## CADTH REIMBURSEMENT REVIEW

# Patient and Clinician Group Input

**durvalumab (Imfinzi)**

(AstraZeneca Canada Inc.)

**Indication:** Imfinzi (durvalumab) is currently under review by Health Canada for the following proposed indication: for the treatment of patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy (CRT).

**November 25, 2024**

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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Patient Input Template for CADTH Reimbursement Reviews

Name of Drug: Durvalumab

Indication: Imfinzi (durvalumab) is currently under review by Health Canada for the following proposed indication: for the treatment of patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy (CRT).

Name of Patient Group: Joint submission by Canadian Cancer Survivor Network, Lung Cancer Canada, and Lung Health Foundation

Author of Submission: Lindsay Timm - Canadian Cancer Survivor Network, Winky Yau - Lung Cancer Canada, Riley Sanders - Lung Health Foundation

## 1. About Your Patient Group

This patient input submission is jointly submitted by the Canadian Cancer Survivor Network (CCSN), Lung Cancer Canada (LCC), and the Lung Health Foundation (LHF).

The Canadian Cancer Survivor Network (CCSN) is a national network of patients, families, survivors, friends, community partners, funders, and sponsors who have come together to take action to promote the very best standard of care, whether it be early diagnosis, timely treatment and follow-up care, support for cancer patients, or issues related to survivorship or quality of end-of-life care. https://survivornet.ca/

Lung Cancer Canada is a registered national charitable organization that serves as Canada's leading resource for lung cancer education, patient support, research and advocacy. Lung Cancer Canada is a member of the Global Lung Cancer Coalition and is the only national organization in Canada focused exclusively on lung cancer. Lung Cancer Canada is registered with CADTH. https://www.lungcancercanada.ca/

The Lung Health Foundation (previously named the Ontario Lung Association) is registered with the CADTH and pCODR. The Lung Health Foundation (Ontario Lung Association) is a registered charity that assists and empowers people living with or caring for others with lung disease. It is a recognized leader, voice and primary resource in the prevention and control of respiratory illness, tobacco cessation and prevention, and its effects on lung health. The Foundation provides programs and services to patients and health-care providers, invests in lung research and advocates for improved policies in lung health. It is run by a board of directors and has approximately 46 employees, supported by thousands of dedicated volunteers. www.lunghealth.ca

## 2. Information Gathering

Together, the Canadian Cancer Survivor Network (CCSN), Lung Cancer Canada (LCC), and Lung Health Foundation (LHF) all worked to produce a survey to be circulated amongst all three of their networks. The survey was disseminated through the three organizations' social media platforms, as well as CCSN's monthly newsletter. There was one individual who responded to the survey who had experience with durvalumab. The survey was conducted from August 1, 2024, to the date of writing of this submission to obtain responses. LCC also conducted three interviews with small-cell lung cancer patients (**TB, CA, JF**) who had direct experience with durvalumab via the ADRIATIC clinical trial, or the drug's Compassionate Access Program on November 13, 2024.

## 3. Disease Experience

From the survey response, the individual detailed that they experience a cough, difficulty fighting infection, fatigue, reduced appetite/weight loss, and nausea as physical symptoms that they deal with daily due to their disease. They also listed work as an activity that they are unable to do on a regular basis due to their lung cancer. Some negative impacts that the individual highlighted that affect their life are, waking up in the night or early morning because of breathing problems, feeling cold, emotional well-being, and excessive time spent attending medical appointments. Fatigue was identified as an aspect of the disease that is more important to control than others. Seeking support from friends, family and/or peers with lung disease or conditions was selected as a strategy that the individual uses to cope with their lung cancer.

**TB** is a caucasian female in her late 60s who worked as a chef and was on her feet for 12-16 hours a day, but also had back problems and her legs would give out on her. She never had any pain or symptoms, but when she went in for her yearly physical, they noticed lesions in her lungs and lymph nodes. She did present with a bit of a cough but thought that it was due to the fact that she was a smoker and was diagnosed in April 2024 with stage III small cell lung cancer in her left lung and it was growing as well as being in the lymph nodes. With radiation and chemotherapy, and later durvalumab, has improved.

**CA** is a caucasian male, now 59 years old. He had smoked for 25 years but quit in July 2020. CA wasn't diagnosed with cancer until March 2024, so he says it wasn't the cancer that drove him to quit smoking. He was not a super active person and also didn't eat very healthily since he worked long hours and was kept busy at work. CA has a few comorbidities including type 2 diabetes. His lung cancer was found incidentally during a scan looking for something completely different – he has plaque in his arteries, so he had a scan to see if the plaque had gotten worse (which it hadn't) but they found the cancer. He didn't have any textbook symptoms for small cell lung cancer, although it was very lucky to be found "early" as he doesn't know what would've happened if it wasn't found then. He didn't cough a lot but had bronchial issues in his youth, so he was never in great shape. Wasn't having a huge amount of shortness of breath, just thought he was out of shape, no coughing up blood, nothing out of the ordinary. It probably took four to six weeks from the initial CT scan that saw something, and had a number of PET scans, lung function tests, then a biopsy to find that it was small cell lung cancer in both lungs, though the tumour was still very contained in the central chest cavity and not in any other organs. Technically he would be in the "extensive stage SCLC" category, but only by technicality because they found one small spot in the second lung. He was told his overall level of disease at diagnosis was low.

CA said he was fully expecting this conversation of being diagnosed with lung cancer at some point in his life, but just not at 49 years old. His mom died of the exact same cancer he currently has, plus he was a smoker for 25 years, so he was expecting to have the conversation in his late 50s or early 60s. Lung cancer was unfortunately something he expected, just not so soon.

**JF** was always quite active and was in the process of retiring. He did smoke at one point but quit 15 years ago, and he just started coughing one day and couldn't seem to get rid of it. Whenever he exercised much, he'd start coughing, which was odd to him, so he went to his family doctor to check it out. The family doctor sent him for x-ray and CAT scan, which confirmed the diagnosis of lung cancer in July 2020. He had no other symptoms other than the cough, which was quite aggravating once he did an exercise. It was very shocking. The same day he was diagnosed with lung cancer, he was sent to The Ottawa Hospital and saw the doctors right away. He had a biopsy done first, then met with the radiologist and oncologist, went over the results and treatments he had to have. Shortly after they booked him in for treatment with chemotherapy on September 23rd, 2020, followed by 30 radiation treatments on the lung starting October 13 and finishing November 24. Then 10 additional radiation treatments on the brain on December 29, which finished Jan 12, 2021. He then started durvalumab in Feb 2021. The diagnosis was small cell lung cancer, but he is unsure what stage it was at.

## 4. Experiences With Currently Available Treatments

From the survey, we were able to identify that the individual had also been treated with osimertinib. When asked about the adverse effects that they experienced the individual identified fatigue as the main adverse effect. The individual expressed that the adverse effects were manageable through exercise. When trying to access osimertinib, the individual detailed that there was financial hardship due to cost and that the treatment failed quickly for them. When asked to rate their experience on osimertinib from 1-10, the individual rated the treatment with a value of eight. When asked how they would tell a friend how they are managing on this treatment, the individual stated that they were managing well. When asked about the benefits of the medication the individual stated ease of administration as the main benefit.

