CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

CEMIPLIMAB (Libtayo)

(Sanofi Genzyme, a division of sanofi-aventis Canada Inc.)

Indication: For the treatment of patients with locally advanced or metastatic basal cell carcinoma (BCC) previously treated with a hedgehog pathway inhibitor.

February 17, 2022

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0260-000
Brand name (generic)	Cemiplimab (Libtayo)
Indication(s)	For the treatment of patients with locally advanced basal cell carcinoma (BCC) previously treated with a hedgehog pathway inhibitor
Organization	Ontario Health (Cancer Care Ontario) Skin Cancer Drug Advisory Committee
Contact information[a]	[redacted]

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☒
	No	☐

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐

The Skin DAC disagrees with the exclusion of patients with metastatic BCC. The recommendation discussed that the use of cemiplimab should not be generalized to patients with metastatic BCC due to low patient numbers and immature results from the Study 1620. From a biological perspective, there is no reason that metastatic disease would not respond to cemiplimab. The Skin DAC believes the indication should be comprehensive to include patients with metastatic BCC, while acknowledging that only a small few patients actually develop metastatic BCC. There is the clinical risk that complete evaluation for metastases may be impacted by the wording of this recommendation. [Generalizability]

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐

The Skin DAC does not think it's appropriate to exclude prior PD-1 therapy as there may be patients who have received prior PD-1 for other tumor types especially other skin cancers. Patients who have one type of skin cancer (i.e. BCC) are at higher risk of having been previously diagnosed with other skin cancers ad the underlying risk factors are the same (UV light exposure). If PD-1 therapy was not previously given for BCC, then patients should be eligible for cemiplimab. [Reimbursement Initiation point 3.1]

The Skin DAC believes that the idealisib exclusion criteria is irrelevant because it is rarely used. [Reimbursement Initiation 3.5]

The DAC states that for first-line drugs for BCC, such as vismodegib, clinicians currently must submit letters from both surgeons and radiation oncologists saying that patients are not eligible for either surgical or radiation treatment.

If a patient processes on fist line vismodegib then it is not anticipated that the patient would be eligible for surgical or radiation as the disease has progressed even further, consequently, the DAC felt that re-submitting documentation that the patient is not eligible for surgery or radiation should not be necessary. The DAC believes the recommendation should state that historical confirmation of unresectable invasive BCC that is not amenable to curative survey or curative radiation therapy would suffice. [Reimbursement Initiation 1.1]

The DAC believes that cemiplimab for BCC requires a different kind of economic analysis because it does not provide a survival benefit. Cemiplimab would improve the quality of life patients that progress and that is not very easy to measure. In the DACs clinical experience, the tools used to evaluate these drugs undervalue their effect on quality of life. The economic analysis limits the impact of cempilimab on these patients. [Reimbursement Pricing 6]

[a] CADTH may contact this person if comments require clarification.

Appendix 2. Conflict of Interest Declarations for Clinician Groups

- 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 feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.
- For conflict of interest declarations:
  - Please 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 declarations are required for each clinician that contributed to the input.
  - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
1. Did you receive help from outside your clinician group to complete this submission?	No	☐
	Yes	☒
OH-CCO provided secretariat support to the DAC in completing this feedback.		
2. Did you receive help from outside your clincian group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
N/A		
B. Previously Disclosed Conflict of Interest		
3. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☐
	Yes	☐
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Dr. Frances Wright • Dr. Teresa Petrella • Dr. Tara Baetz • Dr. Elaine McWhirter • Dr. Marcus Butler		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Dr. Xinni Song*
Position	*OH-CCO Skin Cancer Drug Advisory Committee Member*
Date	*09-02-2022*

☒	**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**
Sanofi	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐

CADTH

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0260
Name of the drug and Indication(s)	Cemiplimab for BCC
Organization Providing Feedback	PAG

1. Recommendation revisions Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.		
Request for Reconsideration	**Major revisions:** A change in recommendation **category** or patient **population** is requested	☐
	Minor revisions: A change in reimbursement **conditions** is requested	☐
No Request for Reconsideration	**Editorial revisions:** Clarifications in recommendation **text** are requested	X
	No requested revisions	☐

2. Change in recommendation category or conditions Complete this section if major or minor revisions are requested
None.

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
None.
b) Reimbursement conditions and related reasons
In the Cost and Cost-Effectiveness summary table, in the “Treatment Cost” row, PAG is requesting the cost of treatment per 28-days as a standard measurement across reviews.
c) Implementation guidance
None.

