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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
Signing a License, Collaboration and Distribution Agreement of Improved New Drug ZUNVEYL for the Treatment of Mild-to-Moderate Dementia of the Alzheimer's Type

China Medical System Holdings Limited (the "Company", together with its subsidiaries, the "Group") is pleased to announce that on 8 January 2025, the Group through a wholly-owned subsidiary of the Company entered into a License, Collaboration and Distribution Agreement (the "Agreement") with Alpha Cognition Inc. ("Alpha") of the improved new drug ZUNVEYL（benzgalantamine delayed-release tablets）（"ZUNVEY" or the "Product") for the treatment of mild-to-moderate dementia of the Alzheimer's type.

In accordance with the Agreement, the Group is entitled to an exclusive right to develop, register, manufacture, import, export and commercialize the Product in Asia (excluding Japan), Australia and New Zealand (the "Territory"), Alpha reserves the right to manufacture and supply in the Territory. The term of cooperation commences on the effective date of the Agreement and extends for twenty years (the "Initial Term"), it may be automatically renewed every five years upon the expiration of the Initial Term unless terminated by notice from either party.

ZUNVEYL

ZUNVEYL was approved in July 2024 by the U.S. Food and Drug Administration (FDA) for the treatment of mild-to-moderate dementia of the Alzheimer's type in adults. As a new generation of acetylcholinesterase inhibitor (AChEI), ZUNVEYL can inhibit the

**For identification purpose only*

acetylcholinesterase from breaking down the neurotransmitter acetylcholine, increase the level of acetylcholine in the central nervous system, and therefore alleviate cognition and memory impairment in Alzheimer's disease patients. As a prodrug of galantamine, ZUNVEYL remains inert as it passes through the stomach and the intestine, and eventually releases the active drug into the bloodstream after being metabolized by the liver. With such a mechanism of action, ZUNVEYL is expected to have equivalent efficacy as galantamine with the potential of reducing gastrointestinal (GI) side effects and addressing certain tolerability issues. Galantamine has accumulated extensive evidence of efficacy and demonstrated long-term clinical benefit in the treatment of mild-to-moderate dementia of the Alzheimer's type since the approval of FDA in 2001. Moreover, GI adverse events documented across all studies for ZUNVEYL were less than 2% and no insomnia was observed. As the second oral therapy approved by FDA for the treatment of Alzheimer's disease during the past decade, ZUNVEYL demonstrates a potentially better safety profile to improve compliance of Alzheimer's disease patients and therefore brings clinical benefits. Patent in regard to use of ZUNVEYL has already been granted in China.

Alzheimer's disease is a chronic, progressive neurodegenerative disease characterized by progressive decline in memory and other cognitive functions, among which some of the patients will progress to dementia. Dementia is a kind of syndrome with acquired cognitive function impairment as the core symptom, and can lead to the reduction of patients' daily living, learning, working and social interaction ability. Alzheimer dementia accounts for 50% to 70% of all types of dementia. According to the epidemiological study results published in the *Lancet Public Health*, there are about 9.83 million patients with Alzheimer dementia in China, of which 7.93 million are mild-to-moderate. With the intensifying aging trend, the number of patients and the consequent disease burden will further increase in the future. Currently the clinical treatment of Alzheimer's disease can be categorized as improving cognitive symptoms and decelerating disease progression, and AChEI belongs to the former. According to the *Research Report on the Diagnosis and Treatment of Alzheimer's disease Patients in China*, the high incidence of side effects is one of the major pain points for existing drugs for Alzheimer's disease, suggesting that Alzheimer's disease patients still have an urgent need for safer therapies.

ALPHA

Alpha is a commercial stage, biopharmaceutical company dedicated to developing treatments for patients suffering from neurodegenerative diseases, such as Alzheimer's disease and cognitive impairment with mild Traumatic Brain Injury. On July 2024, Alpha received approval by the FDA of its New Drug Application (NDA) for ZUNVEYL for the treatment of mild-to-moderate Alzheimer's disease. Alpha will now focus on the development of

commercial manufacturing and commercial sales of ZUNVEYL oral tablet formulation. Additionally, Alpha has three pre-clinical development programs: ZUNVEYL in combination with memantine for the treatment of moderate-to-severe Alzheimer's disease, ALPHA-1062 sublingual formulation for the treatment of mild-to-moderate Alzheimer's disease, ALPHA-1062 intranasal formulation for the treatment of cognitive impairment with mild Traumatic Brain Injury. For more information about Alpha and its pipeline, please visit: https://www.alphacognition.com/ .

REASONS FOR AND BENEFITS OF ENTERING INTO THE AGREEMENT

The Group continues to deploy and develop differentiated and innovative products. As a new generation of acetylcholinesterase inhibitor approved by the FDA, ZUNVEYL will further diversify the Group's innovative drug product matrix and enhance the Group's comprehensive competitiveness. The Product will synergize with the Group's various central nervous system products including the innovative drug VALTOCO (diazepam nasal spray) and the original brand drug Deanxit (flupentixol and melitracen tablets) on sale and the innovative drug Y-3 injection under development in terms of expert network and market resources. Relying on the Group's successful commercialization experience and compliant and efficient commercialization system, if ZUNVEYL is approved for marketing, it will bring a new drug option for the treatment of cognitive impairment in Chinese Alzheimer's disease patients, 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.

Having considered the above, the directors of the Company (the "Directors") are of the view that the Agreement is on normal commercial terms and such terms are fair and reasonable and that the Agreement 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, Alpha 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, 8 January 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. Chen Hongbing as a non-executive director; and (iii) Mr. Leung Chong Shun, Ms. Luo Laura Ying and Mr. Fung Ching Simon as independent non-executive directors.