CADTH

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

Gilteritinib (Xospata) for Acute Myeloid Leukemia

May 20, 2020

Name of the Drug and Indication(s):	Gilteritinib (Xospata) for Acute Myeloid Leukemia (AML)
Eligible Stakeholder Role	Patient Group
Organization Providing Feedback	The Leukemia & Lymphoma Society of Canada
[redacted]	

** 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

The Leukemia & Lymphoma Society of Canada is pleased that pERC has recognized the need for additional treatment options that improve the chances of survival for AML patients.

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

☐ Agrees ☐ Agrees in part ☐ Disagrees

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

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