



CONFIDENTIAL

Embargo date – 14.00 pm, 14th June 2006

PIONEERING BREAST CANCER PREVENTION STUDY STARTS IN NOTTINGHAM

Women in the Nottingham area are being invited to take part in a worldwide breast cancer prevention trial called the International Breast cancer Intervention Study II (IBIS-2).¹ The groundbreaking trial is seen by many experts as the next step in the fight against a disease which affects more than 3,100 women a year in the East Midlands.²

Researchers at the University of Nottingham and Nottingham University Hospitals speaking today during the Association of Breast Surgery's annual meeting, encouraged women interested in joining the study, to come forward and find out whether they are eligible. IBIS-2 has been ongoing in Derby but this is the first time that women in Nottingham can take part in the study.

IBIS-2 is the first trial ever to investigate whether a breast cancer treatment drug called anastrozole³ can prevent the disease in postmenopausal women at higher risk of developing breast cancer. Previous research on the drug as a treatment for early breast cancer showed that it reduced the risk of developing another cancer in the opposite breast by over 50 per cent but this will be the first time the drug is being investigated as a preventive measure.⁴

The study is open to women aged 40-70 years old, who have passed the menopause, have a strong family history of breast cancer or who have been told by their doctors they have other risk factors. This includes women whose mother or sister had breast cancer or ovarian cancer by the age of 50 or under.

Professor John Robertson, Professor of Surgery at Nottingham University and City Hospital, said: "We are happy to be part of such a pioneering study which could prove so important to women who are at higher risk of developing breast cancer. We feel that this study has the potential to change many lives and help lead to thousands fewer women in the UK from developing breast cancer each year."

Lisa Mannion-Phillips, a breast cancer research nurse based at Nottingham University Hospitals' City Hospital campus, added: "It is vital that women who would like to join the study and who think that they may be eligible, come forward and help us to find out more about preventing breast cancer. This study could provide them and future generations with a valuable option in helping to control the disease."

Margaret Collishaw who joined the IBIS-2 trial in Nottingham in 2006 said: "I found out about the study when I received an IBIS-2 information leaflet together with the results of my last mammogram. Cancer is in four generations of my family. My mother was 60 and my sister was 55 when they were diagnosed with breast cancer. My great aunt and my great grandmother also

had breast cancer. This meant that I was considered to be at a higher risk of the disease and eligible to join IBIS-2.”

She continues: “Being part of this trial means that not only am I helping to protect myself against breast cancer but am also playing an important part in preventing the disease for my daughters and granddaughters. Taking part in a trial which may help prevent breast cancer is a very worthwhile contribution and I would urge women who think they may be eligible to come forward.”

In the UK there are around 41,000 women diagnosed with breast cancer every year. Around 80 per cent of these are post-menopausal women.

Researchers are looking for 6,000 women worldwide to take part in the prevention study. There are currently 18 countries taking part in the trial and 37 trial centres in the UK alone.⁵

The study will compare anastrozole with a placebo and look at how many women develop breast cancer as well as any side effects of the drug. Although only half of the women on the study will receive anastrozole, all of the women will receive a bone scan, a mammogram and the best available care.

Women can find out more about the IBIS-2 study by clicking onto www.ibis-trials.org or by contacting the Cancer Research UK information nurses on 020 7061 8355 (lines are open Monday to Friday, 9am to 5pm).

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For media enquiries regarding IBIS-2 and for interviews with IBIS-2 spokespeople and women participating in the study, please contact:

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Notes to Editors

- IBIS-2 is being supported by Cancer Research UK and sponsored by Queen Mary, University of London.
- IBIS-2 study centres currently open for recruitment in the Midlands are Derby City General Hospital, Derby and Nottingham City Hospital, Nottingham.

¹ Anastrozole (trade name Arimidex)

- Anastrozole is one of a group of drugs called aromatase inhibitors. In post-menopausal women, an enzyme called aromatase is the main source of oestrogen. Aromatase inhibitors block the action of aromatase, reducing the levels of oestrogen in the body.
- Anastrozole is known to have some side effects which include hot flushes, vaginal dryness, hair thinning, joint pains and an increased risk of osteoporosis (weakened bones).

² Office for National Statistics. Registrations of cancer diagnosed in 2002, England. Series MB1 no. 33

³ IBIS-2

The IBIS-2 study is a randomised, blinded placebo controlled Phase III clinical study.

The study is divided into two parts:

- The IBIS-2 Prevention part of the study aims to recruit 6,000 post-menopausal women who are at increased risk of developing breast cancer. A number of factors for increased risk can make a woman eligible to enter the study and these are set according to the different age groups. Women can take part in the study if they are aged between 40-70 years and are not on HRT. Women who have had breast cancer cannot enter this part of the study.
- The second part of the study, IBIS-2 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 study 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.

⁴The ATAC study – Arimidex and Tamoxifen Alone or in Combination, results published 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.

⁵UK study centres also open for recruitment are:

Belfast City Hospital, Belfast
 Royal Bolton Hospital, Bolton
 Royal Bournemouth Hospital, Bournemouth
 Royal Sussex County Hospital, Brighton
 Frenchay Breast Care Centre, Bristol
 Bristol Royal Infirmary, Bristol
 University of Wales College of Medicine, Cardiff
 Chelmsford & Essex Centre, Chelmsford
 Cheltenham General Hospital, Cheltenham
 Countess of Chester Hospital, Breast Unit, Chester
 Essex County Hospital, Colchester
 Ninewells Hospital, Dundee
 Western General Hospital, Edinburgh
 Frimley Park Hospital, Frimley
 Northwick Park & St Marks Hospitals, Harrow
 Harlow and St. Margaret's Hospital, Harlow
 Conquest Hospital, Hastings
 The Academic Surgical Unit, University of Hull, Hull
 Western Infirmary, Glasgow
 Airedale General Hospital, Keighley
 Leeds General Infirmary, Leeds
 St James's University Hospital, Leeds
 Royal Liverpool University Hospital, Liverpool
 Guy's Hospital, London
 Royal Marsden, London
 Macclesfield Hospital, Macclesfield
 Christies and Withington Hospitals, Manchester
 Royal Oldham Hospital, Oldham
 Dorset Cancer Centre, Poole Hospital, Poole
 Hope Hospital, Salford
 Cancer Research Centre, Weston Park Hospital, Sheffield
 Staffordshire General Hospital, Stafford
 Morriston Hospital, Swansea
 Mermaid centre, Truro
 Yeovil Hospital, Yeovil