CADTH

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

Nivolumab-Ipilimumab for Non-Small Cell Lung Cancer

March 4, 2021

Template for Stakeholder Feedback on a pCODR Expert Review Committee Initial Recommendation

3 Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s):	Nivolumab (OPDIVO®) plus ipilimumab (Yervoy®) First-line treatment of adult patients with metastatic or recurrent non–small cell lung cancer with no known epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumour aberrations
Eligible Stakeholder Role	Manufacturer
Organization Providing Feedback	BMS 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

Bristol-Myers Squibb Canada (BMS) agrees with the pERC initial recommendation for nivolumab (OPDIVO®) and ipilimumab (Yervoy®) and two cycles of platinum doublet chemotherapy (PDC) for the first-line treatment of adult patients with metastatic or recurrent non–small cell lung cancer (NSCLC) with no known epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumour aberrations. The pERC acknowledged the net overall clinical benefit with nivolumab plus ipilimumab and 2 cycles of PDC compared to PDC based on statistically significant and clinically meaningful improvements in overall survival , progression-free survival and objective response rate, maintenance of quality of life, and manageable toxicities.

BMS is committed to working with the provinces to facilitate access to Canadian patients with non–small cell lung cancer.

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

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