

## Patient Input for CADTH Reimbursement Review

Name of Drug: sacituzumab govitecan (Trodelvy)

Indication: HR+, HER2- advanced or metastatic breast cancer

Name of Patient Group: Rethink Breast Cancer

Author of Submission: MJ DeCoteau

### 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. Rethink's strategic priorities and organizational direction are guided by the unique, unmet needs identified by breast cancer patients and their families. We foster spaces to connect, listen, empower, and rethink breast cancer, together.

#### Programs and Activities

- Rethink Breast Cancer builds community, bringing patients with various stages of breast cancer together through our private and public social spaces and in-person events.
- Rethink runs patient retreats and provides professional psychosocial support.
- Rethink creates and runs education forums and conferences.
- Rethink creates support and education tools, resources, and content.
- Rethink funds and brings the patient voice to breast cancer research.
- Rethink advocates for system changes to cancer care to improve outcomes.

You can find out more at: [Rethink Breast Cancer Instagram](#) and [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 40 individuals that we work extremely closely with as key patient advisors; the 100 patients that share their stories annually on our blog; the 500 patients that participate in our virtual support groups; the 1,600 members of our private peer-support network; the 38,000 people that have joined our Instagram community; and the 150,000 individuals reached each month through the reach of that channel. We listen, learn, engage, and have conversations in all these spaces.

Rethink Breast Cancer has several important patient advisory boards and working groups that offer experience-focused insights on issues related to those affected by and concerned about breast cancer, including:

- Metastatic Breast Cancer Advisory Board
- Early Breast Cancer Advisory Board
- Equity, Diversity, and Inclusion Working Group

Rethink also benefits from regular knowledge exchange with our Scientific Advisory Committee, which includes some of the leading clinician scientists in Canada who treat breast cancer.

For this submission, we have drawn on our general observations and insights gathered this year through programming and meetings with breast cancer patients as described above. This included a consultation with our **Metastatic Breast Cancer Advisory Board in July 2023** specifically focused on gathering insights for this submission.

We have also drawn on the results from an online survey with 78 patients living with metastatic breast cancer (MBC) conducted by Rethink Breast Cancer to document the lived experience of patients and caregivers. Patients completed the survey between September 2018 and April 2019. We also reviewed our survey that we conducted in July 2021 to gather information for input we provided to CADTH that year for Trodelvy for metastatic triple negative breast cancer (mTNBC), which included 20 respondents with experience with Trodelvy.

In addition, we drew on insights from interviews in July 2023 with three MBC patients currently on Trodelvy. **Mechelle** and **Nicole** are Canadian patients with mTNBC, and **Susan** is a US patient with hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) MBC.

This input includes direct quotes and comments from 21 different MBC patients.

**Please read short testimonials from Jessica, Michelle, Vesna, Susan and Mechelle in Appendix B.**

### 3. Disease Experience

Most people in the Rethink community are diagnosed at a younger age. When young 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 take on a young person's life is devastating and traumatic.

Fear of recurrence is a reality for our community and for good reason. Despite improvements made with early detection and treatment for early-stage breast cancer, there's approximately a 20-30% chance that early breast cancer will metastasize. Moreover, 5-10% of newly diagnosed breast cancers are metastatic. There is currently no cure for metastatic breast cancer and patients' goal with treatment is to live as well as they can for as long as they can. Patients with metastatic HR+/HER2- cancers survive 4 to 5 years on average.

Processing this reality of a life-limiting diagnosis is extremely difficult, especially for the young patients in our community and the emotional impacts on quality of life cannot be understated. The physical and psychosocial challenges of metastatic breast cancer negatively impact both the patients and their loved ones who are often their caregivers. Most people with metastatic breast cancer have widespread disease, with metastasis to bone being the most common. Lung, liver, lymph nodes and skin are also commonly involved; while mets to the brain is less common for hormone positive MBC patients, it can happen too. Symptoms of hormone positive MBC depend on the sites of the metastasis and include fatigue, shortness of breath for lung metastasis, pain, and bone fractures for bone mets as well as nausea, headache and of course challenges doing normal daily activity. The challenges and uncertainty of living with MBC affects both the patients and their loved ones who support and help care for them.

