CADTH

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

Decitabine and Cedazuridine (Inqovi) for Myelodysplastic Syndromes

September 22, 2021

3 Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s):	decitabine and cedazuridine (Inqovi)
Eligible Stakeholder Role	Sponsor
Organization Providing Feedback	Taiho Pharma Canada

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

Taiho Pharma Canada agrees with the initial recommendation for decitabine and cedazuridine and supports the early conversion to a final recommendation. Taiho Pharma agrees with pERC that decitabine and cedazuridine therapy offers an additional treatment option with manageable toxicities for patients with MDS, and that the oral route of administration addresses the unmet need for patients to access effective treatment at home without having to visit specialized infusion centres or having to endure the discomfort of injected or infused treatments.

b) 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) 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 additional feedback from Taiho Pharma Canada			

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, 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 additional feedback from Taiho Pharma Canada			