



MEDIA RELEASE

****EMBARGOED UNTIL 00:01AM AUST EST Monday 13 June 2005**

Landmark trial aims to prevent up to 80% of breast cancer in postmenopausal women at increased risk

International survey reveals that up to 1 in 3 women would consider radical breast removal surgery to reduce their risk of developing breast cancer

Monday 13 June 2005: Today, an international survey of the attitudes of over 1,500 women towards breast cancer has revealed that up to one third would consider the removal of both breasts to help prevent the development of the disease¹. But a new breast cancer prevention trial, IBIS-II (International Breast Cancer Intervention Study)*, being launched globally today could reveal an alternative option.

The need for an effective way of helping women to reduce their risk of developing breast cancer was confirmed by the outcomes of a major global survey of 1,588 women aged 45 and over. The survey revealed that nearly half of these women are concerned about developing breast cancer, and up to one third of women surveyed felt so strongly about reducing their chances of developing the disease that they would be prepared to undergo radical surgery to remove both breasts (double mastectomy) prior to diagnosis, if they were known to be at 'high risk'.

"We have shown with IBIS-I** that tamoxifen can prevent breast cancer in some women at increased risk but we must do better as underlined by these survey results. We do understand and have known for some time that women are very concerned about their risk of developing breast cancer. The fact that so many women would consider a double mastectomy to reduce their risk is very relevant to our breast cancer prevention research and IBIS-II in particular," said Professor John Forbes, IBIS-II Co-Chairman, University of Newcastle Australia and Group Coordinator of the Australian New Zealand Breast Cancer Trials Group. "Long-term control of breast cancer depends on successful prevention and that's what IBIS-II is all about" he said.

IBIS-II is an international study to be conducted in 26 countries to investigate the potential of using a once-a-day hormonal therapy for five years to prevent breast cancer in women who are at an increased risk of developing the disease. IBIS-II will be conducted in Australia by the Australian New Zealand Breast Cancer Trials Group. The trial will commence soon in Australia, in the Hunter Region NSW, with other centres throughout Australia and New Zealand following towards the end of 2005.

The IBIS-II Study will evaluate whether the established breast cancer treatment anastrozole ('Arimidex') can also help to prevent the development of the disease, based on the encouraging results of the recently completed and published ATAC (Arimidex, Tamoxifen Alone or in Combination) Trial². Results from the ATAC Trial suggest that anastrozole may have the potential to prevent up to 80% of hormone-sensitive breast tumours. It is currently estimated that each year over 1.2 million women worldwide will be diagnosed with breast cancer, and over 400,000 will die from the disease³. Australia, together with the United States, Western Europe and Canada, has one of the highest incidence rates for breast cancer worldwide.

Professor Tony Howell, IBIS-II Co-Chairman and Professor of Medical Oncology at the Christie Hospital, Manchester UK, commented: "We found from the ATAC trial that anastrozole was effective at preventing breast cancer recurrence and even more effective at preventing new breast cancers in the opposite breast. This, plus a good side effect profile, makes anastrozole a suitable candidate for use in the preventive setting."

Almost half of the women surveyed said that they would be prepared to take a daily tablet to prevent breast cancer, with a similar proportion indicating that they would be willing to participate in a study which evaluated such a medicine.

"The IBIS-II study is extremely important for women, especially those at an increased risk of developing breast cancer" commented Jack Cuzick, John Snow Professor of Epidemiology at Queen Mary, University of London UK, leading researcher from Cancer Research UK and IBIS-II Steering Committee Co-Chairman. "It is vitally important that women come forward to participate in the trial – not just for themselves, but for their daughters, their families and for other women around the world. Many of us already take preventive medicines for heart disease and stroke and this is a major attempt to extend this successful approach to cancer" he said.

IBIS-II will commence soon in Australia, in the Hunter Region NSW, with other centres throughout Australia and New Zealand following towards the end of 2005.

To be eligible for IBIS-II, women must be aged between 40-70 years and not had a previous diagnosis of breast cancer unless this was a particular form of breast cancer called Ductal Carcinoma in situ, been through the menopause, not be taking HRT, have a family history of breast cancer or other defined risk factors.

Women in Australia who may be eligible and who would like to register their interest to participate in IBIS-II should contact 1800 640 709. Women will be contacted when IBIS-II centres throughout Australia are open for accrual later in the year.

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References

1. NOP World, April 2005.
2. ATAC Trialists' Group. Results of the ATAC (Arimidex, Tamoxifen, Alone or in Combination) trial after completion of 5 years' adjuvant treatment for breast cancer. *Lancet* 2005; 365 (9453): 60-62.
3. J. Ferlay, F. Bray, P. Pisani and D.M. Parkin. GLOBOCAN 2002: Cancer Incidence, Mortality and Prevalence Worldwide. IARC CancerBase No. 5. version 2.0, IARC Press, Lyon, 2004.

Notes to editors

* The IBIS-II trial is being coordinated internationally by Cancer Research UK and Queen Mary, University of London UK.

** IBIS-I (International Breast Cancer Intervention Study I) was an international trial testing the drug tamoxifen for prevention of breast cancer in women at increased risk of the disease. IBIS-I showed that tamoxifen was superior to placebo but associated with some side effects.

About the survey

- Research was carried out by NOP World, a global market research agency, in April 2005. The nationally representative surveys were conducted in six countries (Australia, Belgium, Brazil, Germany, Italy and the United Kingdom) via the telephone with 1,588 women aged 45+.
- The survey was undertaken to learn more about women's levels of concern about breast cancer to help with the planning of recruitment strategies to the new prevention trial IBIS-II.

About IBIS- II

- The International Breast Cancer Intervention Study II (IBIS-II) has been designed to investigate the new breast cancer drug, anastrozole, in 10,000 women in 26 countries who are at an increased risk of breast cancer.
- The study will be conducted in Australia and New Zealand by the Australian New Zealand Breast Cancer Trials Group and is funded in Australia by a grant from the National Health & Medical Research Council.
- IBIS-II will commence soon in Australia, in the Hunter Region NSW, with other centres throughout Australia and New Zealand following towards the end of 2005.
- The study will run for 4-6 years.
- Some countries are currently recruiting women to the study.
- The IBIS-II study is a randomised, blinded placebo controlled clinical trial.
- The study is divided into two parts:
 - i. The IBIS-II Prevention part of the study aims to recruit 6,000 postmenopausal women who are at increased risk of developing breast cancer. A number of factors for increased risk have been set for the study and these are set according to the different age groups. Women may be eligible for the trial if they are aged between 40-70 years and have not had a diagnosis of breast cancer, are not on HRT and have a family history of breast cancer or other defined risk factors.
 - ii. The second part of the study, IBIS-II DCIS, will recruit 4,000 women who have been diagnosed with and had surgery to remove a particular early form of breast cancer, which is not growing or spreading, known as DCIS (Ductal Carcinoma In Situ). As well as being at high risk of developing more advanced forms of breast cancer, these women are also more likely to develop a new tumour in the opposite breast. This part of the IBIS-II trial is designed to determine which of the two drugs, anastrozole or tamoxifen, can best prevent new cancers, both in the breast affected by DCIS and in the opposite breast.
- ***Women in Australia who may be eligible and who would like to register their interest to participate in IBIS-II should contact 1800 640 709. Women will be contacted when IBIS-II centres throughout Australia are open for accrual later in the year.***

About the Australian New Zealand Breast Cancer Trials Group

- 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. Additional information can be found at www.anzbctg.org.

For further media information on the IBIS-II study, please contact:

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