MARCH 2019 PBAC OUTCOMES – DEFERRALS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
ABEMACICLIB Tablet 50mg Tablet 100mg Tablet 150mg Verzenio® Eli Lilly Australia Pty Ltd New listing (Major Submission)	Advanced breast cancer	To request an Authority Required listing for the treatment of non-premenopausal patients with hormone receptor positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) locally advanced or metastatic breast cancer.	The PBAC deferred making a recommendation to list abemaciclib for the treatment of non-premenopausal patients with HR+, HER2- advanced breast cancer. However, the PBAC was of a mind to recommend abemaciclib on a cost-minimisation basis to ribociclib, pending provision of a positive TGA Delegate's overview. The PBAC considered that abemaciclib would provide patients with an alternative to ribociclib for HR+, HER2- advanced breast cancer. The PBAC considered that abemaciclib + non-steroidal aromatase inhibitor (NSAI) was non-inferior in terms of comparative effectiveness and safety compared with ribociclib + NSAI while noting there were differences between the safety profiles of abemaciclib and ribociclib. The PBAC considered the cost-minimisation analysis was reasonable when the equi-effective doses are calculated without the duration of therapy being taken into account, in line with the claim of non-inferior comparative effectiveness in terms of progression-free survival.
		Sponsor Comment:	Eli Lilly looks forward to progressing the PBS listing of abemaciclib for advanced breast cancer, following TGA registration on 8th April 2019.
BEVACIZUMAB Solution for I.V. infusion 100 mg in 4 mL Solution for I.V. infusion 400 mg in 16 mL Avastin® Roche Products Pty Ltd Change to listing (Minor Submission)	Glioblastoma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy), Authority Required (STREAMLINED) listing for the treatment of relapsed or refractory glioblastoma.	The PBAC deferred making a recommendation on the Section 100 Authority Required listing of bevacizumab for the treatment of relapsed or refractory glioblastoma. The PBAC considered the efficacy of bevacizumab remains highly uncertain, however quality of life improvements are a plausible outcome, and requested further information to help determine the cost-effectiveness of this therapy. In deciding to defer, the PBAC acknowledged the high unmet clinical need in the proposed population. The PBAC acknowledged the comments from consumers, clinicians and organisations, which described a range of benefits of treatment with bevacizumab including improved quality of life, symptomatic improvement, and a reduction in steroid dose and steroid related side effects.
		Sponsor Comment	Roche is committed to addressing the outstanding matters raised by PBAC to bring bevacizumab to patients with relapsed or refractory gliobastoma at the earliest opportunity.

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BLINATUMOMAB Powder for I.V. infusion 38.5 micrograms Blincyto® Amgen Australia Pty Ltd Change to listing (Major Submission)	Acute lymphoblastic leukaemia (ALL)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of patients with B-cell precursor ALL in patients in haematological complete remission with minimal residual disease following chemotherapy.	The PBAC deferred making a recommendation on the Section 100 Authority Required (Efficient Funding of Chemotherapy) listing of blinatumomab for the treatment of patients with B-cell precursor ALL in haematological complete remission with minimal residual disease following induction chemotherapy. The purpose of the deferral was to request further information from the sponsor on issues around the estimated incremental cost-effectiveness ratio (ICER), overall net financial implications and the proposed Risk Share Arrangement. The PBAC reiterated that there is a high clinical need for more effective treatments for B-cell precursor ALL in the first-line setting where there is the greatest potential for impact on cure rates. The PBAC considered that updated data from the single-arm BLAST study indicated that blinatumomab may be associated with an overall survival advantage. However, the PBAC considered that it remained unclear whether blinatumomab would lead to long-term gains in overall survival given the lack of reliable comparative data and the relative immaturity of data from the BLAST study. The PBAC considered that the ICER was high, uncertain and likely underestimated. The PBAC considered that further work would be required to establish arrangements for listing blinatumomab in a cost-effective manner.
		Sponsor Comment:	Amgen is pleased that the PBAC acknowledged the clinical need for effective treatments for B-ALL. The elimination of MRD with blinatumomab is an important and effective treatment option. Amgen will continue to work with the PBAC with the aim to make blinatumomab available on the PBS for these patients.