After diagnosis, **TB** started on eight sessions of chemotherapy and eight sessions of radiation. She would attend chemotherapy once a month and radiation every day for eight weeks. They were initially going to give her chemotherapy every two weeks, but her white blood cell count was too low. TB experienced more side effects with radiation than chemotherapy. With radiation, she had a hard time swallowing, stomach pains, and lost her voice. Since she had a hard time swallowing, she also had a hard time eating. They gave her a medication to "freeze" her esophagus, but she found that ginger and cinnamon helped more. She also found that a more liquid diet was helpful. During chemotherapy she lost some of her hair but found that she lost more of it after stopping treatment. She did not find that she was nauseous during chemotherapy.

TB had no issues with her day to day and said that it was pretty much normal. Her sister advised her to keep her normal routine so that is what she did. There were the odd days where she would feel a bit more tired but felt that it didn't impact her too much. Climbing the stairs was the most challenging but going down was manageable. She goes for walks a little bit but is not too active. TB also has heart issues.

TB's treating team wanted to radiate her brain as a preventative measure, but she refused as it may have affected her memory and there was no cancer present at the time.

**CA** immediately got set up with a radiation oncologist and medical oncologist in two to three weeks after diagnosis. Just happened that there was a clinical trial open for his type of cancer, and he fit the criteria. He met with the doctors, and they got him started on the clinical trial (doesn't know the name of it) at the same time. Started 35 days of radiation therapy and 4 cycles of chemo at about the same time in late April/early May 2024. Chemotherapy ran basically the entire summer, but he had no idea if what he was feeling was a side effect of radiation, chemotherapy, a symptom of the cancer itself, or something completely different. There were lots of things going on: he was incredibly tired, didn't have much nausea and vomiting, but did lose his hair. There were some points where he didn't have much more strength than to do the bare minimum of day-to-day activities (showering, making food, using the bathroom, etc.), but this was later during the chemo cycles. They gave him another CT scan near the end of the trial in July, and across the board, all the tumours had shrunk and o progression to other areas. They also gave him 10 sessions of preventative radiation to the brain (which was part of the trial), there weren't any tumours there, but they didn't want something to have a chance to grow. His hair still hasn't grown back, but his beard and other areas has, and it's likely his hair won't ever grow back.

CA did four cycles of chemotherapy, during cycle three and four there was a two-week period of feeling like everything was just "rubber", didn't know if he could hold his body upright. He didn't know if it was radiation or chemotherapy. In the short term, it was well worth whatever side effects he had to shrink his cancer and give him more time. There were some points where he didn't have the greatest quality of life. He was still able to work, his work is very flexible with him, which is now mostly a desk job. Wouldn't have been able to do manual labour if that was his job instead. Towards the end of chemotherapy, his quality of life wasn't great. Everything he did on a day-to-day basis had to be planned around rest periods. For example, if he had to shower, he'd have to think it through like "I need 15 mins to shower, but also an extra 20 mins to mentally prepare and get ready for the shower, and another 30 mins when I'm done to recover my energy afterwards." So, a 10 min shower would require almost 1h of his day, so he really had to space things out and take one thing slowly at a time.

**JF** had four rounds of chemotherapy, every three to four weeks. The side effects that he experienced were that he lost his hair, got a little tired the next day, but overall, nothing serious. No nausea or vomiting with chemotherapy. He was able to go about his day-to-day life almost as normal. He had no issues with driving, grocery shopping, cooking, cleaning, etc.

With radiation JF had very little side effects. He had radiation treatment every day except weekends. For the brain radiation, it might have affected his memory. He also had to get hearing aids, he never had hearing problems before the radiation, but he got them in October during radiation. He is not sure what caused it, but the doctor did say it could've been a side effect from brain radiation. He gets frustrated with it if there's a crowd, going into a restaurant or places with lots of people. He has a hard time with the noise, it is hard to focus on one conversation, but just told people he didn't understand them and had to repeat themselves. However, this didn't limit him from socializing and meeting with friends and family for dinner - he still did all that, but maybe just needed a quieter corner to chat. He worked as a councillor in their township, and during the radiation he did have to leave work and retire early because of the memory loss. He said focusing on all the different projects going on and concentrating was the issue, not so much the hearing. During the radiation, his wife also retired at the same time and both of them haven't gone back to work. She still does some part time minor jobs, volunteering, etc.

## 5. Improved Outcomes

When asked about considering new medications to treat lung cancer, we asked respondents to pick their top three responses as to what they consider to be the most important benefit of a new medication or treatment. The individual responded with reduced cost, improved quality of life, and improved energy as their top priority. When asked if there were any needs in their current or previously administered treatments that were not yet being met, the individual replied saying that when treatment failure occurs with TKIs that there are very few/very poor follow-up treatments.

## 6. Experience With Drug Under Review

From the survey response, it was highlighted that fatigue and constipation were the main two adverse effects experienced by this individual when taking durvalumab. The individual did respond saying that these adverse effects were managed by exercise and seeking out emotional support. To access durvalumab, this individual was given compassionate access. When asked to rate their experience with durvalumab on a scale from 1-10, the individual rated the treatment with a value of eight. When asked to describe how they would tell a friend how they are managing while taking durvalumab, the individual stated that they would say that they were managing well. When asked about the benefits of the medication, the individual stated ease of administration as the main benefit.

**TB** started durvalumab on September 26, 2024, about five to six weeks after she had completed her other treatments. So far, she has had no side effects. She has received two treatments thus far that happen at the end of every month. She will be receiving durvalumab once a month for 12 months. She has no issues going about her day to day now. She has been granted access through the compassionate access program so that she is not paying out of pocket. TB is not working anymore and is relying on her pension to support her. If she had to pay for durvalumab, she wouldn't have been able to afford it.

While on durvalumab, TB has no issues going about her life as usual. She is out socializing, running errands, and keeping to her routine with no issues at all. She continues to meet up with friends, go grocery shopping, and clean the house as some examples of what she is able to accomplish. She visits the hospital once a month and her next scan will be in December to see how the treatment is working. TB drives herself about 40 minutes to the appointments with no issues. She feels that she has had no change in independence and functionality. She cooks, cleans, does yard work and if she gets tired, she just stops.

When asked to rank durvalumab on a scale of 1-10, TB rated it a 5, saying that she feels "about the same" with her experience with other treatments versus durvalumab. She didn't have much of a reaction from chemotherapy, but the

radiation was a different story. The chemotherapy never really bothered her, and she feels the same way with durvalumab. When it comes to radiation versus durvalumab though, she would much prefer durvalumab.

When asked if it was worth accessing durvalumab TB said yes. She knew other patients who were on it that had said it was life changing for them. She also feels that if it's going to give her a few extra years then she's all for it. The last MRI she had showed the mass was no longer there, but it's still in the blood. The radiologist says it usually shows up in the brain next, but the brain was clear on the last scan which is good. TB lives with her son and grandchildren and has a good support system. She is taking it day by day but hopes to travel to Arizona for the winter even with the uncertainty of what is to come next.

**CA** finished his last round of chemotherapy IVs in mid-July, but he continued to feel the side effects for a month after and started the 10 rounds of brain radiation over two weeks. A few weeks after that he started the durvalumab roughly around September 2024. As of November 13, he's only had two treatments of durvalumab so far. CA says so far so good, but no update on how cancer has reacted, he won't have his next scan until December. He did find he was more nauseous after the treatments. Hard to tell if they're delayed reactions from the last brain radiation. Ultimately once he came out of the last chemotherapy cycle, he started feeling much better. He's not back to 100 percent normal where he could walk the entire golf course, but now his energy has recovered significantly to where it almost was before the chemo and isn't worried about having to plan his days and tasks around rest periods anymore and is free to just do things as normal.

