Tanvex received BLA approval from FDA

July 01, 2024

Tanvex BioPharma, Inc. (TWSE: 6541) announced that The U.S. Food and Drug Administration (FDA) had completed their review of our submission of NYPOZI (TX01) and approved the biologics license application (BLA) on June 28, 2024. “This milestone has moved the company beyond being a clinical/developmental stage company to a commercial company in the U.S.”, said Henry Chen, Chairman and CEO of Tanvex BioPharma, Inc.

NYPOZI (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 IQVIA, filgrastim product sales were over to $400 million (USD) in the United States of America for the 12 months ended March, 2024. Tanvex’s NYPOZI has been launched in Canada in January 2024.