pan-Canadian Oncology Drug Review Stakeholder Feedback on a pCODR Request for Advice (Patient Advocacy Group)

Bosutinib (Bosulif) for Chronic Myeloid Leukemia

August 1, 2019

3 Stakeholder Feedback on a pCODR Request for Advice

Name of the drug indication(s): **Bosutinib – Chronic Myelogenous Leukemia**

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

3.1 Information to inform the Request for Advice

a) Please indicate your affiliation:

____ Submitter/Manufacturer __X__ Patient Advocacy Group ____ Registered Clinician(s)

Please include name of your organization (or individual names for registered clinicians)
The Chronic Myelogenous Leukemia (CML) Society of Canada

b) Please provide comments on the Request for Advice question(s).

We interviewed several patients who are currently being treated with Bosutinib in Canada, who had been treated with other TKI's and were either resistant or intolerant to the other TKI's currently available for treatment of chronic phase (CP) CML. The majority of patients reported being started on imatinib/Gleevec at diagnosis of CP CML. Initial response to therapy was good, in the majority of the cases. Although one patient reported that there was little clinical response to imatinib with highly intolerable side effects almost immediately at the start. In the other patients, who reported a good response initially to imatinib and a reasonable ability to tolerate side effects, it was a build up of side effects that eventually led to an overall intolerability of the drug, which triggered the switch to another TKI. One patient reported being started on dasatinib/ sprycel at diagnosis. They reported this drug worked very well for about 3 years. Unfortunately the patient developed severe pleural effusions during the 4th year of treatment which necessitated a TKI change. The majority of the patients switched to dasatinib (Sprycel) as an alternative, with the exception of the one patient who started nilotinib (Tasigna). The patient on nilotinib reported that unfortunately nilotinib triggered severe reactions and was only able to stay on this treatment for 6 weeks. This patient later went on to Gleevec. The patients who reported being treated with dasatinib as a 2 nd line treatment, all reported good clinical responses and excellent tolerability. However, in all cases, after a few years of treatment, serious complications of pericarditis, pleural effusions,

necessitated another TKI change.

With the exception of the one patient mentioned earlier, all of the patients we interviewed reported to us that they are very reluctant to try nilotinib given the black box warning. The patients told us that un less they were given the option of a thorough cardio oncology work up, they would not consider trying that drug. We should point out that the majority of the patients we interviewed for this report were below the age of 40 and were diagnosed in their early thirties. We realize that we naturally attracted this age group because our outreach was mainly conducted on-line, through patient chat groups and through appealing to current CML patients being treated with bosutinib via our Facebook page. None-the-less, this patient group is very concerned with QoL, being able to work and provide for their young family, while making treatment choices that may help them preserve their health over the long term treatment.

All of the patients we interviewed and have provided history for here are currently being treated with bosutinib. All of the patients reported to us, as of the time of their interview with us, they are experiencing good clinical results and better tolerability then what they had experienced with their prior TKI therapy. All patients reported going through a few weeks of adjustment to bosutinib which included severe diarrhoea, which was well managed, but has improved significantly.

As a side note, particularly in the younger patient population, these patients do not consider that they have four TKI's to chose from. Interestingly, some of the patients we interviewed hinted to us that they may have chosen to move away from imatinib as they were concerned about being forced to try a generic version, which they have been told is not equivalent or safe as the branded. So, it may have been a combination of the build up of side effects along with the anxiety of having to move to a generic drug that escalated the need for a switch in TKI. We are very concerned about this and would be very concerned if this becomes a trend in general. It is important that we recognize this fact and manage it better. As of January 1, 2020 dastainib will become generic. Patient education on generics will be very important as it will further reduce 'perceived choices' in TKI treatment for a sub set of this patient population.

The CML Society of Canada will certainly need the help of the community and CADTH to better educate this important patient population.

1 About Completing This Template

CADTH's pan-Canadian Oncology Drug Review program invites eligible stakeholders to provide feedback on the Request for Advice made by the pCODR Advisory Committee (PAC) or by the Provincial Advisory Group (PAG).

A Request for Advice is a written request made by PAC or by PAG, to the pCODR Expert Review Committee (pERC) for advice on specific therapeutic, clinical or pharmacoeconomic issues, or regarding a pERC Recommendation, which may result in a new Recommendation. The Request for Advice will be regarding a previous pERC Final Recommendation.

Stakeholders, including the submitter/manufacturer(s) of the drug(s) in question, patient advocacy groups and registered clinician(s) who provided input on the original submission in question are invited to comment or provide information using this template to help inform the question(s) or issue(s) raised by PAC or PAG ten (10) business days from the date of posting on the CADTH website.

When considering a Request for Advice, pERC may address the request by providing one of the following:

a) a revised pERC recommendation that would supersede a previous pERC Final Recommendation

b) a pERC Record of Advice document containing additional context and/or clarifications regarding a pERC Final Recommendation.

In either case, the pERC Record of Advice or revised pERC recommendation and supporting report will be posted ten (10) Business Days following the pERC Meeting on the pCODR section of the CADTH website.

2 Instructions for Providing Feedback on a pCODR Request for Advice

a) Only stakeholders who provided input on the original submission in question are invited to comment or provide information on the Request for Advice.

b) The template for providing *Stakeholder Comments on a pCODR Request for Advice* can be downloaded from the CADTH website. (See https://www.cadth.ca/pcodr/guidelines-procedures-and-templates for a description of the pCODR process and supporting materials and templates.)

c) At this time, the template must be completed in English. The comments should not exceed six (6) pages in length, using a minimum 11 point font on 8 ½" by 11" paper. If comments submitted exceed six pages, only the first six pages will be forwarded to the pERC.

d) Comments should be presented clearly and succinctly in point form, whenever possible. Comments must relate to the question at issue and the information provided must be made fully disclosable.

e) References to support comments may be provided separately.

f) The comments must be submitted via a Microsoft Word document to the pCODR program by the posted deadline date.

If you have any questions about the request for advice process, please e-mail info@pcodr.ca