CADTH

Patient Input Template for CADTH Reimbursement Reviews

Name of Drug: ribociclib (Kisqali)

Indication: Ribociclib for the adjuvant treatment of patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer (eBC), in combination with an aromatase inhibitor (AI), in pre- or perimenopausal women, or men, the AI should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.

Name of Patient Group: Rethink Breast Cancer

Author of Submission: Jenn Gordon

1. About Your Patient Group

Rethink Breast Cancer (Rethink) is a Canadian charity known for making positive change. Rethink educates, empowers and advocates for system changes to improve the experience and outcomes of those with breast cancer, focusing on historically underserved groups: people diagnosed at a younger age, those with metastatic breast cancer and people systemically marginalized due to race, income or other factors. We foster spaces to connect, listen, empower and rethink breast cancer, together. Rethink's strategic priorities and organizational direction are guided by the unique, unmet needs identified by breast cancer patients and their families.

Programs and Activities

- Rethink Breast Cancer builds community, bringing patients with various stages of breast cancer together through our private and public social spaces as well as in-person events
- Rethink runs patient retreats and facilitates peer-support
- Rethink creates and runs education forums and conferences
- Rethink creates support and education tools, resources and content
- Rethink funds and supports breast cancer research

You can find out more by visiting:

Rethink Breast Cancer Instagram
Rethink Breast Cancer Website

2. Information Gathering

For over 20 years, Rethink has been working closely with breast cancer patients in Canada. We learn from and listen to the community to understand their values, priorities and pain points to help drive change and system

improvements. Each year, we learn from the patients we serve, survey and collaborate with. We learn from the 24 individuals that we work extremely closely with as key patient advisors; the 50 patients that share their stories on our blog; the 500 patients that participate in our virtual support groups; the 2,200 members of our private peer-support network; and the 43,000 people that have joined our Instagram community. We listen, learn, engage and have conversations in all these spaces.

For this submission, we have drawn on our general observations and insights gathered through programming and meetings with breast cancer patients as described above. Rethink also conducted in-depth telephone interviews between August 2024 and December 2024 with 4 patients who have experience with ribociclib for HR+, HER2- high risk early breast cancer.

3. Disease Experience

The majority of the people in the Rethink community are diagnosed at a younger age, between 20 and 50 years old. When younger people get breast cancer it may be more aggressive, which can lead to tougher treatments. In addition, those diagnosed in their 20s, 30s and early 40s face age-specific issues such as fertility or family-planning challenges, diagnosis during pregnancy, childcare, impact on relationships, body image, dating and sexuality, feeling isolated from peers who don't have cancer, career hiatuses, and financial insecurity. The physical and emotional toll that a breast cancer diagnosis and treatment takes on a young person's life is devastating and traumatic.

When it comes to those in the community who have been told their breast cancer is at a higher risk of recurrence, treatment is less about controlling an aspect of the illness and more a deep desire to take on whatever treatment(s) are needed to decrease the chance of recurrence and metastasis. They are facing mortality prematurely and many express a goal to treat aggressively to optimize treatment. Here's what patients from our community with early-stage breast cancer had to say about the importance of reducing their risk of recurrence:

"I think when anyone gets a cancer diagnosis, you're always scared of the illness coming back. Especially when I have young kids that I want to be there for, and I have a lot of things I want to do myself. It's not only my kids, but also my life too. I want to be able to enjoy it. Because I feel that I'm doing anything and everything that's available out there to have a lower chance of recurrence, it gives me peace of mind. It gives me less anxiety in my life." – Negar

"I am generally a fan of treatment - the more aggressive the better. In fact, after having chemo done, I advocated to have a total axillary LN dissection, and I also had my ovaries out last year. Again, I don't mind treatment at all, even the side effects that come with it - I'm more concerned about the prospect of mortality." –Ada

"I want to try anything to prevent recurrence, I want to add it to my exercise routine and healthy diet in my bag of tricks." –Jessica

"I had the perspective of, "I'll do it all"; anything I could do to help prevent recurrence I wanted to do. It was worth having any possible additional side effects to know that I was doing everything I could to reduce my risk of recurrence." – Emily

"I have three young kids, so I was really willing to do anything possible to would have done anything to help prevent the cancer from returning" - Liane

4. Experiences With Currently Available Treatments

Current treatment for HR positive HER2 negative early breast cancer depends on the specifics of each individuals' diagnosis and the characteristics revealed on their pathology report. It is usually treated with a combination of surgery, chemotherapy, radiation therapy, and targeted hormone therapy, which can reduce the risk of early-stage breast cancer coming back. Some patients with higher risk, and certain genetic mutations, may also opt for an oophorectomy.

