

## **Prestige Biopharma's Herceptin Biosimilar, Tuznue<sup>®</sup>, Receives EU-GMP Certification**

**Singapore, [21 February 2022]** / Prestige BioPharma Limited (950210: KRX), a Singapore-based biopharmaceutical with operations in USA and South Korea, announced that the manufacturing facility for its Herceptin<sup>®</sup> biosimilar, Tuznue<sup>®</sup>, in Prestige Biologics Co., Ltd. (334970: KOSDAQ), has received European Union Good Manufacturing Practices (GMP) certification. EU-GMP certification is one of the highest standards of pharmaceutical production in the world, and it provides pharmaceuticals with the foundation to start selling their products into European markets.

Tuznue, HD201, is a proposed biosimilar to Roche's Herceptin and can be prescribed for the treatment of HER2 positive breast and metastatic gastric cancer. Tuznue's equivalence to the originator has been demonstrated in 2 Phase 1 trials conducted in Europe and Australia and a global Phase 3 trial, which has been published in scientific journals and conferences. Tuznue has secured global distribution partnerships in major markets, and is currently under Marketing Authorization Application (MAA) review in EU EMA, Canada and South Korea.

Prestige Biopharma has strong pipeline portfolio comprising biosimilars and first-in-class antibody drugs. Following the frontrunning Tuznue, a biosimilar to Avastin<sup>®</sup>, HD204 (Vasforda<sup>®</sup>) is wrapping up the global Phase 3 clinical trial targeting filing to FDA and EMA this year. PBP1510 (Ulenistamab), first-in-class antibody drug for pancreatic cancer, and PBP1502, a biosimilar to Humira<sup>®</sup> are currently in Phase 1/2a and Phase 1 clinical trial in Europe, respectively.

**Lisa S. Park, CEO of Prestige BioPharma, commented:** "EU GMP certification of our manufacturing arm in Korea demonstrated our global standard biomanufacturing facility and system that are applied to all of our products. By achieving one of the key requirements for product registration, we are one step closer to global launch of Tuznue that can enhance affordability of trastuzumab to the patients in need".