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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

MARKETING APPROVAL FOR MEGESTROL ACETATE ORAL SUSPENSION (TOM218) 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**”) 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 Megestrol Acetate Oral Suspension (TOM218, approved for marketing in the United States in 2014) (the “**Product**”), a product for which the Company is an import agent, has been approved for marketing in Mainland China by the National Medical Products Administration of China for the treatment of anorexia associated with acquired immunodeficiency syndrome (“**AIDS**”) as well as significant weight loss of AIDS and cancer patients caused by cachexia. The Product is imported from TWi Pharmaceuticals, Inc. (安成國際藥業股份有限公司) with a specification of 125 mg/mL (150 mL/bottle). The Company owns the exclusive agency for the Product in Mainland China, Hong Kong and Macau, and intends to use the brand name “美適亞®”.

ABOUT TOM218美適亞® – MEGESTROL ACETATE ORAL SUSPENSION

The main ingredient of Megestrol Acetate Oral Suspension is megestrol acetate (a semisynthetic progesterone derivative), which can alleviate the cachexia status of AIDS and cancer patients and effectively improve their appetite, food intake, weight, as well as nausea and vomiting that sometimes occur. Compared to solid dosage forms, oral suspensions can relieve the discomfort of patients in swallowing. At present, the Product is the first high concentration megestrol acetate oral suspension approved for marketing in Mainland China, with a specific oral dose for the treatment of cachexia (recommended initial dose: 625 mg/day (5 mL/day)). Based on ordinary suspension processes, high concentration megestrol acetate oral suspensions adopt nanocrystalline technology to improve patients' treatment compliance and absorption into the body.

According to the latest 2020 global cancer data released by the International Agency for Research on Cancer (IARC) of the World Health Organization, there were 4.57 million new cancer cases and 3 million cancer deaths in China in 2020, and 6 of the top 10 cancers with the highest rates of incidence in China are often accompanied by cachexia, among which the incidence of cachexia associated with gastroesophageal and pancreatic tumors exceeds 65%. Cachexia is an important factor leading to high mortality and shortened survival of patients with advanced tumors.

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 ultimately market TOM218美適亞® 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, 13 May 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.