

Submission to the Pharmaceutical Benefits Advisory Committee Palbociclib (Ibrance®)

January 2017

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 300 member groups from across Australia. More than 3,000 of our members are women who have told us they have had a diagnosis of metastatic breast cancer. The actual number is likely to be considerably higher.

Submission

Breast Cancer Network Australia welcomes the opportunity to provide comment to the Pharmaceutical Benefits Advisory Committee (PBAC) on the major submission to list palbociclib (Ibrance®) with a non-steroidal aromatase inhibitor (letrozole or anastrozole) as initial endocrine-based therapy in postmenopausal women with hormone receptor positive (HR+), HER2-negative (HER2-) metastatic breast cancer.

BCNA strongly supports the inclusion of palbociclib on the Pharmaceutical Benefits Schedule (PBS). We believe it provides a valuable new oral therapy option for people with hormone positive, HER2-negative metastatic breast cancer.

A diagnosis of metastatic breast cancer is devastating for women. There is currently no cure and treatment will continue for the remainder of her life. BCNA believes all Australians living with breast cancer should have the same level of access to innovative cancer drugs as people living in other countries around the world. Palbociclib is currently available to women in over 50 other countries, including Europe and the USA, where it was listed by the Food and Drug Administration (FDA) nearly two years ago.

Palbociclib was granted accelerated approval by the FDA in February 2015 as a break through therapy for use in the treatment of hormone receptor positive, HER2-negative metastatic breast cancer in combination with the drug letrozole. Accelerated approval was granted on the basis of a doubling of the progression free survival interval in patients receiving the combination of palbociclib and letrozole in the PALOMA-1 international trial.

SUPPORTING AUSTRALIANS AFFECTED BY BREAST CANCER

293 Camberwell Road Camberwell VIC 3124

1800 500 258 (03) 9805 2500 beacon@bcna.org.au www.bcna.org.au ABN 16 087 937 531

Participants treated with palbociclib plus letrozole lived about 20.2 months without their disease progressing compared to about 10.2 months in participants receiving only letrozole.ⁱ Subsequent studies have demonstrated that palbociclib in combination with an endocrine therapy significantly prolonged progression free survival compared to endocrine therapy alone or endocrine therapy with placebo.

BCNA is aware that palbociclib is the first new medicine approved by any regulator for the treatment of women with this type of metastatic breast cancer in the first-line setting in nearly 10 years. Women with hormone receptor positive, HER2-negative metastatic breast cancer represent about 60 per cent of all metastatic breast cancer cases.ⁱⁱ As there is no cure for metastatic breast cancer, patients need treatment options that can slow down the progression of their disease, control symptoms and help them to survive and maintain their quality of life for as long as possible.

One of the greatest benefits to women is that this drug is an oral therapy. Delaying the onset of chemotherapy-based treatments has huge advantages for women and their families. This includes significantly reduced toxicities and greater flexibility to maintain a normal life, where women can work, care for children and family members and actively contribute to society in a meaningful and rewarding way.

Even though I am terminal I am still trying to maintain a sense of normality for as long as I can. This means being able to work and remain financially independent and to also maintain a good quality of life. Endless rounds of chemotherapy makes this almost impossible. - Karen

Clinical trials have shown that palbociclib was well tolerated and did not result in symptoms commonly associated with cancer treatment such as nausea, diarrhoea and hair loss.

After learning my breast cancer had returned after eight years and had spread to my bones, I was offered a lifeline in the form of taking part in a clinical trial for palbociclib. Since taking the drugs last July, my initial symptoms of nausea, lack of appetite and fatigue have diminished to the point where they do not figure in my consciousness and I look and feel well. Regular monthly tests have returned positive results and have also revealed that my cancer markers continue to fall. It has been explained to me that this drug should not be seen as a cure for a terminal illness but it should extend my life and give me more time than any other treatment could. Time is so valuable to me, and to any of us really. – Jane

There are also benefits for rural women who, by taking an oral therapy, can avoid having to travel long distances for intravenous treatments.

