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Health and Clinical Excellence**

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PRESS RELEASE

NICE issues draft guidance on trastuzumab (Herceptin) for early breast cancer

NICE has today (Friday 9 June 2006) published draft guidance on Herceptin, just two weeks after the drug was licensed by the regulatory authorities for use in early breast cancer. The draft guidance recommends the drug for women with early stage HER2-positive breast cancer, except where there are concerns about the woman's cardiac function. Final guidance is expected to be issued at the beginning of July 2006, assuming there are no appeals.

NICE Chief Executive Andrew Dillon said: "These proposals are very good news for women with HER2 positive breast cancer. Herceptin, for these women is clinically and cost effective in the early stage of the disease and we look forward to being able to issue final guidance, subject to any appeal against our recommendations, in a few weeks time."

The draft recommendations are as follows:

- 1.1 Trastuzumab, given at 3-week intervals for 1 year or until disease recurrence (whichever is the shorter period), is recommended as a treatment option for women with early-stage HER2-positive breast cancer following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable).
- 1.2 Cardiac function should be assessed prior to the commencement of therapy and trastuzumab treatment should not be offered to women who have a left

ventricular ejection fraction (LVEF) of 55% or less, or who have any of the following:

- a history of documented congestive heart failure
- high-risk uncontrolled arrhythmias
- angina pectoris requiring medication
- clinically significant valvular disease
- evidence of transmural infarction on electrocardiograph (ECG)
- poorly controlled hypertension.

1.3 Cardiac functional assessments should be repeated every 3 months during trastuzumab treatment. If the LVEF drops by 10% from baseline and to below 50% then trastuzumab treatment should be suspended. A decision to resume trastuzumab therapy should be based on a further cardiac assessment and a fully informed discussion of the risks and benefits between the individual patient and their clinician.

The draft recommendations are subject to an appeal period which closes on 28 June 2006. During this period registered stakeholder organisations including those representing healthcare professionals, patients and carers can decide if they wish to appeal against the draft guidance. Final guidance is expected to be issued at the beginning of July 2006, assuming there are no appeals.

Ends

Andrew Dillon, NICE Chief Executive, will be available for comment and interviews.

For more information call the Sarita Tamber on 0207 067 5915 or Lucy Betterton on 0207 067 5903.

Notes to Editors

About NICE

4. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
5. NICE produces guidance in three areas of health:
 - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
 - **health technologies** – guidance on the use of new and existing medicines, treatments and procedures within the NHS

- **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

About process for appraising medicines in the UK

6. NICE issues guidance on the clinical and cost effectiveness of selected new and existing drugs for the NHS in England and Wales. It does this after new medicines have been licensed by the Medicines and Healthcare products Regulatory Agency/European Medicines Evaluation Agency.
7. NICE understands that the Scottish Medicines Consortium (SMC) is also issuing guidance to Scotland on the use of trastuzumab in early breast cancer on Friday 9 June. For further information, contact Colin McAllister on 07813 095930.
8. NICE has introducing a new, rapid process to enable faster guidance on life-saving drugs which have already been licensed and on new medicines close to when they first become available. Details can be found on the NICE website at <http://www.nice.org.uk/page.aspx?o=278604>.