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

SUCCESSFUL PASSING OF EU QP AUDIT ON TOT BIOPHARM'S COMMERCIAL PRODUCTION BASE FOR MONOCLONAL ANTIBODY DRUG SUBSTANCES AND ANTIBODY DRUG CONJUGATES

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 GMP compliance inspection report approved by a Qualified Person ("**QP**") in the European Union ("**EU**") in respect of the manufacturing facilities and associated quality systems of the Group's commercial production base for its self-developed HER2-targeted antibody drug conjugate ("**ADC**") candidate, TAA013.

Pursuant to EudraLex Volume 4 regulations (EU Good Manufacturing Practice, "**EU GMP**") and the guiding principles of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), this EU QP audit involved a comprehensive and in-depth audit mainly focused on the production quality of monoclonal antibody ("**mAb**") drug substances, ADC drug substances and ADC drug products of TAA013. The audit covered manufacturing management system, quality management system, plant facilities and equipment management system, validation and computerized system, data integrity verification and management, material management system, product testing and release management and other aspects, thereby further affirming that the Group's commercial production base possesses EU GMP-compliant quality systems and production capacity. This indicates that the Group's commercial production and quality management systems for mAb drug substances and ADC drugs have been recognized by an international professional institution, laying a solid foundation for the high-quality commercialization of TAA013 and the Group's international development.

ABOUT TOT SUZHOU'S ADC ONE-STOP INDUSTRIALIZATION PLATFORM

Located at the Group's headquarters in Suzhou Industrial Park, TOT Suzhou's ADC one-stop industrialization platform possesses core research and development technology advantages. It is equipped with a full range of capabilities from drug development to commercial production, which can realize the one-stop commercial production of antibodies and ADC drug substances and drug products, as well as flexible and diverse production capacity to meet the needs of different production scales for small trials, pilot tests and commercialization.

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
Dr. Liu, Jun
Chief Executive Officer and Executive Director

Hong Kong, 25 October 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 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.