There is also currently one CDK4/6 inhibitor, abemaciclib, that is available to this patient population to help reduced the risk of recurrence. The intent to treat population for ribociclib is broader than the abemaciclib intent to treat population, which would allow more patients to access a therapy that has proven to help reduce risk of recurrence. In addition, the side effect profile between abemaciclib and ribociclib is different, the duration of treatment is different, and the dosing schedule is different. Having two options for patients and clinicians to choose from is important as co-morbidities might dictate which therapy is more suitable, patient preference around side effects/dosing/duration is an important consideration, and specifics of their diagnosis may dictate that one treatment is more suitable than the other.

5. Improved Outcomes

Each individual patient brings their own personal values and goals to their discussions with their oncology team. Communication and trust in their team is essential. In our experience working closely with many young high risk breast cancer patients, we find most are willing to trade toxicity for confidence in knowing they've "thrown everything they could" at the cancer. In other words, they will choose to endure additional side-effects and impacts on quality of life from the toxicity of a stronger therapy to ensure they are doing everything they can to treat what they know is an aggressive form of breast cancer. That was a take-away mentioned by patients who were interviewed specifically for this submission and other early-stage breast cancer submissions.

Reducing the risk of recurrence is of particular importance to younger women, under the age of 50, who don't just want to have their cancer in remission for 5 or 10 years, but rather for several decades as they are still young, may be in the middle of raising kids, still have a lot they want to accomplish in their careers and their lives.

6. Experience With Drug Under Review

Rethink conducted in depth phone interviews with four patients with high-risk early breast cancer who have experience with ribociclib.

Patient #1: Emily

I was diagnosed in the summer of 2018 at the age of 38. I felt a lump and went to get it checked out. Within 1 month I received my diagnosis. I had stage 3 HR+ breast cancer and received surgery, chemotherapy, radiation, and targeted therapies.

I wasn't aware of ribociclib at the time and finished active treatment in March of 2019. I had reconstruction and recovered from reconstruction before starting ribociclib. My oncologist shared the option of joining the ribociclib trial. I realized I was committing to a 5-year trial that was randomized and I wouldn't know until later if I was receiving ribociclib or not. I was taking tamoxifen and switched to an aromatase inhibitor in order to participate in the trial.

Being a young woman, and also a mom of two daughters, I wanted to help advance breast cancer science, whether it was for me or for others.

Leaving active cancer treatment felt scary, and being able to stay connected with my oncologist and being followed for 5 years provided some reassurance that I was looking for. The trial will be finished in January 2025, but I was informed that I was on the ribociclib arm.

Being diagnosed with cancer at 38 was terrifying. I had no family history, I had no risk factors for being diagnosed with breast cancer. Not having something to point to say "this is why I got cancer' was really destabilizing. The uncertainty and fear, and anxiety was very real; anxiety over every little headache for example.

I had the perspective of, "I'll do it all"; anything I could do to help prevent recurrence I wanted to do. It was worth having any possible additional side effects to know that I was doing everything I could to reduce my risk of recurrence. Although, I don't think that most of my side effects were a result of the ribociclib, I think they were mostly from taking the Zoladex and letrozole. The biggest impact and challenge was that instead of easing into natural menopause, it was like being thrown off a cliff into a medical menopause. Body aches, weight gain, fingernails splitting, thinning hair, aching feet the second I got out of bed. But all of these side effects were most likely not from the ribociclib, so adding it, didn't really impact my quality of life negatively.

I feel amazingly fortunate to be in the trail, and I am thrilled to know I received the drug. It helps my mental health a huge amount. But knowing that I have accessed something in addition to the standard of care makes me feel fortunate.

I have friends who have been diagnosed who can't access ribociclib because it hasn't been approved yet. I'm really glad to see that the results of the trial showed a positive impact and that I was able to access this treatment when I did.

I have two daughters. They're 11. When I was diagnosed with breast cancer, I was faced with the idea that there was a possibility that I wouldn't be here for them; which is something that I had always just taken for granted. The idea that I would miss out on the ability to help them through their life, was too much to bear. Having access to all the treatments that are available gives me reassurance that I have done everything I can to reduce my risk of recurrence. I feel fortunate that I had access to ribociclib. Getting breast caner is incredibly unlucky at my age, and especially concerning and anxiety causing when there's not way to pin-point how to stop it; so, this treatment helps with that. It also helped me have a sense of control in a situation where so many things are out of my control.

