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Submission from Cancerbackup to NICE Appraisal Committee on gemcitabine for locally advanced or metastatic breast cancer

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Cancerbackup welcomes the opportunity to respond to the Appraisal Consultation Document (ACD) for the above appraisal.

As the leading specialist provider of independent information on all types of cancer, Cancerbackup has regular contact with people living with breast cancer and those caring for them. Over 11,000 people telephoned our helpline to talk about breast cancer and there were 201,195 visitors to the breast cancer pages of our website in the year 2004-05.

Cancerbackup believes that everyone with cancer should be offered the most effective treatment, based on the available evidence and the patient's own wishes and preferences. We believe that:

- Patients should have access to the most effective treatments appropriate to them as individuals;
- Patients should be able to choose – in partnership with their oncologist – the treatment that is likely to suit them best in terms of relative benefits and side-effects;
- The impact of treatments on patient's quality of life, as well as length of life, should be given full consideration by the Appraisal Committee.

We urge the Appraisal Committee to recommend that gemcitabine should be available for the treatment of patients with locally advanced or metastatic breast cancer.

Living with advanced breast cancer

About 42,000 people in the UK each year are diagnosed with breast cancer. The causes of breast cancer are not yet completely understood. The risk of developing breast cancer is very small in young women and increases as women get older. More than half of breast cancers occur in women over the age of 65.

Although the results of breast cancer treatment are improving every year, around 12,000 women still die of the disease every year with disease that has spread to form metastases in various organs including bone, liver and lung. This is known as advanced breast cancer. The treatment of breast cancer depends on many factors, including: the stage and grade of the cancer; a person's age; the size of the tumour; whether the cancer cells have receptors for certain hormones (such as oestrogen) or particular proteins (such as HER2); and individual patient choices based on drug efficacy and potential side effects.

Gemcitabine

Gemcitabine is a chemotherapy drug that belongs to a class of drugs known as antimetabolites, used in the treatment of some types of cancer. Previously it has been

used to treat non-small cell lung cancer, pancreatic and bladder tumours. More recently it has been critically evaluated and increasingly used in the treatment of breast cancer.

Gemcitabine is a colourless fluid after being dissolved from a white powder. Gemcitabine may be given: as a drip (infusion) through a fine tube (cannula) inserted into a vein, over a short period of time; or through a central line, which is inserted under the skin into a vein near the collarbone, or a PICC line inserted into a vein in the crook of your arm.

Gemcitabine offers an important additional treatment option for people with advanced breast cancer, offering not only greater overall survival, but also a better toxicity profile. Cancerbackup urges the Appraisal Committee to consider the following points in particular:

1. Gemcitabine can extend overall survival for people with locally advanced or metastatic breast cancer

The JHQG trial demonstrated a three month advantage in overall survival for people given gemictabine/paclitaxel over people given paclitaxel (18.5 months compared to 15.8 months)[1].

This represents a clinically significant difference to patients and could have an impact on the time available to patients, their families and friends.

2. Gemcitabine offers considerable improvements in quality of life for people being treated with advanced breast cancer

Side effects are an important deciding factor for many people and their families, and gemcitabine offers a better toxicity profile for patients[2]. There is currently a need for new combinations of chemotherapy agents which can improve outcomes without toxicity impacting on quality of life, and Gemcitabine appears to be well tolerated and easy to administer.

This not only offers considerable benefits to patients, but can also impact on the overall cost of treating a patient with advanced breast cancer, as they are less likely to require treatment and care for the effects of toxicity.

3. Gemcitabine offers an additional line of treatment for people with advanced breast cancer

It is expected that gemcitabine plus paclitaxel would be used as an alternative to docetaxel plus capecitabine, as it is thought to be equally effective but less toxic. As the Appraisal Committee heard, capecitabine can be an important option in *later* lines of therapy for metastatic breast cancer, but the use of docetaxel plus capecitabine as a first-line choice would reduce the possibility of using capecitabine later on. Using gemcitabine early on would therefore offer increased options for treatment with capecitabine in later lines.

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[1] Albain KS, Nag S, Calderillo-Ruiz G, Jordaan JP, Llombart A, Pluzanska A et al. Global phase III study of gemcitabine plus paclitaxel (GT) vs paclitaxel (T) as frontline therapy for metastatic breast cancer (MBC): First report of overall survival. J Clin Oncol 2004; 22(14): 5S

[2] Chan S et al Gemcitabine plus docetaxel (GD) versus capecitabine plus docetaxel (CD) for anthracycline-pretreated metastatic breast cancer (MBC) patients (pts): Results of a European Phase III study, 2005

4. The use of paclitaxel and gemcitabine is cost effective for the treatment of advanced breast cancer.

Gemcitabine plus paclitaxel provides effective palliation at an economic cost that is less than that associated with docetaxel based regimens. Approval of the paclitaxel-gemcitabine combination will not increase the expenditure on the management of advanced breast cancer but will offer a useful choice over existing options for patients.

We urge the Appraisal Committee to consider the points above, in particular the significant impact of this technology on patients' quality of life, and to recommend gemictabine for the treatment of metastatic breast cancer.

Cancerbackup