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 MINISTRY OF HEALTH OF PERU 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 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 Ministry of Health of Peru (Ministerio de Salud) 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; and

(vi) psoriasis.

B. BASIC INFORMATION OF THE DRUG

Generic name of the drug:	infliximab for injection
Trade name:	類停®
Dosage form:	Injections
Specification:	100mg/vial
Drug manufacturer:	Taizhou Mabtech Pharmaceutical Limited* (泰州邁博太科藥業有限公司)
Drug approval number:	BE-01392 (Peru)

C. ABOUT CMAB008類停® (INFLIXIMAB FOR INJECTION)

CMAB008類停® is the first infliximab developed in the People's Republic of China (the "**PRC**") and 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 Chinese hamster ovary cell expression system, and is a monoclonal antibody targeting TNFα 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 aged above 6 years old, 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類停® 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, Taizhou, Jiangsu Province also successfully passed the good manufacturing practices ("**GMP**") compliance inspection for CMAB008類停® by Jiangsu Provincial Drug Administration.

Infliximab is included in the PRC's basic medical insurance program (the "**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 in Peru and the first infliximab approved for marketing in Peru 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奧邁舒® (omalizumab α for injection) and CMAB009恩立妥® (cetuximab β injection) of Mabpharm have also been approved for marketing by the National Medical Products Administration of the PRC.

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. As of the end of 2023, CMAB008類停® has been marketed on the procurement platform across all the provinces within China, with its sales amount increasing significantly in 2023 as compared to 2022, and extended presence to over 1,000 hospitals (of all levels), primary medical institutions and pharmacies. 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. At present, the Company has launched registration and market exploration in more than 30 countries and/or regions, completed GMP inspections in three countries, and has passed the GMP inspection certification in Brazil, a member country under the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme.

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 2, 2024

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. Hou Sheng as executive Directors; Mr. Jiao Shuge and Dr. Qian Weizhu 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*