



## MEDIA RELEASE

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### ***Landmark adjuvant breast cancer trial published in New England Journal of Medicine***

**Sydney, Australia 20 October 2005** – Today, the New England Journal of Medicine (NEJM) reports that the addition of Herceptin® (trastuzumab) to standard chemotherapy significantly reduces the risk of disease recurrence for women with early-stage HER2-positive breast cancer by **46%**.<sup>1</sup>

The interim results from the international HERA (HERceptin Adjuvant) study provide new hope in the fight against HER2-positive breast cancer, a more aggressive form of the disease affecting approximately 20 – 30% of women with breast cancer<sup>2</sup>. The study allowed for the use of a wide range of chemotherapy regimens before treatment with Herceptin, making the results relevant to many parts of the world.

The HERA study was one of the largest breast cancer trials ever carried out, with more than 5,000 patients in 39 countries including 110 patients from Australia and New Zealand. The HERA trial was conducted in Australia and New Zealand by the Australian New Zealand Breast Cancer Trials Group (ANZ BCTG), and conducted internationally by the Breast International Group (BIG) based in Brussels.

Dr Martine Piccart, international lead investigator of the HERA study and Chair of BIG commented, “Breast cancer is a serious and sometimes life-threatening disease, but with appropriate and timely treatment in the early stages, many women can improve their chances of long-term survival. For women with early-stage HER2-positive breast cancer, results from the HERA study showed that Herceptin, a drug designed specifically for HER2-positive breast cancer, can remarkably reduce the risk of cancer returning.”

Professor John Forbes, Group Coordinator of the ANZ BCTG and Professor of Surgical Oncology at the University of Newcastle said, “These results are some of the most remarkable seen since clinical trials commenced more than 30 years ago. They clearly show that addition of Herceptin produces a better outcome for those women with the particular type of early breast cancer known as HER2-positive and, these results highlight the great value of our collaboration through the ANZ BCTG both nationally and with our international colleagues to obtain these results reliably and rapidly.”

Results from a joint interim analysis of over 3,000 patients from two North American trials provided similar and equally remarkable results for Herceptin in early-stage HER2-positive breast cancer, and were also published in the NEJM today<sup>3</sup>. These data, at a median follow-up of two years, showed that Herceptin in combination with a specific chemotherapy regimen provided a 52% reduction in risk of cancer coming back as well as a 33% reduction in risk of death.

“This is really good news for that special group of women with HER2-positive breast cancer”, said Professor Richard Bell, a member of the international HERA trial executive and Director of Cancer Services at the Andrew Love Cancer Centre, Geelong. “We now have a treatment program which reduces their very high risk of disease recurrence.”

## **About the HERA study**

HERA is one of the largest adjuvant studies ever carried out among breast cancer patients; enrolment to the trial began in December 2001, and nearly 5,100 HER2-positive patients were enrolled at 480 sites in 39 countries across the world.

The study involved collaboration between the BIG group and its affiliated collaborative groups, plus non-affiliated collaborative groups, independent sites and Roche. All study data are managed by a Brussels-based BIG member group, the Breast European Adjuvant Studies Team (BrEAST), with independent statistical analysis carried out in Boston and Scotland by the non-profit research organisation, Frontier Science.

HERA is a randomised trial which, following standard adjuvant systemic chemotherapy and radiotherapy (if applicable), evaluates observation versus Herceptin every three weeks for 12 or 24 months in women with early-stage HER2-positive breast cancer. The HERA study allowed for the use of a wide range of chemotherapy regimens, and both lymph node-positive and lymph node-negative patients were eligible for entry into the trial.

According to the interim analysis, the primary efficacy endpoint was met, showing that in both 12- and 24-month arms, patients who received Herceptin had a statistically significant improvement in disease-free survival (the length of time after treatment during which no disease is found). At a median follow-up of one year, the secondary endpoint of overall survival had not reached statistical significance, but an improvement in overall survival is also possible as the data mature.

The NEJM article provides the results of the comparison between 12 months of Herceptin versus observation, but not a comparison of 12 months versus 24 months treatment duration. The trial will continue to assess this comparison and data are expected in 2008.

