CADTH REIMBURSEMENT REVIEW

Patient and Clinician Group Input

mirvetuximab soravtansine

(AbbVie Corporation)

Indication: For the treatment of adult patients with folate receptor-alpha (FRα) positive*, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens.

March 18, 2025

This document compiles the input submitted by patient groups and clinician groups for the file under review. The information is used by CADTH in all phases of the review, including the appraisal of evidence and interpretation of the results. The input submitted for each review is also included in the briefing materials that are sent to expert committee members prior to committee meetings.

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CADTH

Patient Input Template for CADTH Reimbursement Reviews

Name of Drug: mirvetuximab soravtansine
Indication: For the treatment of adult patients with folate receptor-alpha (FRα) positive*, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens.
Name of Patient Group: Ovarian Cancer Canada
Author of Submission:
Alexandria Tadman
Associate, Government Relations and Advocacy
[redacted]

1. About Your Patient Group

As the only national charity dedicated solely to ovarian cancer, Ovarian Cancer Canada (OCC) (Ovarian Cancer Canada Website) is a patient organization that stands hand-in-hand with the people experiencing, affected by, or at risk of the disease. We reject the notion that ovarian cancer can't be eradicated and are here to demand action, deliver change, and transform lives. We do this through research, advocacy, education and support. We will not rest until women are able to live their lives freely, fully and uninhibited by ovarian cancer.

2. Information Gathering

OCC collected the data presented in this submission from patient and caregiver telephone interviews (in English), from December 16, 2024, to February 28, 2025, and an online anonymous patient and caregiver survey (in English and French) available from February 12 to March 3, 2025. The data was gathered in Canada with participation from one caregiver residing in the U.S.

The telephone interviews and survey were promoted via email to patients in OCC's database and on OCC's peer support online forum (OCC forum OVdialogue). The invite to interview and survey link was also promoted on OCC's social media outlets, including Instagram and Facebook accounts. The survey was also promoted with OCC partners (The Society of Gynecologic Oncology of Canada, gynecologic oncologists, medical oncologists and nurse practitioners). The telephone interview questions were open-ended and have been noted in this report verbatim. The survey had a combination of multiple choice, ranking, checkbox, rating scale and open-ended questions with skip-logic built into the survey so that respondents were only asked questions that were relevant to them.

Both the telephone interviews and online surveys were promoted to those living with platinum-resistant ovarian cancer and their caregivers. The criteria for inclusion were patients whose epithelial ovarian, fallopian tube or primary peritoneal cancer has not responded or is no longer responding to treatment with platinum-based chemotherapy and who have received 1 to 3 prior types of chemotherapy. Please note that one of the patients interviewed has platinum-resistant ovarian cancer but did not fit within the criteria because they have received more than 3 types of chemotherapy. We have included a quote from this patient's telephone interview in the submission and they have been identified using as asterisk (*) at the end of the quote.

There was a total of 10 telephone interviews: 6 were people living with platinum-resistant ovarian cancer and 4 were caregivers of patients with platinum-resistant ovarian cancer.

There was a total of 41 survey respondents: 34 were people living with platinum-resistant ovarian cancer and 7 were caregivers of patients with platinum-resistant ovarian cancer.

Survey respondents living with ovarian cancer included those diagnosed with epithelial ovarian cancer (20), fallopian tube cancer (1) and primary peritoneal cancer (4) and 3 respondents did not know the type of ovarian cancer. Of the thirty-four respondents diagnosed with ovarian cancer, the majority (52%) had been diagnosed between 2022-2024, and 5 respondents were diagnosed between 2019-2021. The majority (95%) of participants had been diagnosed at stage III or IV. The majority of the respondents (91%) have had a recurrence of ovarian cancer. Respondents' ages at diagnosis ranged from 40-73; 1 respondent was under 40, 6 were between the ages of 40-50, 6 were between the ages of 50-60 and 9 were over 60.

Survey and interview participants were from California, Saskatchewan, Alberta, British Colombia, Manitoba, Ontario and Quebec. It should be noted that the number of respondents differs for each question given that some survey participants chose to skip questions.

A total of 3 (1 patient and 2 caregivers) respondents (interviews and online survey) indicated that they or the people for whom they provide care had used mirvetuximab soravtansine as a treatment for ovarian cancer.

3. Disease Experience

Ovarian cancer is the most fatal cancer of the female reproductive system, with a 5-year survival rate of only 44%. This means that 1 in 2 women diagnosed will not live to see 5 years. There is no screening test, the pap test does not screen for ovarian cancer, there is no diagnostic test, there is no vaccine to prevent ovarian cancer and the symptoms are vague, common and non-specific (e.g., bloating, abdominal pain/discomfort, urinary symptoms, change in bowel habits).

Ovarian cancer is not one disease. In fact, it is several different diseases making the path to scientific discoveries and improved treatments particularly complex. For these reasons, ovarian cancer is typically diagnosed in advanced stages (stage III or IV) and there are few effective treatment options long term. With very few exceptions, available treatments have not changed significantly since the 1990s. For the 3,000 Canadians who will be diagnosed with ovarian cancer this year, they will typically be treated with the same methods that their grandmothers had, surgery and chemotherapy, and unfortunately these methods are not successful in most patients.

While most patients respond well to chemotherapy initially, most women develop resistance to this treatment, eventually succumbing to their disease. When ovarian cancer patients develop resistance to platinum-based chemotherapy (platinum-resistant ovarian cancer patients) they are out of effective treatment options.

Ovarian cancer has devastating effects on the lives of thousands of patients and their families. OCC's online survey asked patients to rate how ovarian cancer has impacted various areas of their life on a scale from 1 (no impact) to 5 (extremely negative impact). The areas rated as a 4 (high impact) were: physical activity (36%), self-esteem (32%) and sleep pattern (23%). The areas rated as 3 (moderate impact) were ability to care for their family (32%) level of well-being and ability to care for themselves (41%). When describing how ovarian cancer has affected a caregiver's life, they said it has *"reduced quality of life."*

- *"L'état psychologique très ébranlé négativement. Invalidité professionnelle. Relations familiales et amicales compromises. Les traitements de chimiothérapie dont les effets indésirables très problématiques dont un AVC. Qualité de vie très diminuée."* (Psychological state very negatively affected. Professional disability. Compromised family and friendships. Chemotherapy treatments with highly problematic side effects, including stroke. Reduced quality of life.)

When asked to describe how their daily routines, physical functioning, mental state and overall life have been affected by ovarian cancer, several patients commented on being unable to look to or plan for the future, that their life is all consumed by appointments and the fear of leaving their families:

- *"Having ovarian cancer with know bad prognosis/5y survival of 50% which worsens after experiencing recurrence, dramatically altered my life. There is no more looking into the future and planning for retirement. My work life has suffered and soon I have to quit the work force as highly skilled professional. I have managed to pull myself up again to be there for my children. But these are also the focus of my worst fear. Then I die leaving my children <10y of age without a mom. This, in turn, will impact their ability to grow up as confident and happy adults ready to take on challenging societal task. Having a parent, especially the mom, die*

early on you, often leads to depression and anxiety resulting from loss of some degree of attachment."

- *"I feel limited in planning for the future. I enjoyed travelling but am severely limited in the ability to travel from home. I have constant shortness of breath which makes any activities slow and laboured."*
- *"The cancer routine; appointments, bloodwork, infusions, transfusions, headaches, bruises, scans, neuropathy, bowel disruptions, becomes your full attention."*
- *"My life is very regimented it's all around my treatments and no break due to the drugs not working and my cancer has spread after surgery and 6 rounds of chemo."*
- *"Je vis pour soigner ce cancer et essayer de garder des forces pour passer à travers les traitements. Ce n'est pas une vie."* (I live to treat this cancer and try to keep my strength up to get through the treatments. That's no way to live.)
- *"Appointments, treatments and their effects, procedures, all affect my daily life. Less energy, medical menopause, inability to do many of the things I love, such as running the last several months has been difficult. I find gratitude in each day and seek out joy in any way I can."*
- *"Had to quit my job, tired all the time, loss my physical strength and some of my abilities."*
- *"OC* [ovarian cancer] *is something I think about most days; it feels like a death sentence."*
- *"I have lost the ability to have a family and know that my life is significantly shortened."*

When asked to describe how their life has been affected by learning that they have platinum-resistant ovarian cancer and if that has an impact on how they make decisions, patients have lost hope, the fear of leaving their families has increased and they feel panic and disappointment that they may die before being able to access mirvetuximab soravtansine.

