Via email: consult@pharmac.govt.nz

6 September 2019

Dear PHARMAC,

I write to respond on behalf of BCAC to Pharmac's Consultation on a Proposal to fund fulvestrant (Faslodex®) for post-menopausal (either naturally or induced) women with locally advanced or metastatic (advanced) oestrogen-receptor positive breast cancer whose disease has progressed following previous treatment with either an aromatase inhibitor (letrozole, anastrozole, exemestane) or tamoxifen.

BCAC endorses the proposal to fund fulvestrant in New Zealand for people with Advanced Breast Cancer (ABC). However, we would like to see access to treatment made available **with urgency (under Section 29 of the Medicines Act),** rather than wait until MEDSAFE approval. Our enquiries of the sponsor (AstraZeneca) indicate that the registration process has already been commenced, with preparation of the regulatory submission, but that the process (including preparation of the file and consideration by MEDSAFE) could take up to 9 months, even if fast-tracked. We also **urge PHARMAC to request that MEDSAFE fast-tracks this registration process**.

Under the current proposal, treatment would not be available to New Zealand women until the middle of 2020. New Zealanders with ABC die faster than people in comparable countries, often much faster, and Māori five-year survival is abysmal (1). This is a matter of urgency for those who have this disease and their whānau. Many of the New Zealanders who are already paying for their own treatment with fulvestrant (and accessing it under Section 29) are experiencing significant financial hardship.

Concerning potential patient numbers in your proposal, we consider that PHARMAC has significantly overestimated the number of patients at up to 1750 patients in the first year, and up to 630 patients per year in subsequent years. PHARMAC's estimates certainly need to be reconsidered, given that the Breast Cancer Foundation New Zealand estimated that around 700-1000 people are alive in New Zealand with ABC and 68% of those with ABC are oestrogen-receptor positive at diagnosis [(1)]. This would give a total prevalent population of only 476-680 eligible for treatment in the first year, only some of whom would be in a position to, or would choose to, access treatment.

Certainly, the first-year numbers seem grossly exaggerated and the number for subsequent years also too high. Perhaps the estimates were based on the total number of New Zealanders diagnosed with oestrogen-receptor positive breast cancer, rather than those with advanced oestrogen-receptor positive disease. Any calculation of budgetary impact based on these

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numbers should be reviewed with a view to making the treatment available earlier, rather than delaying access, particularly given the unmet clinical need in this group.

Likewise, PHARMAC's recent RFP for funding of a CDK4/CDK6 inhibitor includes significant overestimates of potential patient numbers, particularly in the first year. We have emailed Geraldine MacGibbon and consult@pharmac.govt.nz about this.

Yours sincerely

Libby Burgess MNZM
BCAC Chairperson

1. Breast Cancer Foundation New Zealand. *"I'm still here" Insights into living - and dying - with Advanced Breast Cancer in New Zealand*. 2018.