CA feels that he basically has had no side effects from the durvalumab. All the things he was feeling, he brought up to his oncologist, but they thought it wasn't related to the durvalumab because it was "too early". He was told some of the more severe side effects start occurring at three months so he's just waiting for that. Nothing new in bloodwork to suggest he's having a reaction. He's on the drug on a compassionate basis since this isn't standard treatment for his cancer.

CA now has no issues with running errands, grocery shopping, cleaning, etc. He goes to hospital twice a month and does durvalumab treatment once a month. He drives himself to all his appointments with no issues. CA just wants more meaningful time where he can do his normal activities. He wants time to sort things out and get things in place in case the worst happens. He has been living by himself in Edmonton since he moved there 20 years ago. CA has family in Nova Scotia that are supportive as they can be, and his friends in the local area are great. He also has a therapist that he talks to frequently.

CA did not feel comfortable giving durvalumab a ranking on the scale from 1-10. His quality of life on durvalumab has been better than chemotherapy/radiation, but it's hard to say if it's better or worse because he doesn't know if the drug is actually working on his tumours yet. He won't know until his first scan. Wouldn't trade one for the other, but so far, side effects have been less harsh with durvalumab. He felt he couldn't choose one or the other. He needed both because if he didn't get the time he had with the trial, maybe he wouldn't have been able to get this durvalumab, or vice versa. He knows he won't reach 75 or 80 years old in his future, but he's also not prepared to die either. Willing to do whatever treatment it takes to stay alive for as long as possible. He does believe that it was worth accessing durvalumab. Since it's currently not standard treatment for his cancer, he had to get approval from Health Canada and the manufacturer for the compassionate access program, but he's not sure who's actually paying for it. He will remain on it for 12 treatments which is approximately 12 months.

CA is taking it day by day and is just happy to have another day. He's still working and works for a company that does industrial inspections. Regardless of his treatments, he has been given a diagnosis for a finite amount of time left, if he didn't enjoy going to work, there's no reason for him to work. Doesn't really have a financial reason to do so, he works because he enjoys what he does. CA is not much of a traveler. If he can find a place to move with perfect weather, he might move there, such as Mauritius. Probably not in the cards to even move to Nova Scotia to be closer to his family because the healthcare system is so different; he's very incredibly grateful for his current healthcare team, and to Health Canada for letting him take this drug.

**JF** started durvalumab very shortly after the brain radiation was complete, in February 2021. He had only had two treatments of durvalumab before he had to stop it, as his experience was much different than TB or CA's. After the

first treatment he got quite sick, and when he went to the second treatment it just got worse. He had no appetite, was vomiting constantly, and had diarrhea. Nothing would stay down. He lost almost 48-50 pounds, and his wife and family thought they were losing him and that he was going to die. One night when he really felt ill after the second treatment, they went to the local ER, and they gave him an IV for about four hours. He was very dehydrated, was not doing well at all. They didn't admit him but just gave him the IV, and he went home. It took a few days for him to get better, the medicine was pretty strong, and they would drop him down to another dose of IV until he got his strength up again. He's unsure if the durvalumab may have worked in shrinking or stabilizing his cancer, but the oncologist said it wasn't worth it, so they stopped the treatment altogether. He's had no further treatments ever since durvalumab. They've just been monitoring with follow up brain and CAT scans every three months, then six months, now maybe in talks of just doing once a year because it hasn't grown at all ever since. There was one brain scan that showed possibly a minor stroke, his right eye was dropping (lazy eye), not sure if that was because of the brain radiation or immunotherapy (this happened after the treatment on durvalumab). They just did another scan for this, but there's no real treatment for it, they just sent him to an ophthalmologist and his local eye doctor said it's possible they could do something about it, hinting at plastic surgery, but it didn't bother him that much, so they said no. Even today in 2024, it's still the same, the eye drooping didn't get better. JF is currently on no treatments, but so far so good.

JF isn't sure if the tiredness is the side effects of radiation or durvalumab, but he still does all the yard work, brings in wood, cuts the lawn, shovels snow, rakes leaves, but he just tires out quicker. The only thing he can't do is handle the chainsaw anymore. He's unsure if it's the loss of strength in his arms to use to start the chainsaw, but once he gets it running, he can do it, but just can't get it started. He still does most of the chores in the house, no issues with cleaning, cooking etc. Must go to the cancer center every six months to see his oncologist, and his last report was really good. He didn't think there's any cancer right now, it's just been scar tissue on the scans. The doctor told them he thinks the two treatments he did have with durvalumab probably helped even if it didn't seem to. Also, it's been three years now without any additional treatment, so it seems like something worked. Still drives himself, even throughout all the treatments.

When asked to rate his overall experience with durvalumab, JF said that he can't really put a number on it. If it did him any good, he would rank it high because he got the extra years, but if not, the sickness he went through was very tough, his family all thought he was dying. When asked if it was worth accessing durvalumab he stated that it was a hard question since for him if it prevented further cancer growth, then yes, but if it didn't work, he wouldn't have advised it to anyone based on his experience.

JF would say he's about 70 percent similar to doing what he used to do before the diagnosis. His energy levels are slightly lower than what they used to be, he'd have to use more energy to do things. Otherwise, he hasn't found anything that's limiting him. In the summer, he goes fishing a lot and goes hunting in the fall/winter. Right now, the cancer hasn't limited him in doing these things. He does plan on having an overseas trip in the spring. He and his wife will be 50 years married this year, so they want to celebrate. They will continue to monitor with scans and will probably be reduced to seeing the doctor once a year because the results have been so good.

## 7. Companion Diagnostic Test

**If** the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments.

What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?
- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

**N/A**

8. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

CCSN, LCC, and LHF are aware of the limitations of this submission given the small number of respondents, however, we believe the experience of TB, CA, and JF are more than relevant as they all have small-cell lung cancer, with direct experience on durvalumab in this indication either through the ADRIATIC clinical trial, or the manufacturer's compassionate access program. Upon analyzing the data of the survey results, it was found that the respondent who had experience with durvalumab had NSCLC. We understand that the focus of this submission was to understand the effectiveness on and burden of small cell lung cancer. However, we feel that it is still important to include the experience of this individual to capture the scope of treatment that can be achieved with durvalumab.

Patients with SCLC have a large unmet need due to a high symptom burden, rapid spread and progression of the disease resulting in poorer outcomes. There are also few viable treatment options, quite unlike those with NSCLC who have a wider range of options. As seen throughout this submission, durvalumab has added to most of the respondent's quality of life and even though most are early in their treatment with this medication, they are already seeing benefits. With Health Canada and manufacturers granting compassionate access to this treatment it allows physicians to see how it acts in the real-life clinical setting. With there being so few viable treatment options available for SCLC, it is important to consider how life changing it is for a patient to have options when other treatment options fail, as they so often do with SCLC. With lung cancer still being the cancer with the highest mortality rate and patients looking to have options, we believe it would be beneficial to have this treatment available to the lung cancer community.

