FDA Accepts TX05 BLA Filing

Oct. 04, 2021

Tanvex BioPharma, Inc. (TWSE: 6541) announced that US Food and Drug Administration (FDA) has accepted its Biologics License Application for TX-05, which was filed under the new biosimilar pathway created in the Biologics Price Competition and Innovation Act of 2009 (BPCIA). The reference product is Herceptin® (trastuzumab). This is the second BLA for Tanvex filed with US FDA.

Tanvex announced positive top-line efficacy and safety data from global Phase III clinical trial in Feb. 2021. According to data from IQVIA, Herceptin® US sales in 2020 was $2.3 billion (USD).

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.