The HERA study has an external Independent Data Monitoring Committee (IDMC) that regularly reviews safety data. No safety concerns were identified by the IDMC, and the incidence of congestive heart failure was very low (0.5% in the Herceptin arms vs. 0% in the observation arm). Patients in this study will continue to be followed for any side effects for up to 10 years.

## **Herceptin is clearly an active drug for HER2-positive breast cancer**

"This is not a chance finding as data from the three large randomised trials show similar results and Herceptin is clearly an active and effective drug for this particular group of women with HER2-positive breast cancer," said Dr Nicholas Wilcken, ANZ BCTG HERA Study Chair and Staff Specialist at Westmead Hospital Sydney. "We now need longer term follow-up to fully evaluate the effect of Herceptin on mortality, long-term side effects and the optimal duration of treatment."

Professor Forbes concluded, "We are particularly grateful to those women in Australia and New Zealand who participated in the HERA trial. Soon after being told they had breast cancer, they have consented to contribute to an international research program that has the potential to improve outcomes for a large number of women with HER2-positive breast cancer worldwide."

**- Release Ends -**

## **Editor's Notes**

### **About breast cancer and Herceptin**

Eight to nine percent of women will develop breast cancer during their lifetime, making it one of the most common types of cancer in women<sup>4</sup>. Each year more than one million new cases of breast cancer are diagnosed worldwide, with a death rate of nearly 400,000 people per year.

In HER2-positive breast cancer, increased quantities of the HER2 protein are present on the surface of the tumour cells. This is known as 'HER2 positivity.' High levels of HER2 are present in a particularly aggressive form of the disease. Research shows that HER2-positivity affects approximately 20-30% of women with breast cancer.

Herceptin is a humanised antibody, designed to target and block the function of HER2, a protein produced by a specific gene with cancer-causing potential. Herceptin has demonstrated improved survival in the advanced (metastatic) setting, where its addition to chemotherapy allows patients to live up to one-third longer than chemotherapy alone.

Roche Products Australia advise that they have submitted the published data to the Therapeutic Drug Administration (TGA). To enable women with HER2-positive early breast cancer widespread access to Herceptin a submission will be made to the Pharmaceutical Benefits Advisory Committee (PBAC) for consideration for listing on the Pharmaceutical Benefits Scheme (PBS) which would follow a positive TGA approval.

### **About the ANZ BCTG**

The Australian New Zealand Breast Cancer Trials Group (ANZ BCTG) is Australia's national breast cancer research group. It is dedicated entirely to breast cancer research through the conduct of multi-institution clinical trials. Working in collaboration with 300 researchers in more than 70 of the leading medical institutions in Australia and New Zealand, and with similar research groups in 15 countries internationally ensures Australia and New Zealand are at the forefront of breast cancer research progress and this delivers benefits to women immediately. Additional information can be found at [www.anzbctg.org](http://www.anzbctg.org).

### **About BIG**

The Breast International Group (BIG) is an international non-profit organisation dedicated to coordinating large breast cancer trials among its members. The participants are well-established clinical research and cooperative groups based in Europe, Australia, New Zealand, South Africa and Canada, with affiliated centres around the world.

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### **References:**

<sup>1</sup> Piccart-Gebhart M, Procter M, Leyland-Jones B, et al. A Randomized Trial of Trastuzumab Following Adjuvant Chemotherapy in Women with HER2 Positive Breast cancer. New England Journal of Medicine 353:16 2005.

<sup>2</sup> Harries M, Smith I. The development and clinical use of trastuzumab (Herceptin). Endocr Relat Cancer 9: 75-85, 2002.

<sup>3</sup> Romond, E., Perez, E. et al. Trastuzumab plus Adjuvant Chemotherapy for Operable HER2 Positive Breast Cancer. New England Journal of Medicine 353:16 2005.

<sup>4</sup> World Health Organization, Globocan 2000: Cancer Incidence, Mortality and Prevalence Worldwide. 2000.

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