24 July, 2018

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Via email: danae.staples-moon@pharmac.govt.nz

Dear Danae

Pertuzumab for patients with previously treated HER-2 positive metastatic breast cancer

In May 2017, you updated us on PTAC's deliberations over our request that funded access to pertuzumab be extended to all patients who were then being treated with trastuzumab for metastatic breast cancer (mBC).

PTAC deferred making a recommendation in 2017, pending publication of further evidence to support pertuzumab's use in pre-treated patients. PTAC noted that such evidence – preferably both survival and quality of life data – should be referred to CaTSoP once available.

We therefore draw your attention to recently presented new data, namely the final overall survival analysis of the PHEREXA study[1] (presented at the June 2018 ASCO meeting in poster form), for consideration at CaTSoP's August meeting. We have enclosed the poster with this letter.

PHEREXA examined trastuzumab (H) plus capecitabine (X) with and without pertuzumab (P) in patients who had progressed during or after first-line trastuzumab-based therapy for HER2-positive metastatic breast cancer. Final results showed a median OS of 37.2 months in the H + X + P arm vs 28.1 months in the H + X arm (a 9.1-month OS increase; HR 0.75; 95%CI 0.60-0.98). The safety profile of the H + X + P regimen was consistent with previous studies of pertuzumab, with no new safety signals observed.

The trial investigators concluded that "the final analysis of OS in PHEREXA was consistent with the interim OS analysis and supports clinical activity of H + P being maintained with longer follow-up."

[1] Ander Urruticoechea et al, "Final overall survival (OS) analysis of PHEREXA: A randomized phase III trial of trastuzumab (H) + capecitabine (X) ± pertuzumab (P) in patients with HER2-positive metastatic breast cancer (MBC) who experienced disease progression during or after H-based therapy"

Given that PHEREXA demonstrated a statistically significant improvement in OS for people with previously-treated HER2-positive mBC, we request that funded access to pertuzumab be extended to the remaining alive patients of the group of c.160 excluded from the original funding decision who are still being treated with trastuzumab (we are personally aware of several who have since died but cannot accurately state how many are still alive or have progressed). Under the circumstances, extension of such funding should be implemented as a matter of urgency.

In addition, we request funded access to pertuzumab for all patients who have progressed during or after first-line trastuzumab in the metastatic setting. This would make pertuzumab available to those of the 160 who have since progressed on trastuzumab, and also to those who had progressed on trastuzumab before pertuzumab was publicly funded (we presume there are very few patients still alive in that situation). Again, the impressive 9.1 months' improved OS for such patients in the PHEREXA trial justifies this wider indication and speaks to the need for timely implementation of funding extension to these patients.

We note that not all patients meeting the above criteria would be suitable for treatment with pertuzumab. However, for those patients likely to benefit from a further line of therapy, we believe it is fair and right for access to be expanded as described. Given the fact that this medicine has potential to extend lives that could otherwise end in the near future, urgent consideration of this matter and implementation of such a listing should be a priority for PHARMAC.

Yours sincerely

Evangelia Henderson
Chief Executive
Breast Cancer Foundation NZ

Libby Burgess
Chair
Breast Cancer Aotearoa Coalition

Encl.