邁博藥業

Mabpharm Limited

迈博药业有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2181)

INSIDE INFORMATION ANNOUNCEMENT ACCEPTANCE OF THE NEW DRUG APPLICATION (NDA) OF OUR CORE PRODUCT CMAB009 BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

A. INTRODUCTION

This announcement is made by Mabpharm Limited (the "**Company**" or "**Mabpharm**", together with its subsidiaries, the "**Group**") pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

The board of directors (the "**Board**") of the Company is pleased to announce that the new drug application ("**NDA**") of CMAB009, a core product of the Company, was recently accepted by the National Medical Products Administration ("**NMPA**") of the People's Republic of China for the treatment of metastatic colorectal cancer.

B. BASIC INFORMATION OF THE DRUG

Generic name of the drug:	Subject to approval by the NMPA
Dosage form:	Injections
Specification:	100mg/10ml/vial
Application classification:	Therapeutic biological products Class 2.4
Drug manufacturer:	Taizhou Mabtech Pharmaceutical Limited* (泰州邁博太科藥業有限公司)
Drug application number:	CXSS2300012

C. ABOUT CMAB009

CMAB009, a recombinant anti-epidermal growth factor receptor ("**EGFR**") chimeric monoclonal antibody, is our new drug candidate based on cetuximab for first-line treatment of metastatic colorectal cancer ("**mCRC**") in combination with FOLFIRI. CMAB009 is the first anti-EGFR monoclonal antibody drug developed in China that applied with the NMPA for NDA for treatment of colorectal cancer. CMAB009 uses the Chinese Hamster Ovary ("**CHO**") expression system, which is different from the mouse myeloma cell SP2/0 expression system used in marketed cetuximab products. The safety and efficacy of CMAB009 have been confirmed from the results of two completed clinical trials. Based on our clinical trial results compared to published clinical trial results for currently marketed cetuximab products, CMAB009 is equally effective as the cetuximab drug currently available for treatment of mCRC, and significantly reduces immunogenicity and decreases the incidence of adverse reactions, such as severe hypersensitivity.

CMAB009 is expected to expand its indications to head and neck squamous cell carcinomas and other cancers in the future. Upon the launch of CMAB009, it is expected to provide affordable biological sovereign remedy with better efficacy for more than 1 million Chinese patients with tumors.

D. IMPACT ON THE COMPANY

CMAB009 is the third product that Mabpharm has filed a drug marketing application for, and we believe that, once approved by the NMPA for marketing, it will be the first anti-EGFR monoclonal antibody drug developed by a local Chinese company marketed in China. Mabpharm focuses on the development of monoclonal antibodies and has an experienced research and development team with key members having more than 20 years of experience in antibody drug development. Mabpharm possesses multiple core technologies, a leading large-scale antibody preparation system in the PRC and an outstanding quality management system. Mabpharm's product pipeline currently includes several monoclonal antibody drugs.

In addition to CMAB009, CMAB008 類停® (infliximab for injection) has been approved for marketing and CMAB007 (omalizumab) will soon be approved for marketing by the NMPA.

With high quality innovative drugs as the foundation, the Company will provide innovative antibody drugs to patients in the PRC by offering more economical and affordable drug supply solutions and fully participating in China's national healthcare system reform initiatives. The Company has also planned to cooperate with partners who have accumulated abundant overseas market resources over a long period of time to rapidly expand the overseas markets.

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: We cannot guarantee that we will be able to successfully commercialize CMAB009.

Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

By Order of the Board
Mabpharm Limited
Jiao Shuge
Chairman

Hong Kong, March 14, 2023

As at the date of this announcement, the Board of Directors of the Company comprises Dr. Wang Hao, Mr. Tao Jing, Mr. Li Yunfeng, and Dr. Li Jing as executive Directors; Mr. Jiao Shuge and Mr. Guo Jianjun as non-executive Directors; and Mr. Guo Liangzhong, Dr. Zhang Yanyun and Mr. Leung, Louis Ho Ming as independent non-executive Directors.

* *For identification purpose only*