Common Drug Review
Patient Group Input Submissions

Revolade (Eltrombopag) for Thrombocytopenia, Chronic Hepatitis C-Associated

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.
Gastrointestinal Society — permission granted to post.
HepCBC Hepatitis C Education and Prevention Society — permission granted to post.

CADTH received patient group input for this review on or before August 28, 2014

CADTH posts all patient input submissions to the Common Drug Review received on or after February 1, 2014 for which permission has been given by the submitter. This includes patient input received from individual patients and caregivers as part of that pilot project.

The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations. While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

GI (Gastrointestinal) Society

1. General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Revolade® (eltrombopag) for the treatment of thrombocytopenia in individuals with hepatitis C
Name of the patient group	Gastrointestinal Society
Name of the primary contact for this submission:	[redacted]
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Website	www.badgut.org
Permission is granted to post this submission	Yes

1.1 Submitting Organization

Our mission: As the Canadian leader in providing trusted, evidence-based information on all areas of the gastrointestinal tract, the GI (Gastrointestinal) Society is committed to improving the lives of people with GI and liver conditions, supporting research, advocating for appropriate patient access to health care, and promoting gastrointestinal and liver health.

Canadian health care professionals request more than 550,000 of our BadGut® Basics patient information pamphlets each year, and tens of thousands of Canadians benefit from our important quarterly publication, the *Inside Tract*® | *Du coeur au ventre*^{MC} newsletter.

Our free BadGut® Lectures from coast to coast cover various digestive and liver conditions for patients, caregivers, and other interested individuals. We also have dynamic websites in English (www.badgut.org) and French (www.mauxdeventre.org). Organized on a number of topics, GI Society support group meetings offer a wealth of information for those newly diagnosed with a gastrointestinal disorder, as well as those who have lived with a condition for years.

Our highly-trained staff and volunteers offer additional patient resources, including responding to information requests and participating in community initiatives. Staff and advisors work closely with health care professionals, other patient groups, governments at all levels, and health care thought leaders on behalf of GI patients. In addition, we occasionally hold continuing education events for pharmacists, nurses, dietitians, and physicians. The GI Society, along with its sister charity, the Canadian

Society of Intestinal Research (CSIR – founded in 1976) has supported a number of significant clinical, basic, and epidemiological research projects in the field of gastroenterology.

1.2 Conflict of Interest Declarations

1.2.1 We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements

The GI Society receives financial contributions from pharmaceutical companies in support of our independent charitable work for Canadians affected by GI/liver conditions. Supporters have no input into the editorial content of our resource material, which is approved by the GI Society's Medical Advisory Council (made up of GI/liver health experts only). Pharmaceutical companies from whom we have received support of any kind, such as charitable donations or grants, sponsorships, subscriptions to the *Inside Tract®* newsletter, etc. in the last two years include:

Abbott Laboratories Ltd, AbbVie Corporation, Amgen Canada Inc, Actavis (as Aptalis Pharma, Forest Laboratories, and Warner Chilcott), AstraZeneca Canada Inc., Bristol-Myers Squibb Canada, Canada's Research-Based Pharmaceutical Companies (Rx&D), Ferring Inc., Gilead Sciences Canada Inc., GlaxoSmithKline Inc., Hoffmann-La Roche Ltd., Janssen Canada, Merck Canada Inc., Medical Futures Inc., Novartis Pharma Canada Inc., Cubist Pharmaceuticals (as Optimer Pharma), Pfizer Canada Inc., sanofi-aventis Canada Inc., Takeda Canada Inc., and Vertex Pharmaceuticals (Canada) Inc.

1.2.2 We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission

None. The GI Society has prepared this submission entirely independently of any outside groups or individuals.

2. Condition and Current Therapy Information

2.1 Information Gathering

This information was obtained primarily through contact (interviews, etc.) with patients affected by hepatitis C (HCV) and HCV nurse specialists, as well as the expertise of our health care professional council and advisors (gastroenterologists, hepatologists, pharmacists).

2.2 Impact of Condition on Patients

Thrombocytopenia, a condition characterized by low platelet levels, causes bruising and easy bleeding. Perhaps most significantly for hepatitis C (HCV) patients, thrombocytopenia makes it difficult or impossible for an effected patient to receive treatment for their hepatitis C. Without HCV treatment, they languish with a stigmatized, malevolent, and infectious disease that can eventually lead to severe liver damage, such as cirrhosis.

HCV can affect patients in every facet of their lives, including professional and personal relationships, and in their ability to perform required duties at work and at home. It's one thing to care for one's self, but many with HCV are also caretakers for others.

HCV becomes chronic in approximately 75% of infected people. Most chronic carriers have few or no symptoms but some report fatigue, general weakness, and vague discomfort in the area around the liver. In about 25%, chronic HCV can lead to cirrhosis of the liver and cirrhosis may lead to liver cancer. All these symptoms and potential outcomes take their day-to-day toll and can lead to death.

