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思路迪医药
3D Medicines

3D Medicines Inc.
思路迪医药股份有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 1244)

VOLUNTARY ANNOUNCEMENT

恩維達® Supplemental Application for Conditional-to-Regular Approval Transition Approved by NMPA

This announcement is made by 3D Medicines Inc. (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis.

The board of directors of the Company (the "**Board**") is pleased to announce that the National Medical Products Administration (NMPA) has approved the supplemental application for 恩維達® (Envafolimab) to transition from conditional approval to regular approval as a domestically produced drug on November 17, 2026, with the notice of approval No. 2026B08210.

ABOUT 恩維達® (generic name: Envafolimab, code: KN035)

恩維達® (generic name: Envafolimab, code: KN035) is a recombinant single domain antibody against programmed death ligand 1 ("**PD-L1**") fused with human Fc, a drug independently invented by Alphamab Oncology (Alphamab, an exempted company with limited liability incorporated under the laws of the Cayman Islands on March 28, 2018 and listed on the Stock Exchange (stock code: 9966), and its subsidiaries, each of which is an Independent Third Party) and co-developed with the Company since 2016. On March 30, 2020, Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (江蘇康寧傑瑞生物製藥有限公司) ("**Jiangsu Alphamab**"), a wholly-owned subsidiary of Alphamab, 3D Medicines and Jiangsu Simcere Pharmaceutical Co., Ltd. (江蘇先聲藥業有限公司) ("**Jiangsu Simcere**"), a subsidiary of Simcere Pharmaceutical Group Limited, the shares of which are listed on the Stock Exchange (stock code: 2096), entered into a cooperation agreement (the "**Simcere Agreement**"). Pursuant to the Simcere Agreement, Jiangsu Simcere has been granted an exclusive marketing right in respect of oncology indications of 恩維達® and the rights of first refusal for in-licenses or transfers in mainland China. In January 2024, the Company entered into a license agreement with Alphamab and Glenmark Specialty S.A. ("**Glenmark**"), pursuant to which the Company and Alphamab agreed to grant Glenmark an exclusive license and the right to sublicence in respect of oncology indications of 恩維達® to, among others, develop and commercialize 恩維達® in India, Asia Pacific (excluding Singapore, Thailand and Malaysia), Middle East and Africa, Russia, Commonwealth of Independent States and Latin America in all fields of use in oncology. Furthermore, it has been approved by the NMPA for the treatment of adult patients with advanced solid tumors who have unresectable or metastatic advanced microsatellite instability-high ("**MSI-H**") phenotype/mismatch-repair deficiency ("**dMMR**") as the global-first subcutaneous injection PD-L1 inhibitor in November 2021.

Cautionary Statement required by Rule 18A.05 and Rule 18A.08(3) of the Listing Rules: The Company may not be able to successfully develop and/or market its core product Envafolimab 恩維達® (also known as KN035) for indications other than the approved indication in previously treated MSI-H/dMMR advanced solid tumors. 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
3D Medicines Inc.
Dr. Gong Zhaolong
Chairman of the Board

Hong Kong, November 18, 2026

As at the date of this announcement, the Board of Directors of the Company comprises Dr. GONG Zhaolong as executive Director, Ms. ZHANG Wenhua, Mr. ZHOU Feng and Ms. CHEN Yawen as non-executive Directors, and Dr. LI Jin, Dr. LIN Tat Pang and Mr. LIU Xinguang as independent non-executive Directors.