- *"I lost hope. Without platinum, there are no good options. I'm on weekly Taxol but that won't get me to an even short remission."*
- *"I realized that I would not be able to be off of chemo for any length of time, and that the parp inhibitor had not worked. This saddened me and increased my fear of leaving my family."*
- *"It's very devastating, it's extremely emotional, it's physical, it's social, it impacts everything. And just the idea, what's next for me if I'm resistant, what is going to be next for me? And yet there's a drug that's out there* [mirvetuximab soravtansine]*, but it's out of reach."*
- *"Comme il y a peu de traitement pour traiter le cancer de l'ovaire, je savais que c'était le début de la fin (excusez l'expression). J'ai vraiment trouvé difficile cette étape, presqu'autant*

que de recevoir le diagnostic. Cela voulait aussi dire que les traitements de PARP n'étaient plus disponibles pour moi. Ce fut un grand deuil." (As there are few treatments for ovarian cancer, I knew this was the beginning of the end (excuse the expression). I really found this step difficult, almost as difficult as receiving the diagnosis. It also meant that PARP treatments were no longer available to me. It was a great disappointment.)

- *"I went to get a 2nd opinion in New York State as well as in Germany. It is difficult to learn that patients in these countries have access to Elahere* [mirvetuximab soravtansine] …*while it is unclear when Canadian patients will have access. Knowing about the aggressiveness of OC* [ovarian cancer] *and that progressive-free survivals are 2-6 months rather than years, it drives me absolutely crazy and very anxious realizing that I might die before the Health Canada approval and funding of Elahere* [mirvetuximab soravtansine] *whereas with it, I would be able to gift my children more time with their mother. It makes me feel let down by a country which I love and which progressiveness I have always admired and participated in."*
- *"I felt panic and disappointment. Only 2 months after finishing treatment I had new lesions and knew I had to keep fighting and wouldn't get any reprieve. I also have learned it means my options are limited for treatment."*

4. Experiences With Currently Available Treatments

When asked what their initial treatments were for ovarian cancer, 95% had surgery, 91% had chemotherapy, 41% used PARP inhibitors, 36% used Bevacizumab and 5% had radiation. Of these, 20 received Carboplatin and Paclitaxel, 8 received Caelyx. 95% of respondents received more than one drug at the same time. When asked if their initial treatments are/were able to manage their ovarian cancer, 24% said they strongly disagree, 43% said they neither agree nor disagree.

- *"Carbo/Paclitaxel may have certainly destroyed some tumor cells. But it is known that clear cell ovarian cancer does not respond well to platin-based chemo. Further, in light of the fact that recurrence rate of OC* [ovarian cancer] *for all women is 70%, how can we think that Carbo/Pac works? It may prevent us from dying right away, but it certainly does not manage cancer long time. I feel, while there has been great success for lung cancer, breast cancer and melanoma, attention to successfully establish personalized targeted drugs for ovarian cancer has lagged behind."*
- *"My OC* [ovarian cancer] *progressed despite treatment."*
- *"I once asked my doctor how long am I going to stay these treatments? And his response was we're trying to keep you alive."*
- *"Non puisque mon cancer a évolué." (*No, because my cancer has progressed.)

- *"I had four treatments of Carboplatin and Paclitaxel with some reduction in CA125, but surgery found there was no effect on the tumours themselves."*
- *"Récidives à trois reprises. Les traitements stabilisent au début et après seulement quelques mois il y a progression de la maladie. Ces traitements sont très décevants et inefficaces."* (Three recurrences. Treatments initially stabilize the disease, but after only a few months, it progresses. These treatments are very disappointing and ineffective.)

OCC's online survey asked patients to rate how side effects of their ovarian cancer treatments have affected their quality of life on a scale from 1 (no effect) to 5 (extremely negative effect). Fatigue, hair loss, bowel problems, neuropathy, and blood problems (e.g. anemia) were rated between moderate to high on this scale.

- *"Extremely negative effects of brain fog, anxiety, depression and catastrophising."*
- *"Shortness of breath due to pleural effusions has had a significant impact."*

When asked about the barriers to accessing treatments, 25% of respondents reported travel as a moderate barrier.

- *"Travel was occasionally difficult until I moved close to the hospital."*
- *"Being all alone, getting help to get to treatment was difficult."*
- *"Required family support and being driven to/accompanied by family members for all my treatments."*
- *"I had to travel for about 2.5 hours, often staying at a hotel overnight, for meetings with the gynecological oncologist and to have surgery."*

When asked to describe the impact of the barriers they experienced in accessing their treatments, one patient described it as *"very negative impact"*.

Patients and caregivers also must take time off work due to treatment and this has a negative financial impact:

- *"…Pour le fardeau financier, j'ai dû prendre ma retraite. J'ai donc une perte de salaire de 30% en plus d'avoir dû appliquer à la RRQ invalidité. Je serai donc pénalisé devant passer à la pension RRQ à 60 ans au lieu de 65 ans. J'aurai aussi une plus petite pension n'ayant pas contribué à mon fond de pension pendant 5 années (de 2021 à 2026) où mon salaire aurait été le plus élevé. Le cancer m'appauvrit donc comme plusieurs d'entre nous."* (…As for the financial burden, I had to retire. I have lost 30% of my salary, in addition to having to apply for RRQ disability. I'll be penalized by having to switch to the RRQ pension at age 60 instead of 65. I'll also have a smaller pension because I didn't contribute to my pension fund for 5

years (from 2021 to 2026) when my salary would have been the highest. Cancer made me poorer, as it does many of us.)

5. Improved Outcomes

80% of patients said that they have considered taking mirvetuximab soravtansine. When asked if they were to take mirvetuximab soravtansine, how important it would be to them that the drug address a list of issues, patients that completed OCC's online survey ranked prolonged survival (70%), improved quality of life (65%) and lengthening time to a recurrence (70%) as extremely important.

In addition to this, patients would need to see "moderate improvement" (63%) in their ovarian cancer from mirvetuximab soravtansine before they would consider taking it. This means that over half of respondents would still consider taking the drug even if there was not "high improvement". This highlights ovarian cancer patients' willingness to receive this treatment, they want the opportunity to make decisions about their care and as one patient said, *"to survive longer*".

Over half (55%) of the patients who responded to the online survey said that they would be willing to tolerate eye problems (blurred vision, dry eyes, sensitivity to light, eye pain, eye redness, or new or worsening vision changes) if mirvetuximab soravtansine were to improve overall daily functioning and prognosis. Hair loss (100%), fatigue (95%), aching joints (79%) and neuropathy (70%) were also highly ranked side effects that patients would be willing to tolerate.

Patients' reasoning for being willing to tolerate the above listed side effects include the *"desire to live"* and that they have already experienced most of the side effects listed and are willing to tolerate them if it means that they will potentially live longer and for the chance at more time.

- *"This is about surviving. I would take any side effect to be a mom for my children as long as I can. I am certain if women would receive more detailed information from their oncologist that there is no effective treatment for platin-resistant recurrence, most of those would tolerate a lot of side effects. The women with OC* [ovarian cancer] *that I have met so far, are very impressive, enduring unbelievable pain and side effect, just to continue to life."*
- *"I have already experienced most of these side effects and can tolerate them if Elahere* [mirvetuximab soravtansine] *can provide prolonged and quality life."*
- *"Si ça augmente la survie elle est prête à subir ces effets qui, de toute façon, font partie des effets secondaires des autres traitements."* (If it increases survival, she's prepared to live with these effects, which in any case are part of the side effects of other treatments.)
- *"I want to live as long as possible to be here with my family!"*
- *"I have already experienced them and being young I want a chance at more time."*

- *"I have been diagnosed with an incurable disease and want to do everything I can to stay alive and be here for my family and children."*

Over half (53%) of patients said that the benefit for them if given the opportunity to take mirvetuximab soravtansine would be "prolonged life". When asked to identify any potential risks for them taking mirvetuximab soravtansine one patient said:

- *"Up to now nothing else has been working so I don't see a risk."*

With respect to ocular side effects another patient said:

- *"Blurry vision but there are now new studies that eye problems are largely reversible. Same was true for mitigating side effects of immune check point inhibitors. First, effectively treat the cancer and then learn how to manage the side effects. And that is ok. Care providers who argue differently, have, themselves, not experienced cancer. People want to live. So, side effects are ok, but only if this is for the cause of survival."*

71% of patients and caregivers said that the benefits of taking mirvetuximab soravtansine outweigh the risks.

