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ASIA EDITION

CMS begins clinical rollout of Silevimig, first bispecific antibody for rabies passive immunisation

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Initial prescriptions have been issued across multiple Chinese hospitals following June approval, marking the start of large-scale clinical use of the fully human bispecific antibody.

China Medical System Holdings has announced that initial prescriptions for Silevimig Injection have been issued at multiple hospitals across China, marking the start of large-scale clinical application of the world's first bispecific antibody for passive immunisation against rabies.

Hospitals issuing the initial prescriptions include Beijing Luhe Hospital of Capital Medical University, Wenzhou People's Hospital, Kaiping Central Hospital, Dongguan Guangji Hospital and Huidong Jilong Ankang Hospital.

Silevimig is a Class 1 innovative drug and the world's first fully human bispecific antibody targeting two epitopes of the rabies virus G protein.

The therapy targets G protein epitopes I and III, in line with the World Health Organization's recommendation for a "cocktail" therapeutic approach.

It is designed to neutralise different rabies virus strains or genotypes and provide immediate protection before active immunity from vaccination is fully established.

Silevimig is currently the passive immunisation product with the smallest dose for rabies, at 0.05 mg/kg.

Compared with human rabies immune globulin, or HRIG, the therapy requires a lower injection volume, which can simplify administration and potentially improve patient compliance.

The product is manufactured using recombinant technology and is non-plasma-derived, eliminating the risk of blood-borne infections associated with plasma-derived products.

CMS said the therapy can also be manufactured at scale through standardised processes, offering consistent quality and reduced batch-to-batch variability.

Silevimig was approved for marketing in China in June 2026.

Following approval, CMS and its partner Genrix Bio advanced work across drug supply, market access and academic promotion, leading to initial prescriptions being issued within approximately two months.

The company said the milestone accelerates the transition of Silevimig from regulatory approval to clinically accessible treatment.

Rabies remains a major public health concern because the disease has a case-fatality rate approaching 100% once clinical symptoms appear.

Post-exposure prophylaxis remains the main preventive strategy and includes wound care, vaccination and passive immunisation when indicated.

Because vaccine-induced antibodies typically require one to two weeks after the first dose to reach protective levels, passive immunisation provides immediate protection during this critical period.

More than 40 million people are exposed to rabies annually in China, with approximately 40% classified as Category III exposure.

However, only around 15% of Category III cases currently receive passive immunisation, according to data cited by CMS.

The company said limited awareness, cost and restricted accessibility remain major barriers.

HRIG remains the primary passive immunisation option in China but depends on plasma from healthy donors, creating supply, cost and safety challenges.

In a Phase III clinical trial in adults in China, Silevimig met its primary efficacy endpoint and demonstrated non-inferior protective efficacy compared with HRIG.

The therapy provided immediate protection during early-stage rabies exposure without compromising the active immune response induced by vaccination.

A Phase III clinical trial in children and adolescents aged two to under 18 years is also ongoing in China.

CMS entered into an exclusive collaboration agreement with Chongqing Genrix Biopharmaceutical in September 2025.

Under the agreement, CMS obtained exclusive commercialisation rights for Silevimig in mainland China and exclusive licensing rights for the rest of Asia Pacific, the Middle East and North Africa.

The launch strengthens CMS’ portfolio of innovative medicines and expands the company’s presence in infectious disease prevention and post-exposure care.