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EMA accepts Prestige Biopharma's MAA for review

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Prestige BioPharma has announced that European Medicines Agency (EMA) has validated and accepted for review the Marketing Authorization Application (MAA) for its trastuzumab biosimilar HD201 (Tuznue).

HD201 is Prestige's lead development candidate biosimilar to Herceptin (trastuzumab), which is indicated for the treatment of adult patients with HER2-overexpressing breast cancer as well as HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. Accordingly, if authorized by the EMA, HD201 (Prestige) would take part in the race along with Herzuma (Celltrion), Kanjinti (Amgen), Ontruzant (Merck Sharp & Dohme), and Trazimera (Pfizer) to seize the EU market as one of the comparable biosimilars, which is currently dominated by Herceptin (Roche).

Furthermore, the positive top-line results from the Phase I / Phase III global clinical trial of HD201 confirm that HD201 is exceptionally biosimilar 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 trials.

Dr Lisa S. Park, Chief Executive Officer of Prestige, commented: "We are very pleased that EMA has initiated the review of the HD201 Marketing Authorisation Application. It is a major step in our endeavor to become a global player focussing on biosimilars and innovative biologics. Our development approach has proven to be highly efficient with regard to trial performance, demonstrating exceptional similarity, and dossier filing."

HD201 is Prestige's first biosimilar to receive a positive Committee for Medicinal Products for Human Use (CHMP) opinion for marketing authorization from the EMA. Based on this achievement, Prestige will continue to move forward with other 8 biosimilars and innovative biologics in its portfolio, which are currently at different stages of development, from nonclinical development to advanced clinical stages.