



Together we're stronger
Tangata tū pakari tonu

Medsafe
New Zealand Medicines and Medical Devices Safety Authority
PO Box 5013
Wellington 6140

7th December 2023

Dear Sir/Madam,

Re: Request for Urgent Consideration of a Registration Application for Trastuzumab Deruxtecan (ENHERTU®) for HER2-low metastatic breast cancer

I write of behalf of the Breast Cancer Aotearoa Coalition (BCAC). BCAC represents over 30 breast cancer charities and groups across Aotearoa, as well as individual members. Our purposes are to support, inform and represent those diagnosed with breast cancer in Aotearoa from an evidence basis.

As you are aware, New Zealand women with metastatic breast cancer have lamentably poor outcomes compared with those in comparable countries internationally (Breast Cancer Foundation New Zealand 2018, Breast Cancer Foundation New Zealand 2022).

Breast Cancer Aotearoa Coalition (BCAC) requests MEDSAFE's urgent consideration of the submission for trastuzumab deruxtecan (ENHERTU) for the treatment of HER2-low breast cancer, which will be submitted by the sponsor, AstraZeneca.

According to published results from the DESTINY-Breast04 clinical trial, trastuzumab deruxtecan (ENHERTU AstraZeneca) can improve both overall survival and progression free survival in women with HER2-low breast cancer. In the trial, treatment with trastuzumab deruxtecan reduced the risk of disease progression or death by 50% versus physician's choice of chemotherapy (based on a hazard ratio [HR] of 0.50; 95% confidence interval [CI]: 0.40-0.63; $p < 0.001$) in patients with HER2-low metastatic breast cancer with HR-positive or HR-negative disease. A median progression-free survival of 9.9 months was seen with trastuzumab deruxtecan versus 5.1 months in those treated with chemotherapy, as assessed by blinded independent central review. A 36% reduction in the risk of death (HR 0.64; 95% CI: 0.49-0.84; $p = 0.001$) was seen with trastuzumab deruxtecan compared to chemotherapy with a median overall survival of 23.4 months versus 16.8 months (Modi, Jacot et al. 2022).



There are currently no other specific treatments approved in New Zealand for this breast cancer subgroup, hence the pressing need for New Zealand women to have access to this treatment as soon as possible.

Results from the DESTINY-Breast04 trial has led to the approval of trastuzumab deruxtecan in many other countries including the United States, United Kingdom, the European Union, Australia and Canada for patients with unresectable or metastatic HER2-low breast cancer.

We urge you to prioritise evaluation and approval of the submission. If you require further information, please do not hesitate to contact the undersigned.

Ngā mihi,



Elisabeth P. J. Burgess MNZM

BCAC Chair

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References

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