TX01 BLA Resubmission

Nov. 22, 2020

Tanvex BioPharma, Inc. (TWSE: 6541) announced that we resubmitted the Biologics License Application (BLA) for filgrastim (TX-01) to US Food and Drug Administration (FDA). The FDA's target review cycle for resubmissions is six months.

Tanvex BioPharma, Inc. submitted BLA in September, 2018, and received Complete Response Letter on September 24, 2019. 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.

TX01, a proposed biosimilar to the reference product – Amgen's NEUPOGEN® -- is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever.

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.