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0260-000
Brand name (generic)	cemiplimab
Indication(s)	Basal cell carcinoma
Organization	Melanoma Canada
Contact information[a]	[redacted]

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐
Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.		
Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☒
	No	☐
If not, what aspects are missing from the draft recommendation?		
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification.		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification. This is an important drug therapy to be added as an option for treatment of advanced disease. The impact on the health and the impact on the emotional state to patients is substantial as the disease is horrific visually as well, so there is a significant gap in treatment for patients. This will help tremendously. We were concerned with the notion that there needs to be a 97% reduction in pricing as this seems overly restrictive and prescriptive for price negotiations. We are concerned that this may cause delays or perhaps prevent the introduction of this much needed therapy. We urge the governments to consider the unmet need.		

[a] CADTH may contact this person if comments require clarification.

Appendix 1. Conflict of Interest Declarations for Patient Groups

- 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 feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

A. Patient Group Information	
Name	*Annette Cyr*
Position	*Chair of the Board*
Date	*11/02/2022*
☒	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.

B. Assistance with Providing Feedback		
1. Did you receive help from outside your patient group to complete your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		

C. Previously Disclosed Conflict of Interest		
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.	No	☐
	Yes	☒

D. New or Updated Conflict of Interest Declaration

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.

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	☐	☐	☐	☒
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0260-000
Brand name (generic)	Libtayo
Indication(s)	Basal cell carcinoma
Organization	Save Your Skin Foundation
Contact information[a]	[redacted]

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐

Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.
We are happy with the positive recommendation and hope that Reimbursement condition 6. (a reduction in price) will not slow this process down. Patients made it clear in the survey that timely access to treatment is of utmost importance. There are limited treatment options for these patients so choice and again timely access are imperative.
The Qualy threshold of $50,000 seems inappropriate for cancer drugs as evidenced by scientific health economics including ICER, and several European countries. The Qualy for cancer should have an ICER of at least $100,000.

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☒
	No	☐

If not, what aspects are missing from the draft recommendation?
We want to re-iterate the comments that patients on this treatment made regarding QOL. Survival is of course extremely important but so is QOL to not only the patient but their caregivers, and we hope the committee has looked closely at all patient input into our submission. It's important that all patients have treatment options and that they and their physician make the best treatment plan for them in a timely fashion.

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐

If not, please provide details regarding the information that requires clarification.

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐

If not, please provide details regarding the information that requires clarification.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☒

If not, please provide details regarding the information that requires clarification.

[a] CADTH may contact this person if comments require clarification.

Appendix 1. Conflict of Interest Declarations for Patient Groups

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- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

A. Patient Group Information	
Name	*Kathy Barnard*
Position	*President*
Date	*15-02-2022*
☒	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.

B. Assistance with Providing Feedback		
1. Did you receive help from outside your patient group to complete your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		

C. Previously Disclosed Conflict of Interest		
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.	No	☐
	Yes	☒

D. New or Updated Conflict of Interest Declaration

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.

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Sanofi	☐	☐	☐	☒
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0260-000
Brand name (generic)	LIBTAYO™ (cemiplimab for injection)
Indication(s)	For the treatment of patients with locally advanced basal cell carcinoma (BCC) previously treated with a hedgehog pathway inhibitor.
Organization	Sanofi Canada Inc.
Contact information[a]	[redacted]

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐

Sanofi agrees with pERC's recommendation to reimburse cemiplimab in the treatment of locally advanced basal cell carcinoma (laBCC) previously treated with a hedgehog pathway inhibitor (HHI). As noted by pERC, there is a significant unmet need in this population of post-HHI laBCC patients, and these patients were able to achieve clinically meaningful response outcomes after treatment with cemiplimab. However, sanofi respectfully disagrees with the CADTH evaluation of the submitted economic model, the exploratory reanalysis of the economic model, and the resulting ICERs and price reduction condition.

