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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

COMPLETION OF DOSING IN THE FIRST PATIENT FOR THE PHASE III CLINICAL TRIAL OF TAA013, AN ANTIBODY DRUG CONJUGATE

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 Group's self-developed HER2 targeted antibody drug conjugate (“**ADC**”) candidate, TAA013, has recently reached a pivotal clinical-stage milestone. The first patient for a pivotal Phase III registrational clinical trial of TAA013 (the “**Study**”) has been dosed. The purpose of the Study is to evaluate the efficacy and safety of TAA013 as compared to lapatinib plus capecitabine in the treatment of patients with unresectable locally advanced or metastatic HER2-positive breast cancer after failure of trastuzumab therapy. If successful, the Study will be used to support the new drug application for TAA013 in China.

About HER2-positive breast cancer: According to public information, breast cancer has the highest incidence rate among female malignant tumors, and HER2-positive breast cancer is a common type of breast cancer. Anti-HER2 therapy is currently a widely used treatment for HER2-positive breast cancer worldwide, which can significantly prolong the survival of patients with HER2-positive advanced breast cancer. The Group hopes that the results of the Study will benefit HER2-positive breast cancer patients and provide clinicians with better treatment options.

About TAA013: TAA013 is an ADC candidate containing trastuzumab emtansine (Trastuzumab-MCC-DM1) which aims to become an affordable alternative drug to Kadcyca for the treatment of HER2-positive breast cancer. TAA013 precisely delivers the highly active cytotoxic drug to tumor cells through the targeting ability of monoclonal antibodies, thereby eliminating the tumor cells. With the strong targeting ability of monoclonal antibody drugs and the high killing power of cytotoxic drugs, ADC drugs can fully leverage the anti-tumor strengths of the two types of drugs, demonstrating the advantages of good selectivity, high efficacy and low side effects.

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, TAA013 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, 23 July 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.