

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



ImmuneOnco Biopharmaceuticals (Shanghai) Inc.

宜明昂科生物醫藥技術（上海）股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 1541)

VOLUNTARY ANNOUNCEMENT

ORPHAN-DRUG DESIGNATION FROM FDA IN RESPECT OF COMBINATION OF IMM01 AND AZACITIDINE FOR THE TREATMENT OF CMML

This announcement is made by ImmuneOnco Biopharmaceuticals (Shanghai) Inc. (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform shareholders and potential investors of the Company about the latest business development of the Group.

The board (the “**Board**”) of directors (“**Directors**”, and each a “**Director**”) of the Company is pleased to announce that the Food and Drug Administration of the United States (FDA) has granted an orphan-drug designation to IMM01 in combination with azacitidine for the treatment of chronic myelomonocyte leukemia (CMML).

ABOUT IMM01

IMM01, the Group’s core product, is an innovative molecule targeting cluster of differentiation 47 (CD47). It is the first SIRP α -Fc fusion protein to enter into clinical stage in China. IMM01 designed with immunoglobulin G1 (IgG1) Fc can fully activate macrophages via a dual mechanism — simultaneously blocking the “don’t eat me” signal by disrupting CD47/SIRP α interaction and delivering the “eat me” signal through the engagement of activating Fc-gamma (Fc γ) receptors on macrophages. Furthermore, the CD47-binding domain of IMM01 was specifically engineered to avoid human red blood cell (RBC) binding. With the differentiated molecule design, IMM01 has achieved a favorable safety profile and demonstrated its ability to activate macrophages.

The Group owns the global intellectual property rights and commercial rights of IMM01. As of the date of this announcement, in relation to IMM01, the Group owned one patent family, which includes issued patents in China, the United States, Japan and the European Union.

The Company has initiated a Phase II trial to evaluate the combination therapy of IMM01 and azacitidine mainly for the first-line treatment of higher-risk (HR) myelodysplastic syndromes (MDS), unfit acute myeloid leukemia (AML) and CMML in China in June 2022, from which so far an encouraging efficacy and safety profile of this combination therapy has been observed.

ABOUT ORPHAN DRUGS

Under the Orphan Drug Act, the FDA may grant orphan-drug designation to drugs or biologic candidates intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the United States. The first applicant to receive FDA approval for the disease or indication for which it has orphan-drug designation is entitled to a seven-year exclusive marketing period. During the exclusivity period, the FDA may not approve any other applications to market the same product for the same disease or condition except in limited circumstance.

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, IMM01, successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

By order of the Board
ImmuneOnco Biopharmaceuticals (Shanghai) Inc.
宜明昂科生物醫藥技術（上海）股份有限公司
Tian Wenzhi
Chairman and Executive Director

Hong Kong, November 8, 2023

As at the date of this announcement, the Board of Directors comprises (i) Dr. Tian Wenzhi, Mr. Li Song and Ms. Song Ziyi as executive Directors; (ii) Dr. Xu Cong, Mr. Yu Zhihua and Mr. Yu Xiaoyong as non-executive Directors; and (iii) Dr. Zhenping Zhu, Dr. Kendall Arthur Smith and Mr. Yeung Chi Tat as independent non-executive Directors.