Our MBC Advisory Board strongly believes in the benefit of metastatic patients accessing palliative/supportive care services early to help address these symptoms.

#### **4. Experiences With Currently Available Treatments**

For people with HR+/HER2- MBC whose disease progresses after 2<sup>nd</sup> line, the current treatment options are mostly limited to standard IV chemotherapy. These chemotherapies are given sequentially usually with diminishing responses with each line of chemotherapy. Although initial lines of chemotherapy may provide a few months of progression free survival, this decreases substantially with later lines.

Metastatic breast cancer patients in our community go to great lengths to avoid standard chemotherapy and they are hit hard both emotionally and physically when it does come to that. In our community, we see a rapid decline once patients progress to having only standard chemotherapies as remaining options.

*“While your tumour is responding to endocrine therapy, you tend to be able to remain longer on the treatment and stable. Then when it starts to progress, and you need to go into chemo because you don’t have anything else, it’s just faster, you know, and things go down so quickly.”*

–**Rosilene**, MBC patient

Patients on standard chemo have a lot of difficulty managing their illnesses. Hospital appointments increase and they become mostly housebound managing side-effects of treatment.

*“On weekly IV chemo, your normal life pretty much ends. It requires two visits per week for either blood work or for the chemo. The rest of the week is managing side effects of nausea, fatigue, pain, worsening neuropathy. And that’s with me being in the cohort of people who “tolerates well.”*

–**Heather**, MBC patient

*“My year on chemotherapy was a full-time job dealing with suppressed neutrophil counts that caused countless treatment delays and quality of life compromising side effects. When I was offered the chance to rely entirely on a newer therapy, the results were game changing and allowed me to get back to my active and scheduled lifestyle as it once had been. Knowing that a cutting-edge treatment option like Trodelvy may be available to me when/if I need it outside of standard of care shelf-life chemotherapies, in the precious time to come, is what helps me stay present and positive as I navigate life with this incurable diagnosis. Everyone deserves a shot at what works best for them and the more therapies available to us are key. Stage 4 needs so much more.”*

–**Jen**, MBC patient, diagnosed de novo

*“My biggest concern with fear of progression, is that my subtype changes from triple positive to any other subtype. So of course, the more treatments that are available that are effective and not chemo are important to me. I already did loads of chemo because my targeted therapy had to go on pause because of the damage to my heart. It was not fun knowing that I could be left on chemo if the cardiotoxicity didn’t improve.”*

–**Margaret**, MBC patient, diagnosed de novo while pregnant

## 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. It’s important that patients have a clear understanding of trade-offs and are well prepared for common side-effects of a given treatment.

When it comes to later lines of therapy, in general, the primary improvement MBC patients seek is to extend their life beyond what is expected with the current publicly funded palliative chemotherapy available and with a better quality of life. They also know a later-line therapy is likely not as easy to tolerate at their first-line MBC treatment was but are anticipating better quality of life than on a weekly IV standard chemotherapy.

As **Jessica**, a hormone positive, MBC patient from our community explains, when the stakes are so high, even a few extra months of survival matter. She explains:

*"...those months could be the difference that lets me see my son start kindergarten; they could be the ones that give me time to get him off diapers before it all falls on dad; Or they could be the first time he says I Love You. While a few months are short on time they are bursting with possibility. Life happens in moments after all. Every scan matters.*

*Only, it's not simply a matter of days, it's also a matter of quality days. It's hard to make memories suffering the side effects of chemo on the couch. It's impossible to keep up with a toddler while managing the debilitating fatigue. An additional line of treatment that allows me quality time with my family is welcomed with open grateful arms...It's not easy for anyone to estimate the value of an extra day of life, but in my case, it could also mean my two-year old has one more day with mom. I'll give him every day I can."*

