



MEDIA RELEASE

******EMBARGOED UNTIL 2.45AM AUST EST 9 DECEMBER 2004**

New era in the fight against breast cancer – first major treatment advance over tamoxifen in 20 years

New long-term clinical trial data released today provide evidence for a new standard in breast cancer treatment over tamoxifen for the first time in 20 years, Australian breast cancer experts say.

The data from the world's largest and longest running international trial in which Australia played an important role, provide renewed hope for postmenopausal women with early stage hormone-sensitive breast cancer.

Published in the eminent medical journal, The Lancet, and presented at the 27th San Antonio Breast Cancer Symposium in the United States, the definitive results from the ATAC ('Arimidex' (anastrozole), Tamoxifen, Alone or in Combination) trial¹ firmly establish that the hormonal treatment anastrozole can **help more women live free of breast cancer**.

The new results from the landmark ATAC trial* show that following surgery, five years' treatment with anastrozole reduces the risk of the cancer returning by an **additional 26% over and above the 50% reduction in risk already offered by tamoxifen**.

Preventing the Return of the Cancer Saves Lives

The greatest fear for women who have been treated for early stage breast cancer is to have their cancer return. Experts agree that the first 5 years following primary surgery is when women are at greatest risk of their disease returning.

The ATAC Study Chairman for the Australian New Zealand Breast Cancer Trials Group (ANZ BCTG)** and a Member of the ATAC International Steering Committee, Professor John Forbes said, *"This data is important for women who are postmenopausal and who have had an early breast cancer that is sensitive to hormones. It is critical that women get the best treatment option available to them at the earliest opportunity after diagnosis to minimise the risk of recurrence"*.

Data from the ATAC trial now conclusively demonstrate that anastrozole provides women with even greater protection than tamoxifen by reducing the risk of breast cancer recurrence by over half as much again. As a result, more women can live cancer free.

A reduction in the risk of recurrence is associated with an improvement in overall survival; anastrozole now offers women the best possible chance to live free from breast cancer. Professor John Forbes added, *"Quite simply, if breast cancer does not return, women will not die from it. With tamoxifen, many women have had to live with the risk that their breast cancer could come back, even before they have completed their course of treatment. Now, for the first time in 20 years, we have a drug that is better than tamoxifen to fight breast cancer – anastrozole."*

Significant Tolerability Advantages Over Tamoxifen

Anastrozole is the only treatment of its type to have extensive safety data with over 5 years of clinical experience in early breast cancer. Tolerability is of primary concern for women with early breast cancer and for the clinicians who treat them. These new data show that anastrozole is better tolerated than tamoxifen, both in terms of serious life threatening side effects such as blood clots, stroke and cancer of the womb lining and other side effects affecting quality of life. Women taking anastrozole in the ATAC trial experienced more fractures and joint pain than those receiving

tamoxifen, which is known to have a positive effect on bone mineral density. However, the side effects of anastrozole are considered more predictable and manageable than some of the serious side effects commonly associated with tamoxifen. Additionally, as a result of the better tolerability profile, women on anastrozole were more likely to stay on therapy for longer than those on tamoxifen.

New Standard of Care Established

The vast majority of patients in the ATAC trial¹ have completed 5 years of treatment and experts now consider that these data are conclusive. As a result of the findings, breast cancer specialists consider that anastrozole should replace tamoxifen as the preferred initial hormonal treatment for postmenopausal women with early breast cancer. *“Too many women have continued to be prescribed tamoxifen, even though it has been shown that it is not the most effective treatment”,* said Professor Anthony Howell, Christie Hospital, UK and Chair of the ATAC International Steering Committee, the group who conducted the trial. *“There is no longer any rationale for offering tamoxifen. These data now establish anastrozole as the preferred treatment option for postmenopausal women with hormone-sensitive, early breast cancer.”*

Good news for women already taking tamoxifen

Whilst the new ATAC data confirm that five years of anastrozole offers patients the best possible chance to prevent their cancer returning, additional data presented today at the 27th San Antonio Breast Cancer Symposium also provided good news for the thousands of women who are already taking adjuvant tamoxifen for early breast cancer. Combined data² from the ABCSG 8 Trial and the ARNO 95 Trial show that, if women have their therapy changed to anastrozole, after 2-3 years of tamoxifen, they have a 41% lower risk of their cancer returning than if they remain on tamoxifen treatment. Furthermore, the use of anastrozole in both newly-diagnosed patients and those who have already started on tamoxifen has recently been endorsed by new clinical practice guidelines from the American Society of Clinical Oncology³ who now recommend that the ideal treatment for postmenopausal women with hormone-sensitive breast cancer should include the use of an aromatase inhibitor, such as anastrozole.

Professor John Forbes added, *“Our first priority is to develop better drugs than tamoxifen which we have now done, and although anastrozole is better tolerated than tamoxifen, it is not free of side effects such as an increased risk of osteoporosis. We need more research trials to find the best way to counteract this. Because of the side effects any woman currently taking tamoxifen or newly diagnosed with breast cancer should discuss their treatment with their surgeon or breast specialist.”*

Professor Forbes concluded, *“These results demonstrate the importance of clinical trials which are the vehicle for translating research data into better outcomes for women in the community. On behalf of the researchers of the ANZ BCTG we thank all the women in Australia and New Zealand for their contribution to these results”.*

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References

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2. Jakesz R, et al. Benefits of switching postmenopausal women with hormone-sensitive early breast cancer to anastrozole after 2 years adjuvant tamoxifen: combined results from the 3,123 women enrolled in the ABCSG Trial 8 and ARNO 95 Trial. Abstract No. 2, San Antonio Breast Cancer Symposium 2004.
3. Winer EP, Hudis C, Burstein HJ et al. American Society of Clinical Oncology Technology Assessment on the Use of Aromatase Inhibitors As Adjuvant Therapy for Postmenopausal Women With Hormone Receptor-Positive Breast Cancer: Status Report 2004. Available on line @ www.JCO.org. To be published in the J Clin Oncol, January 20, 2005.

Notes Editors

* About the ATAC trial

The ATAC trial is the largest and longest running early breast cancer treatment study. The trial reports data from over 9,300 postmenopausal women with early breast cancer who took either anastrozole or tamoxifen once per day for 5 years following their initial breast cancer surgery. This latest analysis compares the two groups of women once the majority had completed their treatment. The new data show that anastrozole reduces the risk of all forms of breast cancer recurrence by an additional 26% over and above that offered by tamoxifen. Furthermore, in women with hormone-sensitive disease, anastrozole provides an additional 16% reduction in the risk of the disease spreading to other parts of the body, compared to tamoxifen.

** The Australian New Zealand Breast Cancer Trials Group (ANZ BCTG) conducted the ATAC study in Australia and New Zealand in 11 centres. The recruitment target was reached and exceeded with a total of 174 women recruited to the study, which contributed to 1.9% of the total international recruitment.

The Australian New Zealand Breast Cancer Trials Group 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.

† The ATAC trial compares 5 years of treatment with tamoxifen to 5 years of treatment with anastrozole, in women newly diagnosed with early breast cancer. 84% of patients in the trial had tumours which are known to respond to hormonal treatment.

Anastrozole became available on the PBS for the treatment of hormone-dependent early breast cancer in postmenopausal women who are intolerant of tamoxifen or in whom tamoxifen is contraindicated on December 1 2004.

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