When asked to explain what it feels like to know that mirvetuximab soravtansine is approved in the U.S. and not in Canada if they were eligible for this treatment, patients and caregivers expressed anger, frustration and disappointment.

- *"We could have had a few more months with our mom if she could* [have] *accessed it* [mirvetuximab soravtansine]. *Since she couldn't and topotecan* [a type of chemotherapy drug] *didn't work the cancer took over and she passed away in hospital after being admitted for a little over two weeks."*
- *"I am extremely angry about this fact and that I do not have the ability to decide for myself whether I can have this treatment in Canada."*
- *"I'm angry. I'm frustrated. Why don't we have access to this drug? And I have to keep on redoing Taxol? When there's a drug that can actually help me or potentially save my life?"*
- *"I honestly did consider looking at it* [accessing mirvetuximab soravtansine]*, you know, maybe the states that were closer to us, but financially it's just impossible...It's hard to take when that happens…having the opportunity to receive the drug would be great…it gives you hope."* *
- *"It's been extremely frustrating as I don't have other treatment options and know there are positive results for women. Especially that it has been approved in the U.S. for so long. There should be no barrier to access when it comes to life-saving treatments."*

- *"If it could be helpful to her, and not too harmful, it's frustrating. I want her to have all the options to fight and/or have a better chance to get to a place she can get some life in with the time she has."*
- *"I did travel to the U.S. to explore this option. I was tested for FOLR1 and the result was Positive 3+, 100%. The travel and cost did not make this option seem feasible…There are not a lot of options in treatment for those with ovarian cancer and knowing that there are options available which are not accessible is very frustrating."*

6. Experience With Drug Under Review

OCC interviewed 1 patient who was treated with mirvetuximab soravtansine in the U.S. and 2 caregivers who have provided care to a family member who was treated with mirvetuximab soravtansine in the U.S.

The patient was diagnosed with Stage III ovarian cancer in 2021 at the age of 69 she resides in Canada and completed her mirvetuximab soravtansine treatment by travelling to the U.S. (California), the drug was accessed by paying out-of-pocket. The patient received mirvetuximab soravtansine treatments in 2023-2024 for a period of sixteen months. When asked to compare the mirvetuximab soravtansine treatments to previous therapies the patient had used:

- *"Obviously the regular chemo is very taxing on the body and low energy. I was pretty normal on ELAHERE* [mirvetuximab soravtansine]*, it was wonderful, absolutely wonderful. It is huge when you don't get sick taking chemo for over a year…It was a good experience in that I did not get sick. There was no nausea, no vomiting, next to no fatigue, I felt good and carried on a regular life. Yeah, that was probably about the best time during the whole treatment period that we had that we were able to travel."*

When asked about the emotional toll that it took on the patient and their family to have to travel to the U.S. for treatment:

- *"It is stressful, no doubt about it. You fly every month, it's not easy when you're 70 years old."*

When asked about tolerating side effects:

- *"I did not have any eye problems for the first while, then later only I had some white dots on my retina, but they did go away, I increased the steroid use on my eyes and with the drops it went away. The next time I had a little bit of inflammation and that went away too but when it was all done obviously there still some residual effects because it loosens the cataracts which I did not have before so now I need cataract surgery in both eyes, so my vision is not good at all."*

When asked if they had any reservations or concerns before taking mirvetuximab soravtansine and if any of those came true:

- *"Not really, when you are facing cancer and facing death because the regular chemo is not working you get so sick on it and then there is something else to try which is positive and then it works, this* [mirvetuximab soravtansine] *did."*

When asked if mirvetuximab soravtansine was easier to use than previous therapies:

- *"Oh yes, because it didn't make me sick it was still an infusion, but it was next to no side effects a walk in the park it was much much better. As long as your tissue sample matches with the ELAHERE* [mirvetuximab soravtansine] *product yes it was wonderful."*

When asked about the advantages of mirvetuximab soravtansine and what they (patient and caregiver) gained from this treatment:

- *"ELAHERE* [mirvetuximab soravtansine] *brought down my markers to significantly below normal level, so like I said, it gave me hope, courage and that this is doable and that I would survive…I can live a normal life, I could garden, I could do housework, I could do everything I normally did."*

- "[The benefits were] *Huge we were having our normal family life again everything was positive and upbeat it was awesome."*

- *"She had a little more energy and more mobile and I didn't have to push a wheelchair quite as much…we would have fun."*

When asked how quickly into treatment these gains were realized the patient said, *"the first one."*

The second caregiver resides in the U.S. their mother was diagnosed in 2022 at age 77 and had platinum-resistant ovarian cancer, she resided in Canada and received treatment in the U.S. (California) from June-August 2024, the drug was accessed by paying out-of-pocket.

Some of the side effects that the patient experienced with other treatments prior to starting mirvetuximab soravtansine included hair loss, psychological challenges, stomach issues, vomiting, gagging and loss of appetite. While using the treatments available to her in Canada at this time, she would be feeling okay for a day following treatment and by day two she wasn't well *"she was tired, she couldn't eat, she was vomiting and had bad stomach acid."*

The caregiver explained that part of their motivation to access the treatment in the U.S. was because she *"was running out of time literally, we looked into loans and that's when we started ELAHERE* [mirvetuximab soravtansine] *treatment in California."* In addition to this, the patient's mother said:

- *"She wanted to live, she wanted to fight, she wanted to live. It is as simple as that."*
- *"No, I am going to beat this, I am going to be okay, I'm going to get better, and she had that huge determination truly to the end."*

After the first mirvetuximab soravtansine treatment their mother's numbers came down by half so they were very hopeful:

- *"Her CA125 number went from being at 3,700 down to 1,800 after the first treatment after that she had the treatment every 21 days."*

The three top issues identified by the caregiver that were managed better by mirvetuximab soravtansine than their mother's previous treatments for ovarian cancer were: shrunk tumour size, prolonged survival and lengthened time to a recurrence. The side effects her mother experienced while taking mirvetuximab soravtansine were fatigue and bowel problems.

When asked about the financial impact of accessing the drug in the U.S.:

- *"Their income wasn't high enough to qualify for a larger line of credit, because of that, they had to resort to a reverse mortgage on their home for the ELAHERE* [mirvetuximab soravtansine] *treatments."*
- *"It was quite an impact. The cost…it was $36,000 U.S. dollars per treatment…she had three treatments…this does not include travel costs."*

When asked to rate the extent to which mirvetuximab soravtansine affected their mother's quality of life, the caregiver selected "somewhat negative" as a result of having to travel for treatment, the stress from this travel and a 3-4 month gap in treatment while trying to secure financing for the treatment.

- *"Travel back and forth to California from* [her home province] *has been exhausting and stressful. Side effects of fatigue and a bit of issues with appetite have made her days harder. It is possible that the reason for her quick decline has also had to do with stress. There was also a 3-4 month gap in treatment while trying to secure financing for Elahere* [mirvetuximab soravtansine]*."*

When we asked the caregiver why her mother stopped her mirvetuximab soravtansine treatment she said, *"she was too weak to travel to California from* [her home province]*."*

7. Companion Diagnostic Test

The drug in review (mirvetuximab soravtansine) companion diagnostic is the folate receptor alpha (FRa) test where patients are required to provide tumour tissue for FRa analysis to determine drug

eligibility. OCC interviewed two patients and two caregivers whose mothers had FRa testing done in the U.S.

