pan-Canadian Oncology Drug Review

Patient Group Feedback on a pCODR Expert Review Committee Initial Recommendation

Fulvestrant (Faslodex) for metastatic Breast Cancer

Canadian Breast Cancer Network

February 1, 2018

1 Feedback on pERC Initial Recommendation

Name of the drug indication(s): fulvestrant (Faslodex) Locally Advanced or Metastatic Breast Cancer

Name of registered patient group: Canadian Breast Cancer Network

**pCODR may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by pCODR.*

1.1 Comments on the Initial Recommendation

a) Please indicate if the patient group agrees or disagrees with the initial recommendation:

____ agrees __x__ agrees in part ____ disagree

Please explain why the patient group agrees, agrees in part or disagrees with the initial recommendation.

The Canadian Breast Cancer Network disagrees with the initial recommendation that the treatment does not address an urgent, unmet need in the given patient population. Our key concerns with the initial recommendation involve the themes of value to patients and choice of treatment

Value to patients:
In our submission, we note the importance to patients of extending the time that their cancer is progression-free, that their quality of life is improved and that their ability to resume childcare and work activities is continued. All of the patients interviewed for our submission with direct experience on the treatment expressed their personal satisfaction with the treatment and noted that their oncologists were pleased by the treatments efficacy at stabilizing and controlling their disease. We would like to reiterate the importance of any therapy that allows patients to live life productively and with an excellent quality of life.

Choice in treatment:

The initial recommendation states that pERC noted that there was no urgent, unmet need in this population and makes reference to the consideration that other treatment options are currently available for this population. However in our patient evidence submission we detailed results from our survey of metastatic patients that demonstrated the importance of personal choice in selecting treatments for metastatic patients. This was further reinforced in our interviews with patients with direct experience of Fulvestrant. Multiple patients mentioned that without this treatment, they would have been left with only chemotherapy as an alternative treatment and both patients expressed concerns with the side effects and tolerability of extensive chemotherapy regimens. As such it is critical that the pERC committee consider that for this patient population, the market availability of other treatment options does not always translate into the actual increase of treatment options for patients in a real-life setting, and as such patients would prefer the ability to decide which treatment option is the best for them.

b) Notwithstanding the feedback provided in part a) above, please indicate if the patient group would support this initial recommendation proceeding to final pERC recommendation ("early conversion"), which would occur two (2) Business Days after the end of the feedback deadline date.

_x___	Support conversion to final recommendation.	____	Do not support conversion to final recommendation.
	Recommendation does not require reconsideration by pERC.		Recommendation should be reconsidered by pERC.

c) Please provide feedback on the initial recommendation. Is the initial recommendation or are the components of the recommendation (e.g., clinical and economic evidence) clearly worded? Is the intent clear? Are the reasons clear?

Page Number	Section Title	Paragraph, Line Number	Comments and Suggested Changes to Improve Clarity

1.2 Comments Related to Patient Group Input

Please provide feedback on any issues not adequately addressed in the initial recommendation based on patient group input provided at the outset of the review on outcomes or issues important to patients that were identified in the submitted patient input. Please note that new evidence will be not considered during this part of the review process, however, it may be eligible for a Resubmission. If you are unclear as to whether the information you are providing is eligible for a Resubmission, please contact the pCODR program.

Examples of issues to consider include: what are the impacts of the condition on patients' daily living? Are the needs of patients being met by existing therapies? Are there unmet needs? Will the agents included in this recommendation affect the lives of patients? Do they have any disadvantages? Stakeholders may also consider other factors not listed here.

Page Number	Section Title	Paragraph, Line Number	Comments related to initial patient group input
9	Patient Based Values	Paragraph 5, Lines 1-15	The submission highlights that for ER positive, Her2 negative metastatic patients, including those with direct experience on the treatment under review, value treatment options that improve survival, provide disease control and improve quality of life.

1.3 Additional Comments About the Initial Recommendation Document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments

pCODR Patient Group Feedback on a pERC Initial Recommendation

About Completing This Template

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All stakeholders have 10 (ten) business days within which to provide their feedback on the initial recommendation and rationale. If all invited stakeholders, including registered patient groups, agree with the recommended clinical population described in the initial recommendation, it will proceed to a final pERC recommendation two (2) Business Days after the end of the feedback deadline date. This is called an "early conversion" of an initial recommendation to a final recommendation.

