CADTH

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

Cabozantinib (Cabometyx) for Hepatocellular Carcinoma

April 22, 2020

3 Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s):	Cabozantinib (Cabometyx) in adult patients with unresectable hepatocellular carcinoma (HCC) in the second-line setting after progression on sorafenib or lenvatinib
Eligible Stakeholder Role	Sponsor
Organization Providing Feedback	Ipsen Biopharmaceuticals Canada Inc

** 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

Ipsen Biopharmaceuticals Canada Inc. agrees with the initial recommendation to reimburse cabozantinib (Cabometyx™) in adult patients with unresectable hepatocellular carcinoma (HCC) in the second-line after progression on sorafenib or lenvatinib.

Ipsen Biopharmaceuticals Canada Inc. agrees that there is a net clinical benefit of cabozantinib compared with best supportive care (BSC) based on clinically meaningful improvement in overall survival (OS) and progression-free survival (PFS) with no detriment to quality of life (QoL). We also agree with pERC's comment that Cabometyx™ is associated with overall manageable toxicities.

Ipsen Biopharmaceuticals Canada is committed to collaborating with the provincial public drug plans to facilitate access to Cabometyx™.

In summary, Ipsen Biopharmaceuticals Canada supports the early conversion of this initial recommendation to a final recommendation.

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

☒ Agrees ☐ Agrees in part ☐ Disagrees

Ipsen Biopharmaceuticals Canada Inc. agrees with pERC that the treatment should be used in adult patients with HCC after their progression on either sorafenib or lenvatinib. We agree with pERC and the CGP that because "there is currently no evidence to suggest that the efficacy of second-line HCC treatments would be influenced by the first-line therapy for drugs with a similar mechanism of action, "it would be reasonable for patients who progress on first-line therapy with sorafenib or lenvatinib to be eligible for cabozantinib" (page 3, initial recommendation)

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
			N/A

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
			N/A