pan-Canadian Oncology Drug Review

Patient Advocacy Group Feedback on a pCODR Expert Review Committee Initial Recommendation

Regorafenib (Stivarga) Resubmission Metastatic Colorectal Cancer

Colorectal Cancer Association of Canada

July 16, 2015

Feedback on pERC Initial Recommendation

Name of the drug indication(s): Regorafenib (Stivarga®) for mCRC

Name of registered patient advocacy: Colorectal Cancer Association of Canada (CCAC)

**pCODR may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by pCODR.*

1.1 Comments on the Initial Recommendation

a) Please indicate if the patient advocacy group agrees or disagrees with the initial recommendation:

____ agrees ____ agrees in part __X_ disagree

Please explain why the patient advocacy group agrees, agrees in part or disagrees with the initial recommendation.

Third and fourth line patients are very much in need of an additional therapeutic option to help manage their metastatic colorectal cancer (mCRC), help maintain QoL and prolong overall survival (OS). The CORRECT and CONCUR Studies have demonstrated Regorafenib's ability to increase OS and progression free survival (PFS). While pERC considered Regorafenib to confer only a modest overall clinical benefit with significant toxicities and decline in Quality of Life (QoL) similar to placebo, patients surveyed have repeatedly reported how important it would be to access additional treatments whose benefits might only be short term despite treatment adverse effects. Patients surveyed would not refuse taking a cancer therapy based on a severe toxicity profile. Furthermore, as stipulated in our submission, the CCAC QoL survey demonstrated that part of maintaining QoL for patients is linked to providing greater access to therapies that treat mCRC. Based on the above-noted points, the pERC recommendation does not align with our patient values.

b) Notwithstanding the feedback provided in part a) above, please indicate if the patient advocacy group 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.

____ Support conversion to final recommendation.	__X__ Do not support conversion to final recommendation.
Recommendation does not require reconsideration by pERC.	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
5	Overall Clinical Benefit	5; 7	A "modest" clinical benefit is nevertheless found to be statistically significant and still a benefit – highly sought after by 3rd and 4th line patients.
5	Overall Clinical Benefit	8-9;	The patients interviewed in our patient vignettes all agreed that dose modifications resolved the Regorafenib-related toxicity issues quite nicely.

1.2 Comments Related to Patient Advocacy Group Input

Please provide feedback on any issues not adequately addressed in the initial recommendation based on patient advocacy group input provided at the outset of the review on outcomes or issues important to patients that were identified in the submitted patient input. Please note that new evidence will be not considered during this part of the review process, however, it may be eligible for a Resubmission. If you are unclear as to whether the information you are providing is eligible for a Resubmission, please contact the pCODR Secretariat.

Examples of issues to consider include: what are the impacts of the condition on patients' daily living? Are the needs of patients being met by existing therapies? Are there unmet needs? Will the agents included in this recommendation affect the lives of patients? Do they have any disadvantages? Stakeholders may also consider other factors not listed here.

Page Number	Section Title	Paragraph, Line Number	Comments related to initial patient advocacy group input
6	Patient Based Values	4; 3	One patient vignette included input of no treatment-induced toxicities and the patient had been undergoing therapy for 18 months. This is a patient for whom early management of toxicities was NOT required and clearly pERC failed to mention this in their recommendation. This patient may fall into a subset of the mCRC population for whom Regorafenib may be clinically effective while maintaining QoL.

1.3 Additional Comments About the Initial Recommendation Document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments
6	Patient Based Values	4;2	Some patients such as Patient #1 reported in our Patient Vignettes continue to benefit from the therapy for a period of at least 18 months. Consideration should, therefore, be given to funding patients who exceed median overall survival period. In cases of a negative recommendation, pCODR should be given the mandate to recommend funding on a risk sharing basis to address this important need while gathering further data.
2	Summary of pERC Deliberations	3;4-5	A modest clinical benefit is nevertheless considered to be a benefit to treatment refractory mCRC patients. In the metastatic setting, long term health is relative and is viewed by patients in small increments, which includes "modest benefits". Falling behind the standard of care to the rest of the world is not viewed as an option by patients.