



Media Release

11 December 2001

New research advance in treatment of early breast cancer in postmenopausal women

The anti-cancer treatment anastrozole ('Arimidex') has proven to be effective in the treatment of early-stage breast cancer in postmenopausal women. It has shown to be significantly more effective, and has a number of important safety benefits, over the current 'gold standard' – tamoxifen.

This is the first time ever that benefits of tamoxifen have been surpassed by another treatment in this setting, and marks an important breakthrough in the management of this devastating disease which still claims the lives of seven women in Australia every day.

Presented at the San Antonio Breast Cancer Meeting in the United States today, these are the initial results from the biggest international breast cancer study ever undertaken with a significant contribution to this study coming from researchers and women in Australia and New Zealand.

The ATAC (**A**rimidex, **T**amoxifen **A**lone or in **C**ombination) trial is an international study, which was conducted in Australia and New Zealand by the Australian New Zealand Breast Cancer Trials Group (ANZ BCTG). This Group is Australia's premier breast cancer research body conducting research for prevention, treatment and cure of breast cancer through a collaborative national clinical trials research program. Professor Michael Baum, Chairman of the international ATAC Steering Committee, presented the results.

The ATAC Study Chairman for the ANZ BCTG, Professor John Forbes of the University of Newcastle, described the outcome as extremely important for postmenopausal women with early breast cancer. "There is clear evidence, that for the first time, we may have a treatment for postmenopausal women with early breast cancer that may be superior to the current best available treatment - tamoxifen. The results are extremely promising and may influence the lives of thousands of women in Australia, and have implications for other research areas including prevention. It is also pleasing that researchers in Australia and New Zealand, along with women who participated in the study, have made an important contribution to this international study," he said.

The study involved over 9,300 postmenopausal women with early breast cancer* (1.9% from Australia and New Zealand) and began in 1996. The trial is comparing five years of treatment with tamoxifen alone, anastrozole alone or a combination of both therapies, following initial surgery. Anastrozole works in a different way to tamoxifen by stopping oestrogen production in postmenopausal women**, and is currently available for the treatment of advanced breast cancer.

The investigators found that when the treatments were given on their own, anastrozole was more effective than tamoxifen in prolonging disease-free survival. This means that it was more likely to prevent the cancer recurring, not only in the same breast, but also in the other breast and elsewhere in the body. In addition, there was a lower incidence of some important side effects in the anastrozole group compared with the tamoxifen-treated group.

The combination of anastrozole plus tamoxifen in the ATAC study gave very similar results to tamoxifen on its own, and there was no additional benefit from giving the two in combination.

Professor Forbes said: "Long-term benefits will be assessed as follow-up on study at this point is less than three years."

Tamoxifen is known to be linked to a small but important risk in endometrial cancer, and with an increased risk of thromboembolic events, such as deep vein thrombosis. The ATAC study results indicate that the risks of both of these side effects are much reduced among patients taking anastrozole. In addition, women in the anastrozole group were less likely to experience 'menopausal symptoms' like hot flushes and weight gain compared to those taking tamoxifen. However, as expected, women taking tamoxifen did have a lower chance of getting joint pains or the types of fractures common in this age group compared with those taking anastrozole.

The ATAC Study involved patients starting on hormonal treatment for the first time. Women who have been taking tamoxifen for a while, can consult their doctor with regards to the options for continued treatment.

Professor Linda Reaby AO, Chair of the Consumer Advisory Panel for the ANZ BCTG said: "These results are extremely important for all women. We can be very proud of the contribution being made by women in Australia and New Zealand who are taking part in this trial."

Professor Forbes also acknowledged the contributions of patients to the ATAC Study. "I want to pay tribute to those women in Australia and New Zealand who have participated in this trial, the results of which have potential benefits for many women worldwide. We have already advised women on the study that results would be presented, and will send further information to them so they can discuss this with their clinicians," he said.

-ends-

For further information, please contact:

Suzette Allcorn or Angela McLeod, Hill & Knowlton.

