

PHARMAC

Pharmaceutical Management Agency

Media release

PHARMAC SUPPORTING INTERNATIONAL TRIAL AND CONTINUING ASSESSMENT OF FUNDING OPTIONS

PHARMAC has announced its financial support for an international trial that will further examine whether 9 weeks or 12 months is the better treatment option for Herceptin.

In addition, PHARMAC is continuing assessment of funding options, including the 9 week treatment option.

Minutes from the November meeting of the Pharmacology and Therapeutics Advisory Committee (PTAC) were released today. PTAC has given a high priority to its recommendation that nine weeks treatment be funded. PTAC also makes clear that supporting a trial is worthwhile given current uncertainty around the optimal treatment length.

PHARMAC's deputy medical director Dr Dilky Rasiah says while there is a high priority recommendation to fund nine weeks, the published 2 year follow up data of the 12 month treatment option (HERA study) will be considered at the 22 February meeting of PTAC.

Dr Rasiah says developing the decision to support an international trial, and continuing investigation of funding, mark very positive steps forward in the consideration of Herceptin.

International trials have raised questions about the optimum duration and sequencing of Herceptin treatment. Trials examining nine weeks concurrent therapy, and 12 month sequential therapy have produced similar results. This raises questions about the optimal timing and treatment approach: questions which the trial being supported by PHARMAC will seek to address.

PHARMAC has indicated funding support of NZ\$3.2m, should the trial proceed. Funding will be provided from PHARMAC's administration reserves, i.e. earlier cost savings in the day-to-day running costs of PHARMAC – not from the drug budget itself. Dr Rasiah says under PHARMAC's legislative mandate, it has the authority to fund research into pharmaceuticals.

“The trial will be addressing important questions and PHARMAC wants to ensure the answers are found.”

The trial, to be headed by Professor Heikke Joensuu of the University of Helsinki in Finland, is aiming to commence recruitment in mid 2007. Professor Joensuu headed the FinHer trial and has extensive international experience in trial design and management.

Dr Rasiah says that, while support for the trial has been promised, New Zealand's participation depends on Herceptin funding decisions, and on support from NZ oncologists to recruit patients.

Professor Joensuu has been in New Zealand this week to meet with New Zealand oncologists about the trial.

Dr Rasiah says that in supporting the trial, PHARMAC has considered the risk to New Zealand of becoming locked into a long-term treatment option, as promoted by Roche.

Other drugs may ultimately be administered along with Herceptin; if so, the already significant costs could increase further, she says.

"There is no problem with such lock-in, or long term treatments, in principle if the evidence strongly supports that, but that is not currently the case with Herceptin."

Dr Rasiah says that the interests of drug companies may not always align with the public interest. This includes concerns with company positions around pricing, treatment lengths, treatment sequencing and research choices (all four of which are important considerations in the present case).

PHARMAC, in representing the public interest, needs to ask the hard questions about these issues and the trial is a means to do this, as is the ongoing careful assessment of evidence.

Notes:

- PTAC (the Pharmacology and Therapeutics Advisory Committee) is a committee of ten senior practicing doctors who meet quarterly throughout the year to provide advice to PHARMAC on the use of pharmaceuticals. PTAC is chaired by Wellington Medical School Head of Department Professor Carl Burgess.
- CaTSOP (Cancer Treatments Sub-committee of PTAC) is one of PTAC's 15 sub-committees comprising specialists in the treatment of cancer.

Herceptin timeline:

Timeline to date:

- **December 2005:** PHARMAC receives application from Roche to fund Herceptin for early breast cancer (an indication, not then approved by Medsafe).
- **18 February 2006:** The Pharmacology and Therapeutics Advisory Committee (PTAC) considers application for early breast cancer. PTAC recommends further information be sought from Roche and for Herceptin to be considered by the cancer treatments sub-committee, should Herceptin be approved by Medsafe.
- **23 March 2006:** Medsafe grants provisional consent to Herceptin.
- **March-May 2006:** Cost-utility analysis undertaken.

- **April 2006:** Cancer Treatments Sub-Committee (CaTSOP) reviews Herceptin evidence.
- **April - June 2006:** Negotiations occur with Roche regarding supply terms and pricing.
- **25 May 2006:** CaTSOP recommendation provided to PTAC. PTAC considered there was insufficient evidence to justify a funding recommendation for 12 months treatment, and sought further information.
- **June/July 2006:** DHBs and PHARMAC decline funding for 12 months treatment with Herceptin, and commit to an ongoing review of evidence on Herceptin.
- **August 2006:** Further data on Herceptin considered by PTAC. PTAC asks the Cancer Treatments sub-committee to consider funding for a nine-week treatment of Herceptin.
- **October 2006:** Cancer Treatment Sub-committee meets.
- **November 2006:** PTAC receives Cancer Treatments sub-committee minute. PTAC recommends nine week treatment be funded (high priority). PTAC also notes more research is needed.
- **December-February 2006-07:** Cost utility analysis of nine week treatment undertaken by PHARMAC; investigation of NZ participation in international clinical trial.

Indicative future timeline:

- **22 February 2007:** PTAC examines further information on Herceptin
- **Late February 2007:** If appropriate, consult DHBs on draft proposal
- **Early March 2007:** If necessary public consultation on a draft proposal to fund Herceptin
- **Late April 2007:** If necessary, recommendation on funding to the PHARMAC Board
- **1 June 2007:** If necessary, implementation of funding (if approved by PHARMAC's Board)

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