Patients are also looking for improvement in quality of life and ability to manage daily life over standard IV chemotherapy. **Michelle** from our MBC Advisory Board is one of those heavily pre-treated MBC patients who has exhausted most of her treatment lines. She explains:

*"Endocrine therapy failed as did cdk4/6 inhibitors. Now on my physician's choice of chemotherapy, the options for my next line are limited. In order to stay on my current line of oral chemotherapy, we have been managing my progression with surgery. The surgery option is like a band-aid solution to a disease that is systemic, and the recovery is hard on me physically and even more so, emotionally, including my family.*

*I would definitely welcome the news that Trodelvy could potentially stave off an escalated next round of treatment with IV chemotherapy as this would significantly decrease my quality of life including my ability to navigate the side effects of IV chemo and my young family.*

*As someone living with mbc and who fits the medical profile for Trodelvy, it's important for both me and my medical oncologist to access newer treatments that provide a quality of life and pfs over what would most likely be an IV chemotherapy for my next treatment line."*

**Diane** is another HR+/HER2- patient on our MBC Advisory Board. She’s had to change treatment several times due to progression and just when she was finding an excellent response from a new targeted treatment, she had a setback with a side-effect from the therapy and had to come off it. In our consultation with our MBC Advisory Board, Diane shared:

*“One thing to consider which happened to me as an MBC patient is having to stop a treatment because of a side effect. Enhertu was working for me, and I wish I could have kept going with it but because I developed pneumonitis, I had to stop and move on to another chemo treatment. So heartbreaking! I have gone through several treatment lines, and I hope that Trodelvy can be in my toolbox.”*

In our 2018–2019 MBC survey, patients rated controlling disease and extending life expectancy as the most important outcomes for treatment. This suggests that patients value long-term health outcomes over immediate concerns like reducing symptoms or managing side effects. (See the full survey results, along with methodology in Appendix C.)

Comments from MBC patients surveyed included:

- Symptoms and shrinking the cancer is the most important thing. Living well is the next most important thing.
- Keep me alive for my kids.
- I want to live, LIVE, and enjoy my life for many more years and not be so afraid.

## 6. Experience With Drug Under Review

It was extremely challenging to find patients to interview who are on Trodelvy for hormone positive metastatic breast cancer. Finding patients on later line therapies is often a challenge, given their heavy disease burden. We did manage to connect with one person in the United States who was very happy to share her experience. **Susan was diagnosed with ER+/HER2- MBC in January 2022** and she is currently on Trodelvy as her third line of treatment for MBC.

*“I wanted to take Trodelvy as a second line of treatment when it was in clinical trial for ER positive patients, but my insurance at the time would not allow it. Then, after capecitabine (Xeloda) failed after one year, I was able to access Trodelvy with my new oncologist at the University of Chicago. It was FDA-approved for use in ER positive patients in the U.S. in February 2023; regardless, had I not had regular access to it, I would have joined a clinical trial pairing Trodelvy with Keytruda so I would have had access to Trodelvy.*

*I wanted to take Trodelvy infusions because it is a new class of more effective treatment than regular chemotherapy. It means a lot for me to have access to this treatment, because I believed it would give me a better shot at effectively treating my cancer than regular chemotherapy would.*

*My oncology nurse said she gives presentations on Trodelvy and that when it was in trial (to gain initial use in 2020-2021, which would have been for TNBC patients), the U.S. stopped the trial early because it would have been unethical for all patients in the trial to not receive Trodelvy because it was shown to be so effective.*

We have been in touch with Susan this July, including on July 27 after a busy week of several appointments. She shared:

*"The radiologist was unable to do my biopsy because the lesion on my liver shrunk so much with three treatments of Trodelvy that it was too small to do and because it is too close to my lung (it would have damaged the lung/the radiologist could not safely get to it). So, that is happy news!*

