



## **Positive top-line efficacy and safety data from global Phase III clinical trial of Tanvex trastuzumab biosimilar candidate, TX05**

Feb. 20, 2021

Tanvex BioPharma, Inc. (TWSE: 6541) today announced results from a Phase III study evaluating efficacy and safety of its trastuzumab biosimilar candidate, TX05, compared with trastuzumab in patients with human epidermal growth factor receptor 2-positive (HER2-positive) early breast cancer. The primary endpoint was an assessment of pathologic complete response (pCR) following neoadjuvant therapy and definitive surgery in the per protocol population. Based on the study design, TX05 was considered equivalent for pCR if the 95% CI of the risk ratio TX05: Herceptin was within 0.755 to 1.325.

Based on independent central review, in the per-protocol population, 48.8% of patients achieved pCR in the TX05 arm versus 45.3% in the Herceptin group. The pCR risk ratio was 1.0783 (95% CI, 0.9185 to 1.2659), which was entirely within the predefined equivalence margins, demonstrating therapeutic equivalence.

### **About Tanvex**

Tanvex BioPharma, Inc. (TWSE: 6541) is a biopharmaceutical company focused on the biosimilar market. The Company is vertically integrated with end-to-end in-house development, manufacturing and commercialization capabilities. Tanvex BioPharma, Inc. is registered in Cayman Islands and has operations and facilities in Irvine, CA, San Diego, CA, and Taipei, Taiwan. Tanvex is publicly traded on the Taiwan Stock Exchange.