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BUPRENORPHINE Injection (modified release) 100 mg in 0.5 mL pre-filled syringe Injection (modified release) 300 mg in 1.5 mL pre-filled syringe Sublocade® Indivior Pty Ltd New listing (Major Submission)	Opiate dependence	To request a Section 100 (Opiate Dependence Treatment Program) listing for the treatment of patients with opioid use disorder.	The PBAC deferred making a recommendation on the Section 100 (Opiate Dependence Treatment Program) listing for buprenorphine long-acting subcutaneous injection (Sublocade®) for the treatment of opioid use disorder. However, the PBAC was of a mind to recommend Sublocade on a cost-minimisation basis to sublingual buprenorphine/naloxone, pending provision of a positive TGA Delegate's overview. The PBAC acknowledged there was a clinical need for an alternative form of medication assisted treatment for opioid dependence, and that a long-acting subcutaneous injection was likely to have both clinical and social advantages for some patients in this treatment setting.
		Sponsor Comment:	The sponsor had no comment.
DABRAFENIB and TRAMETINIB Dabrafenib: Capsule 50 mg Capsule 75 mg Trametinib: Tablet 500 microgram Tablet 2 mg Tafinlar® and Mekinist® Novartis Pharmaceuticals Australia Pty ltd Change to listing (Major Submission)	Melanoma	To request an Authority required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected BRAF V600 mutation positive Stage III malignant melanoma.	The PBAC deferred making a recommendation on the listing of dabrafenib plus trametinib as adjuvant treatment for BRAF V600 mutation positive patients with completely resected Stage III melanoma. In deciding to defer, the PBAC acknowledged that there was a high unmet clinical need for effective therapies to reduce the risk of recurrence for patients with resected Stage III melanoma. The PBAC considered it likely that adjuvant dabrafenib+trametinib provides, for some patients with Stage IIIB, IIIC or IIID disease, a significant improvement in efficacy over routine follow-up, in terms of recurrence-free survival, and a likely benefit in terms of overall survival although there are currently limited data. However, the results of the modelled economic evaluation were unreliable and resulted in an uncertain estimate of cost-effectiveness. The PBAC considered that the sponsor should provide updated restrictions, address the uncertainties relating to the cost-effectiveness model and provide a Risk Sharing Arrangement proposal.
		Sponsor Comment:	Novartis are committed to working with the PBAC to achieve agreement on sustainable PBS listing conditions for dabrafenib and trametinib at the earliest opportunity.

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LENALIDOMIDE Capsule 5 mg Capsule 10 mg Capsule 15 mg Revlimid® Celgene Pty Ltd Change to listing (Major Submission)	Multiple myeloma	Resubmission to request an extension to the Section 100 (Highly Specialised Drug Program) Authority Required listing to include maintenance treatment of patients with newly diagnosed multiple myeloma who have undergone an autologous stem cell transplant (ASCT).	The PBAC deferred making a recommendation on the listing of lenalidomide for the maintenance treatment of patients with multiple myeloma following an ASCT. The PBAC, noting that the resubmission presented a mixed comparator of best supportive care and thalidomide, was satisfied that lenalidomide provides, for some patients, a significant improvement in efficacy over placebo, and a different toxicity profile, but notably lower rates of peripheral neuropathy, compared to thalidomide. The PBAC noted that the resubmission addressed a number of the issues identified by the PBAC during the March 2018 consideration. However, the PBAC considered that at the proposed price the incremental cost-effectiveness ratio versus best supportive care was too high given the level of uncertainty surrounding the economic analyses. In addition, the PBAC considered that the estimates of overall cost were uncertain. The PBAC considered that in the context of the high and uncertain potential cost, a detailed Risk Sharing Arrangement would be required.
		Sponsor Comment:	Celgene is encouraged by the PBAC's recognition of the role of lenalidomide for patients with Multiple Myeloma following an ASCT and is committed to working with the PBAC to secure access to lenalidomide for these patients.