Clinical Evidence – Critical appraisal p.11 and Economic Evidence – 1st Key limitation p.12
CADTH assumed there was no direct or indirect evidence comparing cemiplimab to BSC and evidence derived from the single arm trial on cemiplimab was associated with significant limitations. Therefore, the impact of cemiplimab is highly uncertain and the relative impact versus BSC is unknown. Sanofi believes that despite the design of study 1620 being single arm and open label, it is **not** impossible to draw any conclusions about efficacy with any level of certainty. Study 1620 is the largest prospective study of any systemic therapy in advanced BCC after 1L HHI therapy. The rationale for the open label non-randomized study design is justified as there are no approved treatments in this very small population of patients, which in itself presents patient recruitment challenges. A placebo-controlled trial would also have been unethical since BSC does not offer any benefit as confirmed by clinical experts. The results of Study 1620 as a whole provide compelling evidence that patients with laBCC benefit considerably from cemiplimab treatment as it leads to clinically meaningful deep and durable tumour responses, slowing of disease progression, and survival & HRQoL benefits. Moreover, not only is cemiplimab effective, but it is well tolerated and associated with an acceptable safety profile. When assessing the cemiplimab evidence as a whole, it is clear that it can address the current unmet need, as recognized by CADTH's and the sponsor's clinical experts, while representing a significant and unprecedented advancement for this small, well-defined patient population.

Economic Evidence – 2nd Key limitation on the model structure p.12
CADTH indicated that a model assuming that patients receiving cemiplimab are starting in a 'pre-progression' health state and patients on BSC start in 'post-progression' is not justified and overestimates the benefit of cemiplimab. Sanofi acknowledges that a model wherein BSC patients start in a post-progression state results in an immediate benefit to all cemiplimab patients regardless of response. However, this reasonable simplifying assumption was made out of necessity, as no active therapies currently exist for the treatment of patients who have progressed on an HHI. Due to this lack of treatment options, there are no data on progression-free survival in untreated patients (BSC) who have already progressed on HHIs. Similarly, while health state-specific quality-of-life (QoL) data for the cemiplimab arm were available from Study 1620, there are no QoL data in untreated BSC patients who have already progressed on HHIs, before and after they progress a second time. In partitioned survival models as in the case of the submitted model, patients accrue benefit based on the available data for disease outcomes within each treatment group. As such, benefits accrued by patients in the cemiplimab arm of the model are based on patient outcomes in Study 1620, calculated from responders and non-responders alike, assuming there is benefit in halting progression of disease. Finally, this assumption was also used in the CADTH submission for the HHI

vismodegib, wherein the economic model was likewise structured such that patients on BSC were by default in a progressed disease state. However, in contrast to the CADTH review of cemiplimab, CADTH found the vismodegib model structure to be adequate. As such, CADTH's opinion on the submitted cemiplimab model structure is inconsistent with past CADTH reviews of a product in a similar clinical setting.

Economic evidence – 3rd Key limitation on choice of parametric survival functions and survival benefit from cemiplimab relative to BSC p.12

CADTH indicates that the survival benefit of cemiplimab compared to BSC assumed in the submitted survival model is not expected by clinical experts and the choice of parametric survival function overestimates survival benefit and the delay of progression with cemiplimab. As such, in their reanalyses, CADTH assumed that for every single laBCC patient treated with cemiplimab, no survival benefit would be observed. Although sanofi acknowledges that limitations in the available cemiplimab clinical data create some uncertainty regarding potential survival benefit, the total erasure of any degree of survival benefit for all treated laBCC patients does not align with the expertise that Canadian and international clinicians have provided to sanofi. CADTH's pharmacoeconomic review report (PRR) did note that "although there may be a benefit [of treatment with cemiplimab] relative to progression-free survival… clinical expert feedback suggested that progression itself should not be affecting survival for most patients (>90%)" [pg. 13 of PRR]. Indeed, international and Canadian consulted clinicians expected the cemiplimab benefit demonstrated in Study 1620 to translate into some level of survival benefit in the real world, and therefore believed this benefit should be included in economic model projections. The wording of the CADTH clinical expert input similarly suggests that the CADTH clinical expert anticipated cemiplimab to have a clinically meaningful benefit and a PFS-related benefit on survival in up to 10% of treated patients. In removing the survival benefit of cemiplimab relative to BSC, CADTH assumes a worst-case survival benefit scenario that does not align with clinical experts and, as a consequence, greatly overestimates the cemiplimab ICER to extremes. Furthermore, parametric survival curve selection was based on statistical fit and clinical plausibility, validated by Canadian clinical experts who provided estimates of treatment-specific laBCC survival based on Canadian clinical practice.

