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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
Latest Progress in Collaboration Programs: Positive Data Achieved in the Global Pivotal Phase 3 REGAL Trial for 3D189

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 the latest significant progress in its collaboration programs in respect of 3D189 (Galinpepimut S, GPS) with SELLAS Life Sciences Group, Inc. ("**SELLAS**").

SELLAS Life Sciences Group, Inc. ("**SELLAS**") announced the positive topline primary endpoint results of the global pivotal randomised Phase 3 REGAL trial (Trial ID: NCT04229979) on 17 November 2026. The trial evaluates 3D189, a WT1-targeted therapeutic cancer vaccine in the Group's collaborative pipeline, as single-agent maintenance therapy for acute myeloid leukaemia patients who have achieved second or later complete remission and are ineligible for allogeneic stem cell transplantation.

The REGAL trial has successfully met its pre-specified primary efficacy endpoint. Compared with the investigator's choice of best available treatment, 3D189 reduced the risk of death by 41% with a hazard ratio of 0.59 and a two-sided p-value of 0.035, demonstrating statistically significant and clinically meaningful benefits. The median overall survival of patients in the 3D189 treatment group reached 24.0 months, compared with 14.7 months in the control group. In terms of safety, 3D189 was generally well tolerated with a safety profile consistent with previous clinical studies. No new safety signals were identified, and treatment-related adverse events were mostly mild to moderate local injection reactions.

SELLAS intends to communicate with the U.S. Food and Drug Administration to explore an accelerated approval pathway and plans to submit the Biologics License Application in the first half of 2027. Full secondary endpoint data, subgroup analyses and supplementary study results will be presented at subsequent international medical conferences and published in professional academic journals.

The Group will continue to closely monitor the complete data disclosure, regulatory application and subsequent research and development progress of the 3D189 project. The Company will make further announcements in a timely manner in the event of any material updates pursuant to relevant regulations.

The Company reminds investors that the results of clinical studies are uncertain, and subsequent links such as data statistical analysis, submission of clinical trial reports and drug registration and approval may be affected by various factors, which involves certain risks. The Company will timely disclose the follow-up progress of this clinical trial in accordance with the requirements of the Listing Rules and relevant laws and regulations. Investors are advised to invest prudently and pay attention to investment risks.

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.