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, CMAB009恩立妥® (CETUXIMAB β 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 CMAB009恩立妥® (cetuximab β 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 first-line therapy for RAS/BRAF wild-type metastatic colorectal cancer ("**mCRC**") in combination with the FOLFIRI regimen.

## B. BASIC INFORMATION OF THE DRUG

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| Generic name of the drug: | Cetuximab β |
| Dosage form: | Injections |
| Specification: | 100mg (10ml)/vial |
| Category: | 2.4 |
| Drug manufacturer: | Taizhou Mabtech Pharmaceutical Limited*<br>(泰州邁博太科藥業有限公司) |
| Drug approval number: | Guo Yao Zhun Zi (國藥准字) S20240025 |

## C. ABOUT CMAB009恩立妥® (CETUXIMAB β INJECTION)

CMAB009恩立妥®, a recombinant anti-epidermal growth factor receptor ("**EGFR**") chimeric monoclonal antibody for first-line treatment of mCRC in combination with FOLFIRI. CMAB009恩立妥® is the first anti-EGFR monoclonal antibody innovative new drug developed in China with independent intellectual property rights that was approved by the NMPA for first-line therapy of mCRC. CMAB009恩立妥® was developed and prepared using a specific Chinese Hamster Ovary (CHO) expression process of the Company with an international PCT patent (PCT patent number: PCT/CN2016/070024), which has achieved significant therapeutic efficacy and superior safety, and has been fully substantiated by the results of two completed clinical trials.

At the same time, CMAB009恩立妥® is also expected to expand its indications to pancreatic cancer, head and neck squamous cell carcinomas, cervical squamous cell carcinoma and other cancers, as its administration together with a variety of small molecule drugs has tremendous potential for research and development and application in various other indications such as non-small cell lung cancer. The Group will expedite the clinical and registration work of CMAB009恩立妥® targeting the aforesaid indications.

## D. IMPACT ON THE COMPANY

CMAB009恩立妥® (cetuximab β injection) is the third product of Mabpharm approved for marketing and is the first domestically produced anti-EGFR monoclonal antibody drug with independent intellectual property for treatment of mCRC launched in the Chinese market. CMAB009恩立妥® is expected to provide affordable biological targeted remedy with better efficacy for hundreds of thousands of Chinese patients with tumors.

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 China and an outstanding quality management system. Mabpharm's product pipeline currently includes several monoclonal antibody drugs, and in addition to CMAB009 恩立妥® (cetuximab β injection), CMAB008 類停® (infliximab for injection) and CMAB007奧邁舒® (omalizumab α for injection) of Mabpharm have also been approved for marketing by the NMPA.

With high quality innovative drugs as the foundation, the Company will provide innovative antibody drugs to patients in China 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 business cooperation agreement with Jiangsu Simcere Zaiming Pharmaceutical Co., Ltd* (江蘇先聲再明醫藥有限公司) on August 18, 2023 which has advantageous marketing resources to promote CMAB009恩立妥® in the Chinese mainland, 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 CMAB009恩立妥® (cetuximab β 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, June 25, 2024

*As at the date of this announcement, the Board of Directors of the Company comprises Dr. Wang Hao, Mr. Li Yunfeng, Mr. Tao Jing, 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*