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 APPROVAL FROM THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION ON THE NEW DRUG APPLICATION (NDA) OF OUR CORE PRODUCT, CMAB007 (OMALIZUMAB ALFA FOR INJECTION)

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 alfa for Injection), a core product of the Company, was recently approved by the National Medical Products Administration of the People's Republic of China ("**NMPA**") for the treatment of patients diagnosed with immunoglobulin E ("**IgE**") mediated asthma, which is the first domestic allergic asthma therapeutic antibody new drug in China approved by the NMPA.

B. BASIC INFORMATION OF THE DRUG

Generic name of the drug:	Omalizumab alfa for Injection
Dosage form:	Lyophilized powder injections
Specification:	75mg/vial, 150mg/vial

Drug manufacturer:	Taizhou Mabtech Pharmaceutical Limited* (泰州邁博太科藥業有限公司)
Drug approval number:	Guo Yao Zhun Zi S20230030, Guo Yao Zhun Zi S20230031

C. ABOUT CMAB007

CMAB007, a recombinant humanized anti-IgE monoclonal antibody, is our new monoclonal antibody drug for treatment of patients diagnosed with IgE mediated asthma. 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 monoclonal antibody ("**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.

The antibody drug production base of Taizhou Mabtech Pharmaceutical Limited* (泰州邁博太科藥業有限公司) under the Company in China Medical City ("**CMC**"), Taizhou, Jiangsu Province also successfully passed the GMP compliance inspection for CMAB007 by Jiangsu Provincial Drug Administration.

As at the date of this announcement, CMAB007 is the first mAb asthma therapy developed by a local Chinese company and launched in China. 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 alfa for Injection) is the second product of Mabpharm approved for marketing and is 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.

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 CMAB007 (Omalizumab alfa for Injection) which has been approved for marketing, CMAB008類停® (infliximab for injection) has also been approved for marketing in July 2021, CMAB009 (cetuximab for treatment of metastatic colorectal cancer) has submitted new drug application to the NMPA in March 2023, CMAB807 (denosumab for treatment of osteoporosis) is 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 entered into a cooperation agreement with Jiangxi Jemincare Pharmaceutical Co., Ltd.* (江西濟民可信醫藥有限公司) which has advantageous marketing resources to promote CMAB007 in the PRC, and also planned to cooperate with partners who have accumulated abundant overseas market resources over a long period of time to 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 alfa for Injection).

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, May 23, 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*