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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 FIRST PATIENT ENROLLED IN THE PHASE II CLINICAL TRIAL FOR CAR-T-19 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 completed the first patient enrolment for its Phase II clinical trial for CAR-T-19 injection (“**CAR-T-19 Injection**”) in the PRC, which marked a key milestone of the Group’s development in its product pipeline. CAR-T-19 Injection is indicated for the treatment of pediatric and young adult patients up to and including the age of 25 with relapsed/refractory B cell acute lymphoblastic leukaemia (“**B-ALL**”). Based on the progress of clinical trial for CAR-T-19 Injection, it is expected that the target patient enrolment would complete by the end of 2025 and the preliminary analysis and results would be published in the first half of 2026.

ABOUT THE CAR-T-19 INJECTION

CAR-T-19 Injection is the first product candidate in the CAR-T cell product pipeline of the Group. The Group intends to develop CAR-T-19 for B-ALL and B-cell lymphoma. Acute lymphoblastic leukemia (“**ALL**”) is one of the subtypes of acute leukaemia. It is characterised by a rapid increase in the number of immature blood cells, in which the DNA of the blood cells is mutated, and cannot grow up to function as normal cells. ALL is more common in children than in adults. In 2015, about 12,000 patients were newly diagnosed with B-ALL in China, 30% of whom were refractory and relapsed cases. The new cases of patients diagnosed with ALL increased from approximately 11,600 in 2014 to approximately 13,100 in 2022. In 2022, there were approximately 11,500 new cases involving children under the age of 18 diagnosed with ALL in China, accounting for 87.7% of total ALL patients in China. Due to the development of early screening, the number is estimated to be 13,400 in 2023 and 14,700 in 2030.

Background

Leukaemia is a group of blood cancers that usually begin in the bone marrow and result in high numbers of abnormal blood cells. Most often, leukaemia is a cancer of the white blood cells, but some forms of leukaemia start in other blood cell types. There are several types of leukaemia, which are divided into four types based mainly on whether the leukaemia is acute (fast-growing) or chronic (slower-growing), and whether it starts in myeloid cells or lymphoid cells. ALL is one of the subtypes of acute leukaemia. It is characterised by a rapid increase in the number of immature blood cells, in which the DNA of the blood cells is damaged, and cannot grow up to function as normal cells.

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 over 17 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 the Company, please visit www.eaal.net.

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities of The Stock Exchange of Hong Kong Limited: The Group cannot guarantee that CAR-T-19 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, 3 January 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.