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 |
|---|---|---|---|---|
| AstraZeneca - 2023 (CCSN) | | | | X |
| AstraZeneca - 2024 (CCSN) | | | | X |
| AstraZeneca - 2023 (LCC) | | | X | |
| AstraZeneca - 2024 (LCC) | | | | X |

| | | | | |
|---|---|---|---|---|
| AstraZeneca - 2023 (LHF) | | | | X |
| AstraZeneca - 2024 (LHF) | | | | 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: Lindsay Timm**
**Position: Community Engagement Manager**
**Patient Group: Canadian Cancer Survivor Network**
**Date**: **November 25, 2024**

CADTH

# CADTH Reimbursement Review

## Clinician Group Input

CADTH Project Number: PC0389-000
Generic Drug Name (Brand Name): durvalumab (Imfinzi)
Indication: Durvalumab for the treatment of patients with limited-stage small cell lung cancer (LS-SLC) whose disease has not progressed following platinum-based chemoradiation therapy (CRT)
Name of Clinician Group: Lung Cancer Canada – Medica Advisory Committee
Author of Submission: Dr. Shantanu Banerji (lead), Dr. Sunil Yadav, Dr. Callista Phillips, Dr. Nicole Bouchard, Dr. Randeep Sangha, Dr. Cheryl Ho, Dr. Alison Wallace, Dr. Jeffrey Rothenstein, Dr. Abhenil Mittal, Dr. Biniam Kidane, Dr. Vishal Navani, Dr. David Dawe, Dr. David Stewart, Dr. Silvana Spadafora, Dr. Nathalie Daaboul, Dr. Mark Vincent, Dr. Sara Taylor, Dr. Mahmoud Abdelsalam, Dr. Geoffrey Liu, Dr. Shaqil Kassam, Dr. Ron Burkes, Dr. Normand Blais, Dr. Paul Wheatley-Price, Dr. Quincy Chu, Dr. Rosalyn Juergens, Dr. Kevin Jao, Dr. Stephanie Snow

### 1. About Your Clinician Group

Lung Cancer Canada (LCC) is a national charity with the purpose of increasing awareness about lung cancer, providing support and education to lung cancer patients and their families, to support research, and to advocate for access to the best care for all lung cancer patients in all provinces and territories.

Through the LCC Medical Advisory Committee (MAC), we have been providing clinician input for submissions of new lung cancer drugs to the HTA process for many years. The LCC MAC consists of clinicians and key opinion leaders in the field of lung cancer across the country.

www.lungcancercanada.ca

### 2. Information Gathering

The information provided in this submission is from publicly available sources, primarily published manuscripts and conference presentations, together with clinical experience of members from the MAC. This Submission is entirely independent of the manufacturer (AstraZeneca).

### 3. Current Treatments and Treatment Goals

Small cell lung cancer (SCLC) represents approximately 12% of all lung cancers in Canada and is almost exclusively seen in patients with at least a 30 pack-year smoking history. Rates of SCLC have been declining over the decades due to public health efforts to reduce tobacco smoke consumption. Most patients present at late stage; in 67% of patients the cancer has spread outside the lung and regional lymph nodes (Extensive Stage [ES-SCLC] or stage IV) (Canadian Cancer Statistics – A 2020 special report on lung cancer. Available at http://cancer.ca/Canadian-Cancer-Statistics-2020-EN). The remaining 1/3 of patients present with limited-stage SCLC (LS-SCLC) defined by: 1) Disease confined to one side of the chest +/- regional lymph nodes, 2) Confined to an area that can be encompassed within a radiation port. LS-SCLC roughly corresponds to Stage I-III disease using the TNM staging system for non-small cell lung cancer.

SCLC regardless of stage is characterized by a high response rate to initial cytotoxic chemotherapy. When comprehensive staging investigations confirm LS-SCLC, the treatment goal is curative using an aggressive course of concurrent platinum-etoposide chemotherapy and radiation. Patients with LS-SCLC may present with a high local disease burden in the chest due to the aggressive nature of the disease. This may cause severe breathing symptoms that impact quality of life (QOL). The high rates of response to chemotherapy and radiation leads to a rapid reduction in disease burden, objective symptom improvement, along with the opportunity for disease cure. If disease recurrence is subsequently detected, patients are essentially managed as per Canadian treatment guidelines for ES-SCLC, but are no longer considered curable.

The standard treatment for LS-SCLC is 4 cycles of cytotoxic platinum (cisplatin or carboplatin) and etoposide chemotherapy combined with concurrent (or simultaneous) standardized once-daily or twice-daily radiation doses, with curative intent. Despite initial responses, SCLC including limited-stage disease is characterized by high rates of recurrence that contribute to patient death. Common sites of disease recurrence include the brain, chest, bone, liver, and adrenal glands.

Following standard concurrent chemoradiation for LS-SCLC, median time to progression in one or more locations is less than 16 months and 70% of patients have typically progressed within 5 years. Historical median overall survival (OS) for LS-SCLC treated with concurrent chemoradiation on clinical trial is <30 months and <18 months in the real-world setting. Five-year OS from historic clinical trials is <35%, and 18% in the real-world Canadian context. Some patients are considered for prophylactic cranial irradiation (PCI) to help prevent metastatic recurrence in the brain, which has shown a modest 5% improvement in survival, but can be associated with short- and long-term clinical toxicity. There is an emerging role for MRI surveillance as an alternative to PCI but results from randomized clinical trials are pending.

The current standard of care of concurrent radiation and platinum-etoposide +/- PCI for LS-SCLC has not changed significantly in the last 25 years and there have been no new effective systemic therapy options since 1985. This is in contrast to ES-SCLC where the addition of PD-L1 inhibitors (durvalumab or atezolizumab) to platinum-etoposide chemotherapy has shown an ~2 month absolute improvement in median OS. Chemotherapy + PD-L1 therapy is now the standard of care for ES-SCLC in Canada, where goals of treatment are to improve symptoms and prolong survival, but does not cure the disease.

## 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.

The minority of patients with SCLC are diagnosed with Limited Stage disease after comprehensive staging investigations that currently include invasive biopsy, CT scans of the brain, chest, abdomen, and pelvis +/- a bone scan or PET scan. Patients confirmed with LS-SCLC are treated for cure with aggressive chemotherapy and radiation. Failure to cure the disease results in disease recurrence particularly in sites like the brain, liver and bone which cannot be cured and results in significant symptomatic burden impacting both patient QOL and survival. Currently, <20% of the LS-SCLC population in Canada is cured with the existing standard of care.

Improving cancer cure is the ultimate goal for all cancer patients and providers. No therapy has improved overall survival (OS) and disease cure with LS-SCLC in the last 25 years. The addition of durvalumab post completion of chemoradiation for LS-SCLC has resulted in an absolute increase of median OS of 22.5 months compared to placebo, and represents a major breakthrough resulting in more cases of cured SCLC. Also, the addition of durvalumab may reduce the rates of PCI in many patients with LS-SCLC, thereby preventing short- and long-term neurotoxicity associated with whole brain radiation therapy. Instead, more patients could be followed by serial MRI surveillance, which is emerging as an alternative to PCI.

## 5. Place in Therapy

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

Targeting the immune system is a new treatment paradigm for cancer in general and lung cancer in particular. The addition of immunotherapy to chemotherapy has already shown improved survival and meaningful benefit in the ES-SCLC population. Platinum-etoposide combined with either durvalumab or atezolizumab followed by maintenance immunotherapy as monotherapy is the

standard of care in Canada for patients with ES-SCLC with good performance status and no contraindications to therapy. There is wide uptake and familiarity with the use of immunotherapy to treat ES-SCLC across Canada.

