CONFIDENTIAL

Strict embargo: 00.01hrs
Wednesday 25 January 2006

EARLY FORM OF BREAST CANCER ON THE RISE

THE NUMBER of registered cases of an early form of breast cancer called Ductal carcinoma in situ (DCIS)[1] has increased, according to new figures released today by Cancer Research UK. These show that in 2002 nearly 3800 women in the United Kingdom were diagnosed with DCIS compared with 2910 five years earlier.

DCIS occurs when the cells inside the ducts of the breast have started to turn into cancer cells. Some doctors describe DCIS as a very early form of breast cancer, others call it a 'pre-cancerous condition' because it often develops into an invasive cancer if it is not treated. Women who have had DCIS are at higher risk of getting cancer in the same breast and in the opposite breast as well as being more likely to develop more advanced forms of breast cancer.

The news of the increase in cases of DCIS comes as Cancer Research UK announces the start of a worldwide study to investigate which breast cancer treatment drug, anastrozole or tamoxifen[2], is better at preventing the disease from returning in women who have had DCIS. The groundbreaking study, called *IBIS-2 DCIS*[3], is the largest international trial to compare tamoxifen and anastrozole in the prevention of breast cancer recurrence in women with DCIS.

Professor Tony Howell, IBIS-2 co-chairman and Professor of Medical Oncology at the Christie Hospital, Manchester, commented: "Known cases of DCIS are increasing because of the success of the National Breast Screening Programme. Although screening must continue, it is of vital importance that we find the best treatment to prevent breast cancer from coming back in this rising number of women and we believe that the IBIS-2 DCIS study will help give us the answers."

Many breast cancer experts believe that hormone therapies, like tamoxifen or anastrozole, may be effective in protecting women with DCIS from developing breast cancer in the future although they are still unclear on which therapy is best.

Cancer Research UK's lead researcher on the trial, Professor Jack Cuzick says: "The uncertainty around which is the most appropriate treatment for DCIS could mean that there are women who are potentially missing out on drugs to prevent this cancer from returning. We know from previous research that tamoxifen reduces the risk of invasive breast cancer by over 50 per cent in women with DCIS. We also believe that anastrozole could be the ideal candidate for these women because it has already been proven to be better than tamoxifen at reducing disease recurrence in women diagnosed with invasive breast cancer. Now we need to see whether anastrozole will do better, and have fewer side effects, than tamoxifen for women with DCIS."

More…

EARLY FORM OF BREAST CANCER ON THE RISE (2)…

In a large international trial of over 9,000 women with invasive early breast cancer[4], anastrozole was shown to be better than tamoxifen at reducing recurrence of the disease. The results from this trial also suggested that up to 70-80 per cent of new tumours could be prevented by anastrozole.[4]

Kate Law, head of clinical trials at Cancer Research UK, says: "The IBIS-2 DCIS study is extremely important as more women than ever before are being diagnosed with this disease. This trial will help to confirm which treatment is more effective in helping to prevent the disease from returning and helping women to live free from breast cancer."

Researchers are looking to recruit 4,000 post-menopausal women from around the world, who have had a DCIS in the last six months. To be eligible to enter the study, women must be aged between 40 and 70 and have had surgery to remove a hormone receptor positive DCIS in the last six months. Women who are found to be suitable to take part in the trial will receive either anastrozole or tamoxifen for five years.

Professor Jack Cuzick adds: "We encourage women who think that they may be eligible and who want to take part to consult with their breast cancer consultants as soon as they can. This is because women can only join the study within six months after surgery to remove their DCIS."

The DCIS trial is part of a large international breast cancer study called IBIS-2 that is being supported by Cancer Research UK and sponsored by Queen Mary, University of London. There are 20 countries taking part in the DCIS trial and 42 centres in the UK are now open for recruitment.[5]

For more information on the trial, please log on to the IBIS website (www.ibis-trials.org) or CancerHelp UK (www.cancerhelp.org.uk).

ENDS

For media enquiries please contact Paul Thorne in the Cancer Research UK press office on 02070618352 or the out of hours on 07050264059.

Notes to Editors:

[1] Ductal carcinoma in situ (DCIS)

- DCIS is often removed by a lumpectomy or wide local excision. Some patients are also given radiotherapy following surgery to kill off any abnormal cells left behind.

[2] Anastrozole (trade name Arimidex) and tamoxifen

- Anastrozole is one of a group of drugs called aromatase inhibitors. In post-menopausal women, an enzyme called aromatase is the main source of production 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, joint pains and an increased risk of osteoporosis (weakened bones).

- Tamoxifen is also a hormone treatment but works differently from anastrozole by preventing breast cancer cells from picking up oestrogen.

- Side effects reported on tamoxifen include hot flushes, vaginal bleeding, an increase in blood clots and rarely endometrial cancer.

[3] IBIS-2

The International Breast Cancer Intervention Study II (IBIS-2) is divided into two parts:

1. IBIS-2 DCIS will recruit 4,000 postmenopausal women who have been diagnosed with and had surgery to remove DCIS (Ductal carcinoma in situ). This part of the 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 who have had a mastectomy to remove their DCIS cannot join this arm of the trial but they can be part of the prevention part.

2. 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 trial if they are aged between 40-70 years and are not on HRT.

[4] 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.

[5] UK trial centres currently 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
- Cookridge Hospital, Cookridge
- Derby City General Hospital, Derby
- Dorset County Hospital, Dorchester
- Ninewells Hospital, Dundee
- Eastbourne District General Hospital, Eastbourne
- Western General Hospital, Edinburgh
- St Margaret's Hospital, Epping
- Frimley Park Hospital, Frimley
- Northwick Park & St Marks Hospitals, Harrow
- Conquest Hospital, Hastings
- The Academic Surgical Unit, University of Hull, Hull

- Leeds General Infirmary, Leeds
- St James’s University Hospital, Leeds
- Royal Liverpool University Hospital, Liverpool
- St Bartholomew’s Hospital, London
- Guy's Hospital, London
- Royal Marsden, London
- South Manchester University Hospital, Manchester
- Macclesfield Hospital, Macclesfield
- Royal Oldham Hospital, Oldham
- Northampton General Hospital, Northampton
- Royal Hospital Gosport, Portsmouth
- Hope Hospital, Salford
- Cancer Research Centre, Weston Park Hospital, Sheffield
- Royal South Hants Hospital, Southampton
- Ormskirk and District General Hospital, Southport
- Morriston Hospital, Swansea
- Mermaid centre, Truro
- Clayton Hospital, Wakefield
- Worthing Hospital, Worthing