CADTH

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

Niraparib (Zejula) for Ovarian Cancer

Ovarian Cancer Canada

September 3, 2020

3 Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s):	Niraparib (Zejula)
Eligible Stakeholder Role in Review (Sponsor and/or Manufacturer, Patient Group, Clinical	Patient Group
Organization Providing Feedback	Ovarian Cancer Canada

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

3.1 Comments on the Initial Recommendation

a) Please indicate if the eligible stakeholder agrees, agrees in part, or disagrees with the Initial Recommendation:

☒ agrees ☐ agrees in part ☐ disagree

- *Ovarian Cancer Canada is pleased that pERC agreed that niraparib aligns with patient values and particularly that it fulfills a need for new treatments particularly for patients with BRCA wild-type who have very limited treatment options. These patients feel desperately underserved and undervalued so this acknowledgement by pERC was appreciated.*
- *We are also very pleased that Progression Free Survival (PFS) was understood as a "clinically meaningful end point in relapsed ovarian cancer given that the goals of maintenance treatment are to delay disease recurrence and chemotherapy." This is absolutely in line with what patients state is an important value and we support pERC in this assessment.*
- *As pERC stated: "…almost 70% of women with ovarian cancer are diagnosed at an advanced stage of disease (III or IV), which is associated with a high rate of recurrence and is considered incurable." Given pERC was satisfied with the net clinical benefit of niraparib maintenance treatment, Ovarian Cancer Canada wants Zejula to move to pCPA very quickly so a price can be negotiated to bring this beneficial treatment option to Canadians living with this disease, particularly those who do not have a BRCA mutation and therefore do not have any access to the benefits of a parp inhibitor.*

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

☐ agrees ☐ agrees in part ☐ disagree

N/A

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 pERC Recommendation ("early conversion"), which would occur two (2) 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 in the submission or as additional information 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. If you are unclear as to whether the information you are providing is eligible for a Resubmission, please contact the pCODR program.

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