Immunotech Biopharm Ltd
永泰生物製藥有限公司
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 6978)

VOLUNTARY ANNOUNCEMENT
EAL® WAS GRANTED BREAKTHROUGH THERAPY DESIGNATION FOR TREATMENT OF LIVER CANCER BY THE CENTER FOR DRUG EVALUATION

This announcement is made by Immunotech Biopharm Ltd (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the Company's product, EAL®, was granted breakthrough therapy designation for the prevention of postsurgical recurrence of liver cancer by the Center for Drug Evaluation ("**CDE**") of the National Medical Products Administration ("**NMPA**"). The designation was granted based on the solid clinical efficacy and safety data of EAL®. It will expedite the clinical development of EAL® and accelerate its early access to the patients.

According to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) and the announcement of the NMPA's publication of three documents including the Working Procedures for Review of Breakthrough Therapeutics (Trial) (No. 82 of 2020) (《國家藥監局關於發佈〈突破性治療藥物審評工作程序(試行)〉等三個文件的公告》(2020年第82號)), drugs granted the breakthrough therapy designation are prioritized by the CDE in communications and guidance to promote the drug development progress.

CDE's breakthrough therapy designation (BTD) is designed to expedite the clinical development of innovative drugs presenting significant clinical advantages. Drug candidates with breakthrough therapy designation may be considered for conditional approval and priority review when submitting a new drug application. According to the CDE, the breakthrough therapy designation provides opportunities for more intensive CDE guidance and discussion with respect to clinical trials and development strategy, and for priority review later.

ABOUT EAL®

EAL® is a multi-target cellular immunotherapy product with more than a decade of track record of clinical application in the treatment of cancer. It is a preparation of activated and expanded T cells originally taken from a patient's autologous peripheral blood and cultured using the patented methods. The main active component of the product is $CD8^+$ cytotoxic T cells, whose surface marker is the CD3 molecule.

EAL® is undergoing Phase II clinical trial with the postsurgical recurrence of liver cancer selected as the clinical indication. Based on the Company's communications with the CDE, the Company may apply for marketing approval for EAL® indicated for the prevention of postsurgical recurrence of liver cancer using the interim results of the ongoing clinical trial or the final results at the end of the clinical trial if such results are statistically significant. The Company may further communicate with the CDE to facilitate the assessment after obtaining clinical trial results that support the efficacy of EAL®.

As at the date of this announcement, the Company has completed the enrollment of 430 targeted patients for the Phase II clinical trial. The Company is confident that it will submit a pre-NDA meeting application for the product to the NMPA in 2023 and hopefully launch the product in 2024.

ABOUT THE GROUP

The Group is a leading cellular immunotherapy biopharmaceutical company in China focusing on the research, development, and commercialisation of T cell immunotherapy for almost 17 years. Since its establishment in 2006, it has focused on R&D and clinical applications of cellular immunotherapy drugs for cancers and other major diseases, by applying advanced theories in immunology, cell biology, and genetics.

Its product pipeline features major classes of cellular immunotherapy products, including both non-genetically-modified and genetically-modified products, as well as both multi-target and single-target products. Other than EAL®, its main product candidates include the CAR-T cell series and the TCR-T cell series. To learn more about the Company, please visit www.eaal.net.

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: The Group cannot guarantee that the Company will be able to obtain further approval for, or ultimately market, EAL®, successfully. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
Immunotech Biopharm Ltd
Tan Zheng
Chairman and executive Director

Hong Kong, 5 September 2023

As at the date of this announcement, the Board comprises Mr Tan Zheng as Chairman and executive Director, Dr Wang Yu as executive Director, Mr Tao Ran, Mr Wang Ruihua, Mr Yang Fan and Mr Wang Donghu as non-executive Directors, and Professor Wang Yingdian, Mr Ng Chi Kit and Ms Peng Sujiu as independent non-executive Directors.