All the side effects of chemotherapy treatment and all the medical appointments associated with them just keep adding up. My oncologist is 90kms away. My GP is 50kms away. My lymphoedema clinic is 100kms away and of course they are all in different directions so travel time and appointments cause me stress. – Maria

Since 2015, BCNA has received multiple enquiries from women living with metastatic breast cancer asking how they can access this innovative new therapy. Many of these women have shared with us their distress at not being able to access a drug that has been found to improve survival outcomes but is not approved for use in Australia.

It was incredibly stressful when my oncologist said that palbociclib exists and would probably benefit me but I would have to find it myself from outside of Australia if I wanted to access it. Since June 2016, I've spent approximately \$100,000 on this drug. Personally, it's been worth every cent because it has given me 8 months of active living time, feeling perfectly well, which I would not have had without it. Without it, I would either be dead by now, or suffering all the side effects of heavy-duty chemotherapy. But of course most other breast cancer patients are not able to afford it. I was just lucky that I can use my superannuation money. Even though I had the money (until now at least) I had to find the drug overseas by myself and take all the risks with online purchases. Every month there is more stress, sending such huge amounts overseas and trusting the bottle of 21 pills will arrive safely - Carolyn

Clinical trials for palbociclib have recruited quickly in Australia and many women around the country have missed out on the opportunity to participate. There is currently no patient access program provided by the pharmaceutical company (Pfizer) to assist women to access palbociclib at a reduced price. This means that women like Carolyn only have one option available to them: to import the drug from overseas pharmacies at huge expense and with the potential risk that the drug is not delivered. The financial impact of metastatic breast cancer is profound and the reality is that most Australians will not be able to pay for palbociclib if it is not subsidised.

The cost of breast cancer treatment meant I used all my life savings. This is tough and has resulted in uncertainty. Am I going to have enough money to see me out? How does all of this affect my standard of living and therefore my relationships with family and friends? - Barbara

Without government funding for palbociclib, we will see a two-tier treatment system where those who can find the funding will have access to this new, innovative breast cancer treatment while those who cannot, will not. Families will face very difficult decisions about re-mortgaging or selling the family home to pay for treatment with palbociclib, as we saw when trastuzumab (Herceptin) first became available nearly 20 years ago. For young families with dependent children, there will be a most unpalatable choice - pay for a treatment that may extend their mother's life but leave their father or another relative to raise the children without a secure financial base, or not pay for treatment knowing that it may result in an earlier death.

Living with advanced breast cancer puts an enormous stress on families. Decisions about whether to pay for an expensive treatment can create conflict when that money also needs to be spent elsewhere. It leaves women feeling guilty that they are spending money on treatments when the family really needs it for other things. – Lynne

We note that palbociclib is yet to be approved for use by the Therapeutic Goods Administration. BCNA is very concerned that delays in this process will inhibit the ability of the PBAC to consider this submission. We strongly urge the PBAC to collaborate with the TGA prior to the March meeting to ensure that processes align.

BCNA urges the PBAC to recommend the inclusion of palbociclib on the PBS. It provides an important new first-line treatment for people with hormone receptor positive, HER2-negative metastatic breast cancer that has the additional advantage of being an oral therapy with a low toxicity profile. It is extremely important that this drug is available to everyone who can benefit from it.

Palbociclib has been available to women in the USA for two years. It is heartbreaking that Australian women are not afforded the same opportunity. When you are in my position, you try everything to survive for as long as you can, to be as well as possible and to stay out of hospital. I am at the point where I have to take a break from chemo because of the terrible side effects. I have persevered really hard to keep going but the hand foot syndrome has impacted my quality of life in so many ways. – Wendy

For further information, please contact:
Kathy Wells
Head of Policy, Research and Advocacy
kwells@bcna.org.au
(03) 9805 2562

ⁱ <http://www.esmo.org/Oncology-News/Combination-of-Palbociclib-and-Letrozole-Shows-Promising-Results-in-First-Line-Treatment-of-ER-Positive-HER2-Negative-Advanced-Breast-Cancer>

ⁱⁱ Rocca A, Farolfi A, Bravaccini S, Schirone A, Amadori D. Palbociclib (pd 0332991): targeting the cell cycle machinery in breast cancer. Expert Opin Pharmacother. 2014;15(3):407-420.