*I have my first CT and bone scans on Trodelvy in August to assess its success, but I know from an ultrasound used to perform a biopsy that after three infusions of this targeted treatment, my liver lesion has shrunk significantly."*

Susan will know later in August how the treatment has worked throughout her body, as she has bone mets as well. As she waits for that scan, she shared that she has been able to manage side effects and has been really pleased with the improvements in her physical functioning that she's gained through Trodelvy. Susan said:

*"Trodelvy so far has been much easier for me to tolerate than capecitabine was. With Trodelvy, I have lost the hair on my head, aside from some scraggly ones. I have fatigue on the day of my treatment and the day after. I had a slight rash a few days after my first two treatments, which was controlled with Benadryl cream. I also had a sore throat after the first treatment, along with a mouth sore, but those went away before it was time for my next treatment. I have tons more energy than I did on capecitabine, and for me, Trodelvy has been way more tolerable. I only feel fatigue the day of treatment and the day after it. I've returned to working out (I am a former runner, so staying active is very important to me), and I have the energy back to go on long walks with my dog."*

In addition to hearing this positive feedback from Susan, we recently connected with **Mechelle** and **Nicole** who are both mTNBC patients currently on Trodelvy who also feel strongly about its benefits.

Mechelle was diagnosed in February 2020 with stage 3 TNBC. She was 29 years old. Despite preoperative chemotherapy, lumpectomy, and capecitabine after surgery for residual disease, her disease metastasized in 2021. After a lot of stress and advocacy, Mechelle was able to start on Trodelvy in February 2022, a treatment that has given her the stability she so desperately needed and is enabling some beautiful milestones. Much of what Mechelle shared with us really highlights how important the improvements in her physical functioning have been since starting Trodelvy. She shared:

*"I've had a great experience with Trodelvy. Almost immediately my metastasis in my bones and lungs began to shrink. Just prior to Trodelvy I was diagnosed with a 7cm, very active femur metastasis. I required surgery to stabilize it and prevent it from breaking. I honestly didn't think I'd be able to walk the distances I use to, if at all. Within 6 months of starting Trodelvy I was NEAD in my bones. I've now been NEAD for almost a year and do daily walks of at least an hour.*

*The side effects were tough at the start while on the 100% dose however, my oncologist immediately adjusted my dose to make sure I was comfortable. I'm now on an 80% dose and all side effects (diarrhea and nausea) are managed by prophylactically taking my prescriptions.*

*My life has been completely altered with Trodelvy. Before Trodelvy I hadn't had much success with treatments, having progression after progression. Because of this I found it hard to make plans that were any more than a month away. My fiancé and I got engaged before Trodelvy and I felt the urge to get married immediately since I didn't think I had much time left. Thankfully my fiancé had more faith than I did and after being on Trodelvy for 6 months with great results we decided to set our date to a year from then, August 26, 2023. Sure enough, Trodelvy has kept me mostly stable this whole year so I will get to see my wedding day. Without Trodelvy my oncologist has even said, she doesn't think I'd be alive today."*

Michelle will be getting married in a matter of weeks. Every day, we see people in the MBC community hoping and praying to make their milestones—a trip, a wedding, a graduation, a child's first day of school. We did probe for a little more information about Mechelle's experience with side-effects. She shared that she would recommend Trodelvy to other patients, especially if other options haven't worked for them. That said, she would also *"fore warn them that if their side effects are bad, having a dose reduction should not affect the success of the drug, as it didn't with me. I would warn them that there are a lot of digestion related side effects such as stomach cramping and diarrhea, and that hair loss is almost inevitable. The digestion related side effects are manageable though. So long as the patient stays on top of their prescriptions and are on a dose appropriate to their needs....Trodelvy is better since the side effects are not constant like Capecitabine were. Trodelvy gives me a break here and there."*



These are the types of decisions around trade-offs between potential benefits and managing side-effects of treatment our MBC community considers and speaks to why having treatment options is so important.