One patient sought an assessment for treatment at a cancer centre in Florida following a discussion with their oncologist in the spring of 2024. At that time, the patient was deemed to be resistant to the chemotherapy they had been prescribed. Their doctor suggested that they should see if they would be eligible for mirvetuximab soravtansine. They were advised that the test was not available in Canada and would need to be accessed in the U.S. Some labs that the patient researched indicated that the test would only be available if the patient was being treated at a U.S. facility. When they were in Florida, they requested that the testing be done, and it was arranged. A sample of the patient's tumour was sent to a lab facility in Texas.

The U.S. consultation appointment was scheduled within a month of it being requested. The patient was required to send all records of their treatment including not just reports but original scans as well as a sample of their tumour in order for the appointment to be confirmed. The patient explained this as being *"very stressful as I had had procedures done at three different hospitals and dealing with three very different systems to access information and arrange for it to be sent."*

When asked how the FRa test was done, it was an analysis of the patients' tumour and they reported no adverse effects associated with the testing.

When asked if the test delayed the treatment from the beginning the patient highlighted the lack of availability of the testing in Canada as a barrier and they also experienced delays in receiving their test results.

- *"It was indicated to me that the results of the testing would be available in approximately two weeks from the time received by the lab. This unfortunately did not happen as I had paid* [the Florida cancer centre] *the fee for the testing but then was contacted by the lab that said the funds were not sufficient and would have to be paid directly by me."*

The patient paid $4,500 USD for the FRa testing. There were additional out of pocket costs, paying for the hospital consultation as well as travel costs, the patient is also not aware of any resources that would have paid for the test. They also confirmed that they understood why the test happened.

When asked to comment on coping with any anxiety while waiting for the test result two patients commented:

- *"The delay in getting the testing results was incredibly stressful…"*
- *"I'm sure I was anxious to see whether I was approved or not so we could get started, the markers keep going up and you want to get to the next step. I was very fortunate and*

blessed by God that it came back that my tissue sample was one of the best they had seen so that was a blessing from above."

When asked about any uncertainty they experienced about making a decision given the test result:

- *"Oh no, as soon as we found out it was a very good match, we said ok go for it."*

One caregiver confirmed that her mother's tumor was tested in the U.S. and they learned that she was 100% eligible but the Canadian oncologist's request for mirvetuximab soravtansine was denied.

- *"They were able to test her tumour for the folate receptors, and she's actually 100% eligible. So that's a very frustrating thing as well because she is such a great candidate for this drug…we asked her oncologist to see if we could have access to ELAHERE* [mirvetuximab soravtansine] *in Canada, but the request was denied."*

It is worth noting that we also received feedback from a patient that accessing the FRa testing in the U.S. as a Canadian was not easy or straightforward. Patients and caregivers need the funds, time, ability to travel and knowledge of how to access the test in the U.S., often having to obtain this information through self advocacy and educating themselves on the U.S. system. Oncologists in Canada have informed ovarian cancer patients that they are free to go to the U.S. for treatment but that they can not help a patient with that process.

8. Anything Else?

OCC's platinum-resistant patient population have run out of treatment options and are desperate to access mirvetuximab soravtansine. So are their oncologists. Canadian patients and clinicians know that mirvetuximab soravtansine is the only drug shown to affect overall survival in the platinum-resistant setting. In 2023, OCC surveyed an audience of gynecologic oncologists and gynecologic oncology nurses to ask if there are any ovarian cancer medications that are not currently available in Canada that they would like to see on their province's formulary? The majority of respondents - 24 of 37 - answered mirvetuximab soravtansine.

- *"As the President of the Society of Gynecologic Oncology of Canada I strongly advocate for access to Mirvetuximab for ovarian cancer patients with platinum resistant disease. In Canada, we are currently without effective treatments for this specific group of patients and this drug significantly fills this need. By achieving Health Canada approval for this medication, we will be providing a hopeful treatment and also establishing equity of care for our Canadian population as ELAHERE* [mirvetuximab soravtansine] *is currently only available for our patients who can afford to pay for it themselves by travelling to the United States."* - Dr. Shannon Salvador, Society of Gynecologic Oncology of Canada President, Gynecologic Oncologist in Montreal

- *"Platinum-resistant ovarian cancer is an area of significant unmet need, with many women with ovarian cancer suffering from this condition. Mirvetuximab is a huge step forward for the treatment of these women, who otherwise have no effective treatments available to them. Being able to offer and provide mirvetuximab to my patients would be a significant advancement in the care I can provide and is one of my top priorities for advocacy and access in my current practice."* - Dr. Lesley Roberts, Gynecologic Oncologist in Manitoba

Ovarian cancer patients living in Canada are often just a couple of hours away from the U.S. border. Their families and friends living in the U.S. have access to the drug and they do not. Doctors practicing in the U.S. can prescribe mirvetuximab soravtansine to their American patients, while doctors in Canada are frustrated that they cannot prescribe the same drug to their patients. For many patients, mirvetuximab soravtansine is their last resort. Some patients have shared their willingness to travel to the U.S. to access mirvetuximab soravtansine, but the cost is prohibitive for the vast majority of patients.

- *"I decided to pursue the standard of care here in [Canada], as the potential cost of treatment in Seattle was prohibitive, upwards of $440,000 in Canadian dollars for a full course of [mirvetuximab soravtansine] treatments. I would have had to sell my house; I am not in a position to raise money any other way."* - Patient Member, OVdialogue online community

For Canadians who seek treatment across the border as a last resort, they are remortgaging their homes. They are forced to board planes after a 21-day treatment cycle, exhausted, weak and knowing that they will have to turn around and do it all again shortly after, that is if they have the financial means to do so.

- *"We have no choice, and I am travelling to the U.S. with my mom tomorrow* [May 2024] *so she can start the Elahere* [mirvetuximab soravtansine] *treatment soon. Her oncologist in* [Canada] *was clear, that my mom does not have months to wait for this treatment to be approved by Canada. There are no other options for her in Canada and delaying treatment could cause death or irreparable damage to her. I worry about complications while my mom is there* [U.S.], *knowing if she gets hospitalized it will also be something she will have to pay for...she has already had to remortgage her house and will likely have to take out a second mortgage if she needs to pay for every treatment* (and travel expenses)*. The availability of this drug in Canada would make this situation much less stressful and difficult for her."*

We would strongly advise the CDA to recommend mirvetuximab soravtansine treatment for reimbursement and allow Canadians to access this vital medication for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens.

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
AbbVie Inc.				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: Tania Vrionis
Position: Chief Executive Officer
Patient Group: Ovarian Cancer Canada
Date: March 17, 2025

CADTH

CADTH Reimbursement Review

Clinician Group Input

CADTH Project Number: PC0394-000
Generic Drug Name (Brand Name): Mirvetuximab Soravtansine
Indication: Platinum Resistant Ovarian Cancer
Name of Clinician Group: BC Cancer Gynecologic Oncology Provincial Tumor Group
Author of Submission: Aalok Kumar

1. About Your Clinician Group

The BC Cancer Provincial Gynecological Oncology Tumor Group is comprised of clinicians, pathologists, researchers and allied staff involved in the care of patients with gynecological malignancies in the province of British Columbia. Clinicians include Medical, Radiation, and Gynecological Oncologists as well as General Practitioners in Oncology and Nurse Practitioners. The Tumor Group is responsible for developing evidence based standards of practice, maintaining up to date treatment policies, advocating for access to novel effective therapies and for providing education to the Tumour Group members.

2. Information Gathering

The information for this submission was gathered primarily from the MIRASOL trial, a randomized phase 3, open label trial for patients with platinum resistant ovarian cancer who had received up to 3 lines of systemic therapy and who had a high folate receptor alpha expression, using the PS2+ scoring method. Randomization was 1:1 between standard single agent non-platinum-chemotherapy or Mirvetuximab Soravtansine. The primary end points of the trial were progression free survival (PFS) and overall survival (OS). Safety was also assessed

3. Current Treatments and Treatment Goals

Ovarian cancer is the eighth leading cause of death in Canadian women and fifth leading cause of cancer death. The Canadian Cancer Society estimated that, in 2023 2,800 women in Canada developed ovarian cancer, with 1,750 deaths due to this disease. Since the addition of paclitaxel to standard therapy in the early 1990s and the introduction of PARP inhibitors in the late 2010s, there have been no major practice changing developments in ovarian cancer therapeutics.

