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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 Related to Asset Purchase of Blueberry Therapeutics' Product Portfolio

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 entered into an Asset Purchase Agreement (the "Agreement") with Blueberry Therapeutics Limited ("Blueberry Therapeutics") dated 14 August 2018. According to the Agreement, (i) the Group has acquired all related assets of Blueberry Therapeutics' leading product BB2603 (for the treatment of onychomycosis and tinea pedis) in China (including Hong Kong Special Administrative Region, Macao Special Administrative Region and Taiwan), Republic of Korea, Democratic People's Republic of Korea and Mongolia (the "Territory"); (ii) the Group further acquired access to all related assets of other pipeline products being or to be developed subsequently by Blueberry Therapeutics utilizing its unique nanoformulation delivery system in dermatology and other fields (such as products used for treating atopic dermatitis and acne, etc., together with the product BB2603 as the "Products") in the Territory. The aforementioned assets include, among others, all the national patents covering the development, commercialization and formulation of the Products, national trademarks and necessary regulatory approvals in or for the Territory. In addition, the Group also acquired all the necessary licenses related to the transaction under the Agreement.

Blueberry Therapeutics' nanoformulation delivery system is an innovative, proprietary pharmaceutical technology platform in which small and large molecules (e.g. proteins, peptides and nucleic acids) can be rapidly assembled and packaged into nanoparticles. The

delivery of these nanoparticles to both mammalian and bacterial cells is greatly enhanced, which overcomes the limitations of some existing therapies and opens up new therapeutic possibilities. Based on this technology platform, the Company will seek strategic cooperation with Blueberry Therapeutics to develop more new nano-preparations in the future, including but not limited to creams, sprays, patches, etc., which can be widely used in dermatology and other fields.

This cooperation will further enrich the Group's patented innovative pipeline products and the Group believes that the Products will have broad market prospects after being commercialized in the Territory.

#### **About the Product**

## BB2603 (Phase I/II clinical trial is ongoing in Germany and Phase III clinical trials are scheduled in the US and Europe)

BB2603 (terbinafine-nano) is a novel cutaneous spray of terbinafine hydrochloride with nanotechnology, for the treatment of onychomycosis and tinea pedis. Terbinafine has a wide range of antifungal activity against pathogenic fungi of skin, hair and nails and is recommended for the treatment of onychomycosis and tinea pedis by both the Chinese and foreign guidelines.

Using nanotechnology, BB2603 is designed to greatly enhance delivery of terbinafine to target fungal infection under the nail. BB2603 aims to demonstrate equivalent efficacy and treatment duration but at a dose which is several thousand-fold lower than documented for oral terbinafine, thereby potentially avoiding the systemic side effects and patient monitoring requirements of oral terbinafine. BB2603 is Blueberry Therapeutics' lead development drug candidate and the company will complete a Phase II dose finding study as it approaches Phase III clinical development in the US and EU for the treatment of onychomycosis. In addition, patents of the formulations have been applied for BB2603 in China (Patent Publication No. CN105579028 A, in pending and CN107921137 A, in publication) with terms up to year 2034 and 2036, respectively, if granted.

Onychomycosis and tinea pedis are very common diseases in China, and the incidence of onychomycosis accounts for 2%-18% of the natural population. According to a multi-center epidemiological survey in China, 15.7% of patients in dermatology clinics suffer with onychomycosis. Tinea pedis is also a very common disease in dermatophytosis with high incidence rate of approximately 15% of the population, even up to 30% - 70%, and accounts for about 10% - 20% of dermatology clinics patients in domestic reports. Currently, the treatment of tinea pedis is effective but with high recurrence rate. About 84% of patients have

an average of more than 2 incidents per year. Due to the particularity of the nail bed barrier, topical drugs are difficult to penetrate nails and the local drug concentration cannot reach the minimal inhibitory concentration, resulting in a complete cure rate less than 20% and limited efficacy of onychomycosis. Oral terbinafine is an effective drug for the treatment of onychomycosis; however, for patients who are not suitable or in poor compliance with oral administration, the topical BB2603 provides a better safety option.

Currently, there are no nanoformulations of terbinafine available domestically or overseas. Topical formulations of terbinafine have not been approved for the treatment of onychomycosis and are only used for tinea pedis. The market is in urgent need of drugs with efficacy, safety and compliance in balance; therefore, once approved, BB2603 will have broad market prospects. As for the future, BB2603 together with the company's existing product-the oral terbinafine (Lamisil) will form a complete product portfolio which is expected to have a prominent position in Onychomycosis and Tinea Pedis market.

### **Risk Warning**

There are risks that the Products in the pipeline could not be launched in the market due to the failure of the clinical trials, accordingly shareholders and investors are advised to exercise caution in dealing in the shares and other securities of the Company.

### **About Blueberry Therapeutics**

Blueberry Therapeutics, incorporated in November 2011, is a drug discovery and development company focused on developing innovative nanomedicines for difficult to treat skin and nail infections. The company is using its state of the art nano-formulation technology to develop high value medicines where a reduced dose and improved drug delivery is needed, to overcome existing tolerability and safety profile concerns.

Blueberry Therapeutics combines expert in-house resources with selected external partners and collaborators to take projects through from preclinical research onto de-risked human clinical proof of concept and then on to the market. For more information, please visit http://www.blueberrytherapeutics.com.

The management team at Blueberry Therapeutics has strong drug development backgrounds and extensive business experience. Dr. John Ridden, CEO and co-founder of the company, previously worked in Pfizer and AstraZeneca on drug R&D and project management for more than 18 years. Mr. Andrew Kay, Chairman of the Board of Directors, brings more than 30 years of leadership experience in the pharmaceutical sector. He has led the success of Novartis's Lamisil and has a good understanding of the relevant markets.

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

Hong Kong, 14 August 2018

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.