

January 31, 2022

Attn: Josée Pelletier, National Stakeholder Relations and Advocacy Manager
Bristol-Myers Squibb Canada Co.
2344 Bd Alfred Nobel #300
Saint-Laurent, QC
H4S 0A4

Dear Josée Pelletier,

As the only national Canadian organization representing patients and families affected by a brain tumour, **Brain Tumour Foundation of Canada (BTFC)** has a strong interest in all issues that impact the treatment and quality of life of those in our community. We write to you to express our extreme concern regarding the announcement by Bristol-Myers Squibb (BMS) to discontinue the production and distribution of lomustine-CCNU (CeeNU®) in Canada effective June 2023:

In the email I received from you on July 9, 2021 (attached), it was stated that the impact of discontinuation was assessed to have “limited clinical impact given the availability of therapeutic alternatives”. Our discussions with the top Canadian neuro-oncology clinicians and researchers over the last several months do not support this conclusion.

Dr. James Perry, neuro-oncologist and clinician-investigator at Sunnybrook Health Sciences Centre, reflects the following:

“The lack of access to CeeNU® in Canada will deprive our patients of the current standard of care therapy for many forms of brain cancer. This well-tolerated medication, taken orally at home on just one day every 6 weeks, is the best treatment for recurrent tumours (M Weller, 2020). Even worse, our patients with oligodendroglioma, mainly affecting young Canadians in their 20s to 40s, will be denied a critical component of combination PCV chemotherapy, a treatment that has been shown to double survival time when added after radiation therapy (N. A. Mohile, 2022). The result of the decision to withdraw CeeNU® from the Canadian market will significantly reduce the life expectancy of our patients; in what context is this even acceptable? Last, but not least, because CeeNU® is the most effective treatment for recurrent glioblastoma, it is the drug most commonly used in the control arm of our clinical trials. Lack of access to CeeNU® will paralyze our research and stop our ability as Canadian investigators to participate in leading edge studies that will bring home better treatments for brain cancer.”

Dr. Warren Mason, neuro-oncologist and researcher, Princess Margaret Cancer Centre/University Health Network, has also shared his concerns regarding this announcement:

“Patients with malignant gliomas have few effective systemic therapies. For decades, CeeNU® has been a cornerstone of many proven treatments for patients with primary brain tumours, including PCV chemotherapy (N. A. Mohile, 2022) for oligodendroglial neoplasms and as monotherapy or in combination with bevacizumab for progressive GBM (M Weller, 2020). The loss of CeeNU® from the drug formulary for brain cancers will have a devastating impact on the survival of patients suffering from these diseases.”



Brain Tumour Foundation of Canada strongly takes issue with BMS's decision to discontinue CeeNU® in Canada. On behalf of our patient population, which numbers approximately 55,000 people, and with the support of our neuro-oncology colleagues, we request a meeting with BMS Canada to discuss the following:

1. What criteria was used by BMS to conclude that the discontinuation of CeeNU® would have "limited clinical impact" to patients in Canada and worldwide?
2. What communication was made to federal and provincial drug agencies, including CADTH, to inform them of the discontinuation? If so, has feedback been received?
3. Are there any expressions of interest in succession manufacturing that can be shared at this point, in the interest of patient care and treatment planning?

On behalf of all Canadians who rely on CeeNU® to treat the life-altering diagnosis of a brain tumour, we call upon BMS Canada to recognize and reconsider the tremendous impact the decision to discontinue CeeNU® will have in this country. It remains standard of care here for two specific groups of patients with no other comparative treatment options. As a community stakeholder, we feel it is important and necessary to continue the dialogue on the discontinuation and to work together to ensure there is a workable path forward.

Sincerely,



Susan D. Marshall
Chief Executive Officer
Brain Tumour Foundation of Canada

References

M Weller, E. L. (2020). How did lomustine become standard of care in recurrent glioblastoma? Elsevier, 1-8.

Mohile, N. A. (2022). Therapy for Diffuse Astrocytic and Oligodendroglial Tumors in Adults: ASCO-SNO Guideline. Journal of Clinical Oncology, 1-27.

