

Ms Kristin Michaels CEO SHPA Australia

7th June 2023

Subject: Update to Date of Discontinuation of the Sale and Distribution of CeeNU (lomustine)

Dear Ms Michaels,

Bristol Myers Squibb would like to inform you of an update to the date for discontinuation of the sale and distribution of CeeNU (lomustine). **The date of cease of distribution for Australia and New Zealand will be extended to 30th June 2024.** TGA and Medsafe will be notified on 8th of June, 2023.

This discontinuation includes all dose strengths (10mg and 40mg). The decision to discontinue CeeNU is due to declining demand and the availability of newer, preferred therapies (recommended by current treatment guidelines) for the treatment of brain tumours, such as glioblastomas. As such, the decision to discontinue CeeNU is voluntary and <u>not</u> related to any quality, safety or efficacy issues regarding the product.

In Australia, CeeNU may be used for the treatment of:

1. Brain tumours (primary and secondary).

2. Hodgkin's disease (as secondary therapy).

Lomustine is used in addition to appropriate surgical and/or radiotherapeutic procedures or as a component of various chemotherapeutic regimens in the palliative treatment of primary and metastatic brain tumours.

CeeNU containing combinations should be used as alternative therapy in the treatment of disseminated Hodgkin's disease in patients refractory to other established treatment regimens.

In New Zealand, CeeNU is indicated as palliative therapy to be employed in addition to other modalities, or in established combination therapy with other approved chemotherapeutic agents in the following:

1. Brain Tumours - both primary and metastatic, in patients who have already received appropriate surgical and/or radiotherapeutic procedures.

2. Hodgkin's Disease - as a secondary therapy.

3. Advanced Lung Carcinoma - for small cell carcinoma CeeNU is effective in combination with other appropriate neoplastic agents, particularly cyclophosphamide.

If you have questions or require additional information regarding the decision to discontinue CeeNU please contact the BMS Medical Information Department via <u>medinfo.australia@bms.com</u>.

Sincerely,

Melinda Munns Bristol Myers Squibb Medical Director, ANZ