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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

Approval of Drug Clinical Trials for Uterine Fibroids Indication of Innovative Drug GnRH Receptor Antagonist CMS-D002

China Medical System Holdings Limited (the “Company”, together with its subsidiaries, the “Group”) is pleased to announce that innovative drug CMS-D002 Capsules (“CMS-D002”) self-developed by the Group, has been officially approved by National Medical Products Administration (“NMPA”) of drug clinical trial on 25 September 2025. The approval was obtained on 26 September 2025. NMPA has agreed to conduct a clinical trial evaluating the safety and efficacy of CMS-D002 in the treatment of uterine fibroids.

CMS-D002 is a small molecule gonadotropin-releasing hormone (GnRH) receptor antagonist. GnRH is a decapeptide hormone synthesized by neuroendocrine cells in the hypothalamus and is an important factor in regulating the release of reproductive system hormones. CMS-D002 competitively binds to GnRH receptors on the pituitary gland with endogenous GnRH, blocking the hypothalamic-pituitary-gonadal axis at the central nervous system level, reducing the release of endogenous Follicle-stimulating hormone (FSH) and Luteinizing hormone (LH), thereby inhibiting the secretion of downstream estrogen, progesterone and testosterone, and alleviating the progression of sex hormone-related diseases. CMS-D002 has demonstrated excellent efficacy and safety in preclinical studies. Previously, CMS-D002 was approved by NMPA of drug clinical trial on 6 February 2024 and its Phase I clinical trial in endometriosis is underway steadily. Recently, CMS-D002 has once again received approval of clinical trial from the NMPA, expanding its scope of indications to uterine fibroids. In

addition to endometriosis and uterine fibroids, CMS-D002 may be developed in the future for the treatment of diseases such as prostate cancer.

Uterine fibroids (UFs) are formed by the hyperplasia of uterine smooth muscle tissue and are the most common benign tumor in women. The exact cause is still unclear and may be related to genetic susceptibility and sex hormone levels. High-risk factors include age, race, obesity, and diet. The onset age of UFs is between 15 and 59 years old, and it is most common in women aged 30 to 44. The incidence is increasing year by year, the prevalence rate among women of childbearing age can reach 25%. Currently, the treatment methods for UFs include surgical treatment and drug treatment. Surgical treatment can significantly improve the symptoms of patients with uterine fibroids, but it has safety issues such as blood loss and urinary incontinence; drug treatment includes symptomatic treatment and endocrine treatment. Symptomatic treatment drugs can only improve symptoms such as pain or anemia of uterine fibroids, but cannot reduce the volume of fibroids; endocrine treatment such as GnRH receptor agonists and progesterone receptor modulators can significantly reduce the volume of fibroids by lowering the levels of estrogen and progesterone in patients, but GnRH receptor agonists may cause symptoms to worsen in the early stage of treatment (i.e., the flare-up effect); progesterone receptor modulators have adverse reactions such as liver damage and anti-glucocorticoid effects. Therefore, the current drug treatment for uterine fibroids still faces a huge unmet clinical demand.

Compared with GnRH receptor agonists, GnRH receptor antagonists do not have a “flare-up effect”. They can rapidly and competitively bind to the GnRH receptor and block its activation, quickly inhibiting the release of FSH and LH, thereby suppressing the secretion of downstream estrogens and alleviating the progression of uterine fibroids. At lower doses, partial inhibition can be achieved, while at higher doses, complete inhibition is achieved. Moreover, since the antagonistic effect is reversible, after a period of drug withdrawal, when endogenous GnRH rebinds to the receptor, the patient’s gonadal function is expected to return to normal. CMS-D002, as an oral non-peptide small molecule GnRH receptor antagonist, combined with its excellent preclinical performance, is expected to provide patients with a better treatment option.

CMS-D002 will further enrich the Group’s product portfolio, provide differentiated medication options for patients in China, meet the clinical demand for drugs with good efficacy, safety and patient compliance, and ultimately benefit patients. CMS-D002 will effectively enhance the Group’s strength in the field of gynecological treatment. Leveraging the existing expert networks and market resources, it will improve the competitiveness and market position in this field.

The Group is actively preparing for initiating the relevant clinical trials and strives to launch the Product as soon as possible.

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, 26 September 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.