



Media Release

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American Breast Cancer Guidelines recommend use of aromatase inhibitors instead of tamoxifen for women with postmenopausal early breast cancer

Five years of tamoxifen is no longer the standard of care for postmenopausal women

Tuesday, November 16th 2004: Today, the American Society of Clinical Oncology (ASCO) announced a fundamental change to its internationally recognised¹ guidelines on the use of aromatase inhibitors (AIs) in the treatment of postmenopausal women with hormone-sensitive early breast cancer.

For the first time, the ASCO committee has said that five years treatment with tamoxifen is no longer the optimal treatment choice in this group of patients and has recommended that therapy should include an AI, in order to reduce the risk of recurrence of breast cancer.

These new recommendations are based on results from multiple large randomised trials, and indicate that AIs are appropriate either as initial therapy after surgery or after two to five years of tamoxifen therapy.

The trials evaluated initial therapy with five years of anastrozole instead of five years of tamoxifen; switching to anastrozole or switching to exemestane after two to three years treatment with tamoxifen; or, 2.5 years of letrozole after five years of tamoxifen had been completed. Each of these trials demonstrated a significant advantage for the treatment regimen which included an AI.

Professor John Forbes, Group Coordinator of the Australian New Zealand Breast Cancer Trials Group (ANZ BCTG) which co-ordinated the ATAC² ('Arimidex', Tamoxifen, Alone or in Combination Trial) and other related studies said, "Because the risk of recurrence from breast cancer is highest in the early years after diagnosis, women should have the most effective therapy as early as possible after surgery.

Recognising the importance of the AIs, the Pharmaceutical Benefits Advisory Committee has decided to reimburse the only approved AI in Australia for early breast cancer, anastrozole, from December 1, 2004.

"The trials show that the AIs are more effective than tamoxifen and are well tolerated - for initial treatment instead of tamoxifen for five years; when substituted for tamoxifen after two to three years; or, if added after five years of tamoxifen. These drugs are clearly very active against breast cancer and I believe they should be available as an option for all postmenopausal women with hormone-sensitive early breast cancer, as recommended by the ASCO panel," commented Professor Forbes.

Professor Anthony Howell of Christie Hospital, Manchester, UK, and Chair of the International Steering Committee for ATAC said "Although doctors have been aware of the benefits that anastrozole offers over tamoxifen for some time, many have been awaiting reassurance from guidelines committees such as ASCO before changing their prescribing habits. This is a real milestone in the treatment of early breast cancer. More women will now be able to benefit from the greater protection that anastrozole provides against the cancer coming back, along with a better tolerability profile."

Importantly, the US assessment continues to recognise that each of the AIs are not equivalent. Furthermore, previous guidelines from the working group have reinforced that 'closely related agents with similar mechanisms of action may have different toxicity profiles'.

Postmenopausal women recently diagnosed with a hormone-sensitive early breast cancer or who are currently taking tamoxifen for treatment of this type of early breast cancer, should discuss their treatment with their surgeon and oncologist.

Professor Forbes concluded, "It is important to acknowledge that the thousands of women who participate in such clinical trials contribute to better outcomes, potentially for millions of women worldwide, as has been demonstrated by the revision to the ASCO guidelines."

From December 1, 2004, anastrozole will be reimbursed for the treatment of hormone-dependent early breast cancer in postmenopausal women who are intolerant of tamoxifen or in whom tamoxifen is contraindicated.***

Ends

Issued by Hill & Knowlton on behalf of the ANZ BCTG

References:

¹ 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 J Clin Oncol Volume 23, Number 3, January 2005

²The ATAC (Arimidex, Tamoxifen, Alone or in Combination) Trialists' Group. Anastrozole alone or in combination with tamoxifen versus tamoxifen alone for adjuvant treatment of postmenopausal women with early breast cancer: results of the ATAC trial efficacy and safety update analysis. *Cancer* 2003; 98 (9): 1802-1810.

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Please refer to www.virtualcancercentre.com for a copy of the Consumer Medicine Information (CMI) for Arimidex and tamoxifen

- * Anastrozole is approved for adjuvant treatment of early breast cancer in postmenopausal women with oestrogen/progesterone receptor positive disease, and the first line treatment of advanced breast cancer in postmenopausal women with oestrogen/progesterone receptor positive disease.
- ** It may be appropriate for women with newly diagnosed early breast cancer but as with all medicines it may not be suitable for some individuals – all treatment options should be discussed with a specialist
- *** PBS Information: Restricted benefit
- Treatment of hormone-dependent early breast cancer in postmenopausal women in whom tamoxifen therapy is contraindicated;
 - Treatment of hormone-dependent early breast cancer in postmenopausal women who are intolerant of tamoxifen; and
 - Treatment of hormone-dependent advanced breast cancer in postmenopausal women.

'Arimidex' (anastrozole) is a trademark, property of the AstraZeneca Group of Companies

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