It's been 6 years, I am still on the hormone reducing medications, I am off ribociclib. I am back to a job that I love and that I find a lot of meaning in. I am active with friends and within my community. My girls are starting middle school this year and I am back to being a person who is living their life, and that's not something I will every take for granted again.

Patient #2: Wishes to remain anonymous

I had just finished my school degree in June of 2023, when I was diagnosed with breast cancer in July of that same year at the age of 35. I was diagnosed with HR+, stage 2 or 3 breast cancer, grade 2, with two tumours, one 2.5cm and one 1.5cm.

In August 2023 I started on ribociclib + Zoladex + letrozole. I am being treated at a teaching/research hospital which I feel has made a big difference in giving me the option to try new therapies. My oncologist mentioned that he had seen good results with this therapy in some of his other patients He also mentioned that the side effect profile was better than some of the other therapies. I had surgery in March of 2024, with clear margins, although small in certain spots. The tumour was 30% dead at the time of surgery.

Given that I had just finished school, I had no job, no benefits and no EI hours to use. A social worker helped me apply for several foundations for funds, and the manufacturer co-pay is what is currently covering the cost of ribociclib. Without the assistance program from Novartis, there is no way I could afforded $5,000 per month on my own.

I was able to look for work, secure a job, and then work at that job all while going through treatment. The most noticeable side effects were the medically induced menopause which was a result of the other drugs I was taking as a part of my treatment, not the ribociclib. I did experience neutropenia which was believed to be a result of the ribociclib, but my physician was able to help manage this, and I managed the impact on her immune system by wearing a mask when riding transit, working, or in situations where I may have higher exposure to viruses. It is disruptive trying not to get sick, I often need to isolate myself from friends and family if they are sick, which can be hard.

My oncologist did reduce my dose after surgery and this seemed to really help manage the neutropenia.

I did not lose my hair, which was really nice, and also really helpful because I didn't have to tell people I was sick, which is huge when you're looking for work. It's hard to apply for work when you look sick.
The nausea only happened a few times, but that was manageable. I received some heart scans at the beginning, but it was determined that I was fine, so we stopped the heart scans.

Also, taking an oral drug meant that I wasn't at the hospital all the time.

Patient #3: Liane

I was diagnosed with breast cancer in May 2019 at the age of 41. I found my own lump and went to my family doctor who referred me for an ultrasound, and then I went to Princess Margaret Hospital for a biopsy. I was diagnosed with Stage 2 HR-positive breast cancer. My tumour was 1.9cm and grade 3 with lymph node involvement. While the tumour

was relatively small, the lymph node involvement and grade 3 was what made it harder to deal with and more serious in terms of risk of recurrence.

I went on to have surgery, with immediate reconstruction on the affected breast. I then started chemotherapy at Sunnybrook, 4 weeks after surgery with dose dense ACT. This was followed by radiation for 3 weeks, also at Sunnybrook.

I did a lot of research, a lot of reading, and was looking to do anything I could to reduce my risk of recurrence. I asked my oncologist about studies I could participate in. She had heard about the palbociclib trial, which was closed, but shared that they did have the NATALEE trial for ribociclib open and that I qualified for that trial. I was randomized to receive the drug, which felt to me like was like God answering my prayers. I don't know how to put into words how lucky I feel to have received that cancer drug because I would have done anything to reduce my risk of recurrence.

I have three young kids, so I was really willing to do anything possible to would have done anything to help prevent the cancer from returning. I was incredibly happy to be put in the arm of the trial that received ribociclib. I took this therapy for three years, along with an aromatase inhibitor and Zoladex. I did go off the drug for a short period of time while I had a prophylactic mastectomy on my other breast, which also helped ease my fears of having the cancer return.

I started ribociclib with original dose of 400mg, but there was an issue with my liver. We cut the dose to 200mg and that solved the liver issues, and I didn't have any additional liver issues for the remainder of the time I was taking the drug.

It's hard to know whether the side effects were from the ribociclib or the AI, being thrown into menopause was what caused most of my side effects. There was a lot of fatigue. After my diagnosis I started working out religiously to help manage the side effects. I also changed my diet to help manage side effects and reduce my risk of recurrence. I also experienced really dry eyes. I am still on AI and a monthly injection of Zoladex. I have just come up on the 5-year mark so am finishing up these treatments.