Ph: (02) 9268 0242, Mobile: 0412 259 279 / 0412 388 070

For interview with Professor John Forbes, please contact:

Julie Callaghan, Breast Cancer Institute of Australia

Ph: (02) 4925 3022, Mobile: 0411 242 176

Notes to editors:

* The current treatment strategy for early-stage breast cancer (cancer that has not spread beyond the breast) in postmenopausal women generally consists of surgery to remove the tumour, which may be followed by a course of chemotherapy and/or radiotherapy. Women will usually then go on to take a hormonal treatment — such as tamoxifen— for around five years to reduce the risk of the cancer recurring (this is known as "adjuvant therapy"). The patient group in the ATAC study had completed primary surgery and chemotherapy (if given) and were candidates to receive hormonal adjuvant therapy.

Notes to editors (cont.)

**Tamoxifen is an anti-oestrogen and acts primarily to prevent oestrogen binding to its receptor at tumour sites. Anastrozole is an aromatase inhibitor and acts differently to tamoxifen by blocking the production of oestrogen by the aromatase enzyme pathway – the primary source of oestrogen in postmenopausal women, whose ovaries no longer function.

- The ATAC Study involved investigators from 381 cancer centres in 21 countries, including Australia. It started in 1996 and completed recruitment in 2000, with a total of 9,366 patients participating.
- The Australian New Zealand Breast Cancer Trials Group 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 500 researchers in over 60 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 women taking part in the ATAC Study were randomised to receive treatment with anastrozole 1mg daily, tamoxifen 20mg daily, or the same two agents in combination. Treatment will be continued for five years or until recurrence of the disease, or death.
- After an average of 33 month's follow-up, 317 out of 3,125 women in the anastrozole group relapsed or died compared with 379 out of 3,116 women in the tamoxifen group and 383 out of 3,125 in the combination group.
- In terms of adverse events, deep vein thrombosis was reported in almost twice as many patients taking tamoxifen compared with anastrozole patients (1.7 % vs 1.0%), endometrial cancer occurred in five times as many tamoxifen patients as those treated with anastrozole (0.5% vs 0.1%). Vaginal bleeding was reported in 8.1% of tamoxifen patients and 4.5 % of anastrozole patients respectively. Hot flushes and weight gain were also more common among women treated with tamoxifen compared to those taking anastrozole (hot flushes: 39.7% vs 34.3%; weight gain 11.0% vs 9.2%). Fractures (predominantly of the wrist) were reported in 3.7% of tamoxifen patients and 5.8% of anastrozole patients. Joint pains were reported in 21.2% vs. 27.8% of tamoxifen and anastrozole patients, respectively.
- Anastrozole was first marketed in 1995 and is licensed for use in the first and second-line treatment of advanced breast cancer in postmenopausal women. It is not yet licensed for adjuvant use in patients with early breast cancer.
- The Australian New Zealand Breast Cancer Trials Group (ANZ BCTG) has an elected Board of Directors and a Scientific Advisory Committee, as well as a Consumer Advisory Panel. It conducts studies for prevention, early detection and treatment of breast cancer; and studies which aim to improve a patient's quality of life. The Operations Office, located at the University of Newcastle, NSW coordinates the national research program and the ANZ BCTG Statistical Centre at the NHMRC Clinical Trials Centre conducts analysis of research data.

- The Australian New Zealand Breast Cancer Trials Group (ANZ BCTG) has established itself as a major international contributor to prevention research. The ANZ BCTG was the first research group internationally to begin recruitment to the international breast cancer prevention study – IBIS 1. International recruitment to this study is now complete with Australia and New Zealand contributing the highest per capita recruitment in the world.
- The next phase for prevention research will test the role of anastrozole for prevention of breast cancer in postmenopausal women at increased risk of the disease. This international study will begin in 2002 and be conducted in Australia and New Zealand by the Australian New Zealand Breast Cancer Trials Group.