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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

New Drug Application for First-line Treatment of Biliary Tract Cancer of 恩維達® Accepted by National Medical Products Administration

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 formally accepted the Company’s new drug application (NDA) for its commercial product 恩維達® (generic name: Envafolimab, code: KN035) in combination with the Gemcitabine and Oxaliplatin (GEMOX) regimen for the first-line treatment of unresectable or metastatic biliary tract cancer (BTC).

This acceptance is based on the clinical study results from the Phase III clinical trial (KN035-CN-005), a randomized, parallel-controlled, multicenter Phase III clinical trial designed for Chinese patients with advanced first-line BTC. The trial aims to evaluate the efficacy and safety of 恩維達® (KN035) combined with the GEMOX regimen compared to the GEMOX regimen alone.

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 Sincere Pharmaceutical Co., Ltd. (江蘇先聲藥業有限公司) (“**Jiangsu Sincere**”), a subsidiary of Sincere Pharmaceutical Group Limited, the shares of which are listed on the Stock Exchange (stock code: 2096), entered into a cooperation agreement (the “**Sincere Agreement**”). Pursuant to the Sincere Agreement, Jiangsu Sincere 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 sublicense 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 Envafolelimab 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, January 9, 2026

As at the date of this announcement, the Board of Directors of the Company comprises Dr. GONG Zhaolong as executive Director, Mr. ZHU Jinqiao, 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.