

7 August 2008

PHARMAC reaffirms confidence in 9 week Herceptin treatment

After extensive investigation, PHARMAC has declined an application from the pharmaceutical company Roche to fund 12 month treatments with the breast cancer drug Herceptin, but will continue to fully fund the 9 week treatment.

The publicly funded 9 week treatment is a concurrent treatment (taken with chemotherapy) and is effective for women with HER2-positive early breast cancer.

“A fresh review of the science and other information has failed to convince us that 12 month treatments offer any additional benefits over the concurrent 9 week treatment,” said PHARMAC Chief Executive Matthew Brougham.

As with all its decisions, PHARMAC remains open to re-evaluating its position if new evidence emerges. This could include results from the SOLD study, an international Herceptin clinical trial which PHARMAC is helping to fund, or results from other clinical trials.

The Roche application failed on three grounds: clinical efficacy, cost effectiveness and patient safety (a greater risk of cardiotoxicity and heart problems from longer exposure to Herceptin).

In order to have funded 12 month treatments, PHARMAC needed to be confident that:

- 12 month treatments would deliver health gains greater than could be achieved through a concurrent 9 week treatment; and that
- those benefits would be greater than would be achieved were the money spent on other medicines.

Herceptin for early breast cancer can be administered in two main ways, concurrently with chemotherapy or sequentially after chemotherapy. The Pharmacology and Therapeutics Advisory Committee (“PTAC”), the independent clinical experts that advise PHARMAC, recommended against either 12 month treatment being funded. PHARMAC’s decision is consistent with that advice.

The SOLD study comparing 12 months to 9 weeks, which has been supported by oncologists and sanctioned by approval bodies, would not have been permitted to proceed if the optimal use of Herceptin was already known. Roche itself acknowledged in its submission to PHARMAC that “*the issues of optimal duration and sequence of Herceptin treatment remain unanswered at this time*”.

PHARMAC also gave careful consideration to an updated commercial offer from Roche.

“PHARMAC has commercial-in-confidence arrangements with pharmaceutical suppliers that we don’t want to jeopardise. But I think it is fair and important to put on the public record that Roche’s revised offer has been significantly over-hyped in the media.

This decision, however, was not driven by the price of the 12 month treatments. It was based on a lack of confidence that the expenditure – whatever the exact level – would deliver any additional health gains,” said Matthew Brougham.

“It is disappointing therefore that some commentators continue to assert that Herceptin is a ‘wonder drug’ and that a 12 month treatment is the ‘gold standard’. Such claims are exaggerated and misleading, and ultimately do a disservice to affected women and their families contemplating their treatment options.”

Herceptin is a beneficial add-on treatment, but the extent of those benefits must be kept in perspective. In the clinical trials, which have reported benefits over a short number of years, 74 to 88 out of every 100 patients who did *not* get Herceptin have remained disease free. Looking across all trials, Herceptin (9 weeks or 12 months) had a small but significant benefit, with between 1 and 13 patients out of every 100 treated with Herceptin getting that extra benefit.

Matthew Brougham said that this had been a difficult decision, given the high profile of Herceptin and extensive advocacy for the 12 month treatment.

“It is only natural to feel empathy for sufferers of breast cancer and other serious illnesses. PHARMAC must though look carefully at all funding applications and all relevant evidence – not just agree to what pharmaceutical companies or patient interest groups want. New Zealand’s pharmaceutical budget is not bottomless and it is our duty to ensure that it is well-spent. Even if more funding is provided for medicines, we would go through our normal careful process of deciding how best to spend that money to achieve the best health outcomes. Most New Zealanders would expect we do this to be fair to all.”

PHARMAC is aware of the very high level of public interest in this matter and is making available to the public as much detail about its decision as possible.

PHARMAC conducted a rigorous assessment process and undertook a full consultation; extending the usual response period by one month, seeking new advice from its expert committees and revising its cost-utility analysis.

“About 300 submissions were received, and we are grateful for the high level of engagement. PHARMAC has published a submission summary, underscoring the careful consideration given to the information and perspectives that were shared. Significant other material is on our website. The submissions and advice to the PHARMAC Board can also be provided on request. We want people to have access to the full range of considerations that guided our thinking.”

ENDS

Media contact: Karen Barnsley, 021 436 429

Further information available at www.pharmac.govt.nz (Herceptin button on home page)