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CADTH DRUG REIMBURSEMENT REVIEW

Pharmacoeconomic Report

Sonidegib (Odomzo)

(Sun Pharma Canada Inc.)

Indication: For the treatment of adult patients with histologically confirmed locally advanced basal cell carcinoma (laBCC) that is not amenable to radiation therapy or curative surgery

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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Abbreviations

BCC	basal cell carcinoma
ICER	incremental cost-effectiveness ratio
ITC	indirect treatment comparison
KM	Kaplan-Meier
laBCC	locally advanced basal cell carcinoma
NOC	notice of compliance
pCODR	pan-Canadian Oncology Drug Review
PFS	progression-free survival
QALY	quality-adjusted life-year
RDI	relative dose intensity
TTD	time to discontinuation

Executive Summary

Table 1: Submitted for Review

Item	Description
Drug product	Sonidegib (Odomzo), 200 mg capsule.
Submitted price	Sonidegib, 200mg, capsule: $267.35 per capsule ($8,020.45 per a bottle of 30 capsules)
Indication	For the treatment of adult patients with histologically confirmed locally advanced basal cell carcinoma (laBCC) that is not amenable to radiation therapy or curative surgery
Health Canada approval status	NOC
Health Canada review pathway	Standard
NOC date	Jun 12, 2020
Reimbursement request	As per indication
Sponsor	Sun Pharma Canada Inc.
Submission history	Previously reviewed: No

laBCC = locally advanced basal cell carcinoma; NOC = Notice of Compliance.

Table 2: Summary of Economic Evaluation

Component	Description
Type of economic evaluation	Cost-utility analysis Partitioned survival model
Target population	For the treatment of adult patients with histologically confirmed laBCC that is not amenable to radiation therapy or curative surgery
Treatment	Sonidegib
Comparator	Vismodegib
Perspective	Canadian publicly funded health care payer
Outcome	QALY
Time horizon	10 years
Key data source	BOLT[1] for sonidegib, ERIVANCE[2] for vismodegib, STEVIE[3] for vismodegib (scenario analysis)
Submitted results	• Base case (using ERIVANCE[2] trial data to inform vismodegib): Sonidegib was dominant compared to vismodegib (inc cost = -$22,495 [savings], inc QALYs = 0.089). • Scenario analysis (using STEVIE[3] trial data to inform vismodegib): Sonidegib was dominant compared to vismodegib (inc cost = -$24,701 [savings], inc. QALYs = 0.020).
Key limitations	• The sponsor used a naive comparison to estimate the comparative efficacy of sonidegib compared to vismodegib due to limitations identified with their indirect comparison (ITC). CADTH clinical reviewers deemed the sponsor's ITC evidence to be inconclusive. • The sponsor assumed that sonidegib would be associated with cost savings due to averted wound care over the entire 10-year time horizon. According to the clinical experts consulted by CADTH, typical wound care may last a year, and could be transitioned to informal care after 3 months. The sponsor's assumption likely biased the results in favour of sonidegib. • The sponsor assumed a difference between sonidegib and vismodegib in relative dose intensity (RDI). The assumed difference is uncertain as it is based on naive comparison of trial data. According to the clinical experts consulted by CADTH, RDI is not expected to be different between sonidegib and vismodegib. • The sponsor assumed that patients with laBCC have the same mortality risk as the age-adjusted general population. According to the clinical experts consulted by CADTH, laBCC patients typically have a higher mortality risk profile due to older age. The clinical experts also noted that the modelled overall survival was greater than is typically observed in clinical practice. Furthermore, they provided feedback that patients with progressed disease have higher mortality.
CADTH reanalysis results	• Given the lack of robust information on the comparative effectiveness of sonidegib, the cost-effectiveness of sonidegib is unknown. • CADTH undertook exploratory analyses to correct the sponsor's model and assess the impact of changes based on RDI, patient age, and clinical assumptions, but the validity of these results are uncertain given the limitations with the comparative evidence. • The key drivers of the cost effectiveness of sonidegib are the comparative effectiveness assumptions, and the drug acquisition price.

EQ-5D-3L = EuroQol 5-dimensions 3-level questionnaire; ICER = incremental cost-effectiveness ratio; inc., = incremental; ITC = indirect treatment comparison; laBCC = locally advanced basal cell carcinoma; QALY= quality-adjusted life-year; RDI = relative dose intensity.