The current application will introduce the use of durvalumab consolidation immediately after response to first-line chemoradiation for LS-SCLC. This means that the use of durvalumab will no longer be restricted to patients with ES-SCLC at diagnosis or after disease relapse following chemoradiation alone for LS-SCLC. This will result in fewer cases of LS-SCLC progressing to ES-SCLC and more patients likely to be cured of their disease.

There are no alternative treatments for LS-SCLC. Without treatment, all patients will progress to ES-SCLC where average survival without treatment is <6 weeks.

## 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?

Based on the results of the ADRIATIC study, the most suitable candidates for durvalumab would be:

1. Patients with biopsy proven Limited-Stage Small-Cell Lung Cancer. This represents only 1/3 of SCLC based on the current practice of extensive staging investigation including CT scans +/- bone scans or PET scans. Histologic confirmation of SCLC requires morphologic confirmation on pathology supplemented with confirmatory immunostains at the discretion of the pathologist. The diagnosis of SCLC is routinely made by pathologists in the community and academic practice setting across Canada.
2. Patients who have shown disease stabilization or shrinkage after standard concurrent treatment with cytotoxic platinum-etoposide chemotherapy and thoracic radiation. Patients with disease progression were excluded from the ADRIATIC clinical trial and would be managed per the ES-SCLC treatment guidelines.
3. Patients with an ECOG performance status of 0-1 post chemotherapy and radiation. In the real-world setting, this would also include ECOG 2 patients, similar to the approval of durvalumab and atezolizumab in the ES-SCLC population.
4. Patients of any age. Age was not an exclusion criteria for the ADRIATIC trial as long as patients successfully completed concurrent chemoradiation.

Patients least suitable for durvalumab:

1. Patients with severe or symptomatic auto-immune disorders are generally not suitable for treatment with durvalumab.

## 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?

The most meaningful outcome for patients with LS-SCLC is improved overall survival due to disease cure. Traditionally in oncology, disease cure is often defined as 5-years disease free after completion of front-line curative-intent therapy. In patients with LS-SCLC, this would be defined from when they started chemoradiation for their disease. Equally important is quality of life that can be impacted either by disease burden or treatment toxicity

In the ADRIATIC trial, patients received durvalumab (or placebo) every 4 weeks for up to 2 years. The most common reasons for discontinuing durvalumab were disease progression (46%) and adverse events related to therapy 16.3%). Patient received a median of 9 durvalumab doses on trial. In routine clinical practice, CT scans and/or MRI's are performed every 3-4 months for the first 2 years after completion of chemoradiation to look for objective evidence of disease progression including new metastatic disease. This would remain the same for patients on durvalumab who will also be assessed clinically every 4 weeks prior to each new cycle for treatment toxicity (particularly immune-related side effects) and evolution of cancer-related symptoms. Treatment will be discontinued if drug-related toxicity emerges that is negatively impacting the patient's symptoms, function, and quality of life. Both the

frequency of clinic visits and imaging surveillance are reduced in years 3-5 after completion of chemoradiation. Patients disease free after completion of 5 years post-chemoradiation surveillance are considered cured from their LS-SCLC.

### 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).

Treatment should be discontinued in the setting of unequivocal disease progression, intolerable treatment related adverse effect or patient choice to stop treatment for other reasons.

In some cases, disease progression may occur at an isolated site (e.g. solitary nodule in the lung, liver, bone, brain or adrenal gland). This disease progression may be amenable to curative local therapy with either surgery or radiation allowing for continued treatment with durvalumab. This is similar to currently acceptable practice for patients with ES-SCLC or the more common non-small cell lung cancer (NSCLC).

Not all drug-related adverse events require permanent discontinuation of durvalumab. Some adverse events like rash or transaminitis, may resolve to a brief treatment interruption or supplemental topical therapies. Immunotherapy related endocrinopathies may respond to appropriate hormone supplementation e.g. immunotherapy-induced hypothyroidism.

### 5.5 What settings are appropriate for treatment with durvalumab? Is a specialist required to diagnose, treat, and monitor patients who might receive durvalumab?

Durvalumab after chemoradiation can be administered as an outpatient in a systemic therapy treatment unit. Treatment most often would be given in a specialized cancer hospital with chemotherapy and immunotherapy experience. This can be performed in easily be performed in the community oncology setting. This is already the standard for the use of durvalumab in the treatment of ES-SCLC in most regions of Canada. Treatment should be under the supervision of the appropriate oncology care team.

## 6. Additional Information

Durvalumab represents a major breakthrough towards improving the likelihood of cure following the diagnosis of LS-SCLC. Prior to the ADRIATIC clinical trial, the most contemporary randomized clinical trial in LS-SCLC was the CONVERT trial, which compared two schedules of radiation combined with standard platinum-etoposide chemotherapy. There was no significant difference in survival between the two radiation (once daily and twice daily fraction) schedules. The CONVERT trial established a benchmark of a median OS of 25-30 months. The placebo arm of the ADRIATIC trial showed a median OS of 33.4 months exceeding the historic benchmark. Despite this, with a median follow-up of 37.2 months, the experimental arm with durvalumab consolidation demonstrated a 55.9 month median OS representing a 22.5 absolute improvement in overall survival. This improvement is unprecedented in LS-SCLC.

The ADRIATIC clinical trial required patients receive concurrent chemoradiation prior to starting on durvalumab. In some parts of Canada, logistic barriers necessitate that patients with LS-SCLC receive chemotherapy immediately followed by sequential radiation for LS-SCLC. The patients are still being treated with cure intent but healthcare resources limit concurrent treatment. These patients should also be considered appropriate for durvalumab if there is evidence of disease stability or response after completion of the sequential chemotherapy and radiation. The PACIFIC clinical trial only explored the benefit of durvalumab consolidation after curative intent concurrent chemoradiation for Stage III NSCLC. However, the Canadian community has implemented that durvalumab can be used after objective response or stable disease following either concurrent or sequential chemotherapy and radiation for curative intent Stage III NSCLC.

## 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** | *Shantanu Banerji* |
| **Position** | *Medical Oncologist, CancerCare Manitoba* |
| **Date** | November 25, 2024 |
| ☒ | **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. |

**Conflict of Interest Declaration**

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.

| **Company** | **Check Appropriate Dollar Range** | | | |
|---|---|---|---|---|
| | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *Astrazeneca* | ☐ | ☒ | ☐ | ☐ |
| *Roche* | ☐ | ☒ | ☐ | ☐ |
| *Add or remove rows as required* | ☐ | ☐ | ☐ | ☐ |

### Declaration for Clinician 2

Name: Dr. Shaqil Kassam
Position: Medical Oncologist, Southlake Regional Hospital
Date: November 25, 2024

☒ 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 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** |
| Roche | x | | | |
| Merck | x | | | |
| BMS | x | | | |
| Takeda | x | | | |
| Novartis | x | | | |
| Ipsen | x | | | |
| Sanofi | x | | | |
| Pfizer | x | | | |

