

## Submission to the Pharmaceutical Benefits Advisory Committee Neratinib (Nerlynx®)

February 2019

### About Breast Cancer Network Australia

Breast Cancer Network Australia (BCNA) is the peak national organisation for Australians personally affected by breast cancer. We support, inform, represent and connect people whose lives have been affected by breast cancer. We work to ensure that Australians diagnosed with breast cancer receive the very best support, information, treatment and care appropriate to their individual needs.

BCNA represents more than 120,000 individual members and 280 member groups from across Australia.

### Submission

*I have been taking Nerlynx for five months. I am finding it very manageable and certainly worth the extra percentage points of additional survival that it gives me.*  
– Vanessa, Sydney

BCNA is pleased to support the major submission for neratinib (Nerlynx®) for extended adjuvant treatment of patients with early-stage Human epidermal growth factor receptor-2 positive (HER2+) overexpressed/amplified breast cancer who have received prior adjuvant trastuzumab (Herceptin®) based therapy.

Neratinib is a new treatment for women with HER2-positive, hormone receptor positive early breast cancer. International studies have shown that women with this type of breast cancer have a 20 to 25 per cent chance of breast cancer recurrence within five years of completing adjuvant Herceptin treatment. The phase III ExteNET international clinical trial found that, when started within 12 months of completing Herceptin treatment, 12 months of neratinib can further reduce this risk by up to 42 per cent for women with HER2-positive, HR-positive breast cancer.

Neratinib is an oral medication and is given daily for 12 months in conjunction with an aromatase inhibitor (also oral medication). This means it can be taken at home, wherever the woman may live.

We are aware that diarrhoea is a significant side effect of this medication, particularly in the first two months after starting treatment. However we understand it is transient, with most women diarrhoea-free after two months, and reversible if treatment is stopped.

We've been advised that protocols are in place to help reduce the impact of diarrhoea. These include putting patients on anti-diarrhoeal medication when starting neratinib. We understand that two months of anti-diarrhoeal medication is included when a neratinib script is first filled. A regular phone call service assists patients to manage any diarrhoea.

Other diarrhoea management strategies include reducing the daily dose or taking a short break from treatment.

*The diarrhoea has been manageable and not nearly as bad as the side effects I experienced with chemotherapy. I started Imodium at the same time as I started Nerlynx and that was a very simple and effective remedy. The diarrhoea settled down after a couple of months, but it really didn't worry me as I could manage it with Imodium. I'm not as tired and uncomfortable as I was during chemotherapy treatment. – Vanessa, Sydney*

*The first three months on neratinib were very difficult. Because of ongoing gastro complications from chemotherapy, I couldn't use Gastrostop or any of the anti-diarrhoea medications. So I suffered severe diarrhoea and some nausea and vomiting. I just had to bear it. I know what the benefits of neratinib could be – I am giving myself the best chance of surviving. After three months the side effects started to settle, and now at five months it is much more settled and I only have occasional diarrhoea. I have been able to work my normal two days per week right through my treatment. I know when I am going to have an episode and have never been caught out. – Heather, Sydney*

BCNA strongly believes women with early breast cancer should have current best practice treatments available to them so they can discuss with their treating team the best options for them to reduce their risk of breast cancer recurrence and death from breast cancer.

*I have looked at the clinical trial data and the survival percentage points outweigh the side effects for me. I know that I am only on this drug for 12 months, and that it will increase my chances of a longer life. I have a 16 year old daughter and a husband. Like everyone else, I want to live. – Heather, Sydney*

While there are a number of HER2 therapies now available on the PBS for the treatment of metastatic HER2-positive breast cancer, a significant number of Australian women with metastatic HER-positive breast cancer still die every year despite these therapies being available. Neratinib is a new treatment that can help to prevent women with early stage disease from progressing to metastatic disease. BCNA believes it should be available through the PBS to women who wish to use it.

We understand the full out-of-pocket cost for 12 months of neratinib is approximately \$72,000, well out of the reach of most Australian families. PBS-listing would ensure it is equally and affordably available to all who could benefit from it.

*Nerlynx gives women another treatment choice and I think the more choices the better. It can give you an extra chance of survival. It would be great to have it on the PBS so that everyone has the choice to use it, not just those who can afford it.*  
– Vanessa, Sydney

We note it has been approved for use as an adjuvant therapy in the USA and Europe.

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