Conclusions

Given the lack of robust information on the comparative effectiveness of sonidegib, CADTH could not determine a base case estimate of the cost-effectiveness of sonidegib compared with vismodegib. CADTH undertook a series of exploratory reanalyses based on alternate clinical estimates, and cost assumptions to address some of the identified limitations and key areas of uncertainty. These analyses suggested that if sonidegib is considered no less effective than vismodegib and associated with similar adverse events, then sonidegib may be associated with lower costs based on the available price information. pERC previously recommended a substantial price reduction for vismodegib for patients with advanced BCC; as such, a similar price reduction may be required for sonidegib.

Based on the sponsor's submitted budget impact analysis, sonidegib was associated with a three-year cumulative cost saving of $304,945. CADTH reanalyses suggested that assuming no difference between sonidegib and vismodegib in RDI, and duration of treatment, sonidegib is associated with cost savings of $212,593 over the first three years. If drug acquisition costs are also assumed to be the same, then sonidegib is expected to be budget neutral (i.e., $0 over the first three years).

Stakeholder Input Relevant to the Economic Review

This section outlines the technical details of the pCODR Economic Guidance Panel's evaluation of the economic evidence that is summarized in the executive summary. In accordance with the *Disclosure of Information Guidelines for the CADTH Pan-Canadian Oncology Drug Review*, this section is not eligible for disclosure. It was provided to the pCODR Expert Review Committee (pERC) for their deliberations and the participating drug programs for their information.

Economic Review

This section outlines the technical details of the pCODR Economic Guidance Panel's evaluation of the economic evidence that is summarized in the executive summary. In accordance with the *Disclosure of Information Guidelines for the CADTH Pan-Canadian Oncology Drug Review*, this section is not eligible for disclosure. It was provided to the pCODR Expert Review Committee (pERC) for their deliberations and the participating drug programs for their information.

Appendix 1: Cost Comparison Table

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Appendix 2: Submission Quality

This section outlines the technical details of the pCODR Economic Guidance Panel's evaluation of the economic evidence that is summarized in the executive summary. In accordance with the *Disclosure of Information Guidelines for the CADTH Pan-Canadian Oncology Drug Review*, this section is not eligible for disclosure. It was provided to the pCODR Expert Review Committee (pERC) for their deliberations and the participating drug programs for their information.

Appendix 3: Additional Information on the Submitted Economic Evaluation

This section outlines the technical details of the pCODR Economic Guidance Panel's evaluation of the economic evidence that is summarized in the executive summary. In accordance with the *Disclosure of Information Guidelines for the CADTH Pan-Canadian Oncology Drug Review*, this section is not eligible for disclosure. It was provided to the pCODR Expert Review Committee (pERC) for their deliberations and the participating drug programs for their information.

Appendix 4: Additional Details on the CADTH Reanalyses and Sensitivity Analyses of the Economic Evaluation

This section outlines the technical details of the pCODR Economic Guidance Panel's evaluation of the economic evidence that is summarized in the executive summary. In accordance with the *Disclosure of Information Guidelines for the CADTH Pan-Canadian Oncology Drug Review*, this section is not eligible for disclosure. It was provided to the pCODR Expert Review Committee (pERC) for their deliberations and the participating drug programs for their information.

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Appendix 5: Submitted BIA and CADTH Appraisal

This section outlines the technical details of the pCODR Economic Guidance Panel's evaluation of the economic evidence that is summarized in the executive summary. In accordance with the *Disclosure of Information Guidelines for the CADTH Pan-Canadian Oncology Drug Review*, this section is not eligible for disclosure. It was provided to the pCODR Expert Review Committee (pERC) for their deliberations and the participating drug programs for their information.

References

1. Dummer R, Guminksi A, Gutzmer R, et al. Long-term efficacy and safety of sonidegib in patients with advanced basal cell carcinoma: 42-month analysis of the phase 2 randomised, double-blind BOLT study. *Br J Dermatol.* 2019.

2. Sekulic A, Migden MR, Basset-Seguin N, et al. Long-term safety and efficacy of vismodegib in patients with advanced basal cell carcinoma: final update of the pivotal ERIVANCE BCC study. *BMC Cancer.* 2017;17(1):332.

3. Basset-Séguin N, Hauschild A, Kunstfeld R, et al. Vismodegib in patients with advanced basal cell carcinoma: primary analysis of STEVIE, an international, open-label trial. *Eur J Cancer.* 2017;86:334-348.

4. Pharmacoeconomic evaluation [internal sponsor's report]. In: pan-Canadian Oncology Drug Review sponsor submission: Odomzo (sonidegib), 200 mg oral capsules. Sun Pharma Canada Inc. Brampton (ON): Sun Pharma Canada Inc.; 2020 Jun 15.