We also connected with **Nicole**, who is currently on Trodelvy as her 4<sup>th</sup> line of treatment. Nicole is 50 years old, married with two teenage boys. She was initially diagnosed November 2021 with stage IV metastatic triple negative breast cancer that had spread to her lymph nodes and lungs. Being TNBC, with no funded targeted treatments at the time, she started on Paclitaxel as her first line followed by Capecitabine as her second line. She was progressing through these chemotherapies rapidly and so she ended up paying out of pocket for Enhertu (with the evolution of the breast cancer space she was re-designated as HER2 low). She said the side effects with Enhertu were minimal and it was working in some areas but not all—a node in her armpit grew so she and her oncologist made the decision to move onto Trodelvy.

Trodelvy is Nicole's 4<sup>th</sup> line of treatment. She shared that so far, she has appreciated the benefits of this treatment, saying:

*"Trodelvy has been very good for me, I started in April 2023. The side effects of the drug have been minimal with tiredness, some stomach pain after eating and weight loss. I had already lost my hair by the time I started Trodelvy so not sure if it would have caused hair loss as a side effect. I tend to take an afternoon nap and wake up later than usual in the morning.*

*I believe that Trodelvy has greatly improved the quality of my life, allowing me to go on walks and spend time with my friends and family. While on Trodelvy, I have been able to travel with my good childhood friend and husband to the Poconos in NY for 4 days. We went on some hikes to visit waterfalls and visited an old Victorian coal mining town. The hikes were tiring but the views of the waterfalls were very enjoyable. I believe Trodelvy made this trip possible."*

Other comments Nicole's shared underscore the importance of options for MBC patients other than standard chemotherapy too. Nicole feels that "Capecitabine allowed my cancer to progress rapidly. There really are not many good options without Trodelvy for my situation. If I could go back in time, I would do Enhertu as line 1 and Trodelvy as line 2 treatments, these drugs were clearly better than the other chemo options."

We also wanted to note that Metastatic Triple Negative Breast Cancer patients that we spoke to in 2021 with experience on Trodelvy were positive about their experience with the drug:

- It was great! Very tolerable and I felt “normal.”
- I have made steady improvement. Less fatigue, more energy, regained appetite.
- I would absolutely recommend this drug to other patients with breast cancer. Everyone is different when it comes to what drugs they respond to, but I feel this drug is especially important for those who have failed multiple treatments prior to trying this. I believe I have an MTNBC subtype with high amounts of TROP-2, which is what the drug targets, and I honestly was amazed when I learned my tumors had all shrank substantially. Trodelvy has given me hope and I hope this drug helps others who have failed multiple treatments as well.
- I feel it is a great drug, especially for those with brain mets. As tolerable or more tolerable as other chemos I have been on. Neuropathy hit quick though, and fatigue/insomnia is tough.
- It’s working! Mets in lungs have disappeared, mets in liver and bones are shrinking.
- It is an absolute must. This was the first medicine that got me clear – to NED – after just a couple of months, so it was really a blessing.
- I’m in the USA getting Trodelvy, it is working for me, and I hope every Canadian who is diagnosed with mTNBC has a chance to get this treatment.

## Summary:

Susan, Mechelle and Nicole all valued the disease stability and improvements in physical functioning they have gained on Trodelvy. They all specifically identified that Trodelvy was easier to tolerate than capecitabine. Mechelle, who has been on Trodelvy for the longest of the three, values the time Trodelvy has given her to get engaged and plan her upcoming wedding this month. A common theme we heard from the twenty MBC patients we connected with for this submission is the value of having a later line option other than standard palliative chemotherapy. In our experience, MBC patients value a treatment that offers more time, more disease stability and improvements in day-to-day functioning.

## 7. Companion Diagnostic Test

Not applicable.

