TX05 BLA resubmisson

July 08, 2024

Tanvex BioPharma, Inc. (TWSE: 6541) which holds Taiwan's first biosimilar drug marketing authorization issued by the US Food and Drug Administration (FDA), resubmits the biologics license application (BLA) for trastuzumab (TX05) to the US FDA, a biosimilar product of Herceptin, on July 06, 2024 (Taiwan Time).

TX05 is the second biosimilar drug product independently developed by Tanvex. Its main indications are for breast cancer and gastric cancer. The Phase III clinical trial of TX05 was completed in February 2021, proving its equivalence with the original reference drug in terms of safety and efficacy. Since submitting the BLA and receiving FDA's complete response letter in August 2022, Tanvex has communicated with FDA and submitted supplemental data on numerous occasions; it is now re- submitting officially the TX05 BLA to FDA.

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.

Tanvex's first biosimilar product, Nypozi, was launched in Canada at the beginning of this year and subsequently received its Marketing Authorization in the US at the end of June.

Tanvex specializes in Biological product development and manufacturing. It uses its cGMP facility in the US as a technical base and has adopted a dual strategy for development of biological products and CDMO services for other pharmaceutical companies.