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Prestige Biopharma reports Ph III results for Tuznue

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These top-line results data, which confirm the similarities between HD201 and Trastuzumab, will be presented at an upcoming scientific conference, ESMO 2019 being held September 31 Ã¢â?¬â?? October 1, 2019 in Barcelona, Spain.



Prestige BioPharma has announced positive top-line results from a Phase III global clinical trial (Troika) evaluating the efficacy, safety, and pharmacokinetics (PK) of biosimilar candidate HD201 to Herceptin (trastuzumab). These top-line results demonstrate HD201's exceptional similarity to Herceptin in terms of clinical response and PK, in addition to a comparable safety profile to the range previously observed in other trastuzumab biosimilar clinical trials.

"The results demonstrate that HD201 is the most equivalent biosimilar of Herceptin. Troika has broken many records - fastest recruitment, lowest screening failure and drop-out, most exceptional similarity, and the fastest dossier generation and filing. We are pleased to advance HD201 a step closer to commercialization to benefit the patients with an affordable high-quality trastuzumab," said Dr Lisa S. Park, CEO of Prestige BioPharma.

The study was a randomised, double-blind, parallel group, equivalence, multicentre Phase III trial (study number NCT03013504) designed to compare the efficacy, safety, and pharmacokinetics of HD201 to Herceptin in patients with HER2+ Early Breast Cancer (EBC). In the trial, 502 patients with HER2+ EBC were randomized (1:1) to receive either HD201 in combination with chemotherapy or Herceptin in combination with chemotherapy. HD201 or Herceptin was administered every 3 weeks for 8 cycles (24 weeks). After administration of the final neoadjuvant study drug dose, surgery was performed within 3-8 weeks followed by an adjuvant treatment period for 10 cycles. The primary efficacy endpoint of the study was total pathological complete response (tpCR) whereas the secondary endpoints were breast pCR, pCR without DCIS, ORR, breast conservation rate, DFS, PFS, OS, PK, PD, and biomarkers and safety.

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Prestige BioPharma is a Singapore-based biopharmaceutical company focusing on the development of biosimilars and new antibody therapeutics. Its lead program, HD201 trastuzumab biosimilar, has been filed with EMA in April 2019 and will also be filed with USFDA in 2019. Prestige BioPharma's next products in line include a Bevacizumab biosimilar (HD204) in Phase III, an Adalimumab biosimilar (PBP1502) in Phase I and an innovative anti-PAUF mAb (PBP1510) for the treatment of pancreatic

cancer in preclinical stages. Manufacturing facilities for global commercial supply are located in Osong, South Korea.