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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

UPDATE ON THE DYNASTY-BREAST02 GLOBAL PHASE 3 CLINICAL TRIAL OF TRASTUZUMAB PAMIRTECAN

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 announcements of the Company dated September 5, 2025 and April 9, 2026 in relation to the development progress of DB-1303/BNT323. The board of directors of the Company (the “**Board**”) announces that the DYNASTY-Breast02 global Phase 3 clinical trial (NCT06018337) met its primary endpoint, demonstrating a statistically significant, yet modest improvement in progression-free survival (“**PFS**”) with trastuzumab pamirtecane (DB-1303/BNT323), an investigational HER2-targeting antibody-drug conjugate (“**ADC**”), compared to investigator’s choice of chemotherapy in chemotherapy-naïve patients with HR+/HER2-low metastatic breast cancer who have progressed on endocrine therapy. At this interim analysis for the secondary endpoint of overall survival (“**OS**”), data were not mature.

A higher rate of interstitial lung disease (“**ILD**”) was reported in this trial compared to prior trials with trastuzumab pamirtecane, with most cases being Grade 1 and 2. Severe and fatal events were reported in a small proportion of patients (Grade 3 – 5). Otherwise, the overall safety profile was consistent with prior clinical trials and no new safety signals were observed.

The available efficacy and safety data, as of this data cut-off date, suggest that the potential benefit to patients would be limited in the context of the HR+/HER2-low metastatic breast cancer treatment landscape. The Company and BioNTech SE (“**BioNTech**”), the Company’s collaboration partner for trastuzumab pamirtecane, will discuss the data and determine next steps.

The Company and BioNTech are developing trastuzumab pamirtecan in three ongoing clinical trials, including two global Phase 3 clinical trials, in HR+/HER2-low metastatic breast cancer (NCT06018337) and in HER2-expressing recurrent endometrial cancer (NCT06340568), as well as in a global Phase 1/2 clinical trial (NCT05150691) in patients with advanced/metastatic solid tumors.

ABOUT DYNASTY-BREAST02

DYNASTY-Breast02 is a global Phase 3 randomized, multi-center, open-label clinical trial in patients living with HR+/HER2-low metastatic breast cancer whose disease has progressed on at least two lines of prior hormone therapy or within six months of first line hormone therapy plus cyclin-dependent kinase (CDK) 4/6 inhibitor in the metastatic setting. The primary endpoint of the clinical trial is PFS with a key secondary endpoint of OS. In the trial, 541 patients with HER2-low expression (IHC 2+/ISH- and IHC 1+) were randomized 1:1 to receive either trastuzumab pamirtecan or investigator's choice single-agent chemotherapy (capecitabine, paclitaxel or nab-paclitaxel).

ABOUT TRASTUZUMAB PAMIRTECAN

Trastuzumab pamirtecan (DB-1303/BNT323) is a third-generation topoisomerase-1 inhibitor-based ADC targeting HER2 being developed by BioNTech and the Company. Trastuzumab pamirtecan was built from the Company's proprietary Duality Immune Toxin Antibody Conjugates (DITAC) platform. HER2 is a surface-expressed protein on solid tumors and has been linked to the aggressive growth and spread of cancer cells.

Trastuzumab pamirtecan is being evaluated in an ongoing Phase 1/2 trial (NCT05150691) in patients with advanced/metastatic solid tumors and in Fern-EC-01, a randomized Phase 3 clinical trial (NCT06340568) evaluating trastuzumab pamirtecan compared with investigator's choice of single agent chemotherapy in previously treated patients with HER2-expressing advanced recurrent endometrial cancer, which is currently enrolling patients.

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 trastuzumab pamirtecan (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, October 26, 2026

As at the date of this announcement, the Board of the Company 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.