I am willing to endure the side effects. You cannot put a price on offering that choice to someone and giving them the option to take that therapy. I consider myself extremely lucky to be put into the study and to receive the drug. I really hope that this becomes available to anyone that it could help.
I would do this 1000 times over to reduce my risk of recurrence. I really hope than anyone in my situation is able to access this and is given this choice.

Patient #4 – Cecilia

I was 41 at when I was diagnosed in June 2018 with stage 3B HR-positive Her2-negative invasive ductal carcinoma, which had also spread to the lymph nodes. I found the lump myself and was referred for a diagnostic mammogram and eventually a biopsy.

I received surgery, 5 ½ months of chemotherapy and 5 or 6 weeks of radiation. My oncologist was the one who mentioned the study with ribociclib to me and I indicated right away that I was very interested in participating if I met

the criteria. If it wasn't for my oncologist being so involved in research and discussing this option with me, I would not have know about this trial option.

I was on the ribociclib arm of the trial and received ribociclib in combination with an aromatase inhibitor and Zoladex. I took ribociclib for the recommended time frame of three years and was able to take the recommended dose of 400mg for the full three years. I did have low neutrophil count a couple of times but would just take an extra week off and that would resolve it, this only happened a couple of times.

At the beginning of the study there were lots of initial visits to the hospital for monitoring, so it was a fairly big time commitment for the first couple of months, but then once the initial testing was complete and it was determined that I wasn't experiencing any serious side effects then the frequency of visits for monitoring decreased.

I did have some side effects but couldn't really tell if it was from ribociclib or the other drugs. It's mostly menopausal symptoms that I have felt and everything that goes with that medically induced menopause. It didn't do anything to reduce my quality of life though, the side effects have not impacted my ability to do anything I want to do. In fact, taking these therapies has actually allowed me to start doing the things I did before.

I joined trial for a couple of reasons, part of it was for me, reducing the risk of the cancer coming back; part of it was also being able to contribute to research to help others who are diagnosed in the future.
I would not have been able to afford this drug if I had to pay out of pocket; I have a good job, but still, the cost of this would have prevented me from taking it so I appreciate that I was able to access ribociclib and have the cost covered through the trial. It was a gift.

The cost benefit of providing people with this drug to reduce the risk of recurrence is much cheaper than treating someone for stage IV cancer. I am working full time, am a contributing member of society, I pay taxes; this is a much more cost-effective way of dealing with cancer than paying for the cost of treatments for someone with a stage IV diagnosis. Ideally, this should become standard of care so that anyone who could benefit has access.

I am enjoying the post treatment phase of my life. I am a mom, a wife, and I have a busy fulfilling career. I am grateful that I was able to have all of the treatments that I did to help prevent the cancer from returning.

7. Companion Diagnostic Test

N/A

8. Anything Else?

We'd like to emphasize that young, high-risk breast cancer patients want more effective tools in their toolbox that will help improve their chances against this challenging disease that's turned their life-plans upside-down.

As we ponder “anything else,” we think about those in our metastatic breast cancer community that we know so well—and their loved ones. We think about those we’ve lost. Too, too many at such a young age over the years. Their families will never be the same. The CDK 4/6 inhibitors have been more of a game-changer in our community than we could have ever imagined, and by providing another option for early-stage patients to reduce their risk of recurrence, we can help patients and families avoid a metastatic breast cancer diagnosis. This therapy provides another option for those with HR+ HER2- breast cancer that is at a high risk of recurrence, and can give patients a tangible way to help achieve their goa of reducing their risk of recurrence.

And, finally, as more and more oral therapies are developed for the treatment of breast cancer, barriers to care increase in some provinces for patients who are under the age of 65. It is important that provinces recognize that younger people with cancer are having to navigate yet another challenge when trying to access optimal care to reduce their recurrence. Economic reports continue to demonstrate the treating an early-stage breast cancer has significantly lower costs to the health system then treating metastatic breast cancer. Ensuring the recurrence reducing treatments are accessible to all patients helps ensure optimal outcomes for patients and for the health system.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH reimbursement review process, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

   No.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

   No.

3. List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have direct or indirect interest in the drug under review.

Table 1: Financial Disclosures

Check Appropriate Dollar Range With an X. Add additional rows if necessary.

Company	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
Novartis 2024				X
Novartis 2023				X

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Jenn Gordon
Position: Lead, Strategic Operations and Engagement
Patient Group: Rethink Breast Cancer
Date: January 2, 2025