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Duality Biotherapeutics, Inc.

映恩生物

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

(Stock code: 9606)

INSIDE INFORMATION

BIOLOGICS LICENSE APPLICATION FOR DB-1303/BNT323 FOR UNRESECTABLE OR METASTATIC HER2-POSITIVE BREAST CANCER IN ADULTS ACCEPTED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

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).

Reference is made to the announcement of the Company dated September 5, 2025, regarding the latest update on the development progress of the Company’s Core Product DB-1303/BNT323. The board of directors (the “**Board**”) is pleased to announce that, based on the positive results obtained from the Phase III pivotal clinical trial (study code: DB-1303-O-3001) and the feedback from the pre-submission communication with the Center for Drug Evaluation (CDE) of the National Medical Products Administration (the “**NMPA**”) regarding the Biologics License Application, the submitted Biologics License Application (the “**BLA**”) has been accepted by the NMPA.

The DB-1303-O-3001 trial is a randomized, controlled, open-label, multi-center Phase III clinical trial designed 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. As per the review by the Independent Data Monitoring Committee (IDMC), the Phase III clinical trial achieved the primary endpoint progression-free survival (PFS). In the pre-specified interim analysis, DB-1303 demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint compared with the control arm, with a favorable safety and tolerability profile.

ABOUT DB-1303/BNT323

DB-1303 (partner BioNTech SE development code: BNT323; International Nonproprietary Name (INN)/United States Adopted Name (USAN): Trastuzumab pamirtecan; proposed Chinese generic name: 帕康曲妥珠單抗) is a clinical-stage HER2 ADC candidate built on the Company's proprietary DITAC (Duality Immune Toxin Antibody Conjugates) technology platform.

Trastuzumab pamirtecan is currently being studied across multiple solid tumors and exploring innovative combination therapy regimens, including two global pivotal clinical trials: the DYNASTY-Breast02 study (NCT06018337) for first-line treatment of HER2-low, hormone receptor-positive (HR+) metastatic breast cancer, and the BNT323-01 study (NCT06340568) for second-line treatment of endometrial cancer; as well as a Phase I/II novel combination clinical trial BNT323-03 (NCT06827236), designed to evaluate trastuzumab pamirtecan in combination with pumitumab for the treatment of patients with hormone receptor-positive or -negative, HER2-low, ultralow or negative advanced/metastatic breast cancer.

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 endometrial cancer 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, Europe, Australia and other countries.

Cautionary Statement as required by Rule 18A.05 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, April 9, 2026

As at the date of this announcement, the Board comprises (i) Dr. ZHU Zhongyuan, Mr. ZHANG Shaoren and Dr. HUA Haiqing 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.