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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 a Distribution Agreement for**

#### **Ophthalmic Drugs Lucentis® and Beovu®**

China Medical System Holdings Limited (the “Company”, together with its subsidiaries, the “Group”) is pleased to announce that on 27 October 2025, the Group through subsidiaries of the Company entered into a Distribution Agreement (the “Agreement”) with Novartis Pharma Services AG (“Novartis”) for Ranibizumab Injection (trade name: Lucentis) (“Lucentis®”) and Brolucizumab Injection (trade name: Beovu) (“Beovu®”).

In accordance with the Agreement, the Group has obtained the exclusive right to import, distribute, sell and promote as specifically agreed upon in the Agreement in the People's Republic of China (for the purpose of the Agreement, excluding the Hong Kong Special Administrative Region, the Macao Special Administrative Region and Taiwan) (the “Territory”); Novartis will continue to be responsible for the production and supply of the products. The term of cooperation comes into effect on the effective date of the Agreement and remains valid for a period of five years.

### **LUCENTIS®**

Lucentis® is a recombinant humanized monoclonal antibody Fab fragment targeting vascular endothelial growth factor (VEGF). It targets and inhibits human vascular endothelial growth factor A (VEGF-A), thereby suppressing vascular endothelial cell proliferation, neovascularization, and vascular leakage. As the first anti-VEGF drug approved for ophthalmic use in China, Lucentis® has been approved for the treatment

of multiple ocular neovascular diseases since its launch in China in 2011, including neovascular age-related macular degeneration (nAMD), diabetic macular edema (DME), macular edema following retinal vein occlusion (RVO), choroidal neovascularization (CNV), diabetic retinopathy (DR), and retinopathy of prematurity (ROP). In 2017, Lucentis® was included in the National Reimbursement Drug List (NRDL) for Basic Medical Insurance, Work-Related Injury Insurance, and Maternity Insurance. It has accumulated mature clinical application experience, providing reliable support for numerous patients with ocular fundus diseases.

Ocular neovascular diseases are a group of severe blinding ophthalmic conditions characterized by increased vascular permeability, vascular leakage, and loss of vascular integrity, mainly including nAMD, DR, DME, RVO, CNV, ROP, etc. Anti-VEGF drugs are recommended as first-line therapy for ocular neovascular diseases in multiple authoritative guidelines. According to a Frost & Sullivan report, the number of patients with ocular neovascular diseases in China is projected to increase from 47.8 million in 2019 to 61.2 million in 2030. The Chinese ophthalmic anti-VEGF drug market is expected to grow from RMB 2.4 billion in 2019 to RMB 18.6 billion in 2030. As stated in Anti-VEGF Drugs for Fundus Neovascular Diseases, Lucentis®—the first anti-VEGF drug approved for the treatment of ocular neovascular diseases in China—has demonstrated favorable safety and efficacy in multiple clinical trials. It has been widely used in the treatment of ocular neovascular diseases, and its launch represents a major advancement in clinical ophthalmic treatment.

## **BEOVU®**

Beovu® is a novel VEGF-A-targeted humanized single-chain antibody fragment. It received approval from the National Medical Products Administration of China (NMPA) in May 2025 for the treatment of DME. As the current anti-VEGF drug with the smallest molecular weight (only 26 kDa), Beovu® is administered once every 6 weeks during the loading phase of the DME treatment (compared to once every 4 weeks for other anti-VEGF drugs) and once every two to three months during the maintenance phase. In the global Phase 3 KESTREL and KITE Studies for treatment-naïve DME patients, Beovu® met all primary efficacy endpoints and the visual benefit persisted until Week 100. Additionally, patients in the Beovu® 6mg group had less intraretinal fluid (IRF) and/or subretinal fluid (SRF). The median number of injections of Beovu® in the first year (7 times) was lower than that of aflibercept (9 times), while its overall safety profile was comparable to the latter. Data from the Chinese real-world study (BEST Study) showed that for previously treated and inadequately controlled DME patients, BCVA

improved by 6.1 letters from baseline 1 week after the first injection of Beovu<sup>®</sup>, and by 10 letters after the third injection (Week 12). Beovu<sup>®</sup> provides a more optimized treatment option for previously treated DME patients.

DME is a retinal thickening caused by capillary leakage in the macular area, which is the result of the breakdown of the blood retinal barrier and mainly affects central vision. According to a Frost & Sullivan report, there are approximately 7.89 million DME patients in China in 2025. However, even with the current standard anti-VEGF regimens, approximately 30%-50% of DME patients still exhibit suboptimal fluid control. A survey in the 2022 White Paper on the Current Status of Chronic Disease Management for Common Ocular Fundus Diseases in China showed that treatment adherence among Chinese patients is relatively poor, with over 30% of DME patients failing to complete the loading phase treatment. There is an urgent clinical need for more potent, longer-lasting, and more adherence-friendly treatment options to improve the diagnosis and treatment of DME patients. As a next-generation anti-VEGF drug, Beovu<sup>®</sup> offers a potential solution to this challenge. Leveraging its innovative advantages of ultra-small molecular weight and high concentration, Beovu<sup>®</sup> significantly improves retinal anatomical structure, helps more DME patients gain visual improvement, and alleviates treatment burden.

## **NOVARTIS**

Novartis is a globally renowned pharmaceutical company headquartered in Basel, Switzerland. The company focuses on four core therapeutic areas with urgent patient needs—Cardiovascular, Renal and Metabolic Disease, Oncology, Immunology, and Neuroscience—as well as five key technology platforms: Chemotherapy, Biotherapy, xRNA, Radioligand Therapy, and Gene and Cell Therapy.

## **REASONS FOR AND BENEFITS OF ENTERING INTO THE AGREEMENT**

This collaboration will enhance the overall competitiveness of the Group's ophthalmology business company, CMS Vision, in the field of ophthalmology. CMS Vision already covers ophthalmic disease areas such as fundus diseases, asthenopia and glaucoma. With the addition of Lucentis<sup>®</sup> and Beovu<sup>®</sup>, the portfolio will generate strong synergies with the marketed exclusive drug Augentropfen Stulln Mono Eye Drops (Esculin and Digitalisglycosides Eye Drops) and the marketed exclusive medical device EyeOP1 Glaucoma Treatment Device in terms of customer base, expert resources, and channel networks. This will further strengthen CMS Vision's academic brand competitiveness in ophthalmology, provide positive momentum

for sustained collaboration and the development of clinically needed innovative ophthalmic products, and offer patients more diverse treatment options. At the same time, CMS Vision's professional ophthalmology team will integrate marketing channels and academic resources to improve the overall team efficiency. The collaboration 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 collaboration 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, Novartis 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.

The 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, 27 October 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.*