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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)*

**(Stock Code: 867)**

### **Voluntary and Business Update Announcement**

#### **New Drug Application of Diazepam Nasal Spray Approved in China**

China Medical System Holdings Limited (the “Company”, together with its subsidiaries, the “Group”) is pleased to announce that on 7 June 2023, the New Drug Application (NDA) of Diazepam Nasal Spray (the “Product”) received approval from the National Medical Products Administration of China (NMPA). The Product is the first nasal spray formulation of diazepam in China, and it is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures) that are distinct from a patient’s usual seizure pattern in patients with epilepsy 6 years of age and older. The Company has obtained the drug registration certificate on 12 June 2023.

The Product is one of the Group’s important and innovative products. To benefit epilepsy patients in China as soon as possible, the Group will swiftly complete the asset transfer transaction and prepare for commercialization in an orderly way.

#### **Diazepam Nasal Spray**

The Product is a proprietary formulation of diazepam administered through the nasal mucosa, via a unique combination of Vitamin E-based solvents and Intravail® absorption enhancer. Intravail® transmucosal absorption enhancement technology enables the non-invasive delivery of a broad range of proteins, peptides and small-molecule drugs. The Product is the first drug approved in China for the treatment of seizure clusters. It can be administered intranasally at the appropriate time by patients or their caregivers under prescription from a doctor and guidance from medical staff. This can meet current clinical needs of domestic epilepsy

*\* For identification purpose only*

patients with cluster seizures who lack accessible and convenient treatment options which can be administered anytime and anywhere, and can provide better treatment options for patients with recurrent epilepsy. The active pharmaceutical ingredient of the Product is Diazepam, belonging to the class of benzodiazepines, which are the first-choice drugs for the treatment of seizure clusters. The Product has high bioavailability, outstanding absorbability, tolerance and reliability, and has the differentiated advantage of seizure rescue, with the characteristic of convenience and optimization through intranasal administration. There is a pending patent claiming composition and use in China. The results of the Product's US related clinical trial showed that 87% of seizure cluster episodes used a single dose of the Product over a 24-hour period. A post hoc analysis of these data showed the Product had a rapid onset of action with the median time from administration of the Product to seizure cessation of 4 minutes. Further analyses showed that using the Product as intermittent rescue therapy significantly improves the quality of life of epileptic patients and may reflect a beneficial effect in increasing time between seizure clusters.

The Product has also been approved for marketing in the United States of America.

According to the clinical diagnosis and treatment guidelines epilepsy volume (revision in 2023), seizure clusters/acute repetitive seizures are defined as  $\geq 3$  seizures/24h for adults,  $\geq 3$  seizures/12h for children,  $\leq 8$ h between each seizures, and the consciousness returning to normal level between the two seizures. Seizure clusters are common in certain epilepsy syndromes, menstrual seizures, and drug-refractory epilepsy. If not treated in time, some will develop into status epilepticus, endangering the lives of patients. In recent years, domestic and foreign scholars have paid more attention to the prevalence of active epilepsy, that is, the ratio of the number of epileptic seizures occurring in a certain period of time (1 or 2 years) to the average population in the same period. The prevalence of active epilepsy in China is 4.6‰ and the annual incidence rate is about 30 in 100,000 people. According to this estimation, there are about 6.4 million active epilepsy patients in China, and about 0.3 million new cases reported each year. However, due to a lack of proper awareness towards epilepsy and limited medical resources, the current treatment gap, which is the proportion of patients who do not receive regular treatment, for patients with active epilepsy in China is 49.8%. Based on this, it is estimated that about 3 million patients with active epilepsy in China have not received appropriate treatment. Seizures in patients with active epilepsy are diverse, with seizure clusters being a sudden clinical event. At present, there is still a lack of epidemiological research on seizure clusters in China. According to overseas studies, the rate of outpatient incidence of seizure clusters is about 15% and therefore it is estimated that nearly 500,000 patients with active epilepsy receiving regular treatment still have seizure clusters.

## **Asset Transfer Transaction**

On 20 August 2018, the Group and A&B (HK) Company Limited (“A&B”) entered into a framework asset transfer agreement, whereby the Group has agreed to acquire all the related assets of the Product in Mainland China, Hong Kong Special Administrative Region, Macao Special Administrative Region and Taiwan from A&B, and assumed all rights and obligations in respect of the assets. For further details, please refer to the announcement of the Company dated 20 August 2018. On 20 April 2022, the Group and A&B entered into a further agreement for the related assets of the Product in respect of Singapore. The parties have not finalized the terms and conditions of the above asset transfer (the “Transaction”), including the consideration for the assets. The parties are still in negotiation. A&B is a company wholly-owned by Mr. Lam Kong, who is a director and a controlling shareholder (as defined in the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “Listing Rules”)) of the Company. As A&B is a connected person of the Company by virtue of its being an associate of Mr. Lam Kong, the Transaction constitutes a connected transaction of the Company under Chapter 14A of the Listing Rules. The Company will comply with the relevant provisions of the Listing Rules including publishing a circular to shareholders and seeking independent shareholders’ approval, if applicable, and make relevant announcement(s) as and when appropriate.

The announcement is made on a voluntary basis. Shareholders and investors are advised to exercise caution when 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, 12 June 2023

*As at the date of the announcement, the directors of the Company comprise (i) Mr. Lam Kong, Mr. Chen Hongbing 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.*