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

## Declaration for Clinician 3

**Name: Quincy Chu**
**Position:** Medical Oncologist, Cross Cancer Institute, Edmonton, AB
**Date:** November 25, 2024

☒ **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 3**

| Company | Check appropriate dollar range* | | | |
|---|---|---|---|---|
| | **$0 to $5,000** | **$5,001 to $10,000** | **$10,001 to $50,000** | **In excess of $50,000** |
| Abbvie | X | | | |
| Amgen | X | | | |
| AnHeart | X | | | |
| Astellas | X | | | |
| Astra Zeneca | | X | | |
| Boehringer Ingelheim | X | | | |
| BMS | X | | | |
| Daichii Sankyo | X | | | |
| Eli Lilly | X | | | |
| GSK | X | | | |

| | | | | |
|---|---|---|---|---|
| Janssen | X | | | |
| Meck | X | | | |
| Novartis | X | | | |
| Ocellaris | X | | | |
| Pfizer | X | | | |
| Roche | | X | | |
| Takeda | X | | | |

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

### Declaration for Clinician 4

Name: Dr. Mahmoud Abdelsalam
Position: Medical Oncologist, Horizon Health Network
Date: November 25, 2024

☒ 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 4**

| Company | Nature or description of activities or interests | Check Appropriate Dollar Range | | | |
|---|---|---|---|---|---|
| | | $0 to 5,000 | $5,001 to 10,000 | $10,001 to 50,000 | In Excess of $50,000 |
| BMS | Advisory role, Honoraria and travel grants | ☐ | ☒ | ☐ | ☐ |

| New or Updated Declaration for Clinician 5 | |
|---|---|
| **Name** | *Biniam Kidane* |
| **Position** | *Associate Professor, Dept of Surgery, University of Manitoba* |
| **Date** | November 25, 2024 |
| ☒ | **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. |

**Conflict of Interest Declaration**

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.

| Company | Check Appropriate Dollar Range | | | |
|---|---|---|---|---|
| | $0 to 5,000 | $5,001 to 10,000 | $10,001 to 50,000 | In Excess of $50,000 |
| *AstraZeneca* | ☐ | ☐ | ☒ | ☐ |
| *Merck* | ☒ | ☐ | ☐ | ☐ |

| | | | | |
|---|---|---|---|---|
| *Roche* | ☐ | ☒ | ☐ | ☐ |
| *Bristol Myers Squibb* | ☒ | ☐ | ☐ | ☐ |
| *Medtronic* | ☒ | ☐ | ☐ | ☐ |

| **New or Updated Declaration for Clinician 6** | |
|---|---|
| **Name** | *Dr. Alison Wallace* |
| **Position** | *Assistant Professor Department of Surgery, Division of Thoracic Surgery and Department of Pathology, Dalhousie University. Thoracic Surgeon QEII HSC, Halifax. NS.* |
| **Date** | November 25, 2024 |
| -☒ | **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. |

**Confli-ct of Interest Declaration**

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.

| **Company** | **Check Appropriate Dollar Range** | | | |
|---|---|---|---|---|
| | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *Merck* | ☒ | ☐ | ☐ | ☐ |
| *Bristol Myers Squibb* | ☒ | ☐ | ☐ | ☐ |
| *AstraZeneca* | ☒ | ☐ | ☐ | ☐ |

**Declaration for Clinician 7**

**Name: NATHALIE DAABOUL**
**Position: Hematologist-Oncologist, Université de Sherbrooke**
**Date:** November 25, 2024

**x 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 7**

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

| | | | | |
|---|---|---|---|---|
| Amgen | x | | | |
| AstraZeneca | x | | | |
| BMS | x | | | |
| Eisai | x | | | |
| Jazz | x | | | |
| Merck | x | | | |
| Novartis | x | | | |
| Pfizer | x | | | |
| Sanofi | x | | | |
| Takeda | x | | | |
| Taiho | x | | | |

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

| **New or Updated Declaration for Clinician 8** | |
|---|---|
| **Name** | *Ronald Burkes* |
| **Position** | *Medical Oncologist Mount Sinai Hospital* |
| **Date** | November 25, 2024 |
| ☒ | **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. |

**Conflict of Interest Declaration**

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.

| **Company** | **Check Appropriate Dollar Range** | | | |
|---|---|---|---|---|
| | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *AZ / Pfizer* | ☒ | ☐ | ☐ | ☐ |
| *Merck / Taiho / Takeda / Amgen* | ☒ | ☐ | ☐ | ☐ |
| *Add or remove rows as required* | ☐ | ☐ | ☐ | ☐ |

## Declaration for Clinician 9

Name: Silvana Spadafora
Position: Medical Oncologist, Algoma District Cancer Program
Date: November 25, 2024

☒ 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 9**

| Company | Check appropriate dollar range* | | | |
|---|---|---|---|---|
| | $0 to $5,000 | $5,001 to $10,000 | $10,001 to $50,000 | In excess of $50,000 |
| Astra Zeneca | | X | | |
| Merck | | X | | |
| Novartis | | X | | |

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

## Conflict of Interest Declaration for Clinician 10

Name: Dr. Kevin Jao
Position: Medical Oncologist, Hôpital Sacré-Cœur, Montreal
Date: November 25, 2024

☒ 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.

| Bristol-Myers Squibb | Nature or description of activities or interests | Check Appropriate Dollar Range | | | |
|---|---|---|---|---|---|
| | | $0 to 5,000 | $5,001 to 10,000 | $10,001 to 50,000 | In Excess of $50,000 |
| Bristol-Myers Squibb | Advisory Role | ☒ | ☐ | ☐ | ☐ |

## Conflict of Interest Declaration for Clinician 11

Name: Dr. Abhenil Mittal
Position: Medical Oncologist, Health Sciences North, Assistant Professor, Northern Ontario School of Medicine
Date: November 25, 2024

☒ 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 11**

| Company | Check appropriate dollar range* | | | |
|---|---|---|---|---|
| | $0 to $5,000 | $5,001 to $10,000 | $10,001 to $50,000 | In excess of $50,000 |
| Gilead | X | | | |
| Knight Therapeutics | X | | | |
| Janssen | X | | | |
| Roche | X | | | |

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

## Declaration for Clinician 12

Name: Dr. Rosalyn Juergens
Position: Chair, LCC Medical Advisory Committee; Medical Oncologist, Juravinski Cancer Center
Date: November 25, 2024

☒ 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 12**

| Company | Check appropriate dollar range* | | | |
|---|---|---|---|---|
| | $0 to $5,000 | $5,001 to $10,000 | $10,001 to $50,000 | In excess of $50,000 |
| Bristol Myers Squibb | x | | | |
| Astra Zeneca | | x | | |
| Merck Sharp and Dohme | x | | | |
| Roche | x | | | |

## Declaration for Clinician 13

**Name:** Dr. Paul Wheatley-Price
**Position:** Medical Oncologist, The Ottawa Hospital. Associate Professor, Department of Medicine, University of Ottawa
**Date** November 25, 2024

☒ **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 13**

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

| | | | | |
|---|---|---|---|---|
| Astra Zeneca | X | | | |
| Jazz Pharmaceuticals | X | | | |
| Amgen | X | | | |
| Janssen | X | | | |
| Novartis | X | | | |
| Merck | X | | | |
| BMS | X | | | |
| Roche | X | | | |
| EMD Serono | X | | | |
| Pfizer | X | | | |
| Bayer | X | | | |
| Novartis | X | | | |

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

| **New or Updated Declaration for Clinician 14** | |
|---|---|
| **Name** | *Vishal Navani* |
| **Position** | *Medical Oncologist, University of Calgary* |
| **Date** | November 25, 2024 |
| ☒ | **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. |

**Conflict of Interest Declaration**

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.