If any one of the invited stakeholders does not support the initial recommendation proceeding to final pERC recommendation, pERC will review all feedback and comments received at the next possible pERC meeting. Based on the feedback received, pERC will consider revising the recommendation document as appropriate. It should be noted that the initial recommendation and rationale for it may or may not change following consultation with stakeholders.

The final pERC recommendation will be made available to the participating provincial and territorial ministries of health and cancer agencies for their use in guiding their funding decisions and will also be made publicly available once it has been finalized.

Instructions for Providing Feedback

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- Individual patients should contact a patient group that is representative of their condition to have their input added to that of the group. If there is no patient group for the particular tumour, patients should contact pCODR for direction at pcodrinfo@cadth.ca.

b) Feedback or comments must be based on the evidence that was considered by pERC in making the initial recommendation. No new evidence will be considered during this part of the review process; however, it may be eligible for a Resubmission.

c) The template for providing *pCODR Patient Group Feedback on a pERC Initial Recommendation* can be downloaded from the pCODR website. (See http://www.pcodr.ca/www.cadth.ca/pcodr for a description of the pCODR process and supporting materials and templates.)

d) At this time, the template must be completed in English. Patient groups should complete those sections of the template where they have substantive comments and should not feel obligated to complete every section, if that section does not apply to their group. Similarly, groups should not feel restricted by the space allotted on the form and can expand the tables in the template as required.

e) Feedback on the initial pERC recommendations **should not exceed three (3) pages in length,** using a minimum 11 point font on 8 ½″ by 11″ paper. If comments submitted exceed three pages, only the first three pages of feedback will be forwarded to the pERC.

f) Feedback should be presented clearly and succinctly in point form, whenever possible. The issue(s) should be clearly stated and specific reference must be made to the section of the recommendation document under discussion (i.e., page number, section title, and paragraph). Opinions from experts and testimonials should not be provided. Comments should be restricted to the content of the initial recommendation.

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Note: Submitted feedback is publicly posted and also may be used in other documents available to the public. The confidentiality of any submitted information at this stage of the review cannot be guaranteed.

pan-Canadian Oncology Drug Review

Patient Group Feedback on a pCODR Expert Review Committee Initial Recommendation

Fulvestrant (Faslodex) for metastatic Breast Cancer

Rethink Breast Cancer

February 1, 2018

1 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Faslodex (fulvestrant) for non-visceral locally advanced or metastatic HER2- breast cancer

Name of registered patient group: Rethink Breast Cancer

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1.1 Comments on the Initial Recommendation

a) Please indicate if the patient group agrees or disagrees with the initial recommendation:

____ agrees _X_ agrees in part ____ disagree

Please explain why the patient group agrees, agrees in part or disagrees with the initial recommendation.
Rethink Breast Cancer agrees with pERC conclusions about the net clinical benefit of Faslodex for non-visceral locally advanced or metastatic HER2- breast cancer as well as its alignment with patient values. However, we disagree with pERC's statement about the absence of an urgent unmet need within this patient population.

b) Notwithstanding the feedback provided in part a) above, please indicate if the patient group would support this initial recommendation proceeding to final pERC recommendation ("early conversion"), which would occur two (2) Business Days after the end of the feedback deadline date.

__X__ Support conversion to final recommendation.
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Page Number	Section Title	Paragraph, Line Number	Additional Comments
2	Potential Next Step for Stakeholders	Paragraph 3, Lines 1-2	While alternative treatment options for this patient population do exist, pERC acknowledged "a continued need for new and effective therapies for patients with advanced or metastatic breast cancer that provide improvements in patient survival, have more favourable toxicity profiles, and improve quality of life." pERC also noted that "the most effective treatment tends to be the one first employed, making the selection of such first-line therapy critical to a patient's cancer journey." As such the potential clinical benefits from Faslodex, noted by pERC, represent an urgent need for first-line patients.

			In light of these facts, we believe it is inaccurate to say that “there is no urgent unmet need in this patient population.”

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