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CHINA MEDICAL SYSTEM HOLDINGS LIMITED

康哲藥業控股有限公司*

(Incorporated in the Cayman Islands with Limited Liability)

(Hong Kong Stock Code: 867)

(Singapore Stock Code: 8A8)

Voluntary and Business Update Announcement

Signing Collaboration Agreements for Class 1 Innovative Biologic

Recombinant Humanized Anti-tetanus Toxin Monoclonal Antibody

Vecantoxatug Injection and Recombinant Fully Human Bispecific Antibody Against Rabies Virus Silevimig Injection

China Medical System Holdings Limited (the “Company”, together with its subsidiaries, the “Group”) is pleased to announce that on 22 September 2025, the Group through subsidiaries of the Company entered into two separate exclusive Collaboration Agreements (the “Agreements”) with Chongqing Genrix Biopharmaceutical Co.,Ltd. (“Genrix Bio”) for Vecantoxatug Injection (GR2001, “Vecantoxatug”), a Class 1 therapeutic biological product indicated for passive immunization against tetanus, and Silevimig Injection (GR1801, “Silevimig”), a Class 1 therapeutic biological product indicated for passive immunization following suspected rabies virus exposure, respectively.

In accordance with the Agreements, the Group has obtained exclusive commercialization rights for Vecantoxatug and Silevimig in mainland China and exclusive licensing rights for the rest of the Asia-Pacific region, the Middle East and North Africa. The collaboration terms respectively extend until ten years after Vecantoxatug and Silevimig receive their marketing approvals in Mainland China (the “Initial Term for each Product”). Unless terminated or dissolved under the terms set forth in the Agreements, the Agreements will automatically renew for successive ten-year periods upon expiration of the Initial Term for each Product.

VECANTOXATUG

Vecantoxatug is a recombinant humanized monoclonal antibody against tetanus neurotoxin (TeNT), which is self-developed by Genrix Bio. Vecantoxatug binds to the fragment C domain of the TeNT heavy chain (TeNT-Hc). TeNT is an about 150 kDa single-chain protein that undergoes post-translational modification to form an active toxin composed of heavy and light chains. By specifically binding TeNT-Hc, Vecantoxatug effectively blocks toxin entry into neurons, providing passive immunization. In May 2024, Vecantoxatug was designated Breakthrough Therapy by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA). Its Phase III clinical trial for passive immunization against tetanus successfully met the primary efficacy endpoint. The patent for Vecantoxatug has been granted in China. The New Drug Application (NDA) for Vecantoxatug in China was submitted to the CDE and was formally accepted by the CDE on 22 May 2025.

Tetanus is an acute and specific infection caused by *Clostridium tetani* (*C. tetani*) entering the body through wounds. It affects individuals across all age groups and, in the absence of medical intervention, is almost universally fatal—particularly among infants and the elderly. Even with active treatment, global mortality remains as high as 30–50%, with an estimated 500,000 to 1,000,000 cases reported annually worldwide. *C. tetani* is ubiquitous in soil and the environment, and is also present in the intestines of mammals. As the pathogen invades through skin or mucosal injuries, causing the acute and specific infection, prevention remains the most effective strategy. Currently available passive immunization agents, commonly known as tetanus shot, —tetanus antitoxin (TAT), equine-derived tetanus immunoglobulin (F(ab')₂), and human tetanus immunoglobulin (HTIG)—face notable limitations in safety and accessibility, including risks of allergic reactions, potential infectious pathogen transmission, and limited availability. Consequently, there remains a pressing clinical need for new preventive and therapeutic options. Vecantoxatug is able to provide greater protection than HTIG, while demonstrating excellent safety, tolerability, and low immunogenicity. With enhanced controllability and accessibility, Vecantoxatug has the potential to offer patients an advanced preventive and therapeutic option.

SILEVIMIG

Silevimig is a recombinant, fully human bispecific antibody against rabies virus (RABV), which is self-developed by Genrix Bio. It targets the viral envelope glycoprotein (G protein) of RABV and blocks its interaction with host receptors by binding to epitopes I and/or III. Through this mechanism, Silevimig prevents RABV from invading neural tissue prior to the establishment of full protection by active rabies vaccination, thereby helping to prevent rabies infection. Silevimig is the world's first bispecific antibody developed for passive immunization against rabies. Its molecular design is consistent with the recommendations of

the World Health Organization (WHO) for anti-RABV antibody development, which emphasize the use of “cocktail” combinations of monoclonal antibodies targeting distinct antigenic sites to ensure broad effectiveness across different viral strains and genotypes. In a Phase III clinical trial for post-exposure passive immunization in adults, Silevimig met its primary efficacy endpoint, demonstrating non-inferior protective efficacy compared with human rabies immunoglobulin (HRIG), the currently most used passive immunization product in China. The study confirmed that Silevimig provides immediate protection during the early stages of rabies virus exposure without compromising the active immune response induced by vaccination. The patent for Silevimig has been granted in China. The NDA for Silevimig was submitted to CDE for use in adults requiring passive immunization following suspected rabies virus exposure. The application was formally accepted by CDE on 14 January 2025. In addition, in July 2025, the NMPA approved the clinical trial application for Silevimig in children and adolescents aged 2 to <18 years requiring passive immunization following suspected rabies virus exposure. This Phase III clinical trial is currently in progress.

