

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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
Related to Signing a License Agreement of the Innovative Product Desidustat
with Zydus

China Medical System Holdings Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that the Group through its wholly-owned subsidiary signed a License Agreement (the “**Agreement**”) with Cadila Healthcare Limited (“**Zydus**”) for its product Desidustat (ZYAN1) (the “**Product**”) on 20 January 2020. According to the Agreement, the Group through its wholly-owned subsidiary will gain a royalty bearing, exclusive, sub-licensable license under the licensed technology and Zydus data to develop, register and to manufacture, use and commercialise the Product in Greater China (including Mainland China, Hong Kong Special Administrative Region, Macao Special Administrative Region and Taiwan) (the “**Territory**”), and the manufacturing of the final product will be localized by the Group in China with technology transfer from Zydus. The term of the Agreement starts on the date of signing the Agreement until the last date of the occurrence of the following: (i) the expiration of the last-to-expire patent containing a valid claim covering the manufacture, use, import, offer for sale or sale of the Product in the Territory; (ii) ten years after the first commercial sale of the Product in the Territory; (iii) the expiration of all regulatory exclusivities for the Product in the Territory. Upon the expiration of the aforementioned term, the Agreement may be renewable for every single period of five years thereafter as per certain conditions defined in the Agreement.

Through this collaboration, the Group's product portfolio will be further enriched and extended upon occurrence of the perspective commercialisation of the Product in the Territory.

About the Product

Desidustat (Phase III clinical trial is ongoing oversea)

Desidustat is a novel oral Hypoxia-inducible factor-prolyl hydroxylase inhibitor (HIF-PHI) for treating anemia in chronic kidney disease (CKD) patients. CKD is involving gradual loss of functioning of kidneys and eventually lead 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 anemia. HIF-PHI promotes erythropoiesis through increasing endogenous erythropoietin, improving iron availability, and reducing hepcidin.

It has been reported that more than 120 million people are estimated to be living with CKD in China. Anemia is one of the frequent complications of CKD. A survey in China showed that the prevalence of anemia 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 hemoglobin (Hb) level reaching the target value (110~120g / L)) was only 8.2% for anemia patients in non-dialysis CKD and 35.2% for hemodialysis CKD, showing large unmet healthcare need. Compared with the existing therapy, Desidustat is administrated orally, thus expecting to improve the treatment compliance of patients.

Zydus had initiated two Phase III trials of Desidustat. The DREAM-ND (ClinicalTrials.gov Identifier: NCT04012957) Phase III trial is being conducted in CKD patients not-on-dialysis. The DREAM-D Phase III trial (ClinicalTrials.gov Identifier: NCT04215120) is being conducted in CKD patients on dialysis. A randomized, double-blind, placebo-controlled, parallel group, multicentric phase 2 clinical trial had been conducted on 117 anemia patients in non-dialysis CKD. After 6 weeks of treatment, as compared to placebo, in all three Desidustat arms, the therapy showed statistically significant improvement in the primary endpoint, change in Hb from baseline. In addition, the Hb responder rates in secondary endpoint were over 60% in all three Desidustat arms. In terms of safety, no serious adverse event was reported and there was no significant change in vital signs, electrocardiographic parameters, or safety laboratory values.

A material patent has been granted in Mainland China, Hong Kong Special Administrative Region, Macao Special Administrative Region and Taiwan concerning Desidustat, which is a new molecular entity. The composition of matter patent will expire in December 2033.

About Zydus

Zydus is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies, including small molecule drugs, biologic therapeutics and vaccines. The group employs nearly 25,000 people worldwide, including 1,400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. More information about Zydus can be found at www.zyduscadila.com.

By order of the Board
China Medical System Holdings Limited
Lam Kong
Chairman

Hong Kong, 20 January 2020

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. Cheung Kam Shing, Terry, Mr. Wu Chi Keung and Mr. Leung Chong Shun as independent non-executive directors.