PAN-CANADIAN ONCOLOGY DRUG REVIEW

pan-Canadian Oncology Drug Review

Submitter or Manufacturer Feedback on a pCODR Expert Review Committee Initial Recommendation

Ipilimumab (Yervoy) for Advanced Melanoma

April 18, 2012

Feedback on pERC Initial Recommendation Name of the Drug and Indication(s):	**Yervoy (ipilimumab) for the treatment of advanced melanoma (unresectable Stage III and Stage IV melanoma) in patients who have received prior systemic therapy**
Role in Review (Submitter and/or Manufacturer):	**Manufacturer**
Organization Providing Feedback:	**Bristol-Myers Squibb Canada Co. (BMS)**

3.1 Comments on the Initial Recommendation

a) Please indicate if the Submitter (or the Manufacturer of the drug under review, if not the Submitter) agrees or disagrees with the initial recommendation:

__X__	*agrees*	____	*agrees in part*	____	*disagree*
Please explain why the Submitter (or the Manufacturer of the drug under review, if not the Submitter) *agrees, agrees in part or disagrees with the initial recommendation.*					

BMS recognizes that a thorough assessment of both the clinical and economic value of ipilimumab has been performed by pCODR and endorsed by the pERC.

The clinically meaningful benefit demonstrated by the hazard ratios for overall survival, median survival time and the proportion of patients surviving at one and two years, in Hodi 2010 was appropriately considered and weighed in the clinical evaluation. Limitations of the trial design, including gp100 vaccine and HLA-A*0201 status were also appropriately considered and did not impede the clinical review.

A need for effective standard treatment for metastatic melanoma in previously treated patients was clearly acknowledged.

Patient based values and inputs were well incorporated and balanced. The manufacturer recognizes that a limited amount of quality of life data was collected and is working on a plan to address this.

BMS is committed to training all healthcare professionals in the administration of ipilimumab including side effect management.

pCODR considered the submitted cost-effectiveness model robust and where data was limited, appropriate proxies were provided including expert opinion, survey and chart reviews.

As per the initial recommendation, BMS will work with provinces on pricing arrangements to improve cost-effectiveness and address provincial concerns.

b) Notwithstanding the feedback provided in part a) above, please indicate if the Submitter (or the Manufacturer of the drug under review, if not the Submitter) 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. Recommendation does not require reconsideration by pERC.*	____	*Do not support conversion to final recommendation. Recommendation should be reconsidered by pERC.*

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

The wording and intent in both the clinical and economic evidence presented on the initial recommendation were clear.BMS does not wish to provide any further comment and suggestion on this document.

However, there was confusion on the clinical guidance report, relating to the questions put forth by the PAG. Questions were not clearly identified as "asked and answered". Suggestion is to more clearly identify what questions have been posed with corresponding answers.