Unfortunately, the majority of patients diagnosed with ovarian cancer end up developing platinum resistant ovarian cancer, associated with a poor prognosis, survival in the range of 6-12 months. Treatment options in this setting are quite limited with limited efficacy. The AURELIA trial investigated the use of Bevacizumab along with non-platinum chemotherapy. A modest

improvement in progression free survival was seen to be associated with the addition of bevacizumab, 6.7 versus 3.4 months (HR 0.48, 95%CI 0.38-0.60, p<0.0001), however no significant difference was noted in overall survival [3].

Beyond the above combination, remaining treatment options are non-platinum-based chemotherapy with response rates in the range of 10-15% and have no significant impact on survival [4]. Patients diagnosed with platinum resistant ovarian cancer represent a group with a high unmet need for more efficacious treatment options.

Targeting Folate Receptor Alpha In Ovarian Cancer With Mirvetuximab Soravtansine (MIRV)

Folate receptor alpha (FRa) is a biomarker commonly overexpressed on ovarian cancers, minimally expressed on normal tissues [5-8]. MIRV is a first in class antibody drug conjugate (ADC) targeting FRa. MIRV is made of an FRa binding antibody, a cleavable linker and the maytansinoid DM4, a potent tubulin targeting agent [5-8]. Prior trials have demonstrated single agent MIRV activity with a tolerable safety profile.

In the single arm SORAYA trial [9] of MIRV in FRa positive, bevacizumab pre-treated platinum resistant patients with advanced ovarian cancer, objective response was 32.4% with 5 complete and 29 partial responses, median duration of response of 6.9 months. The median overall survival was 15 months (95% CI, 11.5 to 18.7). Based on these results, the FDA granted accelerated approval to MIRV for FRa positive platinum resistant patients who previously received 1-3 lines of prior systemic therapy.

Given the results above, the confirmatory phase 3 MIRASOL trial was conducted in patients who had platinum resistant ovarian cancer and who had received up to 3 lines of systemic anticancer therapy, along with having a high FRa tumor expression, using the PS2+ scoring method [10]. The purpose of the trial was to evaluate the efficacy of MIRV versus investigators choice chemotherapy (paclitaxel OR liposomal doxorubicin OR topotecan). A total of 453 patients were randomized in a 1:1 fashion to receive either MIRV intravenously every 3 weeks or to chemotherapy as per standard dosing schedules depending on the chemotherapy chosen. The primary endpoint was progression free survival (PFS) and overall survival (OS) as a secondary endpoint.

The use of MIRV was associated with a significant improvement in in median PFS, 5.62 vs 3.98 months, p<0.001). The restricted mean PFS at 1 year was 6.13 vs 4.72 months favoring MIRV. There was significantly greater percentage of patients who received MIRV and who achieved an objective response, 42.3 vs 15.9%, p<0.001. Median OS was also significantly improved with the use of MIRV compared to chemotherapy, 16.46 vs 12.75 months, HR 0.67, 95%CI, 0.50 – 0.89, p=0.005. Median duration of response was 6.77 vs 4.47 months favoring MIRV [11].

This is the only phase III trial thus far demonstrating significant improvement in overall survival in patients diagnosed with platinum resistant ovarian cancer, once again highlighting the significant unmet need for these patients.

4. Treatment Gaps (unmet needs)

4.1. Considering the treatment goals in Section 3, please describe goals (needs) that are not being met by currently available treatments.

Presently treatment with standard non-platinum chemotherapy with or without bevacizumab provides a very modest benefit and limited duration of response. The data demonstrating survival improvement with the novel ADC MIRV is unique as this is the first time overall survival has been improved for patients diagnosed with platinum resistant ovarian cancer. This new treatment is well tolerated which means that not only will women live longer but also better, without disease progression.

5. Place in Therapy

5.1. How would the drug under review fit into the current treatment paradigm?

Is there a mechanism of action that would complement other available treatments, and would it be added to other treatments?

Is the drug under review the first treatment approved that will address the underlying disease process rather than being a symptomatic management therapy?

Would the drug under review be used as a first-line treatment, in combination with other treatments, or as a later (or last) line of treatment?

Would the drug under review be reserved for patients who are intolerant to other treatments or in whom other treatments are contraindicated?

Is the drug under review expected to cause a shift in the current treatment paradigm?

Please indicate whether or not it would be appropriate to recommend that patients try other treatments before initiating treatment with drug under review. Please provide a rationale for your perspective.

The use of MIRV for patients with high FRa expression will become the standard of care treatment once patients are deemed platinum resistant, replacing non-platinum chemotherapy +/- bevacizumab, which will be then used upon further progression. The use of MIRV as the first option in the setting of platinum resistance will allow patients to take a break from standard cyto-toxic therapy which is typically associated with a risk of significant toxicities. This in turn will be associated with improved quality of life. The use of MIRV as the first option in the setting of platinum resistance will represent the introduction of a new line of therapy for patients, giving them more options to maintain disease control with the potential to extend survival.

5.2. Which patients would be best suited for treatment with the drug under review? Which patients would be least suitable for treatment with the drug under review?

Which patients are most likely to respond to treatment with drug under review?

Which patients are most in need of an intervention?

Would this differ based on any disease characteristics (e.g., presence or absence of certain symptoms, stage of disease)?

How would patients best suited for treatment with drug under review be identified (e.g., clinician examination/judgement, laboratory tests (specify), diagnostic tools (specify))

Are there any issues related to diagnosis?

Is a companion diagnostic test required?

Is it likely that misdiagnosis occurs in clinical practice (e.g., underdiagnosis)?

Is it possible to identify those patients who are most likely to exhibit a response to treatment with drug under review?

Based on the results of the MIRASOL trial, the patients most likely to benefit from the use of MIRV will be patients diagnosed with platinum resistant ovarian cancer who demonstrate a high FRa expression using the PS2+ scoring method. This requires a companion diagnostic test.

Patients diagnosed with platinum resistant ovarian cancer have very limited options for treatment of their disease, and therefore represent a high unmet need population. These patients would be identified by their prior response to platinum-based therapy as well as whether there is presence of high FRa expression on a tumour sample, scored by the PS2+ method.

5.3 What outcomes are used to determine whether a patient is responding to treatment in clinical practice? How often should treatment response be assessed?

Are outcomes used in clinical practice aligned with the outcomes typically used in clinical trials?

What would be considered a clinically meaningful response to treatment? Consider the magnitude of the response to treatment. Is this likely to vary across physicians?

Examples: improved survival; reduction in the frequency/severity of symptoms (provide specifics regarding changes in frequency, severity, etc.); attainment of major motor milestones; ability to perform activities of daily living; improvement of symptoms; and stabilization (no deterioration) of symptoms.

In clinical practice, the outcome of PFS and OS are the standard measures for assessing treatment benefit. These improvements were demonstrated in the MIRASOL trial, thus demonstrating the impact of this new treatment. Response to treatment as assessed by clinical and radiological parameters is the standard practice for oncologists involved in the delivering systemic therapy. A meaningful response to treatment is determined by integrating many different aspects, but may include evidence of symptom improvement, radiologic evidence of disease response or evidence of disease stability. An assessment of benefit would also require that the treatment was well tolerated and safe. This is all standard practice across physicians working in oncology.

5.4 What factors should be considered when deciding to discontinue treatment with the drug under review?

Examples: disease progression (specify, e.g. loss of lower limb mobility); certain adverse events occur (specify type/frequency/severity); or additional treatment becomes necessary (specify).

The decision to discontinue treatment entails a comprehensive assessment of 1) patient symptoms, 2) radiologic assessment, 3) laboratory parameters 4) treatment toxicity and patient safety and 5) patient wishes.

