



FDA Accepts TX01 BLA Filing

Nov. 28, 2018

Tanvex BioPharma, Inc. (TWSE: 6541) announced that US Food and Drug Administration (FDA) has accepted its Biologics License Application for filgrastim (TX-01), which was filed under the new biosimilar pathway created in the Biologics Price Competition and Innovation Act of 2009 (BPCIA).

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.

“This filing acceptance of TX-01 represents an important accomplishment for the company’s entrance into the biosimilar market. Tanvex BioPharma strives to be part of the pharmaceutical healthcare solution to affordability and access to high-quality biologics”, said Dr. Allen Chao, CEO of Tanvex BioPharm, Inc.

As ongoing support for the US biosimilar market is witnessed through positive changes in legislation, prescription reimbursement model, and uptake in both FDA approval and commercialization of biosimilars in the US, we believe the US healthcare systems are beginning to embrace the use of biosimilars.

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.