Rabies is an acute zoonotic disease caused by RABV, clinically characterized by hydrophobia, aerophobia, pharyngeal muscle spasms, and progressive paralysis. With a case-fatality rate approaching 100%, it is one of the deadliest diseases worldwide. At present, there is no proven treatment for rabies once clinical symptoms appear. Standardized Post-Exposure Prophylaxis (PEP), comprising wound care, vaccination, and passive immunization administered as needed, remains the most effective rabies prevention strategy. As vaccine-induced antibodies require 1 – 2 weeks after the first dose of vaccine injection, to reach protective levels (≥ 0.5 IU/mL), passive immunization provides immediate coverage during this high-risk window. According to the *the National Regulation for the Rabies Exposure Prophylaxis (2023 Edition)*, patients with Category III exposure and those with severe immunodeficiency and Category II exposure should receive passive immunization at the same time as the first dose of rabies vaccine. In China, more than 40 million people are exposed to rabies annually, of whom approximately 40% (16 million) fall under Category III exposure. However, due to factors such as limited awareness, high cost, and restricted accessibility, only about 15% of Category III cases receive passive immunization. Currently approved passive immunization options in China include human rabies immunoglobulin (HRIG) and equine rabies antiserum (ERA), both of which provide immediate protection by preventing viral entry into neural tissue. HRIG must be sourced from repeatedly immunized healthy donors, making it difficult and costly to obtain. And it is associated with potential risks of blood-borne infections (e.g., HIV, hepatitis B, hepatitis C). ERA, being a heterologous protein, is prone to adverse reactions such as serum sickness and anaphylactic shock. Beyond HRIG and ERA, only two rabies antibody products have been approved in China to date. Silevimig is the world’s first recombinant, fully human bispecific antibody for passive immunization against

rabies, which is consistent with the WHO recommended “cocktail” approach. Its approval is expected to provide patients with broad and robust protection.

GENRIX BIO

Genrix Bio (Stock Code: 688443), founded in 2015, is an innovative biopharmaceutical company driven by advanced antibody drug discovery technology to address critical clinical needs. Genrix Bio is committed to the development of monoclonal and bispecific antibodies for autoimmune diseases, infectious diseases, and oncology. Its capabilities span across antibody molecular discovery, process development and quality research, clinical trials, and large-scale commercialization. Learn more about Genrix Bio and its products at <https://www.genrixbio.com/>

REASONS FOR AND BENEFITS OF ENTERING INTO THE AGREEMENTS

Our Group continues to advance differentiated innovative products. The market for tetanus and rabies passive immunization remains substantial, yet existing passive immunization products are constrained by safety and accessibility concerns. Vecantoxatug is a passive immunization agent with an excellent safety profile, which delivers superior protection compared with human tetanus immunoglobulin (HTIG), providing rapid and durable immune defense for patients. Silevimig is the world’s first recombinant, fully human bispecific antibody targeting both epitope I and epitope III of the rabies virus glycoprotein, developed in accordance with WHO recommendations. Silevimig can be manufactured at scale with standardized, and also demonstrates broad neutralization, low immunogenicity, minimal interference with vaccine-induced active immunity, and controlled production cost. If approved, Vecantoxatug and Silevimig will provide novel therapeutic options for patients requiring urgent tetanus and post-exposure prophylaxis against rabies in China. Moreover, Vecantoxatug and Silevimig are expected to achieve synergies in expert networks and market resources with our Group’s existing portfolio. The products are therefore anticipated to have a positive impact on our Group’s overall business performance.

Having considered the above, the directors of the Company (the “Directors”) are of the view that the agreements is on normal commercial terms and such terms are fair and reasonable and that the agreements is in the interests of the Company and its shareholders as a whole.

LISTING RULES IMPLICATIONS

To the best of the Directors’ knowledge, information and belief after having made all reasonable enquiries, Genrix Bio is a third party independent of the Company and its

connected persons (as defined in the Rules Governing the Listing of the Securities on The Stock Exchange of Hong Kong Limited (the “Listing Rules”)). Therefore, this transaction does not constitute a connected transaction of the Company under Chapter 14A of the Listing Rules. As all relevant applicable percentage ratios (as defined in the Listing Rules) of this transaction are less than 5%, this transaction does not constitute a notifiable transaction of the Company under Chapter 14 of the Listing Rules.

This announcement is made on a voluntary basis by the Company and aims to inform potential investors and shareholders of the Company of the latest business developments of the Group. Shareholders and investors are advised to exercise caution in dealing in the shares and other securities of the Company.

By order of the Board
China Medical System Holdings Limited
Lam Kong
Chairman

Hong Kong, 22 September 2025

As at the date of the announcement, the directors of the Company comprise (i) Mr. Lam Kong and Ms. Chen Yanling as executive directors; and (ii) Mr. Leung Chong Shun, Ms. Luo Laura Ying and Mr. Fung Ching Simon as independent non-executive directors.