BioDrugs

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PEER-REVIEWED PLAIN LANGUAGE SUMMARY

Trastuzumab is a biologic drug used to treat patients with certain types of breast cancer and stomach cancer. Biosimilars are medications that are almost identical to and indistinguishable from original biologic drugs, but usually less expensive and more accessible. The main purpose of this study was to compare the efficacy (treatment effects) of HLX02 (trastuzumab biosimilar) with reference trastuzumab in patients with HER2-positive recurrent or metastatic breast cancer. Other objectives were to evaluate the safety of HLX02 by monitoring adverse events (AEs) and assessing its potential to induce antibody production (which can prevent a drug from being effective). HER2-positive recurrent or metastatic breast cancer patients were randomly allocated to receive HLX02 (n = 324) or European Union (EU)-sourced trastuzumab (n = 325). Study drugs (HLX02 or EU-trastuzumab) were given intravenously with an initial dose of 8 mg/kg, followed by 6 mg/kg every three weeks for up to 12 months. Statistical analyses showed that HLX02 was equivalent to trastuzumab in efficacy evaluations. AEs observed in HLX02 treatment group were consistent with those seen with trastuzumab in the current and previous clinical studies. Additionally, there were no statistically significant differences in the tendency to stimulate antibody production between the two study drugs. To conclude, HLX02 and reference trastuzumab had similar efficacy and safety profiles. These data support the approval of HLX02 as a trastuzumab biosimilar.