

Submission to the Pharmaceutical Benefits Advisory Committee Abemaciclib (Verzenio®)

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

Breast Cancer Network Australia (BCNA) is pleased to support the major submission for abemaciclib (Verzenio®) for the treatment of non-premenopausal patients with hormone receptor positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) locally advanced or metastatic breast cancer.

Abemaciclib belongs to the CDK4/6 inhibitor class of drugs, used to treat the most common form of breast cancer – hormone receptor positive breast cancer. As PBAC members may be aware, BCNA lobbied for several years for the inclusion of CDK 4/6 inhibitors on the PBS. We were very pleased when ribociclib (Kisqali®) was listed in July 2018.

CDK 4/6 inhibitors have shown great results in numerous international clinical trials and have significantly improved outcomes for people with HR+, HER2- metastatic breast cancer. The MONARCH3 trial, comparing abemaciclib + an aromatase inhibitor with placebo + an aromatase inhibitor, found median progression free survival in the abemaciclib group was almost twice that of the placebo group - 28.2 months compared with 14.8 months. Women tell us how much they value an additional 14 months on an oral medication which offers them good quality of life and the ability to continue with their normally daily activities. This is particularly so noting that the next treatment most women will be offered will be chemotherapy, with its associated toxicities.

I have been taking abemaciclib for a number of months. I have found that it is easy to take the capsules, and blood tests indicate a good positive response. In general I feel very well indeed and have been able to lead a normal and active life. I have found the oral route of therapy particularly convenient as I have a full time and very demanding job. Oral medication does not interfere with my professional duties, unlike conventional chemotherapy or injected medication, both of which require time consuming appointments. – Robyn, NSW

The inclusion of abemaciclib on the PBS will provide people newly diagnosed with HR+, HER2- locally advanced or metastatic breast cancer with a second publicly-funded CDK inhibitor option. The great value in this is that abemaciclib has a different structural make-up to ribociclib (and palbociclib) and as such has a different side effect profile.

I have tolerated the abemaciclib very well. The only side effect was a change in the consistency of my faeces, which are softer than normal but not actual diarrhoea. This change was noticeable about two days after I commenced the medication. I have occasionally had a bowel motion that is more like diarrhoea, however this is usually a one off and, unlike normal diarrhoea, is controllable. I have not needed to take Gastrostop or similar medication and have not had to modify my diet. I have not had any of the other listed side effects of abemaciclib. In short, the medication has been tolerated very well and the change in bowel habits just sufficient to provide reassurance that it was actually working! – Robyn, NSW

Abemaciclib does not cause cardiac issues, making it a good option for women with heart problems. Ribociclib is not recommended for women with, or at risk of developing, Long QTc syndrome (a heart rhythm condition that can cause fast, chaotic heartbeats). The inclusion of abemaciclib on the PBS will give these women a CDK 4/6 inhibitor option.

Abemaciclib is also less likely to cause neutropenia, and so can be useful for women with bone marrow involvement that renders them prone to neutropenia.

Another benefit of abemaciclib is that it is a small molecule that is more likely to cross the blood brain barrier and may be more effective than other CDK 4/6 inhibitors in preventing and/ or treating brain metastases, which is a devastating complication of metastatic breast cancer.

The continuous dosing schedule for abemaciclib will appeal to some women ahead of the three weeks on, one week off schedule of ribociclib.

BCNA supports the inclusion of abemaciclib on the PBS as an additional first-line CDK 4/6 treatment option for people with locally advanced or metastatic HR+, HER2– breast cancer.

Further, we note that abemaciclib has also performed well as a later line treatment, either as a monotherapy or in combination with fulvestrant. We hope that an application for this purpose will be submitted to PBAC to allow people who have received previous treatment for metastatic breast cancer to access this important new class of drugs. BCNA regularly receives calls from women trying to access a CDK 4/6 inhibitor as a later line treatment.

For me, the only inconvenience with abemaciclib was the need to organise compassionate access, which I much appreciated but which inevitably took up time for a number of people. I fully support the submission by BCNA as this valuable medication should be readily available to all those who need it. – Robyn, NSW

For further information, please contact my Chief of Staff, Kathy Wells at kwells@bcna.org.au or (03) 9805 2534.

A handwritten signature in red ink, consisting of a stylized 'K' followed by a long horizontal stroke.

Kirsten Pilatti
Chief Executive Officer