## 8. Anything Else?

We are grateful there are now targeted therapies for all breast cancer subtypes. Prior to the introduction of CDK 4/6 inhibitors into the treatment landscape, it was common for the young hormone positive breast cancer patients in our community to die within two years of their metastatic diagnosis. While things are better than 10 years ago, for the metastatic community, the uncertainty does not go away. Later line therapies that work better than palliative chemotherapy is vital.

When it comes to “anything else,” we give our last patient quote to **Vesna**, a wise, thoughtful veteran member of our MBC Advisory Board. She raises another “why” on behalf of the community:

*“Consider the MBC patient facing yet another setback. Someone who’s cancer has progressed on their current treatment and must now once again grapple with the uncertainty and fear with what lies ahead. **This patient will have a harder time being accepted into a clinical trial with each subsequent line due to restrictive inclusion criteria that often excludes patients who’ve been heavily treated from participating.** An ever-diminishing list of treatments is reduced yet again, with chemotherapy being one of the few options still available.*

*Many of us remember the experience of chemotherapy with an earlier stage diagnosis; the memories linger. While the cancer that resides in my body is stable at this time, I am told with fair certainty that one day, this treatment will fail, and the cancer will grow again. It will bring me back to square one, requiring my oncologist to choose whatever treatment would give me the best chance of staving off debilitating illness again. An additional line of treatment offers hope and compassion to those carrying the burden of experience.”*

Trodely achieved improvement in overall survival in a heavily pre-treated group of patients. And so many symptoms of treatment were improved compared to chemotherapy; it was especially encouraging to see in the recent trial results that Trodelvy showed improvement in physical functioning. The MBC community wants to “live” with their disease in a way that lets them truly live, create experiences and memories with family. This is just so important.

Rethink is grateful to the 20 metastatic patients who are quoted directly in this input submission for sharing their insights and experiences with us. And we are grateful for the opportunity to bring forward these important voices from the metastatic breast cancer community to the CADTH decision making process.

## Appendix A: 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.

We asked Gilead to provide us with information about the general characteristics of the drug and its benefits and side-effects.

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 |
|---------------------|--------------|-------------------|--------------------|-----------------------|
| Gilead 2022 funding |              |                   |                    | X                     |
| Gilead 2023 funding |              |                   | 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:** MJ DeCoteau

**Position:** Executive Director

**Patient Group:** Rethink Breast Cancer

**Date:** July 28, 2023

## Appendix B:

### **Trodelvy for HR+ HER2- MBC: Patients share their WHY**

#### **Jessica's Why:**

"Trodelvy might not seem to extend survival rates by any significant amount of time, but those months could be the difference that lets me see my son start kindergarten; they could be the ones that give me time to get him off diapers before it all falls on dad; Or they could be the first time he says I Love You.

While a few months are short on time they are bursting with possibility. Life happens in moments after all. Every scan matters.

Only, it's not simply a matter of days, it's also a matter of quality days. It's hard to make memories suffering the side effects of chemo on the couch. It's impossible to keep up with a toddler while managing the debilitating fatigue. An additional line of treatment that allows me quality time with my family is welcomed with open grateful arms.

When decision makers are looking at these numbers, they are often blind to the realities of the younger cancer community. My life hasn't yet slowed down, I haven't moved into the stage where changes are mostly expected and long coming. It's not easy for anyone to estimate the value of an extra day of life, but in my case, it could also mean my two-year old has one more day with mom. I'll give him every day I can." — **Jessica, living with HR+ HER2- MBC**



## Appendix B:

### **Michelle's Why:**

"Trodelvy being considered for HR+ HER2- MBC is super important to me because I am one of those heavily pre-treated MBC patients who has exhausted the majority of my treatment lines for standard of care. Endocrine therapy failed as did CDK 4/6 inhibitors. Now on my physician's choice of chemotherapy, the options for my next line are limited. In order to stay on my current line of oral chemotherapy, we have been managing my progression with surgery. The surgery option is like a band-aid solution to a disease that is systemic and the recovery is hard on me physically and even more so, emotionally, including my family.