In some cases, there is clear lack of benefit from treatment with deterioration in patient function, worsening cancer symptoms and radiologic evidence of disease progression. These are the most common reasons for treatment discontinuation and are assessed and identified as part of standard practice for oncologists. In some cases, toxicity or patient safety may lead to treatment discontinuation even when there is evidence of disease response to therapy. This is expected to be a less common reason for treatment discontinuation.

5.5 What settings are appropriate for treatment with [drug under review]? Is a specialist required to diagnose, treat, and monitor patients who might receive [drug under review]?

Examples: Community setting, hospital (outpatient clinic), specialty clinic

If a specialist is required, which specialties would be relevant?

Patients under the direct supervision of an oncologist in any setting could appropriately receive MIRV for the management of platinum resistant ovarian cancer with high FRa expression. This would include community and hospital settings. Treatment is always in the out-patient setting. Patients in remote areas of Canada could also receive this treatment with guidance from an oncologist having experience in the use of cyto-toxic therapy and ADCs and with appropriate patient and care team education. Access to optometry or ophthalmology will also be necessary to ensure the ocular toxicity associated with MIRV is properly assessed and managed.

6. Additional Information

Is there any additional information you feel is pertinent to this review?

<Enter Response Here>

7. Conflict of Interest Declarations

To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the clinician group input. CADTH may contact your group with further questions, as needed. Please see the *Procedures for CADTH Drug Reimbursement Reviews* (section 6.3) for further details.

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

No

2. Did you receive help from outside your clinician group to collect or analyze any information 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 two years AND who may have direct or indirect interest in the drug under review. **Please note that this is required for each clinician who contributed to the input — please add more tables as needed (copy and paste). It is preferred for all declarations to be included in a single document.**

N/A

Declaration for Clinician 1

Name: Aalok Kumar
Position: Medical Oncologist AND Provincial Systemic Chair, Gynecologic Oncology, BC Cancer
Date: 09-03-2025

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

Table 1: Conflict of Interest Declaration for Clinician 1

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
GSK	X			
Abbvie	X			
Merck	X			

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 2

Name: Anna Tinker
Position: Medical Oncologist
Date: 14-03-2025

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

Table 2: Conflict of Interest Declaration for Clinician 2

Company	Check appropriate dollar range*

	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 3

Name: <Enter full name>
Position: <Enter currently held position>
Date: <DD-MM-YYYY>

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

Table 3: Conflict of Interest Declaration for Clinician 3

	Check appropriate dollar range*			
Company	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 4

Name: <Enter full name>
Position: <Enter currently held position>
Date: <DD-MM-YYYY>

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

Table 4: Conflict of Interest Declaration for Clinician 4

	Check appropriate dollar range*			
Company	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Add company name				
Add company name				

Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 5

Name: <Enter full name>
Position: <Enter currently held position>
Date: <DD-MM-YYYY>

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

Table 5: Conflict of Interest Declaration for Clinician 5

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

References:

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[11] Moore KN, Angelergues A, Konecny GE, Garcia Y, Banerjee S, et al. Mirvetuximab Soravtansine in FRa Positive Platinum Resistant Ovarian Cancer. 2023;389:2162-74

CADTH

CADTH Reimbursement Review

Clinician Group Input

CADTH Project Number: PC0394-000
Generic Drug Name (Brand Name): mirvetuximab soravtansine (TBC)
Indication:
Manufacturer Requested Reimbursement Criteria[1]:
For the treatment of adult patients with folate receptor-alpha (FRα) positive*, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens.

Name of Clinician Group: Ontario Health (Cancer Care Ontario) Gynecologic Cancer Drug Advisory Committee ("OH (CCO) Gyne DAC")
Author of Submission: Members of OH (CCO) Gyne DAC

1. About Your Clinician Group

OH(CCO)'s Drug Advisory Committees provide timely evidence-based clinical and health system guidance on drug-related issues in support of CCO's mandate, including the Provincial Drug Reimbursement Programs (PDRP) and the Systemic Treatment Program.

2. Information Gathering

Information was gathered via teleconference call and emails.

3. Current Treatments and Treatment Goals

Current treatment options:

- Weekly paclitaxel, pegylated liposomal doxorubicin, topotecan, single agent or in combination with bevacizumab
- Clinical trial if available
- Best supportive care

Treatment Goals: Improve PFS, OS, symptoms, symptomatic disease, quality of life.

4. Treatment Gaps (unmet needs)

4.1. Considering the treatment goals in Section 3, please describe goals (needs) that are not being met by currently available treatments.

-Limited Efficacy of Standard Chemotherapy, Single-agent chemotherapy (e.g., pegylated liposomal doxorubicin, topotecan, or paclitaxel) has low response rates (~10-15%) and limited progression-free survival (PFS)/limited duration of response. This provides an option for unmet need for pt with platinum resistant ovarian cancer who otherwise have very few treatment options

-MIRV provides a biomarker-driven option for FRα-high patients, expanding personalized treatment strategies.

-MIRV has a tolerable safety profile. There is unique side effect with eye toxicity which can be managed with early intervention.

-MIRV, as an ADC, offers a novel mechanism of action by delivering a potent cytotoxic agent (DM4) directly to tumor cells, bypassing some resistance mechanisms.

5. Place in Therapy

5.1. How would the drug under review fit into the current treatment paradigm?

- MIRV would provide a treatment option to those who have failed existing platinum resistant options
- The MIRASOL study included people who were immediately platinum resistant and some that had received platinum resistant treatment
- The data is tricky; prior receipt of bevacizumab (“bev”) and sequencing in platinum-resistant (PL-R) setting need to be addressed.
- About 60% of pts on study received prior bev (uncertain if the study provided break-down in terms of whether received in front-line or recurrent setting).
- PFS benefit was maintained regardless of prior receipt of bev but per Figure 2, OS benefit was not stat significant in subgroup of patients who received prior bev (n=142 HR 0.74; CI 0.54–1.04). This is not just a power issue as OS benefit was maintained in smaller subgroup without prior bev exposure (n=62, 0.51; 0.31–0.86).
- Some member of the DAC finds it difficult to justify recommending MIRV as standard first-line in PL-R setting for bev naive pts given no head to head comparison data with chemo/bev.
- If we think patients should have previously received bev (unless CI), should flag that OS was not significant post bev, and would be approving based on PFS benefit and OS benefit in all comers (somewhat driven by bev naive pts). Would perhaps have to reconsider whether bev should be reimbursed post-MIRV (no data to support).
- There is limited data to support bev/MIRV sequencing, and subgroup data suggests MIRV may not be as effective post bev.

- If we allow all-comers without restricting on prior bev, the DAC would suggest the use of real-world data to review 1) bev data post MIRV to ensure remains effective and 2) OS in patients who have previously received bev (since no stat sig OS benefit in this subgroup)

5.2. Which patients would be best suited for treatment with the drug under review? Which patients would be least suitable for treatment with the drug under review?

- Best suited – Patients who are platinum-resistant; This drug would provide an option for patients with FRα positive disease (high FRα tumor expression (≥75% of cells with ≥2+ staining intensity))

- high FRα tumor expression (≥75% of cells with ≥2+ staining intensity) was a selection biomarker for this trial, and eligible population should be restricted.

- Patients with high grade serous epithelial ovarian, primary peritoneal or fallopian tube cancer

- Least suitable – patients with low FRα expression, platinum-sensitive disease, those with severe liver or eye toxicities, peripheral neuropathy > grade 1; a chronic corneal disorder, a history of corneal transplantation, or an active ocular condition for which they were receiving ongoing treatment and monitoring

5.3 What outcomes are used to determine whether a patient is responding to treatment in clinical practice? How often should treatment response be assessed?

- History and physical exam. CT scan and Ca125

- Re: ocular toxicity

- ocular examinations: all pts received ocular examinations at screening + at onset of ocular symptoms and at every other cycle thereafter. This may be difficult for many of the centres re: access to ophthalmologists.

5.4 What factors should be considered when deciding to discontinue treatment with the drug under review?

- intolerance to treatment, i.e treatment related toxicities

- disease progression

- patient’s decision to stop treatment

5.5 What settings are appropriate for treatment with [drug under review]? Is a specialist required to diagnose, treat, and monitor patients who might receive [drug under review]?

