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PRESS RELEASE

Update on appraisal of hormonal treatments for the treatment of early breast cancer, compared with tamoxifen

As part of the eighth wave of referrals, the Department of Health and the Welsh Assembly Government have asked the National Institute for Clinical Excellence (NICE or the Institute) to conduct an appraisal of hormonal treatments for the adjuvant treatment of early oestrogen-receptor positive breast cancer, compared with tamoxifen, and to provide guidance on their use to the NHS in England and Wales.

The Institute does not usually issue guidance on unlicensed indications and currently tamoxifen is the gold standard hormonal treatment licensed as a first line adjuvant therapy in the treatment of early oestrogen-receptor positive breast cancer.

The aromatase inhibitors are not currently licensed in the UK as direct alternatives to tamoxifen. Anastrozole is licensed only as an alternative to tamoxifen for the treatment of early breast cancer in women for whom tamoxifen is contraindicated, letrozole is licensed only as a pre-operative therapy to allow subsequent breast conserving surgery in women not originally considered candidates for this and exemestane is licensed only for advanced breast cancer.

Clinical trials are underway to generate data and evidence to support future licence applications for these products as possible alternatives to tamoxifen. In response to comments received during consultation on the scope on this issue, the Institute is suspending this appraisal. The Institute intends setting the timelines of the appraisal to coincide with the availability of data and the licensing process for these indications

and will provide detailed appraisal timelines when more precise information on licensing dates becomes available.

Anne-Toni Rodgers, Executive Lead for this appraisal said, “NICE aims to issue guidance on new indications as close to the time of licensing as possible. We will be closely monitoring the licensing process and will ensure we time this appraisal to coincide with the availability of data”.

Ends

For more information call Lucy Betterton on 020 7067 5903 and 07747 865 562

Notes to Editors

About NICE

1. NICE is part of the NHS. It is the independent organisation responsible for providing national guidance on treatments and care for those using the NHS in England and Wales. Its guidance is for healthcare professionals and patients and their carers to help them make decisions about treatment and healthcare. For further information about NICE you can visit www.nice.org.uk.
2. NICE produces guidance in three areas of health:
 - the use of new and existing medicines and treatments within the NHS in England and Wales – technology appraisals
 - the appropriate treatment and care of patients with specific diseases and conditions within the NHS in England and Wales – clinical guidelines.
 - whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use– interventional procedures.NICE also funds three enquiries that undertake research into the way patients are treated to identify ways of improving the quality of care (the investigations are known as confidential enquiries).
3. NICE guidance and recommendations are prepared by independent groups that include professionals working in the NHS and people who are familiar with the issues affecting patients and carers.

About technology appraisals

4. Technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS in England and Wales, such as:
 - medicines (for example, drugs)
 - medical devices (for example, hearing aids or inhalers)
 - diagnostic techniques (tests used to identify diseases)
 - surgical procedures (for example, repairing hernias)
 - health promotion activities (for example, patient education models for diabetes).
5. Our technology appraisal recommendations are prepared by an independent Committee, who include healthcare professionals working in the NHS and people who are familiar with the issues affecting patients and carers. The Committee considers the evidence on the clinical and cost effectiveness of the technology – this includes hearing the views of, and evidence from, clinical health professionals, experts and patients.

6. NHS organisations in England and Wales have to make the resources and facilities available to enable NICE guidance to be implemented. In January 2002 the Government announced a legal obligation for the NHS to provide funding for treatments and drugs recommended by NICE as a part of its technology appraisals work programme.

About this appraisal

7. The original remit from the Department of Health asked NICE "To advise on the clinical and cost-effectiveness of hormonal treatments, for the adjuvant treatment of early oestrogen-receptor positive breast cancer, compared with tamoxifen."
8. The ATAC trial, in which anastrozole is compared with tamoxifen, has reported preliminary findings but is not expected to report mature survival data until middle to late 2004.
9. Results from a trial comparing letrozole and tamoxifen are expected by 2005.
10. A trial comparing exemestane and tamoxifen is underway.
11. Aromatase inhibitors are a family of hormonal treatments, which act predominantly by blocking the conversion of androgen to oestrogen in the peripheral tissues and are classified as either nonsteroidal or steroidal agents. Anastrozole and letrozole are potent nonsteroidal aromatase inhibitors and exemestane is an irreversible steroidal aromatase inhibitor.