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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**  
**New Drug Application of**  
**Class 1 Innovative Drug Y-3 for Injection for Acute Ischemic Stroke**  
**Accepted in China**

China Medical System Holdings Limited (the “Company”, together with its subsidiaries, the “Group”) is pleased to announce that on 11 December 2025, the New Drug Application (NDA) of Class 1 Innovative Drug Y-3 for Injection (proposed English generic name: Loberamisal for Injection) (“Y-3 for Injection” or the “Product”) has been accepted by National Medical Products Administration of the People’s Republic of China (NMPA). The Product is a brain cytoprotectant indicated for the treatment of acute ischemic stroke.

As the world's first brain cytoprotectant developed based on the important targets PSD-95-nNOS and MPO, in the pathological processes of stroke, Y-3 for Injection acts on multiple key pathological processes of the ischemic cascade in ischemic stroke. Through multi-target, highly selective synergy, it is more conducive to exerting brain cytoprotective effects. The Product has an excellent therapeutic effect on ischemic stroke and the potential to prevent post-stroke depression and anxiety symptoms. The Phase III clinical trial of the Product in China was conducted by Beijing Tiantan Hospital, Capital Medical University as the leading site. It has enrolled nearly 1,000 patients with acute ischemic stroke within 48 hours of onset across approximately 40 research centers nationwide, aiming to evaluate the efficacy and safety of Y-3 for Injection in treating patients with acute ischemic stroke within 48 hours of onset. The Phase III clinical study met the primary efficacy endpoint, with patients achieving significant clinical benefits and an overall favorable safety profile. The key study results are

planned to be presented at international academic conferences, and the full study will be published in international academic journals.

The pathological processes of acute ischemic stroke are highly complex and interconnected. There is an urgent clinical need for multi-target, multi-mechanism coordinated interventions to achieve more effective regulation of the complex ischemic cascade, thereby improving treatment outcomes and enhancing patients' quality of life. Y-3 for Injection is able to uncouple PSD95-nNOS, inhibit MPO activity, and enhance the activity of  $\alpha_2$ -GABA<sub>A</sub> receptor (a subtype of GABA<sub>A</sub> receptor with antidepressant and anxiolytic effects). With this multi-target, highly selective synergistic mechanism, it is expected to achieve a technological breakthrough in the simultaneous intervention of "stroke treatment and prevention of post-stroke depression and anxiety", making Y-3 for Injection a promising novel brain cytoprotectant with excellent efficacy and more comprehensive therapeutic effects.

According to the *Guideline for Prevention and Treatment of Cerebrovascular Disease (2024 Edition)* issued by the National Health Commission, approximately 3.94 million new stroke cases occur in China each year, accounting for one-third of the global new cases. Among these, ischemic stroke accounts for about 72%, with over 2.8 million new cases annually; the number of existing stroke patients in China has exceeded 28 million. Data from China's cause-of-death monitoring in 2021 shows that stroke-related deaths accounted for 23% of the national total deaths. Over the past three decades, the disease burden of stroke-related disabilities in China has continued to increase. Coupled with factors such as the accelerating aging of the population, the pressure of stroke prevention and control will further intensify in the future, posing enormous challenges to patients' families and society. In addition, post-stroke depression and anxiety are common complications of stroke, with incidence rates of approximately 30% and 25% respectively. They can hinder the recovery of patients' neurological functions, even increase the risk of death, and severely affect patients' prognosis. Y-3 for Injection holds significant potential value for the long-term neurological function improvement and overall prognosis of a vast number of stroke patients, indicating broad market prospects.

On 24 August 2023, the Group through a wholly-owned subsidiary of the Company entered into a Collaboration Agreement (the "Agreement") with Neurodawn Pharmaceutical Co., Ltd. ("NeuroDawn"), a clinical needs-oriented pharmaceutical company driven by innovation and R&D. In accordance with the Agreement, the Group obtains an exclusive promotion right in mainland China, the Hong Kong Special Administrative Region, and the Macau Special Administrative Region. The term of the Agreement is permanent.

The central nervous system (CNS) is one of the core advantageous fields of this Group, where a deeply integrated layout has been progressively established. The addition of Y-3 for Injection will further enrich and optimize the Group's differentiated innovative pipeline in the CNS field, and will also generate strong synergies with the marketed products VALTOCO (Diazepam Nasal Spray) and Deanxit (Flupentixol and Melitracen Tablets), as well as the improved new drug ZUNVEYL (Benzgalantamine Gluconate Enteric-coated Tablets), which is currently under NDA review, in terms of expert networks and market resources. Leveraging the Group's successful commercialization experience and compliant and efficient commercialization system, if the Product is approved for marketing, it will bring a new drug option for Chinese patients with ischemic stroke, meeting the clinical need for drugs of both efficacy and safety, improving disease diagnosis and treatment practices, thereby benefiting patients. The Product is expected to have a positive impact on the Group's financial results.

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, 11 December 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; (ii) Mr. Leung Chong Shun, Ms. Luo Laura Ying and Mr. Fung Ching Simon as independent non-executive directors.*