tanvex

FDA accepts TX05 BLA resubmission

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Tanvex BioPharma, Inc. (TWSE: 6541) announced that US Food and Drug Administraion (FDA) has accepted its trastuzumab (TX05) BLA resubmission which was resubmitted in July. This moves Tanvex a step closer toward a BLA approval from FDA. The BsUFA date is in early January of 2025.

TX05, a biosimilar product of Herceptin, is the second biosimilar drug product independently developed by Tanvex. Its main indications are for breast cancer and gastric cancer. Tanvex already holds Taiwan's first biosimilar drug marketing authorization issued by the US FDA for its first biosimilar drug product Nypozi. Tanvex launched Nypozi in Canada at the beginning of this year and plans to launch it in the US in early next year.

According to IQVIA marketing data, sales of Herceptin and related biosimilar products in the US market during the past 12 month ending March 2024 were approximately $1.1 Billion.