

Kelun-Biotech reports Phase III benefit for trastuzumab botidotin in HER2-positive breast cancer

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Published Phase III data show median progression-free survival of 11.1 months with trastuzumab botidotin versus 4.4 months with T-DM1 in previously treated HER2-positive unresectable or metastatic breast cancer.



Sichuan Kelun-Biotech Biopharmaceutical has reported published Phase III results for trastuzumab botidotin in patients with HER2-positive unresectable or metastatic breast cancer who had previously received trastuzumab and taxane-containing regimens.

Results from the registrational study were published in the Journal of Clinical Oncology.

The randomised, open-label, multicentre Phase III study enrolled 365 patients who were assigned 1:1 to receive trastuzumab botidotin or trastuzumab emtansine, or T-DM1.

The primary endpoint was progression-free survival assessed by blinded independent central review, with secondary endpoints including overall survival, objective response rate and duration of response.

At the April 26, 2025 data cut-off, with a median follow-up of 14.9 months, median progression-free survival was 11.1 months with trastuzumab botidotin compared with 4.4 months with T-DM1.

The hazard ratio was 0.39, meeting the primary endpoint of the study.

Progression-free survival benefit was also observed across all prespecified subgroups.

Trastuzumab botidotin produced an objective response rate of 76.9%, compared with 53.0% for T-DM1.

Median duration of response was 12.2 months with trastuzumab botidotin versus 5.7 months with T-DM1.

Overall survival data remained immature in both groups, although the trastuzumab botidotin arm showed a trend towards improved survival with a 38% reduction in the risk of death.

In terms of safety, Kelun-Biotech said trastuzumab botidotin was associated with a low incidence of interstitial lung disease.

Rates of haematological, hepatic and gastrointestinal toxicities were lower than those observed with T-DM1, alongside lower rates of serious adverse events and treatment discontinuations.

The most common treatment-related adverse events associated with trastuzumab botidotin were ocular events, which the company said could be managed and were generally reversible with standardised strategies.

Trastuzumab botidotin is a HER2-targeted antibody-drug conjugate developed by Kelun-Biotech.

The Phase III findings had previously been presented as a late-breaking oral presentation at the 2025 European Society for Medical Oncology Congress.

The product has already received approval from China's National Medical Products Administration for adult patients with unresectable or metastatic HER2-positive breast cancer who have received one or more prior anti-HER2 therapies.

The publication provides additional clinical evidence supporting trastuzumab botidotin as a treatment option in previously treated HER2-positive metastatic breast cancer.