe consequences.Ã?Â¢Ã¢â??Â¬Ã?Â•

PATH also leads a multicountry JE project that is taking a regional approach to the adoption, introduction, and scale-up of JE vaccination in endemic countries, building on the lessons learned and best practices developed over the past decade.