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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)

INSIDE INFORMATION ANNOUNCEMENT

TERMINATION OF PHASE III CLINICAL TRIAL STUDY AND DEVELOPMENT OF TAA013

This announcement is made by TOT BIOPHARM International Company Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) pursuant to Rule 13.09(2) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and the Inside Information Provisions (as defined under the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

The board of directors of the Company (the “**Board**”) announces that, based on a comprehensive and prudent analysis and evaluation of the future commercial value and market sales of TAA013, the Group's self-developed HER2 targeted antibody-drug conjugate (“**ADC**”), and taking into account the Company's strategic planning, the Group has decided to terminate the Phase III clinical trial study and development of TAA013 in China.

I. About TAA013

TAA013 is an ADC drug composed of a recombinant humanized anti-HER2 monoclonal antibody covalently linked to the microtubule inhibitor DM1 via the linker SMCC. It is proposed to be mainly used for treating unresectable locally advanced or metastatic HER2-positive breast cancer after failure of trastuzumab therapy. The drug is currently undergoing Phase III clinical study 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.

II. Reasons for and Benefits of Termination

With the recent significant changes in the current market competitive landscape of ADC drugs for the treatment of HER2-positive breast cancer, after the comprehensive evaluation by the Company's management, it is believed that the future market sales and potential commercial value of TAA013 among products in the same field will be far lower than the market expectations under the Company's early planning. Taking into account the Company's strategic transformation, in addition to better allocating its resources to the research and development of its existing product pipelines as well as sales of its launched products, the Company will also continue to vigorously develop its CDMO business involving ADCs and antibody drugs. After consideration by the Board, the Group has decided to terminate the further development of the drug, and this will not have any significant impact on the Group's subsequent financial conditions. The Board is of the view that this decision demonstrates the Company's determination to focus on the development of its key businesses, is in line with the Company's overall strategy, and can safeguard the interests of the Company and its shareholders as a whole.

III. Subsequent Matters Relating to TAA013

Upon the termination of Phase III clinical trial of TAA013, based on the disease progression and drug availability in respect of certain subjects who remain in the trial, and taking into account the judgment of researchers and the wishes of those subjects, the Group will decide on the provision of appropriate treatment options for those subjects.

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, 17 March 2023

As at the date of this announcement, the executive director of the Company is Dr. Liu, Jun; the non-executive directors of the Company are Mr. Fu, Shan, Ms. Yeh-Huang, Chun-Ying 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.