



Clinical Trial Completion of Treatment for TX05

October 22, 2020

Tanvex BioPharma, Inc., a biotechnology company focused on developing biosimilars, today announced that the final patient has completed neoadjuvant treatment in the Company's pivotal Phase III TX05 trial.

The trial includes a total of 809 study subjects with newly-diagnosed breast cancer who were candidates for neoadjuvant therapy followed by definitive surgery. TX05 is a proposed biosimilar to Herceptin® (trastuzumab). The clinical data collection will be completed and validated in the coming weeks. Top-line results are expected to be announced in Q1, 2021. Tanvex is planning to submit a marketing application (BLA) to the US FDA in mid-2021.

The global Phase III 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.

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.