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 Desidustat Tablets Accepted in China

China Medical System Holdings Limited (the "Company", together with its subsidiaries, the "Group") is pleased to announce that on 22 April 2024, the New Drug Application (NDA) of Desidustat Tablets ("Desidustat Tablets" or the "Product") has been accepted by the National Medical Products Administration of China (NMPA). The Product is a novel, oral Hypoxia-Inducible Factor-Prolyl Hydroxylase Inhibitor (HIF-PHI) for treating anaemia in non-dialysis adult, Chronic Kidney Disease (CKD) patients.

CKD involves the gradual loss of functioning of kidneys and eventually leads to kidney failure. If kidneys are healthy, they will naturally secrete beneficial levels of a hormone called Erythropoietin (EPO), which encourages red blood cell production. If the kidneys are impaired, they will produce reduced levels or tire of EPO production completely, leading to anaemia. HIF-PHI promotes erythropoiesis through increasing endogenous erythropoietin, improving iron availability and reducing hepcidin.

It is estimated that more than 120 million people are living with CKD in China. Anaemia is one of the frequent complications of CKD. A survey in China showed that the prevalence of anaemia in patients at CKD stage 1 to 5 were 22.0%, 37.0%, 45.4%, 85.1%, and 98.2%, respectively. The target-achieving rate (the haemoglobin (Hb) level reaching the target value (110~120g / L)) was only 8.2% for anaemia patients in non-dialysis CKD and 35.2% for haemodialysis CKD, showing a large unmet healthcare need.

**For identification purpose only*

China Phase III trial of the Product has demonstrated positive results. The primary endpoint of the Hb mean change from baseline to the period of Week 7-9 has indicated that, Desidustat is more effective than placebo in increasing Hb level. The least squares mean and 95% CI of Hb change from baseline to the period of Week 7-9, using covariance model analysis, has shown an increase of 16.38 g/l [95%CI: 14.50, 18.26] in the Desidustat group and a decrease of 1.13 g/l [95%CI: -3.68, 1.41] in the placebo group, for a between-group difference of 17.52 g/l [95%CI:14.353, 20.681], with the lower limit of 95% CI above 0.

The Product is administrated orally, thus expecting to improve the treatment compliance of patients and to meet the unmet treatment needs in the field of CKD anaemia, including both dialysis and non-dialysis patients.

Desidustat Tablets have been approved for marketing in India.

CMS INTERNATIONAL DEVELOPMENT AND MANAGEMENT LIMITED, a wholly-owned subsidiary of the Group, obtained an exclusive license for the Product from Zydus Lifesciences Limited (earlier known as Cadila Healthcare Limited) on 20 January 2020.

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, 23 April 2024

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.