| **Company** | **Check Appropriate Dollar Range** | | | |
|---|---|---|---|---|
| | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *Janssen* | ☐ | ☐ | ☒ | ☐ |
| **Consulting -** Novotech Pty, Pfizer, Sanofi, Astra Zeneca, EMD Serono, Oncology Education, Sanofi, Janssen, Roche, MSD, Bristol Meyers Squibb, Takeda | ☐ | ☐ | ☒ | ☐ |
| **Speaking –** Ipsen, Astra Zeneca, MSD, Bristol Meyers Squibb | ☐ | ☐ | ☒ | ☐ |
| **Research –** Astra Zeneca (Inst), Janssen (Inst) | | | X | |
| **Travel –** EMD Serono, Pfizer, Sanofi | | | X | |

## Declaration for Clinician 15

**Name:** Normand Blais
**Position:** Medical Oncologist, CHUM Cancer Center, Montreal
**Date:** November 25, 2024

☒ **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 15**

| Bristol-Myers Squibb | Nature or description of activities or interests | Check Appropriate Dollar Range | | | |
|---|---|---|---|---|---|
| | | $0 to 5,000 | $5,001 to 10,000 | $10,001 to 50,000 | In Excess of $50,000 |
| Abbvie | Advisory Board and Honoraria | ☒ | ☐ | ☐ | ☐ |
| Amgen | Advisory Board and Honoraria | ☒ | ☐ | ☐ | ☐ |
| Astra Zeneca | Advisory Board and Honoraria | ☒ | ☐ | ☐ | ☐ |
| Beigene | Advisory Board and Honoraria | ☒ | ☐ | ☐ | ☐ |
| Bristol-Myers Squibb | Advisory Board and Honoraria | ☒ | ☐ | ☐ | ☐ |
| EMD Serono | Advisory Board and Honoraria | ☒ | ☐ | ☐ | ☐ |
| Merck | Advisory Board and Honoraria | ☒ | ☐ | ☐ | ☐ |
| Novartis | Advisory Board and Honoraria | ☒ | ☐ | ☐ | ☐ |
| Pfizer | Advisory Board and Honoraria | ☒ | ☐ | ☐ | ☐ |
| Roche | Advisory Board and Honoraria | ☒ | ☐ | ☐ | ☐ |
| Sanofi | Advisory Board and Honoraria | ☒ | ☐ | ☐ | ☐ |
| Astra Zeneca | Research Funding to institution | ☐ | ☐ | ☐ | ☒ |

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

## Declaration for Clinician 16

Name: Dr Randeep Sangha
Position: Medical Oncologist, Cross Cancer Institute
Date: November 25, 2024

☒ 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 9: Conflict of Interest Declaration for Clinician 16**

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

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

## Declaration for Clinician 17

Name: Dr Sunil Yadav
Position: Medical Oncologist, Saskatoon Cancer Centre
Date: November 25, 2024

☒ 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 12: Conflict of Interest Declaration for Clinician 17**

| Bristol-Myers Squibb | Nature or description of activities or interests | Check Appropriate Dollar Range | | | |
|---|---|---|---|---|---|
| | | $0 to 5,000 | $5,001 to 10,000 | $10,001 to 50,000 | |
| Bristol-Myers Squibb | Advisory Board | ☒ | ☐ | ☐ | |
| Astra Zeneca | Advisory Board and Speaking | ☒ | ☐ | ☐ | ☐ |
| Merck | Advisory Board and Speaking | ☐ | ☐ | ☒ | ☐ |
| Roche | Advisory Board and Speaking | ☐ | ☒ | ☐ | ☐ |
| Takeda | Advisory Board and Speaking | ☒ | ☐ | ☐ | ☐ |

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

| New or Updated Declaration for Clinician 18 | |
|---|---|
| **Name** | *David J. Stewart* |
| **Position** | Professor of Medicine, University of Ottawa and The Ottawa Hospital |
| **Date** | November 25, 2024 |
| ☒ | **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. |
| **Conflict of Interest Declaration** | |
| 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. | |

| Company | Check Appropriate Dollar Range | | | |
|---|---|---|---|---|
| | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *Merck Canada 2021, 2023* | ☒ | ☐ | ☐ | ☐ |
| *AstraZeneca Canada 2021, 2023* | ☒ | ☐ | ☐ | ☐ |
| *Abbvie Canada 2021, 2022, 2023* | ☒ | ☐ | ☐ | ☐ |
| *Canadian Agency for Drugs and Technologies in Health 2021* | x | | | |
| *Amgen Canada 2022* | x | | | |

| **New or Updated Declaration for Clinician 19** | |
|---|---|
| **Name** | *Dr. Geoffrey Liu* |
| **Position** | *Medical Oncologist* |
| **Date** | November 25, 2024 |
| ☒ | **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. |

**Conflict of Interest Declaration**

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.

| Company | Check Appropriate Dollar Range | | | |
|---|---|---|---|---|
| | **$0 to 5,000** | **$5,001 to 10,000** | **$10,001 to 50,000** | **In Excess of $50,000** |
| *Pfizer* | ☐ | ☒ | ☐ | ☐ |
| *Novartis* | ☒ | ☐ | ☐ | ☐ |
| *Anheart* | ☒ | ☐ | ☐ | ☐ |
| *Takeda* | X | | | |
| *AstraZeneca* | | X | | |
| *Jazz* | X | | | |
| *Roche* | X | | | |
| *Johnson & Johnson* | X | | | |
| *EMD Seron* | X | | | |
| *Merck* | X | | | |

## Declaration for Clinician 20

Name: Dr. David Dawe
Position: Medical Oncologist, CancerCare Manitoba
Date: November 25, 2024

☒ 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 8: Conflict of Interest Declaration for Clinician 20**

| Name of Organization | Nature or description of activities or interests | Check Appropriate Dollar Range | | | |
|---|---|---|---|---|---|
| | | $0 to 5,000 | $5,001 to 10,000 | $10,001 to 50,000 | In Excess of $50,000 |
| AstraZeneca | Advisory boards | ☒ | ☐ | ☐ | ☐ |
| Merck | Advisory Boards | ☒ | ☐ | ☐ | ☐ |
| AstraZeneca | Research Grant | ☐ | ☐ | ☒ | ☐ |
| Boehringer-Ingelheim | Honoraria | ☒ | ☐ | ☐ | ☐ |

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

## Declaration for Clinician 21

Name: Dr Nicole Bouchard
Position: Respirologist, Sherbrooke University Hospital
Date: November 25, 2024

☒ 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 21**

| Company | Nature or description of activities or interests | Check Appropriate Dollar Range | | | |
|---|---|---|---|---|---|
| | | $0 to 5,000 | $5,001 to 10,000 | $10,001 to 50,000 | In Excess of $50,000 |
| Astra Zeneca | Advisory Role/Conference | ☒ | ☐ | ☐ | ☐ |
| Bristol-Myers Squibb | Advisory Role/Research | ☒ | ☐ | ☐ | ☐ |
| Merck | Advisory Role /Research/Conference | ☒ | ☐ | ☐ | ☐ |
| Bayer | Advisory Role | ☒ | ☐ | ☐ | ☐ |
| Pfizer | Conference/Research | ☒ | ☐ | ☐ | ☐ |

| | | | | | |
|---|---|---|---|---|---|
| Roche | Advisory Role | ☒ | ☐ | ☐ | ☐ |

## Declaration for Clinician 22

**Name:** Callista Phillips
**Position:** Medical Oncologist and Clinical Lead, Oncology Clinic, Joseph Brant Hospital
**Date:** November 25, 2024