Economic evidence – 4th and 5th key limitations on resource utilization with BSC p.12 and CADTH reanalysis p.13

CADTH's reanalysis used assumptions regarding resource utilization and frequency of wound dressings do not account for the clinical expert opinions used to inform the submitted cemiplimab economic model. The increased resource use in BSC-treated patients relative to cemiplimab-treated patients was based on consultations with Canadian clinical experts, which substantiated the practitioner visits, monitoring requirements, and wound care requirements included in the submitted economic model. The assumption that 25% of pre-progression patients required wound care was also based on the CADTH review of vismodegib, wherein CADTH clinical expert input resulted in a CADTH reanalysis that attributed wound care costs to 25% of patients regardless of response. Sanofi does not agree with CADTH's linking of wound care costs to objective response (OR). Consulted clinicians unanimously felt that achieving stable disease without an OR still conferred significant clinical benefit. CADTH's assumption that patients must experience an OR for wound care requirements to lessen underestimates wound care-related clinical benefits and contradicts previous CADTH opinion.

CADTH reanalysis – CADTH exploratory reanalysis using various assumptions p. 13

CADTH performed an exploratory reanalysis using different assumptions leading to extreme ICERs and results suggesting a 97% price reduction to achieve cost-effectiveness. Sanofi stands firmly behind the cemiplimab pharmacoeconomic submission. The CADTH exploratory analysis ICER and price reduction estimates are based on inadequate assumptions that greatly underestimate the benefits and cost-effectiveness of cemiplimab. In addition to the earlier comments, sanofi believes that the QoL data taken from Study 1620 are robust and should not be replaced with highly uncertain assumptions in a scenario analysis. The post-progression utilities used in the model come directly from QoL data from Study 1620 patients, and as such are not a source of uncertainty. In contrast, the CADTH scenario analysis uses a highly uncertain assumption wherein **QoL** benefit is dependent on patients achieving an objective **clinical** response. In comments on the PRR, CADTH justified this assumption on the basis of a perceived bias in favour of cemiplimab due to the model structure assumption that BSC patients begin treatment in a progressed state. As noted above, this assumption was made out of necessity due to a lack of data. Furthermore, CADTH found this same model structure to be adequate in the vismodegib submission for advanced BCC. Moreover, given the lack of data on actual outcomes in laBCC patients on BSC, there is no evidence that this assumption favours cemiplimab. Accounting for all of the above, the CADTH exploratory reanalysis and the resulting extreme ICERs and price reduction are not considered to be appropriate. These reanalyses are based on a WTP threshold

of $50,000/QALY, which highly undervalues the meaningful patient benefit elicited by cemiplimab in a rare cancer population with high unmet need. Sanofi reiterates its support for the economic model submitted to CADTH, which is grounded in the clinical evidence, aligns with clinical expert feedback, and results in an ICER of $61,738/QALY. Based on this ICER and a more appropriate WTP threshold of $100,000 per QALY, cemiplimab has a 97% probability of being cost-effective in the treatment of post-HHI laBCC patients at the submitted price.

Expert committee consideration of the stakeholder input

2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☒
	No	☐

In part: Although the committee may have considered some of the stakeholder input, the recommendation does not align with the pharmacoeconomic evidence provided within the submission and that CADTH used assumptions in their reanalysis that did not consider clinical expert opinions and critically appraised economic model structure already accepted by CADTH for laBCC patients. This results in extreme ICERs and price reduction estimates for cemiplimab in the treatment of post-HHI laBCC.

Clarity of the draft recommendation

3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐

In part: sanofi is unclear as to why CADTH opted to use some of the assumptions that did not appropriately account for the clinical evidence submitted, in order to reach extreme cost-effectiveness estimates. Sanofi believes it made considerable efforts to reflect the opinions of Canadian and international oncology experts in the treatment of advanced BCC, the clinical evidence available and submitted to CADTH, in addition to using a model structure and findings accepted by CADTH's Economic Guidance Panel of experts for an oncology drug in a similar context.

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐

In part: Treatment initiation (p.3; condition 3): While the reimbursement conditions are clear, the rationale for some of the conditions may not be explicitly stated. As such, reimbursement condition 3 may unnecessarily restrict cemiplimab use in some patient groups. It states that as a condition of cemiplimab initiation, patients must not have any of the following: Prior treatment with PD-1/PD-L1 pathway inhibitors, untreated brain metastasis that are considered active, active autoimmune disease requiring treatment, active infection requiring treatment, or prior treatment with idelalisib. While these subgroups were not included in Study 1620, based on the cemiplimab product monograph, Health Canada did not consider that cemiplimab should be contraindicated for these patients. Post-HHI laBCC patients endure symptoms and disfigurement which severely impact QOL and have no active therapy options to mitigate disease burden. Given this high unmet need, as well as the recognition by Health Canada that contraindication against cemiplimab use is not required, SGZ believes that preventing cemiplimab access for these patients deprives them and their physicians of the latitude to make nuanced treatment decisions based on patient-specific risk-benefit ratios.