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Prestige BioPharma publishes phase 3 results of Herceptin Biosimilar

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The Result of the Phase 3 Study for Prestige BioPharma's Herceptin Biosimilar, HD201(Tuznue), Published in JAMA Oncology

Prestige BioPharma, a Singapore-based biopharmaceutical with operations in USA and South Korea, announced positive efficacy and safety results of the Phase 3 study for HD201 (TROIKA), a biosimilar to Herceptin®(trastuzumab), published in JAMA Oncology in March.

The publication highlights comparative efficacy and safety data for patients who received 1-year of treatment with HD201 or referent trastuzumab and completed a median follow-up of 31 months. The study met its primary endpoint (tpCR) and showed equivalent efficacy and comparable safety profile. The tpCR rates were 45% and 48.7% for HD201 and referent trastuzumab, respectively. The difference between the two groups was not significant at ?3.8% (95% CI, ?12.8% to 5.4%) and fell within the predefined equivalence margins. The results regarding secondary endpoints bpCR, overall response, and response based on mammography, ultrasonography, or clinical tumor evaluations supported the comparable efficacy between HD201 and referent trastuzumab. Similar safety, PK and immunogenicity results were reported for the two treatment arms.

The final analysis for the 3-year Event-free survival (EFS) and Overall survival (OS) results is currently ongoing. The preliminary results of the current final analysis indicate highly comparable 3-year EFS and OS rates for HD201 and reference trastuzumab.

Tuznue® has secured global distribution partnerships in major markets including Europe, the Middle East, South America, and Asia. It is currently under Marketing Authorization Application (MAA) review in EU EMA, Canada and South Korea.