Outpatient administration at chemo suites.

6. Additional Information

- Testing for folate receptor α (FRα) will be needed.

- Anecdotally, the DAC learned recently from some American colleagues that the ocular exams can be done by optometrist. AbbVie provides a training program for those willing, so can be done by optometrist in community which may be more accessible than ophthalmologist. Patients may have to pay out-of-pocket expenses to see an optometrist (unless they have insurance) vs ophthalmologist (where access may be limited at some centres).

7. Conflict of Interest Declarations

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

   OH (CCO) PDRP provided secretariat support to the group.

2. Did you receive help from outside your clinician group to collect or analyze any information 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 two years AND who may have direct or indirect interest in the drug under review. **Please note that this is required for each clinician who contributed to the input — please add more tables as needed (copy and paste). It is preferred for all declarations to be included in a single document.**

Declaration for Clinician 1

Name: Dr. Rachel Kupets
Position: Lead, OH (CCO) Gyne DAC
Date: 07-03-2025

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

Table 1: Conflict of Interest Declaration for Clinician 1

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				

Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 2

Name: Dr. Tiffany Zigras
Position: Member, OH (CCO) Gyne DAC
Date: 11-03-2025

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

Table 2: Conflict of Interest Declaration for Clinician 2

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Merck	X			
GSK	X			
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 3

Name: Dr. Josee-Lyne Ethier
Position: Member, OH (CCO) Gyne DAC
Date: 18-03-2025

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

Table 3: Conflict of Interest Declaration for Clinician 3

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 4

Name: <Enter full name>
Position: <Enter currently held position>
Date: <DD-MM-YYYY>

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

Table 4: Conflict of Interest Declaration for Clinician 4

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 5

Name: <Enter full name>
Position: <Enter currently held position>
Date: <DD-MM-YYYY>

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

Table 5: Conflict of Interest Declaration for Clinician 5

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

CADTH

CADTH Reimbursement Review

Clinician Group Input

CADTH Project Number: PC0394-00
Generic Drug Name (Brand Name): Mirvetuximab soravtansine
Indication: For the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens.
Name of Clinician Group: Society of Gynecologic Oncology of Canada (GOC)
Author of Submission: Lesley Roberts

1. About Your Clinician Group

The Society of Gynecologic Oncology of Canada (GOC) is a non-profit multidisciplinary organization. It is the national society representing health care professionals including physicians, nurses, pharmacists, and scientists involved in the treatment and prevention of gynecologic cancer. GOC strives to improve the care of women with, or who are at risk of, gynecologic cancer by raising standards of practice, encouraging ongoing research, promoting innovation in prevention, care and discovery, and advancing awareness.

Website: https://gyneoncology.ca/

2. Information Gathering

The information in this submission represents data from completed and published clinical trials, as outlined in the references below. These were identified through a literature review specifically focusing on trials investigating platinum-resistant ovarian cancer. Physician members of the Board of Directors of GOC, representing Gynecologic Oncology physicians across the country, were also surveyed regarding their expert opinion on the treatment of platinum resistant ovarian cancer.

References:

Matulonis et al. 2023. Efficacy and safety of mirvetuximab soravtansine in patients with platinum-resistant ovarian cancer with high folate receptor alpha expression: Results from the SORAYA study. Journal of Clinical Oncology. 41:2436-2445.

Moore et al. 2021. Phase III, randomized trial of mirvetuximab soravtansine versus chemotherapy in patients with platinum-resistant ovarian cancer: primary analysis of FORWARD I. Annals of Oncology. 32(6): 757-765.

Moore et al. 2023. Mirvetuximab soravtansine in FRα-positive platinum-resistant ovarian cancer (MIRASOL). New England Journal of Medicine. 389:2162-2174.

Moore et al. 2024. Safety and tolerability of mirvetuximab soravtansine monotherapy for folate receptor alpha-expressing recurrent ovarian cancer: an integrated safety summary. Gynecologic Oncology. 191:249-258.

Pujade-Lauraine et al. 2014. Bevacizumab combined with chemotherapy for platinum-resistant recurrent ovarian cancer: the AURELIA open-label randomized phase III trial. Journal of Clinical Oncology. 32(13): 1302-1308.

3. Current Treatments and Treatment Goals

Ovarian cancer is the second most common gynecologic cancer and the leading cause of death from gynecologic malignancy. Canadian Cancer Statistics estimated that 3000 women will be newly diagnosed with ovarian cancer in Canada in 2024, with an age-standardized incidence rate of 12.9 per 100,000 women. Most cases (>85%) diagnosed are epithelial ovarian cancer. Approximately 2000 women are estimated to have died of ovarian cancer in Canada in 2024. Unfortunately, there is currently no effective screening for ovarian cancer and initial symptoms are very vague. Therefore, most patients are diagnosed in later stages (Stage III-IV) where curative intent treatment is rarely successful. The 5-year overall survival for all-comers with epithelial ovarian cancer is 45% in Canada, which decreases to 39% and 17% for Stage III and IV disease respectively (Canadian Cancer Statistics).

Given the potential for prolonged survival, initial treatment of epithelial ovarian cancer is multimodal and provided with curative intent. Treatment typically involves a combination of surgical cytoreduction and systemic chemotherapy, most commonly carboplatin and paclitaxel. While initial ovarian cancer treatment is typically effective with high response rates, most patients will subsequently relapse and develop recurrent disease.

Recurrent epithelial ovarian carcinoma is typically characterized by intraabdominal carcinomatosis, causing significant symptom burden. Patients frequently struggle with recurrent ascites, recurrent pleural effusions, and bowel issues including partial or complete small bowel obstructions. Hospitalization is frequent and morbidity of the disease is high. Current goals of treatment in this setting are limited to improving progression-free survival, delaying disease progression, and improving quality of life by reducing severity of symptoms.

Recurrent epithelial ovarian carcinoma is classified based upon time since last dose of platinum-containing chemotherapy. Patients who recur more than six months' following their last dose of platinum-containing chemotherapy are considered platinum sensitive, whereas patients who recur within six months from their last dose of platinum-containing chemotherapy are platinum resistant. All patients with recurrent epithelial ovarian cancer will eventually progress to a platinum-resistant state. Platinum-resistance is associated with a poor prognosis, with response to standard systemic chemotherapy options in the 15-20% range. The AURELIA trial (Pujade-Lauraine et al, 2014) informed current standard of care for platinum-resistant ovarian cancer. In this trial, they randomized patients with measurable platinum-resistant ovarian cancer to investigator selected single agent chemotherapy (pegylated liposomal doxorubicin, weekly paclitaxel, or topotecan) alone or single-agent chemotherapy with bevacizumab. The results demonstrate the very poor prognosis of platinum-resistant ovarian cancer, with a median PFS in the chemotherapy alone group of 3.4 months. The addition of bevacizumab improved median PFS to 6.7 months, with an overall response rate of 27.3%. Non-chemotherapy treatment options are even less effective and include hormonal therapy (tamoxifen or aromatase inhibitors) with an anticipated response rate of approximately 15%. Many patients, given the toxicity of treatment and low response rates, will opt for best supportive care in these circumstances.

Mirvetuximab soravtansine is an antibody-drug conjugate that targets folate-receptor alpha (FRα). The mechanism of action is through disruption of microtubules in ovarian cancer cells. FRα is a cell membrane-bound receptor that mediates transport into epithelial cells, with limited expression on normal cells but upregulation on ovarian cancer cells. Using a PS2+ scoring of FRα staining system via the VENTANA FOLR1 RxdD assay, 32-36% of high grade serous epithelial ovarian cancer tumors have been shown to express FRα in clinical trials (Matulonis et al, 2023; Moore et al, 2023).

