CADTH

pan-Canadian Oncology Drug Review Stakeholder Feedback on a pCODR Expert Review Committee Initial Recommendation (Sponsor)

Ribociclib (Kisqali) plus Fulvestrant for Advanced or Metastatic Breast Cancer

April 22, 2020

3 Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s):	Kisqali in combination with fulvestrant for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy.
Eligible Stakeholder Role	Manufacturer for the drug under review
Organization Providing Feedback	Novartis Pharmaceuticals

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

3.1 Comments on the Initial Recommendation

a) Please indicate if the stakeholder agrees, agrees in part, or disagrees with the initial recommendation:

☒ Agrees ☐ Agrees in part ☐ Disagrees

Novartis is pleased with pCODR's review and pERC recommendation to reimburse Kisqali in combination with fulvestrant as an initial therapy or following disease progression in patients with HR positive, HER-negative advanced or metastatic breast cancer.

Eligible patients include men and post-menopausal women who have not received any prior treatment for ABC or have received up to one line of treatment for ABC. Treatment should be continued until disease progression or unacceptable toxicity. Patients should have good performance status and not have active or uncontrolled metastases to the central nervous system.

Novartis also agrees with pERC that Kisqali in combination with fulvestrant aligns with patient values of delaying disease progression, prolonging life while maintaining QOL and avoiding chemotherapy. Novartis also agrees with pERC that Kisqali has manageable side effects profile.

b) Please indicate if the stakeholder agrees, agrees in part, or disagrees with the provisional algorithm:

☐ Agrees ☐ Agrees in part ☐ Disagrees

Not applicable. Provisional algorithm was not included in this submission, as it was not a requirement at the time the pre-submission form was submitted.

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

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

3.2 Comments Related to Eligible Stakeholder Provided Information

Notwithstanding the feedback provided in part a) above, please indicate if the stakeholder would support this initial recommendation proceeding to final recommendation ("early conversion"), which would occur two business days after the end of the feedback deadline date.

☒ Support conversion to final recommendation.

Recommendation does not require reconsideration by pERC.

☐ Do not support conversion to final recommendation.

Recommendation should be reconsidered by pERC.

If the eligible stakeholder does not support conversion to a final recommendation, please provide feedback on any issues not adequately addressed in the initial recommendation based on any information provided by the stakeholder during the review.

Please note that new evidence will be not considered at this part of the review process, however, it may be eligible for a resubmission.

Additionally, if the eligible stakeholder supports early conversion to a final recommendation; however, the stakeholder has included substantive comments that requires further interpretation of the evidence, including the provisional algorithm, the criteria for early conversion will be deemed to have not been met and the initial recommendation will be returned to pERC for further deliberation and reconsideration at the next possible pERC meeting.

Page Number	Section Title	Paragraph, Line Number	Comments related to Stakeholder Information