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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

PHASE III CLINICAL TRIAL APPLICATION OF TAB014 AUTHORIZED BY FDA

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, as notified to the Group by the United States Food and Drug Administration (FDA), the investigational new drug (IND) application in respect of the Phase III clinical trial of monoclonal antibody drug TAB014 (recombinant humanized anti-vascular endothelial growth factor (VEGF) monoclonal antibody) intravitreal injection for the treatment of wet (neovascular) age-related macular degeneration (wAMD) has recently been authorized by the FDA.

Based on the data from the Phase I clinical trial of TAB014 conducted in the People's Republic of China (“**China**”) and relevant clinical literature data, this IND application is a direct application for authorization to conduct Phase III clinical trial (being exempted from Phase II clinical trial). It is also the Group's first project with IND application submitted and authorized overseas, which is significant for the Group's entry into the international market.

The clinical research and commercialization project in relation to TAB014 was listed by the Development Center for Medical Science & Technology of the National Health Commission of China as a special major project for technologies of innovative manufacturing of major new drugs at the end of 2019.

About TAB014

TAB014 is a monoclonal antibody product for the treatment of wet (neovascular) age-related macular degeneration (wAMD), retinal vein occlusion (RVO), choroidal neovascularization (CNV) and other eye diseases. Among these, the main pathological feature of wAMD is choroidal angiogenesis in the macula, with VEGF playing an important role in the angiogenesis process. TAB014 is able to bind specifically to VEGF and block it from binding to its receptors, thereby inhibiting angiogenesis. TAB014 will eventually be administered as an intravitreal injection for the treatment of wAMD.

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, TAB014 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, 2 February 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.