I would definitely welcome the news that Trodelvy could potentially stave off an escalated next round of treatment to IV chemotherapy as this would significantly decrease my quality of life including my ability to navigate the side effects of IV chemo and my young family. As someone living with MBC and who fits the medical profile for Trodelvy, it's important for both me and my medical oncologist to access newer treatments that provide a quality of life and PFS over what would most likely be an IV chemotherapy for my next treatment line." — **Michelle, living with HR+HER2-MBC**



*Photos of Michelle and her kids*

## Appendix B:

### **Vesna's Why:**

"Consider the MBC patient facing yet another setback. Someone who's cancer has progressed on their current treatment and must now once again grapple with the uncertainty and fear with what lies ahead. This patient will have a harder time being accepted into a clinical trial with each subsequent line due to restrictive inclusion criteria that often excludes patients who've been heavily treated from participating. An ever-diminishing list of treatments is reduced yet again, with chemotherapy being one of the few options still available.

Many of us remember the experience of chemotherapy with an earlier stage diagnosis; the memories linger. While the cancer that resides in my body is stable at this time, I am told with fair certainty that one day, this treatment will fail and the cancer will grow again. It will bring me back to square one, requiring my oncologist to choose whatever treatment would give me the best chance of staving off debilitating illness again. An additional line of treatment offers hope and compassion to those carrying the burden of experience." — **Vesna, living with HR+HER2-MBC**



## Appendix B:

### **Susan's Why:**

"Trodelvy is my third line of treatment for MBC. I am ER positive. I wanted to take Trodelvy as a second line of treatment when it was in clinical trial for ER positive patients, but my insurance at the time would not allow it. Then, after Capecetabine (Xeloda) failed after one year, I was able to access Trodelvy with my new oncologist at the University of Chicago. It was FDA-approved for use in ER positive patients in the U.S. in February 2023; regardless, had I not had regular access to it, I would have joined a clinical trial pairing Trodelvy with Keytruda so I would have had access to Trodelvy. I wanted to take Trodelvy infusions because it is a new class of more effective treatment than regular chemotherapy. It means a lot for me to have access to this treatment, because I believed it would give me a better shot at effectively treating my cancer than regular chemotherapy would. My oncology nurse said she gives presentations on Trodelvy and that when it was in trial (to gain initial use in 2020-2021, which would have been for TNBC patients), the U.S. stopped the trial early because it would have been unethical for all patients in the trial to not receive Trodelvy because it was shown to be so effective.

The radiologist was unable to do my biopsy [this week] because the lesion on my liver shrunk so much with three treatments of Trodelvy that it was too small to do and because it is too close to my lung (it would have damaged the lung/the radiologist could not safely get to it). So, that is happy news! I have my first CT and bone scans on Trodelvy in August to assess its success, but I know from an ultrasound used to perform a biopsy that after three infusions of this targeted treatment, my liver lesion has shrunk significantly.

Trodelvy so far has been much easier for me to tolerate than Capecetabine was. With Trodelvy, I have lost the hair on my head, aside from some scraggly ones. I have fatigue on the day of my treatment and the day after. I had a slight rash a few days after my first two treatments, which was controlled with Benadryl cream. I also had a sore throat after the first treatment, along with a mouth sore, but those went away before it was time for my next treatment. I have tons more energy than I did on Capecetabine, and for me, Trodelvy has been way more tolerable. I only feel fatigue the day of treatment and the day after it. I've returned to working out (I am a former runner, so staying active is very important to me), and I have the energy back to go on long walks with my dog."

