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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

DRUG REGISTRATION APPROVAL FOR TEMOZOLOMIDE CAPSULE (TOZ309) 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 the Company's self-developed Temozolomide Capsule (TOZ309, with the proposed brand name “替至安® (Tazian®)”) (the “**Product**”) has been granted drug registration approval by the National Medical Products Administration (“**NMPA**”). The Product is deemed to be a generic drug that has passed the consistency of quality and efficacy evaluation and can be marketed in mainland China (i.e. excluding Hong Kong, Macau and Taiwan regions) for the treatment of: (1) newly diagnosed glioblastoma multiforme, initially combined with radiotherapy, and then as maintenance therapy; and (2) glioblastoma multiforme or anaplastic astrocytoma that recurs or progresses after conventional treatment.

The Product was filed for marketing as an NMPA New Category 4 chemical drug (generic drug), the specifications of which include 20mg x 5 capsules/bottle and 100mg x 5 capsules/bottle.

About TOZ309 Tazian® – Temozolomide Capsule

TOZ309 Tazian® is the generic drug of Temozolomide Capsule “TEMODAR® (泰道®)”. Temozolomide is an alkylating agent of imidazotetrazine with anti-tumor activity, which can kill cancer cells by damaging their DNA. With improved efficacy and fewer side effects compared to conventional chemotherapy, Temozolomide Capsules are used as a first-line medication for both newly diagnosed and recurrent glioma.

Only three Temozolomide Capsules products have been marketed in mainland China, including the original drug “TEMODAR® (泰道®)” which was approved by the United States Food and Drug Administration (FDA) in 1999, and was approved by NMPA to enter the China’s market in 2007. The sales of Temozolomide Capsules reached approximately RMB1.8 billion in 2018 and is expected to grow to approximately RMB2.5 billion by 2023 in mainland China’s market, according to Frost & Sullivan.

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 TOZ309 Tazian® 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, 31 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.