☒ **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 22**

| | 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 | | | |
| Bayer | X | | | |
| Roche | X | | | |

## Declaration for Clinician 23

**Name:** Stephanie Snow
**Position:** Professor Dalhousie University, Medical Oncologist QEII Health Sciences Centre, Halifax, NS
**Date:** November 25, 2024

☒ **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 23**

| | 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 | |
| Astellas | X | | | |
| BMS | | X | | |
| Taiho | X | | | |
| Roche | | | X | |
| Merck | | X | | |
| GSK | X | | | |
| Janssen | X | | | |
| Pfizer | X | | | |
| Sanofi | X | | | |

| | | | | |
|---|---|---|---|---|
| Knight | X | | | |
| Lilly | X | | | |
| Takeda | X | | | |

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

### Declaration for Clinician 24

Name: Dr. Mark Vincent
Position: Medical Oncologist, London Regional Cancer Centre
Date: November 25, 2024

☒ 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 24**

| Company | Nature or description of activities or interests | Check Appropriate Dollar Range | | | |
|---|---|---|---|---|---|
| | | $0 to 5,000 | $5,001 to 10,000 | $10,001 to 50,000 | In Excess of $50,000 |
| | | | ☐ | ☐ | ☐ |

### Declaration for Clinician 25

Name: Dr. Cheryl Ho
Position: Medical Oncologist, BC Cancer
Date: November 25, 2024

☒ 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 25**

| Company | Nature or description of activities or interests | Check Appropriate Dollar Range | | | |
|---|---|---|---|---|---|
| | | $0 to 5,000 | $5,001 to 10,000 | $10,001 to 50,000 | In Excess of $50,000 |
| Bayer | Advisory role | ☒ | ☐ | ☐ | ☐ |
| Roche | Advisory role, travel, research grants | ☐ | ☐ | ☐ | ☒ |

### Declaration for Clinician 26

Name: Dr Jeffrey Rothenstein
Position: Medical Oncologist, Lakeridge Health
Date: November 25, 2024

☒ 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 26**

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

## Declaration for Clinician 27

Name: Dr Sara Taylor
Position: Medical Oncologist, BC Cancer Agency, Kelowna
Date: November 25, 2024

☒ 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 27**

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

CADTH

# CADTH Reimbursement Review
# Clinician Group Input Template
# CADTH Reimbursement Review

## Clinician Group Input

CADTH Project Number: PC0389-000
Generic Drug Name (Brand Name): Durvalumab (Imfinzi)
Indication: For the treatment of patients with limited-stage small cell lung cancer whose disease has not progressed following platinum-based chemoradiation therapy (CRT)
Name of Clinician Group: OH (CCO) Lung Cancer Drug Advisory Committee
Author of Submission: Dr. Donna Maziak and members of OH (CCO) Lung Cancer Drug Advisory Committee

### 1. About Your Clinician Group

OH(CCO)'s Cancer Drug Advisory Committees provide timely evidence-based clinical and health system guidance on drug-related issues in support of CCO's mandate.

### 2. Information Gathering

Information was gathered by email.

### 3. Current Treatments and Treatment Goals

Limited stage small cell lung cancer treatment is often curative in intent, but rarely achieves this. Treatment has consisted of platinum based chemotherapy for 4 cycles, concurrent or sequential with thoracic radiation. This is followed by prophylactic cranial irradiation to prevent brain metastases.

For ~ 70% of patients, they progress and subsequently receive palliative therapies, including systemic therapy with chemotherapy and durvalumab, but life expectancy is short.

For the durvalumab indication requested - "maintenance", there is no current standard therapy after chemoradiation +/- brain radiation. Patients are followed periodically and treatment may begin at recurrence.

Any treatment given in the setting of maintenance/adjuvant, such as durvalumab in this case, the goal is prevention of disease recurrence or delay, and improvement in overall survival (or "cure").

### 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 mentioned, the majority of patients with limited stage small cell lung cancer will have disease recurrence and die from their disease. There is a significant treatment gap.

## 5. Place in Therapy

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

The drug would be used after standard systemic therapy with platinum and etoposide, as well as radiation treatments. In settings where the cancer recurs while on durvalumab, the use of more durvalumab in the metastatic setting would not occur. The drug works differently than chemotherapy or radiation therapy,and would not replace either.

### 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?

Patients with limited stage small cell lung cancer, who have completed chemotherapy and radiation therapy, who have not had significant pneumonitis, disease progression, or autoimmune disease, would be most suitable. Patients with a poor disease related performance status, those who have radiation pneumonitis, would not be suitable. Patients who have mixed histologies (small cell/non-small cell) would be suitable and be considered.

There is no companion diagnostic test required. The diagnosis is standard, misdiagnosis is rare. At this time it is not possible to identify patients more or less likely to benefit.

### 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?

This is treatment after chemoradiation, and it's only possible to tell if there is unequivocal progression. In general, patients will be followed by skilled clinicians to evaluate for progressive disease based on signs, symptoms, radiology and laboratory tests. Chest imaging (CT or CXR) every 3-6 months will be done, and imaging of abdomen, bones, brain, pelvis, done on a symptom derived basis.

**Outcomes used in clinical practice align with those in clinical trials – overall survival being the most important.**

Improved survival is clinically meaningful in general if the absolute number is greater than 5%, or a median of greater than 6 months, which this drug appears to beat. Ultimately patient choice as to what is clinically meaningful for them.

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

Disease recurrence/progression would be main reason to discontinue drug, or significant immune toxicity, or life threatening/limiting other illnesses. The other reason to discontinue treatment is completion of 2 years of therapy with no evidence of progression.

### 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 supervised by a physician with specialized expertise giving immunotherapy, including medical oncologists, general practitioners in oncology, etc. Generally treatment would be given in outpatient clinics (oncology), including at all levels (1-4). Treatment would not generally be as inpatient, except in rare circumstances (i.e. if patient is hospitalized chronically for a non-cancer condition).

## 6. Additional Information

This appears to be a significant, meaningful improvement in survival for patients with  a very poor prognosis.

Patients who complete 2 years of adjuvant durvalumab and then relapse whould be considered for durvalumab plus chemotherapy for ES SCLC if there is a treatment free interval of 6 months or greater.

## 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.

   OH (CCO) provided a secretariat function 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, Donna Maziak
**Position:** Lead, OH-CCO Lung/Thoracic Cancers Drug Advisory Committee (OH-CCO Lung DAC)
**Date:** 18-Nov-2024

☒ **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** |

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

## Declaration for Clinician 2

Name: Dr. Andrew Robinson
Position: Member, OH-CCO Lung DAC
Date: 14-Nov-2024

☒ 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 |
| AstraZeneca | x | | | |
| Roche | x | | | |

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

## Declaration for Clinician 3

Name: Dr. Mihaela Mates
Position: Member, OH-CCO Lung DAC
Date: 12-Nov-2024

☒ 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**

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

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

## Declaration for Clinician 4

Name: Dr. Peter Ellis
Position: Member, OH-CCO Lung DAC
Date: 14-Nov-2024

☒ 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** |
| AstraZeneca | x | | | |
| Roche | x | | | |

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

## Declaration for Clinician 5

Name: Dr. Michela Febbraro
Position: Member, OH-CCO Lung DAC
Date: 14-Nov-2024

☒ 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 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** |
| AstraZeneca | x | | | |
| Roche | x | | | |

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