Duality Biotherapeutics, Inc.

映恩生物

(Incorporated under the laws of the Cayman Islands with limited liability)

(Stock code: 9606)

INSIDE INFORMATION

PRIMARY ENDPOINT MET FOR PHASE III CLINICAL TRIAL OF DB-1303/BNT323 IN PATIENTS WITH HER2-POSITIVE UNRESECTABLE OR METASTATIC BREAST CANCER

INTRODUCTION

This announcement is made by Duality Biotherapeutics, Inc. (the "**Company**") pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the **"Listing Rules**") and the Inside Information Provisions under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

The board of directors (the "**Board**") is pleased to announce that as per the review by the Independent Data Monitoring Committee (IDMC), the Phase III clinical trial of DB-1303/BNT323 in patients with HER2-positive unresectable or metastatic breast cancer, who have previously received trastuzumab and a taxane (the "**Trial**") achieved the primary endpoint of progression-free survival (PFS) as evaluated by blinded independent central review (BICR), compared with the control arm.

Based on the results from the interim analysis, the Company plans to communicate with the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China regarding the submission of a Biologics License Application (BLA) of DB-1303/BNT323.

DESIGN, PURPOSE AND CONCLUSION OF THE CLINICAL TRIAL

The Trial is a randomized, controlled, open-label, multi-center Phase III clinical trial conducted in China to evaluate the efficacy and safety of DB-1303 compared with T-DM1 in patients with HER2-positive unresectable or metastatic breast cancer who have previously received trastuzumab and a taxane.

ABOUT DB-1303/BNT323

DB-1303/BNT323 is a clinical-stage HER2 ADC candidate that is being evaluated in two ongoing registrational trials (one global trial and one in China) and one additional global potentially registrational study. Our partner, BioNTech SE ("**BioNTech**") is preparing an application for the drug marketing authorization in respect of DB-1303/BNT323 as a second or subsequent line of therapy in HER2-expressing advanced endometrial cancer in 2025. DB-1303/BNT323 is designed with a stable, cleavable linker and proprietary topoisomerase-based payload that aims to lower off-target toxicity and enhance antitumor activity, including bystander killing effects. These features may enable DB-1303/BNT323 to potentially serve as a new therapeutic option for patients with HER2-expressing advanced solid tumors, including both patients with high and low expression levels of HER2.

DB-1303/BNT323 has obtained Fast Track and Breakthrough Therapy Designations from the FDA and Breakthrough Therapy Designation from the NMPA for the treatment of HER2-expressing advanced EC in patients who progressed on or after treatment with immune checkpoint inhibitors. Moreover, DB-1303/BNT323's treatment responses have been observed in a range of tumors, including breast cancer, endometrial cancer, ovarian cancer, colorectal cancer and esophageal cancer, and are supported by global clinical data from patients across the U.S., China, Australia and other countries.

Cautionary Statement as required by Rule 18A.08(3) of the Listing Rules: There is no assurance that the Company will ultimately develop, market and/or commercialize DB-1303/BNT323 successfully. 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
Duality Biotherapeutics, Inc.
Dr. ZHU Zhongyuan
Chairman of the Board, Executive Director and Chief Executive Officer

Hong Kong, September 5, 2025

As at the date of this announcement, the Board comprises (i) Dr. ZHU Zhongyuan, Mr. ZHANG Shaoren and Ms. SI Wen as executive directors; (ii) Mr. CAI Zhiyang and Dr. YU Tao as non-executive directors; and (iii) Mr. XIE Dong, Mr. GAO Fengyong and Ms. CHUAI Shuyin as independent non-executive directors.