



**MEDIA RELEASE**

**13 September 2002**

## ***Breast cancer prevention results published:***

- ***Tamoxifen can prevent breast cancer in healthy women at increased risk***
- ***But too early to know if benefit outweighs risk***
- ***No evidence that Hormone Replacement Therapy (HRT) is detrimental for tamoxifen prevention***

Results from the International Breast Cancer Intervention Study (IBIS) show that tamoxifen can prevent breast cancer in healthy women at increased risk. The results are published in this week's issue of the prestigious medical journal *The Lancet*.

Tamoxifen is well established for treatment of breast cancer, but results from earlier clinical trials on the use of tamoxifen to prevent breast cancer in healthy women at increased risk have previously reported mixed results. With publication of the IBIS results it is now clear that overall evidence supports a reduction in the risk of breast cancer.

In IBIS, tamoxifen was shown to reduce breast cancer incidence by about a third (32%) compared with women given the placebo (101 cancers on placebo, 69 on tamoxifen).

"During the last 25 years of breast cancer trials the ultimate goal has always been prevention," said Professor John Forbes, IBIS Study Chairman in Australia and New Zealand. "This is now a reality at least for some women. These results open up new directions in prevention research which will ultimately lead to fewer women diagnosed with breast cancer."

But researchers say it is too early to assess the overall risk to benefit ratio of tamoxifen as a preventative strategy for all women for breast cancer.

"Although tamoxifen has a well established role for treatment of early breast cancer, the overall balance of risk and benefit in the preventative setting is still unclear," said Professor Forbes. "Long term follow up of women in IBIS is essential to study breast cancer incidence and mortality, other causes of death and side effects."

IBIS is conducted in Australia and New Zealand by the Australian New Zealand Breast Cancer Trials Group (ANZ BCTG) and involves 7,139 healthy women at increased risk of breast cancer from the United Kingdom, Europe and Australia and New Zealand (2,674 women from 19 institutions in Australia and New Zealand) (*graphic available*). IBIS was supported in Australia by the National Health and Medical Research Council.

Coordinated internationally by Cancer Research UK, IBIS is a double-blind placebo controlled randomised trial of tamoxifen, 20 mg/day for five years, in women who were aged 35–70 years and who were at an increased risk of breast cancer (eg. they had a family history of the disease or had a benign lesion associated with an increased risk of breast cancer).

The tamoxifen prevention effect was confined to the more common, hormone sensitive type of breast cancer - oestrogen receptor (ER) positive. There was no reduction in the incidence of the less common type of ER negative breast cancer.

“Our research in the ANZ BCTG must now aim to better identify those women at increased risk of hormone sensitive breast cancer, and alternatives to tamoxifen with less serious side effects,” said Professor Forbes. “We must also identify strategies to prevent breast cancers that are not dependent on oestrogen.”

Approximately 40% of women in IBIS took Hormone Replacement Therapy (HRT) during the trial. There was no evidence that the tamoxifen prevention effect was any less for these women. Nor was there any evidence that these women had any greater risk of serious side effects. The follow up however is still relatively short and ongoing follow up is needed to confirm these findings.

“The lack of any negative effect from HRT was a surprise,” said Professor Forbes. “This is potentially important to many women and longer follow up will help to clarify this.”

As anticipated, endometrial cancer—considered to be a risk factor for women given tamoxifen—was more common in the tamoxifen group (11 instances compared with 5 in the control group), but this increase was not statistically significant. As also anticipated, tamoxifen use was associated with an increased risk of blood-clotting complications, especially after surgery or long periods of immobilisation. The investigators comment that an increased risk of blood-clotting complications could contribute to a higher death rate from all causes in women given tamoxifen. Each of these two side effects occurred in less than 1 in 1,000 women per year on the study.

All women in IBIS have been informed of the results and invited to continue follow up in IBIS. The response has been very strong in favour of continuing and this will help to obtain more information on duration of the prevention effect and the role of HRT.

Individual women at increased risk of breast cancer should discuss their risk with their doctor.

“Women in Australia and New Zealand and researchers of the ANZ BCTG have played a vital role in these important prevention research results,” said Professor Forbes. “Publication of the results provides a sound foundation to undertake new prevention research strategies which will ultimately impact on the lives of women throughout the world.”

**Spokespeople from the ANZ BCTG are available for comment.**

**To arrange interviews and for more information, please contact:**

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**IBIS Frequently Asked Questions can be obtained from the ANZ BCTG website: [www.anzbctg.org](http://www.anzbctg.org)**

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