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Breakthrough breast cancer drug anastrozole ('Arimidex') brought one step closer for patients after publication of research results in the Lancet

"...results could be as significant to breast cancer treatment as the results first seen with tamoxifen nearly 20 years ago..."

Anastrozole – the drug which has shown great promise as a new treatment option for early breast cancer with a number of significant benefits over tamoxifen – was brought one step closer to patients today, as the groundbreaking results from the ATAC trial (**A**rimidex', **T**amoxifen **A**lone or in **C**ombination) were published in the Lancet.

The landmark Lancet paper makes the important conclusion: "Evidence from this first analysis of the ATAC trial is encouraging, and these results could be as significant to breast cancer treatment as the results first seen with tamoxifen nearly 20 years ago. An important consideration at this time is how to treat newly diagnosed patients. An overall assessment of the benefits versus harm, based on current data, supports the use of anastrozole for the adjuvant treatment of early breast cancer in postmenopausal women, meaning that there is now a choice of adjuvant endocrine therapy for postmenopausal women with hormone-responsive tumours".

The ATAC trial – which showed that anastrozole is more effective and has a number of important tolerability benefits over the current gold standard, tamoxifen – is the largest ever international breast cancer treatment trial. It was conducted in Australia and New Zealand by the Australian New Zealand Breast Cancer Trials Group (ANZ BCTG).

The fact that the results have been granted fast-track publication by an eminent international journal such as the Lancet is a measure of the importance of the data to physicians and women with early breast cancer.

The ATAC Study Chairman for the ANZ BCTG and a Member of the International Steering Committee, Professor John Forbes of the University of Newcastle, described the initial results from ATAC as one of the most important advances in control of breast cancer. "It opens up new research opportunities for treatment and prevention of breast cancer. Women and researchers in Australia and New Zealand have made an important contribution to this international study," he said.

This publication of the ATAC results comes at a time when practitioners and regulatory authorities are increasingly recognising a need in breast cancer research for high quality data from trials with large numbers of women participating over a long period of time. Such trials properly assess not only how effective treatments are, but also their side-effect profile. This latter point is particularly important where treatments are taken for a long time, such as in the adjuvant treatment of early breast cancer where hormonal therapy is generally given for 5 years.

In the ATAC trial published today, over 9,300 women took part (1.9% from Australia and New Zealand), with approximately 3,000 women having completed more than 3 years of treatment. Additional longer-term follow-up is scheduled in the trial and this is expected to further endorse the excellent tolerability profile of anastrozole in early breast cancer.

Key highlights from the ATAC trial results include:

Improved performance versus tamoxifen:

- The ATAC publication shows that anastrozole is significantly more effective than tamoxifen in terms of improving disease-free survival in early breast cancer. This means that it was more likely to prevent the cancer recurring in the same breast, in the other breast, or elsewhere in the body.
- This efficacy result was even more prominent in women with hormone receptor-positive tumours – which are likely to respond to the hormonal therapy. This group represent the largest group of patients presenting with breast cancer.

Good tolerability profile:

- The Lancet paper points out the important consideration of tolerability of drugs used in the early breast cancer setting – where they will be prescribed for long periods of time.
- Reassuringly then, this long-term study of anastrozole in this setting confirmed the benefits of the drug over tamoxifen which had already been established in many trials and experience in patients with advanced metastatic breast cancer.
- These advantages shown for anastrozole include a significant reduction in the incidence of hot flushes, thromboembolic events such as deep vein thrombosis, vaginal bleeding and cancer of the womb (endometrial cancer) when compared to tamoxifen.
- Tamoxifen was associated with a lower risk of musculo-skeletal disorders and fractures compared with anastrozole treatment. According to the Lancet publication, this difference in fracture rate may be due to the protective effect on bone of tamoxifen compared with an untreated population. However, some additional effect could be due to profound oestrogen suppression. On the basis of epidemiological data, the number of fractures reported in the anastrozole group were similar to that expected in postmenopausal women of similar age.

The publication of these findings will help support clinicians and patients as they discuss the most appropriate treatment choice for postmenopausal women with early breast cancer. The need to consider anastrozole as one of these choices, has also been highlighted in other recent assessments of the ATAC data.

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Notes to editors:

- Anastrozole is a potent, highly selective, non-steroidal oral aromatase inhibitor used in the hormonal (endocrine) treatment of breast cancer in postmenopausal women. With over half a million patient years of experience, anastrozole is currently the most widely used aromatase inhibitor in the world.
- Anastrozole is the only aromatase inhibitor proven to be superior to tamoxifen, in terms of both efficacy and tolerability in the treatment of postmenopausal breast cancer patients with either early or advanced disease. Most recently, results from the ATAC ('Arimidex', Tamoxifen, Alone and in Combination) study – the world's largest cancer treatment study to date – have clearly demonstrated the superior efficacy and favourable tolerability profile of anastrozole compared to tamoxifen as adjuvant treatment in early breast cancer.
- Anastrozole is already licensed for use as both first- and second-line treatment in postmenopausal women with advanced breast cancer. Following first presentation of the ATAC results, it is now promoted in Japan for adjuvant use in postmenopausal women with early breast cancer. Regulatory approval for use in this new indication is also being sought in other major markets and is expected to be granted throughout 2002.
- 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.