The biggest physical factor patients report having to manage is fatigue. What's worse, the fatigue can be unpredictable. Some have to ask themselves each morning, "Will I have enough energy to do the things I need to do today?" If HCV symptoms disrupted their sleep the night before, as it often does for patients with more severe disease, then the answer will be "No."

Similarly, the disease can affect cognitive functions. Try to imagine getting through your day when your memory and focus are impeded because your body has to work so hard to clear toxins via a liver that is functioning at far less than capacity.

The GI Society represents patients with a variety of gastrointestinal and liver conditions, almost all of which are highly stigmatized. It is not easy to talk about an infection with hepatitis C as it is to, say, disclose a heart or lung condition. Patients can begin to define their lives by their disease while hiding it from others. They suffer from depression, anxiety, isolation, and other mental health consequences of hepatitis C.

A cure means freedom from days filled with debilitating fatigue and from lives dominated by stigma-centred fear. Healthy people with optimism about their lives and physical health can have a positive impact on reducing the public healthcare burden. Additionally, as individuals with hepatitis C carry on with the virus ravaging their bodies, they are more likely to spread the disease to others; by eradicating the virus from infected individuals, we can prevent further spread. Patients suffering from HCV with thrombocytopenia would have a chance to pursue a cure through HCV treatment if they could just receive effective treatment for thrombocytopenia.

2.3 Patients' Experiences With Current Therapy

The previous standard of care treatment for hepatitis was long and gruelling, but new triple therapy medications are an improvement over dual therapy and many patients express a willingness to endure some risks and side-effects. However, hepatitis C patients with thrombocytopenia might never get the chance to even try available treatments.

Affordable access to Revolade® could be the missing piece of the treatment puzzle that leads some patients – otherwise abandoned to a life sentence with this disease or death – to a new hope for a cure.

2.4 Impact on Caregivers

Hepatitis C, especially when it becomes severe or is accompanied by complications like thrombocytopenia, sometimes means having to take time off work and major childcare or other caregiver duties, putting an extra societal burden on other family members. If more individuals can pursue a cure from hepatitis C through treatment, then fewer patients' family members and caregivers will experience hardship.

3. Information About the Drug Being Reviewed

3.1 Information Gathering

This information was obtained primarily through contact (interviews, etc.) with patients affected by hepatitis C, hepatitis C nurse specialists, and the expertise of our health care professional council and advisors (gastroenterologists, hepatologists, pharmacists).

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

3.2.1 Based on no experience using the drug

On behalf of the many Canadian patients we represent, I encourage you to recommend coverage within Canadian drug programs for this crucial new medication that can support more hepatitis C patients in Canada while they go through treatment to achieve a cure from this crushing disease. We understand that two of the most important criteria that CADTH considers are cost effectiveness and the impact a new medication will have on the population. We believe eltrombopag (Revolade®) deserves coverage based on both factors.

Physicians prescribe Revolade® to increase a patient's level of platelets, a type of blood cell that allows the blood to clot, thus preventing or reducing bleeding. This is important to hepatitis C patients because many of these individuals suffer from thrombocytopenia, which makes it difficult or impossible to receive effective hepatitis C treatment.

Studies show that Revolade®, used prior and during hepatitis C treatment, gives these patients a more reasonable chance of staying on their hepatitis C treatment medications, at the optimal dose and for the required amount of time, in order to effectively cure them of hepatitis C.

Revolade® is not about making things in life more convenient for patients, but it is about enabling more of them to adhere to treatment and get back to their normal lives as soon as possible. We urge you to recommend that this Health Canada-approved medication be included in the coverage lists of Canadian drug plans.

We know new medications are expensive, but in the long-term, unhealthy people are more of a burden on the health care system than are healthy people. For patients who have severe forms of the disease (e.g., cirrhosis, liver cancer), the long-term effect of being denied appropriate treatment will likely be far more costly, due to liver transplants or other, ongoing expensive medical interventions.

Low socioeconomic status is a risk factor for hepatitis C, which means one of the demographics that is most susceptible to becoming infected with hepatitis C is also very unlikely to be able to afford this new medication on their own. While they languish with this disease, their chances of recovery are diminished, not just physical recovery, but in the sense of getting over the disease and moving forward with their lives as valuable citizens in the community.

It makes sense to us, and to the patients who we represent, that when a medication is available that contributes to a cure, then the person with the disease should have reasonable access. Please don't leave hope beyond their grasp.

Not everyone with hepatitis C would benefit from Revolade®, but for patients with thrombocytopenia who need it, we strongly encourage a positive recommendation for coverage.

4. Additional Information

None.

