# FDA delayed inspection for TX01

May 20, 2021

Tanvex BioPharma, Inc. announced that it received a complete response letter (CRL) from United States Food and Drug Administration (FDA) in response to the Biologics License Application (BLA) for TX01, a proposed biosimilar to Neupogen® (filgrastim). FDA decided on TX01 BLA that manufacturing site inspections must be completed before FDA can approve the BLA, and FDA is monitoring public health situation as well as travel restrictions to actively define an approach for scheduling inspections.

Based on the CRL, Tanvex will continue to update FDA with supplemental information and the Company plans to work closely with FDA to get the application can be approved.

**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.