Response from FDA for TX01

Sep. 25, 2019

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).

The CRL indicates the review cycle for the BLA is complete however there are certain items that need to be addressed before the application can be approved. FDA did not request additional clinical data or express concern related to product safety.

The Company plans to work closely with FDA to address all items in the CRL and resubmit the BLA as soon as possible. The FDA's target review cycle for resubmissions is six months.

"Tanvex is committed to providing patients and physicians affordable treatment options, including TX01", stated Allen Chao, Ph.D., CEO of Tanvex.

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.