HepCBC Hepatitis C Education and Prevention Society

1. General Information

Name of the drug CADTH is reviewing and indication(s) of interest	REVOLADE for use for Low Platelets in Chronic Hepatitis C
Name of the patient group	HepCBC Hepatitis C Education and Prevention Society
Name of the primary contact for this submission:	[redacted]
Position or title with patient group	[redacted]
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Telephone	250-595-3892
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Website	www.hepcbc.ca
Permission is granted to post this submission	Yes

1.1 Submitting Organization

HepCBC is a non-profit society run by and for people infected and affected by hepatitis C. Our mission is to provide education, prevention and support to those living with HCV. Our office with our only paid employee (an office mgr.) is in Victoria, BC. We also have activities and groups in Nanaimo, BC and Surrey, BC. Our representatives attend provincial and federal-level conferences and we give information and support world-wide through our website. We publish a monthly bulletin, the hepcbull. We focus on providing "clean and sober" peer support groups, anti-stigma activities, prevention education to young people, and encourage testing among at-risk groups -- including those who are no longer at risk but may have contracted hepatitis C decades ago. We work alongside local HIV/AIDS organizations in support of co-infected people.

1.2 Conflict of Interest Declarations

1.2.1 We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements

HepCBC Hepatitis C Education & Prevention Society has received funding for hepatitis C-oriented projects such as publishing educational materials, organizing educational forums, attending and presenting at educational conferences, advertising in newspapers (events and hepatitis C patient awareness), and holding awareness activities from the following pharmaceutical companies over the last three years: Merck Pharmaceuticals, Hoffman-LaRoche, Vertex Pharmaceuticals, Gilead Sciences, Janssen Pharmaceuticals, Bristol-Myers Squibb, Boerhinger-Ingelheim, and AbbVie.

1.2.2 We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission

The author of this report has attended several educational conferences and meetings for which registration and travel expenses were funded by the pharmaceutical companies listed above.

2. Condition and Current Therapy Information

2.1 Information Gathering

This report was developed using data provided by seven (7) individuals:

1. A patient survey advertised through our website and our email list. No one replied to it, unfortunately.
2. Input from two (2) HCV+ volunteers who have actively manned HCV+ phone and email support systems for several years, and have extensive knowledge of patient concerns and experiences.
3. Aggregate input from five (5) HCV+ participants at our August monthly support groups has also been added.

2.2 Impact of Condition on Patients

As a patient group for those affected by hepatitis C, we at HepCBC have had extensive experience with people suffering from low platelets as a result of cirrhosis. The best way of dealing with CHC cirrhosis is to cure the hepatitis C so the liver damage will stop. However, many people with this advanced level of the disease are ineligible to get treatment due to low platelets which put them in clear danger of bleeding to death. This is particularly the case if the patient also suffers from bleeding varices.

An additional problem is that patients who are on interferon treatment often develop low platelets, and if this situation cannot be reversed, they are pulled off treatment. These patients are condemned to worsening CHC, including likely development of cirrhosis over time as well of increased risk of liver cancer and liver failure.

2.3 Patients' Experiences With Current Therapy

CHC patients with low platelets are currently given infusions, injections, and less frequently, transfusions. These are both painful and inconvenient. Mostly, they don't seem to get any treatment at all.

2.4 Impact on Caregivers

That patients are either ineligible for treatment, or must stop treatment, due to low platelets, can be devastating to family, friends, and caregivers as well as the patient. This is particularly frustrating if they know a drug is out which could solve this problem, and is in once a day oral form, yet it is not accessible by Canadian CHC patients. Often the caregiver must take over raising children and being the sole breadwinner of the family, at the same time that the patient's need for attention is also increasing. This puts incredible strain on the caregiver and frequently leads to family breakdown. This situation can be a drain on the larger society, which in the end, often ends up helping support the patient and the family as well.

3. Information About the Drug Being Reviewed

3.1 Information Gathering

Same as in Section 2.1.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

3.2.1 Based on no experience using the drug

- Patients who are ineligible for treatment, or unable to complete treatment, could have these barriers lifted, so more people would be able to clear the virus. These people would have a great chance for a longer, more productive life.
- Patients are generally willing to do almost ANYTHING to get rid of hepatitis C virus, so if this drug enabled them to initiate and complete treatment, those we at HepCBC deal with every day would be delighted to put up with fairly severe side-effects if that meant they would be cured.
- Unfortunately we know that the potential side-effects of this drug can be quite devastating, and that patients need be carefully prepared and monitored during treatment with this drug. Those with very advanced cirrhosis will likely not even be able to take this drug at risk of hepatic decomposition, ironically due to REVOLADE's high hepato-toxicity. That it also should not be used in elderly patients or those with reduced renal or cardiac problems is not good news for the large aging population of HCV+ Baby Boomers.
- This drug would likely result in fewer deaths, higher rates of treatment starts and completions, fewer hospital visits, and less time off work. This health improvement could result in greater financial stability, greater mental stability, and fewer family breakdowns.

3.2.2 Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply

We do not know of anyone who has had experience with REVOLADE.

4. Additional Information

(HepCBC): We fully support listing REVOLADE in Canada for use with any patient with chronic hepatitis C and low platelets, depending on extremely close monitoring of those patients whose condition may potentially contraindicate the drug. Hopefully as new treatments for HCV develop which do not result in low platelets, and as patients are treated before their disease has developed into advanced cirrhosis, drugs such as REVOLADE will no longer be required.