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, CMAB008 (INFLIXIMAB 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 CMAB008類停® (infliximab for injection), a core product of the Company and a recombinant anti-tumor necrosis factor-α ("**TNF-α**") human-mouse chimeric monoclonal antibody independently developed by the Company, was recently approved by the National Medical Products Administration of the People's Republic of China ("**NMPA**") for the treatment of:

(i) ulcerative colitis in adults;

(ii) ankylosing spondylitis;

(iii) rheumatoid arthritis;

(iv) Crohn's disease in adults and pediatric patients aged above 6 years old;

(v) fistula Crohn's disease;

(vi) psoriasis;

B. BASIC INFORMATION OF THE DRUG

Generic name of the drug:	infliximab for injection
Trade name:	類停®
Dosage form:	Injection
Specification:	100mg per bottle
Registration classification:	Therapeutic biological product
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 S20210025

C. ABOUT CMAB008類停® (INFLIXIMAB FOR INJECTION)

CMAB008類停® is the first China-made infliximab approved for marketing, which is a monoclonal antibody biosimilar independently developed by the Company and a core product of the Company. CMAB008類停® uses the CHO expression system, and is a monoclonal antibody targeting TNFα (tumor necrosis factor α) that specifically merges with TNFα and blocks the inflammatory cascade response caused by TNFα; it is mainly used for treatment of ulcerative colitis in adults, ankylosing spondylitis, Crohn's disease in adults and pediatric patients, fistula Crohn's disease, rheumatoid arthritis and psoriasis.

The researches we have completed have shown that, compared to other anti-TNFα drugs on the market, CMAB008類停® (infliximab for injection) has a stronger affinity for TNFα and a stronger glycosylation character, with rapid onset of effect, long-lasting efficacy, long dosing intervals and no hypersensitivity reactions. The results of our completed researches including, clinical trials, non-clinical comparative studies, and pharmacological comparisons of CMAB008類停® have also shown that CMAB008 is identical to the original infliximab in terms of efficacy, safety, pharmacological profile and quality.

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 CMAB008 by Jiangsu Provincial Drug Administration.

As of the date of this announcement, the only other infliximab currently available for sale in the People's Republic of China (the "**PRC**") is "Remicade", an imported drug sold by Xian Janssen. Infliximab is included in the PRC's national medical insurance drug catalogue, and in accordance with relevant regulations on medical insurance of the PRC, our CMAB008類停® is applicable to the medical insurance coverage of infliximab, thus providing a new and more economical and affordable option for patients.

D. IMPACT ON THE COMPANY

CMAB008類停® (infliximab for injection) is the first product of Mabpharm approved for marketing and the first infliximab approved for marketing which is manufactured in the PRC.

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 CMAB008 類停® (infliximab for injection) which has been approved for marketing, CMAB007 (omalizumab for allergic diseases such as asthma) developed by the Company has completed clinical trials and will soon file for new drug application in the PRC, CMAB807 (denosumab for osteoporosis and tumor bone metastasis) and CMAB009 (cetuximab for metastatic colorectal cancer) are in Phase III clinical trials, and CMAB819 (nivolumab for multiple metastatic solid tumors) is also in Phase I clinical trials.

CMAB008類停® is approved for the treatment of six indications which has huge long-term unmet market demand with more than 10 million patients in the PRC which is still growing. With high quality innovative drugs as the foundation, Mabpharm 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 initiated cooperation with partners who have accumulated abundant overseas market resources over a long period of time to rapidly expand to 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 CMAB008類停® (infliximab 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, July 14, 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*