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
THE CLINICAL TRIAL APPROVAL FOR THE aT19 INJECTION

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 has received an approval of the Investigational New Drug Application ("**IND**") for Phase I clinical trial from the Centre for Drug Evaluation (the "**CDE**") of the National Medical Products Administration for the aT19 injection (the "**aT19 Injection**"). The aT19 Injection is an injection of CD19-targeted chimeric antigen receptor T cells ("**CAR-T cells**") for sequential use after treatment of relapsed refractory B-cell-derived acute lymphoblastic leukemia ("**B-ALL**") for the prevention of CD19-positive relapses for patients under the age of 25. The goal of this injection is to address the pain point of possible CD19-positive relapse after CD19-targeted CAR-T cells for B-ALL treatment. The Group submitted the IND application to the CDE in November 2023. The Phase I clinical trial for the aT19 Injection are expected to start in the year end of 2024.

ABOUT aT19 INJECTION

The active component of our aT19 Injection product candidate is autologous T cells genetically modified to express CD19. The gene introduced therein is an encoded gene structure that can express human CD19 protein. The reinfusion of the aT19 Injection after injecting the CAR-T-19 Injection has the potential to reactivate CAR-T cells, restart the proliferation of CAR-T cells, and induce more immune memory cells, thereby increasing the chance of killing trace amounts of residual CD19-positive tumour cells and of preventing recurrence. Through multiple stimulations from CD19 antigen, the number of CAR-T cells with immune memory function may also increase, thereby prolonging the immune surveillance duration of CAR-T cells and reducing the probability of recurrence of CD19-positive tumours.

The aT19 Injection has certain commonality with our CAR-T-19 Injection product candidate (both of them are products based on the genetic modification by T cells via lentiviral vectors), so the previous process can be applied in the pharmaceutical process development, thereby shortening the product development period.

Background

Acute lymphoblastic leukemia ("**ALL**") is a subtype of acute leukemia. It is characterized by a rapid increase in the number of immature blood cells with mutations in their DNA and an inability to grow into normal cells. ALL is more common in children than in adults. In 2015, there were approximately 12,000 new B-ALL patients in China, of which 30% were refractory relapsed cases. The number of new ALL patients increased from approximately 11,600 in 2014 to approximately 12,400 in 2018. In 2018, there were approximately 10,700 children under the age of 18 newly developed ALL in China, accounting for 86.3% of the total number of ALL patients in China. Due to the development of early screening, it is estimated to reach 13,400 cases in 2023 and 14,700 cases in 2030. Currently, CD19-targeted CAR-T cell therapy has achieved amazing therapeutic effects, but long-term follow-up results showed that 30% to 60% of patients relapsed within one year after CAR-T therapy, and more than 50% of them were CD19-positive relapses, which may be related to the insufficient duration of survival of CAR-T cells in the body.

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 18 years. Since its establishment in 2006, it has focused on research and development 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 Immunotech, 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 aT19 Injection will ultimately be successfully developed and marketed. 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, 19 February 2024

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.