CADTH

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

Apalutamide (Erleada) for metastatic Castration Sensitive Prostate Cancer

April 22, 2020

3 Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s):	Erleada® (apalutamide) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).
Eligible Stakeholder Role	Manufacturer of the drug under review
Organization Providing Feedback	Janssen Inc. Canada

** 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

Janssen Inc. agrees with the committee's decision that there is a net clinical benefit that apalutamide plus ADT provides compared with ADT monotherapy based on a statistically significant and clinically meaningful improvement in radiographic progression-free survival (rPFS), an improvement in overall survival (OS), a manageable toxicity profile, no detriment to quality of life (QoL), and a need for less toxic treatment options in this population of patients.

Janssen Inc. agrees with pERC's conclusion that apalutamide plus ADT aligns with the following patient values: disease control, no detriment to QoL, and additional treatment choice.

Additionally, Janssen Inc. agrees with the clinician input that, apalutamide can be used broadly in an "all-comer" mCSPC population.

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

☒ Agrees ☐ Agrees in part ☐ Disagrees

Janssen Inc. agrees with clinicians that apalutamide plus ADT shows efficacy among all men with mCPSC, is better tolerated compared to chemotherapy, and may require less monitoring compared to abiraterone acetate plus prednisone.

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
			No Comment

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
			No Comment