I am interested in new and better ways of treatment for MBC, and I believe Trodelvy is this. I would like decision-makers to know that access to Trodelvy is something every person affected by MBC needs to have, and if they and their doctors decide it is a good option for them, they should be allowed to take it." — **Susan, living ER+ HER2- MBC currently on Trodelvy**



## Appendix B:

### **Mechelle's Why:**

"I've had a great experience with Trodelvy. Almost immediately my metastasis in my bones and lungs began to shrink. Just prior to Trodelvy I was diagnosed with a 7cm, very active femur metastasis. I required surgery to stabilize it and prevent it from breaking. I honestly didn't think I'd be able to walk the distances I use to, if at all. Within 6 months of starting Trodelvy I was NEAD in my bones. I've now been NEAD for almost a year and do daily walks of at least an hour.

The side effects were tough at the start while on the 100% dose however, my oncologist immediately adjusted my dose to make sure I was comfortable. I'm now on an 80% dose and all side effects (diarrhea and nausea) are managed by prophylactically taking my prescriptions.

My life has been completely altered with Trodelvy. Before Trodelvy I hadn't had much success with treatments, having progression after progression. Because of this I found it hard to make plans that were any more than a month away. My fiancé and I got engaged before Trodelvy and I felt the urge to get married immediately since I didn't think I had much time left. Thankfully my fiancé had more faith than I did and after being on Trodelvy for 6 months with great results we decided to set our date to a year from then, August 26, 2023. Sure enough Trodelvy has kept me mostly stable this whole year so I will get to see my wedding day. Without Trodelvy my oncologist has even said, she doesn't think I'd be alive today." — **Mechelle, living with triple negative MBC, currently on Trodelvy**



*Mechelle with her fiancé, one month after their engagement*

## Appendix C: MBC Patient Survey Results

Information for this report was gathered through an online survey published in English and circulated through communications from Rethink Breast Cancer as well as the Rethink Network and other partner organizations. Messages were also posted on Facebook and Twitter as well as the Breastcancer.org, Cancer Connection and Cancer Survivors Network online discussion forums. 78 metastatic breast patients completed the survey between September 2018 and April 2019.

An independent contractor was hired to develop this survey and present the results. Survey questions were all reviewed by Rethink staff and Metastatic Patient Advisory Board prior to being posted online.

Rethink Breast Cancer asked respondents to evaluate the importance of different outcomes for their breast cancer treatment on a scale of 1 (not important) to 5 (very important). All the listed outcomes were considered important with no average scores lower than 4.4. However, controlling disease and extending life expectancy were rated as the most important results suggesting that patient values prioritize long-term health outcomes over immediate concerns like reducing symptoms or managing side effects.

| Importance of outcome                  | 1 - not important | 2          | 3            | 4            | 5 - very important | Average    |
|--|-------------------|------------|--------------|--------------|--------------------|------------|
| Controlling disease progression        | 0.00%<br>0        | 0.00%<br>0 | 0.00%<br>0   | 2.60%<br>2   | 97.40%<br>75       | 4.97<br>77 |
| Reducing symptoms                      | 1.30%<br>1        | 0.00%<br>0 | 12.99%<br>10 | 19.48%<br>15 | 66.23%<br>51       | 4.49<br>77 |
| Maintaining quality of life            | 0.00%<br>0        | 0.00%<br>0 | 1.30%<br>1   | 12.99%<br>10 | 85.71%<br>66       | 4.84<br>77 |
| Managing side effects                  | 1.30%<br>1        | 1.30%<br>1 | 12.99%<br>10 | 19.48%<br>15 | 64.94%<br>50       | 4.45<br>77 |
| Achieving NED (no evidence of disease) | 1.32%<br>1        | 1.32%<br>1 | 1.32%<br>1   | 6.58%<br>5   | 89.47%<br>68       | 4.82<br>76 |
| Extending life expectancy              | 0.00%<br>0        | 0.00%<br>0 | 0.00%<br>0   | 2.63%<br>2   | 97.37%<br>74       | 4.97<br>76 |

Comments included:

- Symptoms and shrinking the cancer is the most important thing. Living well is the next most important thing.
- Keep me alive for my kids.
- I want to live, LIVE and enjoy my life for many more years and not be so afraid.