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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 NEW INDICATIONS OF 朴欣汀® (TAB008, BEVACIZUMAB INJECTION, PUSINTIN®) 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 new indications 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 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, and these indications are: recurrent glioblastoma multiforme; epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer; and cervical cancer. Taking into account these indications and also advanced, metastatic or recurrent non-squamous non-small cell lung cancer (nsNSCLC) and metastatic colorectal cancer (mCRC), 朴欣汀® has a total of five indications approved.

Glioblastoma multiforme is the most common and most malignant primary intracranial tumor in adults, accounting for about 57% of all gliomas and 48% of all primary malignant tumors of the central nervous system. It is characterized by high incidence, high recurrence rate, high mortality rate and low cure rate. According to a report by Cancer Today, a global cancer research institute of the World Health Organization, there were about 79,000 new cases of brain and central nervous system tumors and 65,000 deaths in China in 2020. As one of the important approaches to the treatment of glioblastoma multiforme, bevacizumab has been included in many authoritative guidelines and consensus at home and abroad.

Cervical cancer and ovarian cancer are two common gynecological malignancies characterized by high morbidity rate and high mortality rate, respectively. 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, there were about 110,000 new cases of cervical cancer and 60,000 deaths, and about 55,000 new cases of ovarian cancer and 38,000 deaths, in China.

With the supplemental application for new indications of 朴欣汀® approved by the NMPA, the market potential of 朴欣汀® will be further expanded, and its accessibility to cancer patients in China will be enhanced.

ABOUT 朴欣汀®

朴欣汀® (bevacizumab injection, intended English trade name: Pusintin®) is a biological antibody drug self-developed by TOT Suzhou, which obtained the marketing approval from the NMPA on 30 November 2021. 朴欣汀® is a biosimilar to 安維汀® (Avastin®), which has been approved for the treatment of nsNSCLC, mCRC, glioblastoma multiforme (GBM), hepatocellular carcinoma (HCC), ovarian cancer and cervical cancer in China. 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, 9 March 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, 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.