5. Shingler SL, Garside J, Samanta K, et al. Utilities for advanced basal cell carcinoma. *J Med Econ.* 2013;16(6):777-783.

6. National prescription drug utilization information system: plan information document. Ottawa (ON): Canadian Institute for Health Information; 2019: https://secure.cihi.ca/free_products/NPDUIS-plan-information-comparison-2019-en.pdf. Accessed 2020 Jul 13.

7. Beauchemin C, Letarte N, Mathurin K, Yelle L, Lachaine J. A global economic model to assess the cost-effectiveness of new treatments for advanced breast cancer in Canada. *J Med Econ.* 2016;19(6):619-629.

8. Schedule of benefits for physician services under the Health Insurance Act: effective April 1, 2020. Toronto (ON): Ontario Ministry of Health; 2020: http://www.health.gov.on.ca/en/pro/programs/ohip/sob/physserv/sob_master20200429.pdf. Accessed 2020 Jul 13.

9. Schedule of benefits for laboratory services: effective July 1, 2020. Toronto (ON): Ontario Ministry of Health; 2020: http://www.health.gov.on.ca/en/pro/programs/ohip/sob/lab/lab_mn2020.pdf. Accessed 2020 Jul 13.

10. pan-Canadian Oncology Drug Review final economic guidance report: vismodegib (Erivedge) for basal cell carcinoma Ottawa (ON): CADTH; 2014: https://cadth.ca/sites/default/files/pcodr/pcodr-erivedge-bcc-fn-egr.pdf. Accessed 2020 Oct 22.

11. Saad F, Fleshner NE, So A, et al. The burden of symptomatic skeletal events in castrate-resistant prostate cancer patients with bone metastases at three Canadian uro-oncology centres. *Can Urol Assoc J.* 2018;12(12):370-376.

12. Hogg D, Osenenko K, Szabo SM, et al. Standard gamble utilities for advanced melanoma health states elicited from the Canadian general public [abstract]. *Pigment Cell Melanoma Res.* 2010;23(6). https://onlinelibrary.wiley.com/doi/full/10.1111/j.1755-148X.2010.00767.x. Accessed 2020 Jul 13.

13. Loughran T, Reyes A, Pletscher M, Krivasi T, Hatswell AJ. Mapping from SF-36 trial data to EQ-5D utilities in advanced basal cell carcinoma [abstract]. *Value Health.* 2017;20(9):A449.

14. Bansback N, Tsuchiya A, Brazier J, Anis A. Canadian valuation of EQ-5D health states: preliminary value set and considerations for future valuation studies. *PLoS One.* 2012;7(2):e31115.

15. Ontario Ministry of Health. Drug Benefit Prices (DBPs) for products reimbursed under the EAP. 2020; http://www.health.gov.on.ca/en/pro/programs/drugs/odbf/odbf_except_access.aspx. Accessed 2020 Oct 22.

16. CADTH pCODR Expert Review Committee (pERC) final recommendation: vismodegib (Erivedge) for metastatic or locally advanced basal cell carcinoma Ottawa (ON): CADTH; 2014 Jan 10: https://cadth.ca/sites/default/files/pcodr/pcodr-erivedge-bcc-fn-rec.pdf. Accessed 2020 Oct 22.

17. Odomzo (sonidegib): 200 mg oral capsules [product monograph]. Brampton (ON): Sun Pharma Canada Inc; 2020 Jun 11.

18. Erivedge (vismodegib): 150 mg capsule [product monograph]. Mississauga (ON): Hoffmann-La Roche Limited; 2020 May 11: https://pdf.hres.ca/dpd_pm/00056365.PDF. Accessed 2020 Nov 4.

19. Budget impact analysis [internal sponsor's report]. In: pan-Canadian Oncology Drug Review sponsor submission: Odomzo (sonidegib), 200 mg oral capsules. Sun Pharma Canada Inc. Brampton (ON): Sun Pharma Canada Inc; 2020 Jun 15.

20. Bridgman AC, Fitzmaurice C, Dellavalle RP, et al. Canadian burden of skin disease from 1990 to 2017: results from the Global Burden of Disease 2017 study. *J Cutan Med Surg.* 2020;24(2):161-173.

21. Mohan SV, Chang ALS. Advanced basal cell carcinoma: epidemiology and therapeutic innovations. *Curr Dermatol Rep.* 2014;3(1):40-45.

22. Statistics Canada. Population estimates on July 1st, by age and sex [Table: 17-10-0005-01 (formerly CANSIM 051-0001)]. 2020; https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1710000501. Accessed 2020 Jul 13.