东曜药业

TOT BIOPHARM International Company Limited

東曜藥業股份有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1875)

INSIDE INFORMATION ANNOUNCEMENT

MARKETING APPROVAL FOR 朴欣汀® (TAB008, BEVACIZUMAB INJECTION, PUSINTIN®) OBTAINED FROM THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

This announcement is made by TOT BIOPHARM International Company Limited (the "**Company**", together with its subsidiaries, the "**Group**") pursuant to Rule 13.09(2) 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 under the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

The board of directors of the Company (the "**Board**") is pleased to announce that the Group's self-developed 朴欣汀® (TAB008, bevacizumab injection, Pusintin®) has been officially granted approval by the National Medical Products Administration ("**NMPA**") for marketing in mainland China (i.e., excluding Hong Kong, Macau and Taiwan regions) for the treatment of patients with advanced, metastatic or recurrent non-squamous non-small cell lung cancer ("**nsNSCLC**") and patients with metastatic colorectal cancer ("**mCRC**"). 朴欣汀® is the first antibody drug of the Group approved for marketing.

ABOUT 朴欣汀®

朴欣汀® is an anti-vascular endothelial growth factor monoclonal antibody (anti-VEGF mAb) and is a biosimilar to Avastin®. Avastin® has been the most widely used anti-VEGF mAb drug with abundant real-world evidence of its efficacy and safety since its entry into the market in 2004. Avastin® has been approved for various indications by other countries for use in combination with chemotherapy and other treatments to treat a wide range of tumors, including mCRC, advanced nsNSCLC, glioblastoma, renal cell carcinoma, ovarian cancer, cervical cancer, breast cancer and liver cancer. In China, Avastin® has been approved for the treatment of nsNSCLC, mCRC, glioblastoma multiforme (GBM), hepatocellular carcinoma (HCC), ovarian cancer and cervical cancer. According to the "Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars" (《生物類似藥相似性評價和適應症外推技術指導原則》) issued by the Center for Drug Evaluation of the NMPA, 朴欣汀® will be eligible for application by way of extrapolation for use in all indications of Avastin® approved in China.

According to the data published by the International Agency for Research on Cancer (IARC) of the World Health Organization, lung cancer and colorectal cancer are the top two cancers with the largest number of new cancer cases in China, with about 816,000 and 555,000 new cases in 2020, respectively. Given their wide range of indications and with a large demand from patients, bevacizumab injections have a huge unmet market potential in China. The Company believes that 朴欣汀® will provide a high-quality and affordable treatment option for cancer patients in China. According to the data from IQVIA, global sales of bevacizumab injections were USD6.09 billion and sales in China were RMB3.63 billion in 2020.

Cautionary statement required by Rule 18A.05 of the Listing Rules: The Company cannot guarantee that it will be able to ultimately market 朴欣汀® successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the securities of the Company.

By order of the Board
TOT BIOPHARM International Company Limited
Dr. Liu, Jun
Chief Executive Officer and Executive Director

Hong Kong, 1 December 2021

As at the date of this announcement, the executive directors of the Company are Ms. Yeh-Huang, Chun-Ying and Dr. Liu, Jun; the non-executive directors of the Company are Mr. Fu, Shan, Dr. Kung, Frank Fang-Chien, Mr. Kang, Pei and Mr. Qiu, Yu Min; and the independent non-executive directors of the Company are Ms. Hu, Lan, Dr. Sun, Lijun Richard and Mr. Chang, Hong-Jen.