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

ACCEPTANCE OF NEW DRUG APPLICATION FOR BEVACIZUMAB INJECTION (TAB008, A BIOSIMILAR TO AVASTIN®) BY 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 the National Medical Products Administration (NMPA) of the People's Republic of China ("**China**", and for the purpose of this announcement only, excluding Hong Kong, Macau and Taiwan) has accepted the new drug application (the "**NDA**") for the Group's self-developed antibody drug TAB008 in China. TAB008, which is a biosimilar to bevacizumab injection sold under the trade name of "安維汀® (Avastin®)" in China, is one of the core products of the Company. The Group intends to use "Pusintin® (朴欣汀®)" as the trade name of TAB008.

Bevacizumab as an effective drug for cancer therapy has huge market demand in China, and the commercialization of TAB008 is expected to provide a safe, effective and economical alternative drug for more cancer patients in China.

The NDA is primarily based on clinical data generated from two clinical studies (the "**Studies**"), both comparing TAB008 with Avastin®, namely a comparative pharmacokinetics study in healthy subjects, and a comparative safety and efficacy study in advanced or recurrent non-squamous non-small cell lung cancer ("**NSCLC**") patients. The Studies have met their pre-defined primary endpoints.

About TAB008 – Pusintin® (朴欣汀®)

TAB008 is an anti-vascular endothelial growth factor monoclonal antibody (anti-VEGF mAb) and is a biosimilar to bevacizumab for the treatment of advanced, metastatic or recurrent NSCLC, metastatic colorectal cancer and other malignant tumors. 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 to treat a wide range of tumors, including metastatic colorectal cancer (mCRC), advanced NSCLC, glioblastoma, renal cell carcinoma, ovarian cancer, cervical cancer, breast cancer and liver cancer.

Cautionary statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: The Company cannot guarantee that it will be able to develop, or ultimately market, TAB008 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
Yeh-Huang, Chun-Ying
Executive Director

Hong Kong, 4 September 2020

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.