



## **Tanvex submits TX01 NDS responses to Health –Canada**

Nov. 17, 2020

Tanvex BioPharma, Inc. (TWSE: 6541) announced the submission of TX01 New Drug Submission (NDS) responses to Health Canada. We submitted TX01 NDS to Health Canada in January 2019, and received a Notice of Deficiency (NOD) issued by Health Canada in December 2019, we believe all deficiencies have been adequately addressed. We expect the review to be completed in approximately 180 days by Health Canada.

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.

According to data from IMS, filgrastim product sales (including Neupogen® and Grastofil®) were over \$100 million (USD) in the Canada for the 12 months ended August, 2020.

### **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.