# pan-Canadian Oncology Drug Review

# Provincial Advisory Group (PAG) Feedback on a pCODR Expert Review Committee Initial Recommendation

# Idelalisib (Zydelig) for Follicular Lymphoma

**September 29, 2016**

# 3 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Idelalisib (Zydelig) for Follicular Lymphoma

Endorsed by: Provincial Advisory Group Vice-Chair

Feedback was provided by seven of nine provinces (Ministries of Health and/or provincial cancer agencies) participating in pCODR.

## 3.1 Comments on the Initial Recommendation

a) Please indicate if the PAG (either as individual PAG members and/or as a group) agrees or disagrees with the initial recommendation:

__x__ agrees _____ agrees in part ___ disagree

Most PAG members providing feedback agreed with the pERC initial recommendation.

One member disagreed with the recommendation based on comments from their tumour group.

b) Notwithstanding the feedback provided in part a) above, please indicate if the PAG would support this initial recommendation proceeding to final pERC recommendation ("early conversion"), which would occur within 2(two) business days of the end of the consultation period.

| | | | |
|---|---|---|---|
| __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. |

Most PAG members providing feedback supported early conversion.

One member would like pERC to reconsider the significance of the data presented noting that the heavily pre-treated and very refractory patients in the trial are reflective of heavily pre-treated, refractory patients seen in clinical practice who have no other treatment options.

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 |
|---|---|---|---|
| | | | |
| | | | |

### 3.2 Comments related to PAG input

Please provide feedback on any issues not adequately addressed in the initial recommendation based on the PAG input provided at the outset of the review on potential impacts and feasibility issues of adopting the drug within the health system.

| Page Number | Section Title | Paragraph, Line Number | Comments related to initial PAG input |
|---|---|---|---|
| | | | |

### 3.3 Additional comments about the initial recommendation document

Please provide any additional comments:

| Page Number | Section Title | Paragraph, Line Number | Additional Comments |
|---|---|---|---|
| | | | PAG indicated that a phase 3 trial comparing idelalisib to a current standard of care would be more appropriate to determine its clinical benefit in a very common subtype of lymphoma (follicular) |
| Page 5 | | Line 1 | A provincial tumour group provided feedback through its PAG member: "*Although the follicular lymphoma group was a subgroup, it was the largest group of the NHL in the study (58%). That group overall was very heavily pretreated - very refractory not only to rituximab but to R-chemo combinations, including Benda/CHOP/CVP. So this is truly a refractory NHL population, where there is a large unmet need. Other than ASCT, these patients have no other options.*<br>*The PFS and OS there are likely clinically meaningful based on above. The clinical guidance panel report (on page 8) also mentioned these PFS results were 'clinically meaningful'.*"<br>The tumour group also noted that:<br>• *a RCT is always ideal but the comparator group would have been challenging to formulate. (there are some data with GA101 (obinutuzumab) in this space of rituximab refractoriness)*<br>• *from the Delta study, it appears this group was heavily pre-treated based on their table of baseline characteristics. The provincial tumour group is not sure what measure would make the patients more favourable than what we see in practice* |

| | | | |
|---|---|---|---|
| | | | • *from the trial, the # of patient who did or did not have symptoms at time of enrolment could not be identified.*<br>• *Refractoriness was defined per protocol as less than a partial response or progression of disease within 6 months after completion of a prior therapy.*<br>• *One can argue that patients who achieve less than a PR to a regimen would have been eligible for this study if they were asymptomatic, and we don't know what % were in this category versus the 'progression of disease within 6 months' category."* |
| | | | Relating to concerns with Health Canada alerts on safety and stopping of trials, a tumour group noted that the "*deaths were based on 1st line trials, where death is not as likely to happen, vs. the relapsed setting, where death is more likely. But with CMV monitoring, PCP prophylaxis, this may be mitigated*" |

## About Completing This Template

pCODR invites the Provincial Advisory Group (PAG) to provide feedback and comments on the initial recommendation made by the pCODR Expert Review Committee. (See www.pcodr.ca for information regarding review status and feedback deadlines.)

As part of the pCODR re view process, the pCODR Expert Review Committee makes an initial recommendation based on its review of the clinical, economic and patient evidence for a drug. (See www.pcodr.ca for a description of the pCODR process.) The pERC initial recommendation is then posted for feedback and comments from various stakeholders. The pCODR Expert Review Committee welcomes comments and feedback that will help the members understand why the PAG, either as individual PAG members and/or as a group, agrees or disagrees with the pERC initial recommendation. In addition, the members of pERC would like to know if there is any lack of clarity in the document and if so, what could be done to improve the clarity of the information in the pERC initial recommendation. Other comments are welcome as well.

All stakeholders have 10 (ten) business days within which to provide their feedback on the initial recommendation and rationale. If all invited stakeholders agree with the recommended clinical population described in the initial recommendation, it will proceed to a pERC final recommendation by 2 (two) business days after the end of the consultation (feedback) period. 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 a pERC final 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 pERC final 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

a) Only members of the PAG can provide feedback on the pERC initial recommendation; delegates must work through the PAG representative to whom they report.
    a. Please note that only one submission is permitted for the PAG. Thus, the feedback should include both individual PAG members and/or group feedback.

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

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

d) At this time, the template must be completed in English. PAG 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. Similarly, PAG 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 pERC Initial Recommendation 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.

g) References to support comments may be provided separately; however, these cannot be related to new evidence. New evidence is 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 considering to provide is eligible for a Resubmission, please contact the pCODR Secretariat.

h) The comments must be submitted via a Microsoft Word (not PDF) document to the pCODR Secretariat by the posted deadline date.

i) If you have any questions about the feedback process, please e-mail submissions@pcodr.ca.

*Note: Submitted feedback may be used in documents available to the public. The confidentiality of any submitted information cannot be protected.*