Lapatinib and trastuzumab in combination with an aromatase inhibitor for the first-line treatment of metastatic hormone-receptor-positive breast cancer that overexpresses HER2

Breakthrough Breast Cancer is dedicated to improving and saving lives through breast cancer prevention, early diagnosis, more targeted treatments and better services for everyone affected by breast cancer.

This submission reflects the views of Breakthrough, based on our experience of working with people with personal experience of, or who are concerned about, breast cancer. We regularly consult with members of our Campaigns and Advocacy Network (Breakthrough CAN) for their views on a range of breast cancer issues. Breakthrough CAN brings together over 1,800 individuals, regional groups and national organisations across the UK to take action locally on our national campaigns to secure important improvements to breast cancer research, treatments and services. Through supporting and training members, Breakthrough CAN aims to increase the influence of breast cancer advocates in decisions regarding breast cancer issues.

Breakthrough welcomes the opportunity to comment on this appraisal consultation document.

We are disappointed the Appraisal Committee is unable to recommend lapatinib or trastuzumab in combination with an AI for the first-line treatment of metastatic hormone-receptor-positive breast cancer that overexpresses HER2.

Has all the relevant evidence been taken into account?

There is no cure for metastatic breast cancer and treatment options are used to alleviate symptoms, delay progression or improve survival. For this patient group maintaining quality of life for as long as possible is currently the best outcome. Some women may live full lives for some time and treatments that can help them to do this are welcomed. It is therefore essential more treatment options are made available to this patient group.
Treatment with trastuzumab or lapatinib plus an AI has been shown to be more effective than treatment with an AI alone. Findings from both TAnDEM and EGF30008 trials found that although no statistically significant gains were made in overall survival when trastuzumab or lapatinib were added to an AI, the gains in progression free survival were significant. Progression-free survival is something that patients with metastatic breast cancer say is very important to them. Delayed time to disease progression, if associated with few severe side effects of treatment, allows patients with metastatic breast cancer to continue with some aspects of their normal daily life and delays the associated debilitating symptoms and emotional distress this progression may bring. It may also allow the patient to be able to continue to carry out normal daily activities such as caring for their families or

Breakthrough Breast Cancer
Registered Office
Weston House
246 High Holborn
London WC1V 7EX

Telephone 020 7025 2400
Textphone 18001 020 7025 2400
info@breakthrough.org.uk
breakthrough.org.uk

Patron HRH The Prince of Wales

continuing to work or simply enjoying spending quality time with their loved ones. For patients with metastatic breast cancer the importance of this should not be underestimated.

Lapatinib plus an aromatase inhibitor has the added advantage of being an oral treatment. As a first line treatment for metastatic breast cancer this is a very attractive option as it would be easier for patients to carry out their lives in as normal a way as possible and reduce the time spent visiting hospital. Administration by tablet form also reduces NHS costs of treatment provision as well as patient costs associated with attending hospital such as parking, travel, time off work and child care.

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

We are disappointed the Appraisal Committee is unable to recommend lapatinib or trastuzumab in combination with an AI for the first-line treatment of metastatic hormone-receptor-positive breast cancer that overexpresses HER2. As a patient organisation, Breakthrough would like to emphasise how crucial it is for this patient group to have treatment options, especially ones that can improve quality of life and allow as little disruption to normal life as possible. The TAnDEM and EGF30008 clinical trials which looked at the efficacy of combining these hormone and biological therapies showed clinical benefit and statistically significant gains in progression free survival upon combination. However, Breakthrough acknowledges that combining AIs with lapatinib or trastuzumab is an expensive treatment.

Are the provisional recommendations sound and a suitable basis for guidance to the NHS?

It is vital that the appraisal process is seen by all stakeholders to be fair and rigorous and that all conclusions are clearly stated. Therefore, we welcomed the fact that the appeal regarding the original ACD was successful and that as a result the end of life criteria with relation to trastuzumab plus an aromatase inhibitor were revisited, even though this did not change the overall decision not to approve this treatment.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief?

None of which we are aware.

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