# Tanvex BioPharma Submits its First Biologics License Application to U.S. FDA For TX-01

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Tanvex BioPharma, Inc. (TWSE: 6541) announced the submission of its biologics license application (BLA) to the U.S. Food and Drug Administration (FDA) for TX-01, a proposed biosimilar to the reference product Neupogen® (filgrastim) which is indicated for chemotherapy induced neutropenia.

“The submission of the BLA for TX-01 represents an exciting milestone for Tanvex. Such remarkable action takes Tanvex one step closer to launching its very first biosimilar product in the U.S. market,” said Dr. Allen Chao, Chief Executive Officer of Tanvex BioPharma.

According to data from IQVIA, filgrastim product sales (including Neupogen®, Zarxio®, and Garnix®) were approximately $700 million in the U.S. in 2017. According to Allied Market Research, the global biosimilar market generated sales of $2.25 billion in 2014 and is forecasted to grow at a CAGR of 49% from 2015 to 2020, with sales reaching approximately $26.6 billion in 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.