The MIRASOL trial (Moore et al, 2023) enrolled pre-treated recurrent high grade serous epithelial ovarian cancer patients who were platinum resistant and had FRα staining in > 75% of viable tumor cells. Patients were randomized to mirvetuximab soravtansine 6 mg/kg q3weeks versus investigator's choice single agent chemotherapy (weekly paclitaxel, pegylated liposomal doxorubicin, or topotecan). The median progression free survival was improved with mirvetuximab soravtansine compared to investigators' choice chemotherapy alone (median PFS 5.62 months versus 3.98 months, HR 0.65, p<0.001). The objective response rates seen with mirvetuximab was 42.3%, the highest response rate observed in a platinum-resistant ovarian cancer population to date. Overall survival was also noted to be significantly longer with mirvetuximab soravtansine (16.46 months vs 12.75 months, HR 0.67, 95% CI, 0.50 to 0.89; P=0.005)). Mirvetuximab soravtansine is the first novel treatment to offer an overall survival advantage in the platinum resistant epithelial ovarian cancer population.

4. Treatment Gaps (unmet needs)

4.1. Considering the treatment goals in Section 3, please describe goals (needs) that are not being met by currently available treatments.

As described above, most patients diagnosed with epithelial ovarian cancer will recur at some point in their cancer journey. Recurrent epithelial ovarian cancer is defined by sensitivity to platinum-containing chemotherapy, with all patients eventually becoming platinum resistant. Current treatment options for platinum-resistant ovarian chemotherapy include systemic chemotherapy alone, systemic chemotherapy plus bevacizumab, hormonal therapy, or best supportive care. All currently available treatments have response rates less than 30%. The majority are associated with significant toxicity, and at best provide progression free survival of approximately 7 months.

It is clear from this data that the treatment of platinum-resistant epithelial ovarian cancer is an area of significant unmet need. Available treatments are unable to reverse the course of disease, and patients rapidly become refractory to individual lines of treatment. Administration of many regimens is weekly (e.g., paclitaxel or topotecan), which places significant time and financial toxicity on patients and the health care system. Systemic chemotherapy is also associated with adverse events, which may be treatment limiting or insurmountable for many patients already living with the symptom burden of advanced cancer.

5. Place in Therapy

5.1. How would the drug under review fit into the current treatment paradigm?

Mirvetuximab soravtansine is an antibody drug conjugate, a novel mechanism of action for the treatment of epithelial ovarian cancer. Similar to existing treatments such as chemotherapy, mirvetuximab soravtansine is designed to address the underlying disease process.

Mirvetuximab soravtansine would fit into the current treatment paradigm as an additional treatment option for platinum resistant recurrent high grade serous ovarian cancer. It is used as monotherapy and would not be given in combination with other treatments. It is expected that mirvetuximab soravtansine will cause a shift in the current treatment paradigm of platinum resistant ovarian cancer, as it is the most effective treatment currently available for this subset of patients.

5.2. Which patients would be best suited for treatment with the drug under review? Which patients would be least suitable for treatment with the drug under review?

Mirvetuximab soravtansine is best suited for patients with platinum resistant recurrent high-grade serous ovarian cancer who have positive FRα staining in > 75% of viable tumor cells. FRα companion diagnostic testing will be required to establish which patients with platinum resistant recurrent ovarian cancer are candidates for mirvetuximab soravtansine. FRα staining has been demonstrated to be maintained throughout disease course, and therefore diagnostic testing on pre-existing tumor specimens is acceptable. Repeat biopsies do not need to be performed.

Recurrence of ovarian cancer can be diagnosed clinically, radiologically, or biochemically, though typically a combination of modalities is used. Patient selection for mirvetuximab soravtansine would depend on time since last platinum-containing chemotherapy. Mirvetuximab soravtansine is indicated for patients with platinum resistant disease, i.e., a platinum free interval of $\leq$ 6 months.

Patient's least suitable to treatment with mirvetuximab soravtansine include those with poor functional status (e.g., ECOG 4) or with pre-existing conditions that may worsen impact of known adverse events of mirvetuximab soravtansine. Ocular toxicity is a unique adverse event observed with the use of mirvetuximab soravtansine. Patients with known chronic corneal disorders, a history of corneal transplantation, or an active ocular condition would not be suitable for treatment.

5.3 What outcomes are used to determine whether a patient is responding to treatment in clinical practice? How often should treatment response be assessed?

Response to therapy would be based on clinical assessment (symptom burden and physical examination) and radiologic tumor burden assessment via CT or MRI. Tolerability of treatment and clinical assessment is performed prior to every cycle of therapy (every 3 weeks), and radiologic assessment is performed every 3 cycles of therapy (every 9 weeks).

A clinically meaningful response to treatment would be defined as radiographic disease control (tumor response or stabilization on CT/MRI) with improvement in cancer-related symptom burden and tolerable toxicity. Improved progression-free survival is clinically meaningful, even in the absence of overall survival for patients with such poor overall prognosis.

5.4 What factors should be considered when deciding to discontinue treatment with the drug under review?

Treatment would be discontinued in the following situations:

- Disease progression:
    - Disease progression can be identified clinically or radiologically. Stable disease is considered treatment response and not an indication to discontinue treatment in isolation
- Adverse events:
    - Grade 4 treatment-related adverse events warrant treatment discontinuation
    - Grade 2-3 adverse events associated with mirvetuximab soravtansine may warrant dose reduction, interruption or treatment discontinuation
    - Most commonly reported grade 3 or higher adverse events with this treatment regimen included:
        - Ocular toxicity (keratopathy, blurred vision, dry eye)
        - Abdominal pain
        - Fatigue
- Patient preference:
    - Patients can and may choose to discontinue treatment at any time, irrespective of adverse events or disease response

5.5 What settings are appropriate for treatment with [drug under review]? Is a specialist required to diagnose, treat, and monitor patients who might receive [drug under review]?

Treatment regimen would be administered as outpatient therapy in a comprehensive cancer center setting and is best prescribed by specialist physicians (medical oncologists, gynecologic oncologists) with experience and knowledge in treating gynecologic cancer.

6. Additional Information

Treatment of platinum-resistant epithelial ovarian cancer is an area of significant unmet need. Mirvetuximab soravtansine represents a novel therapeutic agent that provides superior benefit to any existing treatment, including improved progression free survival, overall survival, and objective response rate, for patients who are found to be FRα positive. This pharmaceutical represents an extremely important treatment option for recurrent ovarian cancer patients.

As an antibody-drug conjugate, mirvetuximab soravtansine has unique adverse effects owing to bystander effect. Studies demonstrate that this is primarily ocular toxicity, with 56% of patients reporting ocular adverse events in the MIRASOL trial. Of note, nearly all ocular adverse events resolved to grade 0-1 and only 1.8% of participants discontinued therapy due to ocular adverse events. However, best practice for patients initiating and continuing mirvetuximab soravtansine is regular ocular examinations, necessitating access to optometry or ophthalmology services while on treatment.

7. Conflict of Interest Declarations

To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the clinician group input. CADTH may contact your group with further questions, as needed. Please see the *Procedures for CADTH Drug Reimbursement Reviews* (section 6.3) for further details.

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

   No

2. Did you receive help from outside your clinician group to collect or analyze any information 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 two years AND who may have direct or indirect interest in the drug under review. **Please note that this is required for each clinician who contributed to the input — please add more tables as needed (copy and paste). It is preferred for all declarations to be included in a single document.**

Declaration for Clinician 1

Name: Lesley Roberts
Position: Gynecologic Oncologist, Assistant Professor
Date: 23-02-2025

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

Table 1: Conflict of Interest Declaration for Clinician 1

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**

AstraZeneca	X			
AbbVie	X			

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 2

Name: <Enter full name>
Position: <Enter currently held position>
Date: <DD-MM-YYYY>

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

Table 2: Conflict of Interest Declaration for Clinician 2

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 3

Name: <Enter full name>
Position: <Enter currently held position>
Date: <DD-MM-YYYY>

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

Table 3: Conflict of Interest Declaration for Clinician 3

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 4

Name: <Enter full name>
Position: <Enter currently held position>
Date: <DD-MM-YYYY>

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

Table 4: Conflict of Interest Declaration for Clinician 4

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 5

Name: <Enter full name>
Position: <Enter currently held position>
Date: <DD-MM-YYYY>

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

Table 5: Conflict of Interest Declaration for Clinician 5

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.