

Tanvex BioPharma, Inc. (Tanvex) (6541.TWO), today(09/28/2017) announced its plans for an international Phase 3 trial of its biosimilar drug candidate, TX05, its investigational trastuzumab biosimilar (a proposed biosimilar to Herceptin®) in patients with early stage breast cancer. In accordance with advice from the US Food and Drug Administration, the global Phase 3 trial, *“A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer”*, has been designed to compare the therapeutic equivalence of biosimilar candidate TX05 to Herceptin in HER2-positive, early-stage breast cancer patients based on the pathological complete response rate following neoadjuvant therapy. Approximately 800 patients are anticipated to be enrolled from about 209 study centers in 19 countries. The primary efficacy endpoint, pCR, will be assessed through specimens obtained during surgery and analyzed by a central review of local histopathology reports. Equivalence will be considered to be demonstrated if the 95% confidence interval of the risk ratio of the pCR rates (TX05/Herceptin) is within a predefined interval agreed between Tanvex and FDA.

Worldwide, nearly 2 million women are diagnosed with breast cancer each year, making it the second most common cancer in the world. Approximately 20% to 30% of primary breast cancers are HER2-positive.

“This represents another major milestone for our company. TX05 will be our second biosimilar product to enter Phase 3 trials and reinforces our commitment to expand access to affordable, high quality products to patients with serious illness,” said Allen Chao, PhD, CEO of Tanvex.

US sales of Herceptin® were US\$2.7 billion in 2016.

About TX05

TX05 is a proposed biosimilar to Herceptin® (trastuzumab). Trastuzumab is a recombinant DNA-derived humanized monoclonal antibody for use in the treatment of Human Epidermal growth factor Receptor 2-positive (HER2+) breast cancer and HER2+ gastric cancer.

About Tanvex

Tanvex BioPharma, Inc. is a clinical-stage development company focused on the biosimilar market. The Company is vertically integrated with end-to-end in-house development and manufacturing 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 Taipei Exchange Emerging Stock Market (ticker: 6541.TWO).