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 CMAB007 (OMALIZUMAB) 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 CMAB007 (omalizumab), a core product of the Company, was recently accepted by the National Medical Products Administration of the People's Republic of China ("**NMPA**") for the treatment of allergic asthma, which is the first domestic allergic asthma therapeutic antibody new drug in China with NDA submitted.

B. BASIC INFORMATION OF THE DRUG

Generic name of the drug:	Omalizumab
Dosage form:	Lyophilized powder injections
Specification:	75mg/bottle, 150mg/bottle
Application classification:	Therapeutic biological products Class 3.4
Drug manufacturer:	Taizhou Mabtech Pharmaceutical Limited* (泰州邁博太科藥業有限公司)
Drug application number:	CXSS2101034 Guo, CXSS2101035 Guo

C. ABOUT CMAB007 (OMALIZUMAB)

CMAB007 (omalizumab), a recombinant humanized anti-immunoglobulin E ("**IgE**") monoclonal antibody, is our new monoclonal antibody drug for treatment of asthma patients who remain inadequately controlled despite med/high dose of inhaled corticosteroids plus long acting beta adrenoceptor agonists treatment. We believe that, once approved by the NMPA for marketing, it will be the first monoclonal antibody ("**mAb**") asthma therapy developed by a local Chinese company and launched in China. CMAB007 combines with free IgE to form an anti-IgE complex that inhibits the high affinity IgE receptor and thereby prevents the allergic response. The safety and efficacy of CMAB007 have been confirmed by the results of four clinical trials of a total of 824 subjects who have been administered with CMAB007, which was the largest clinical trial of mAb treating asthma in China. Based on our clinical trial results, CMAB007 can improve asthma patients' conditions with lower-dose inhaled corticosteroids and reduce the incidence of acute asthma attacks.

CMAB007 is expected to expand its indications to chronic idiopathic urticarial, seasonal allergic rhinitis and food allergies in the future. Currently, we expect that CMAB007 may be approved by the NMPA for marketing in the fourth quarter of 2022. Upon the launch of CMAB007, it is expected to provide affordable biological sovereign remedy with better efficacy for more than 20 million Chinese patients with allergic diseases.

D. IMPACT ON THE COMPANY

CMAB007 (omalizumab) is the second drug to be submitted for marketing application by the Company. We believe that, once approved by the NMPA for marketing, it will be the first mAb asthma therapy developed by a local Chinese company and launched in China, which is highly effective, safe and convenient, and will greatly enhance the well-being of more than 20 million patients suffering from allergic diseases in China. The Company 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. The Company's product pipeline currently includes several monoclonal antibody drugs.

In addition to CMAB007 (omalizumab) which has been submitted the NDA, CMAB008類停® (infliximab for injection) has been approved for marketing, CMAB807 (denosumab for treatment of osteoporosis and tumor bone metastasis) and CMAB009 (cetuximab for treatment of metastatic colorectal cancer) are in Phase III clinical trials, and CMAB819 (nivolumab for treatment of metastatic non-small cell lung cancer, hepatocellular carcinoma and head and neck squamous cell carcinomas) is in Phase I clinical trial.

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 CMAB007 (omalizumab).

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, October 15, 2021

As at the date of this announcement, the Board of Directors 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 Dr. Liu Linqing as independent non-executive Directors.

* *For identification purpose only*