CADTH

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

Brigatinib (Alunbrig) for ALK+ Non-Small Cell Lung Cancer

April 21, 2021

Stakeholder Feedback on a pCODR Expert Review Committee Initial Recommendation

3 Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s):	Brigatinib (ALUNBRIG) for ALK+ NSCLC
Eligible Stakeholder Role	Sponsor
Organization Providing Feedback	Takeda

** 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

Takeda agrees with the initial recommendation and supports early conversion to a final recommendation in order to ensure timely access to brigatinib for patients with unmet needs.

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
2	pERC recommendation	Paragraph 3, lines 6-8	The statements on the anticipated budget impact within each of these sections are unclear. On page 4, "…pERC noted that the anticipatory budget impact was likely small…". However, in the recommendation box on page 2, "CADTH's reanalysis of the sponsor's budget impact analysis suggests that the budget impact of introducing brigatinib to the market is moderate but was underestimated." In order to improve clarity, the wording in the recommendation box should reflect pERC's conclusion on page 4.
4	Summary of pERC Deliberations	Paragraph 5, lines 2-4.	

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
N/A			