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)

VOLUNTARY ANNOUNCEMENT

APPROVAL OF SUPPLEMENTAL APPLICATION FOR HEPATOCELLULAR CARCINOMA (HCC) AS A NEW INDICATION OF 朴欣汀® (TAB008, BEVACIZUMAB INJECTION) RECEIVED FROM THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

This announcement is made by TOT BIOPHARM International Company Limited (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business updates of the Group.

The board of directors of the Company (the "**Board**") is pleased to announce that TOT BIOPHARM Co., Ltd. (東曜藥業有限公司) ("**TOT Suzhou**"), a wholly-owned subsidiary of the Company, has recently received a notice of approval of its supplemental application for hepatocellular carcinoma (HCC) as a new indication of 朴欣汀® (bevacizumab injection) issued by the National Medical Products Administration ("**NMPA**"). This supplemental application was made by way of extrapolation for use in other indications approved for the original drug in mainland China pursuant 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. As such, 朴欣汀® has been approved for all six indications approved for the original drug in mainland China, including advanced, metastatic or recurrent non-squamous non-small cell lung cancer (nsNSCLC); metastatic colorectal cancer (mCRC); recurrent glioblastoma multiforme; epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer; cervical cancer; and hepatocellular carcinoma.

Liver cancer is one of the most common malignant tumors in China, and hepatocellular carcinoma is the most common form of liver cancer, accounting for about 90% of all cases. According to the latest global cancer burden data for 2020 released by the International Agency for Research on Cancer (IARC) of the World Health Organization, liver cancer is the fifth most common malignant tumor and the second leading cause of tumor death in China, and the number of new cases of liver cancer in China accounts for 45.3% of all cases worldwide. Liver cancer has gradually become one of the major diseases threatening the health of people around the world, especially in China.

In June 2021, Roche announced that the combination of its bevacizumab, Avastin®, with atezolizumab, for the treatment of unresectable hepatocellular carcinoma in patients who have not previously received systemic therapy, has been approved by the NMPA for marketing, providing a novel treatment option for patients with liver cancer. At present, this combination therapy has also been listed as a preferred therapy for first-line treatment of advanced hepatocellular carcinoma by many domestic and foreign clinical guidelines.

ABOUT 朴欣汀®

朴欣汀® (bevacizumab injection, intended English trade name: Pusintin®) is a biological antibody drug (a biosimilar to 安維汀® (Avastin®)) self-developed by TOT Suzhou, which obtained the marketing approval from the NMPA on 30 November 2021. The monoclonal antibody commercial production of 朴欣汀® is carried out by adopting the Perfusion-Batch Hybrid Technology (PB-Hybrid® Technology) self-developed by the Group, which enables seed expansion in 25L WAVE bioreactors and a direct scale-up to 2,000L bioreactors. As compared with commonly-used technologies in the industry, this technology has obvious cost advantages in terms of simplified technical processes, shortened production cycles and reduced production costs.

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

Hong Kong, 8 April 2022

As at the date of this announcement, the executive directors of the Company are Dr. Liu, Jun and Ms. Yeh-Huang, Chun-Ying; the non-executive directors of the Company are Mr. Fu, Shan and Mr. Qiu, Yu Min; and the independent non-executive directors of the Company are Ms. Hu, Lan, Mr. Chang, Hong-Jen and Dr. Wang, De Qian.