

**7.12 BLINATUMOMAB,
Injection 38.5 microgram [1 vial] and inert substance solution
[10 mL vial], 1 pack,
Blincyto[®],
Amgen Australia Pty Ltd.**

1 Purpose of Application

- 1.1 The minor resubmission requested a revision to the July 2016 positive recommendation for blinatumomab for the treatment of relapsed or refractory, Philadelphia chromosome negative, B-precursor acute lymphoblastic leukaemia (Ph-B-precursor ALL) as the conditions of the managed entry scheme (MES), as specified in the recommendation, cannot be met.

2 Requested listing

- 2.1 No changes to the requested listing were proposed in the minor resubmission.
- 2.2 As the majority of patients in the Phase II studies received less than two treatment cycles, in July 2016 the PBAC considered it appropriate that the restriction limit use to a maximum of 5 cycles of blinatumomab, as specified in the product information.
- 2.3 In July 2016 the PBAC considered that the restriction should remain silent on age, noting that most paediatric patients up to 16 years of age are already being treated appropriately through clinical trials. The minor resubmission stated that if the restriction remained silent on age that this would have a direct impact on the number of patients expected to receive blinatumomab, not just on the estimated uptake rate, but the entire eligible patient population.
- 2.4 In July 2016, the PBAC reiterated that PBS subsidised blinatumomab should not be provided to public hospital inpatients, and therefore that the maximum quantities and repeats as suggested by the Secretariat were appropriate for the public hospital listing to account for the first 9 days of cycle 1 and the first 2 days of cycle 2 being provided to inpatients. This will result in the public and private hospital listings having different numbers of repeats.

3 Background

- 3.1 Blinatumomab was TGA registered on 9 November 2015 for the treatment of adults with relapsed or refractory Ph-B-precursor ALL.
- 3.2 Blinatumomab was previously considered by the PBAC in November 2015 and July 2016.
- 3.3 At the July 2016 meeting the PBAC recommended listing blinatumomab for the treatment of relapsed or refractory Ph-B-precursor ALL under an MES. The key input

for the MES was the proportion of patients alive two years after starting blinatumomab or standard care from the TOWER clinical trial. The minor resubmission stated that patients in the TOWER trial will not be followed for survival for two years. Data are available based on a median follow-up of 11.7 months in the blinatumomab arm and 11.8 months in the standard care arm, and there will be no further follow up for efficacy due to the early termination of the trial for efficacy.

- 3.4 The minor resubmission requested that the price for blinatumomab be calculated using the currently available 12 month overall survival data from TOWER with no requirement for a MES.
- 3.5 Table 1 presents a summary of the July 2016 resubmission, PBAC comments and the current resubmission.

Table 1: Summary of the blinatumomab July 2016 resubmission and current resubmission

Component	July 2016 resubmission	Current resubmission
Requested PBS listing	Written authority Section 100 (HSD) listing for relapsed or refractory Ph B-precursor ALL. PBAC Comment: PBAC recommended listing under Section 100 (EFC). PBAC reiterated that the first 9 days of initial treatment, and the first 2 days of first continuing treatment, should be provided as a hospital inpatient and therefore not PBS subsidised. PBAC considered restriction should remain silent on patient age.	Unchanged
Requested price	\$ [REDACTED] PBAC Comment: Price back-calculated based on respecified base case resulting in reduced price of \$ [REDACTED].	\$ [REDACTED]
Main comparator	Standard care chemotherapies PBAC Comment: Unchanged from November 2015 submission and remained appropriate.	Unchanged.
Clinical evidence	<ul style="list-style-type: none"> Two single-arm Phase II studies: <ul style="list-style-type: none"> MT103-211: pivotal study (n=225) MT103-206: dose-finding study (n=36) A retrospective historical control study (20120310) using SC (n=1,139) <p>Preliminary data from randomised controlled, Phase III trial (the TOWER Trial) provided in PSCR.</p> <p>PBAC Comment: Weighted historical control data from patients diagnosed post-2000 should be used for the comparator. The PBAC considered that data from the ongoing randomised trial (TOWER), after patients have been followed beyond two years, should be the source of evidence to address uncertainty in incremental proportion of patients alive.</p>	12 months of TOWER data are provided. The resubmission stated that two years of data will not be available.
Key effectiveness data	<p>The PSCR and Pre-PBAC response provided preliminary efficacy results of the median overall survival for each arm of the TOWER trial.</p> <p>Median OS blinatumomab = 7.7 months (5.6, 9.6) Median OS SC chemotherapy = 4.0 months (3.3, 4.3) Incremental median OS = 3.7 months (HR = 0.71 (0.55, 0.93))</p> <p>PBAC Comment: The preliminary results from the TOWER trial provide reassurances that evidence that is more robust will be forthcoming to better inform the clinical effectiveness.</p>	Unchanged. The resubmission stated that the median follow up is 11.8 months in the SC arm and 11.7 months in the blinatumomab arm. There will be no further follow up for efficacy.

Public Summary Document – November 2016 PBAC Meeting

Component	July 2016 resubmission	Current resubmission
Key safety data	<p>The PSCR provided preliminary safety results for each arm in the TOWER trial.</p> <p>All treatment related adverse events: Blinatumomab (N = 267) = 214 (80.1%) SC chemotherapy (N = 109) = 92 (84.4%)</p> <p>PBAC Comment: The preliminary safety results from TOWER indicate that blinatumomab is likely to be superior in terms of comparative safety compared to standard care chemotherapy.</p>	Unchanged.
Clinical claim	<p>Blinatumomab was superior in terms of both comparative effectiveness and safety over SC combination chemotherapies.</p> <p>PBAC Comment: The claim of superior comparative effectiveness and safety was reasonable in light of the preliminary results provided from the TOWER trial.</p>	Unchanged
Economic evaluation	<p>Cost-utility model with cost/QALY \$45,000 - \$75,000. This was based on the inclusion of all patients in Study 20120310.</p> <p>PBAC Comment: The use of post-2000 patient data from Study 20120310 increased the ICER to \$75,000 – \$105,000. The PBAC recommended respecifying the base-case to use weighted post-2000 data for the comparator to maintain an ICER of \$45,000 - \$75,000/QALY.</p> <p>The PBAC reiterated that the preferred input into the economic model is the mature (2 years or 25 months of follow-up) comparative results from the TOWER trial.</p>	Cost-utility model with cost/QALY \$45,000 - \$75,000 using 12 months of data from the TOWER trial.
Number of patients	<p>Year 1: less than 10,000 patients; Year 5: less than 10,000 patients</p> <p>PBAC Comment: The estimated number of adult patients was reasonable.</p>	Unchanged. The resubmission considered that the recommendation for the restriction to remain silent on patient age has a direct impact on the number of patients expected to receive blinatumomab.
Estimated cost to PBS	<ul style="list-style-type: none"> • Less than 10,000 treated patients and less than \$10 million net cost to PBS in Year 5 • \$20 - \$30 million net cost to PBS over the first 5 years of listing <p>PBAC Comment: The PBAC noted that the estimated number of adult patients treated with blinatumomab as presented in the resubmission was reasonable.</p>	Less than 10,000 treated patients and less than \$10 million net cost to PBS in Year 5. Total of \$20 - \$30 million net cost to PBS over the first 5 years of listing.
Risk sharing arrangement	<p>Financial cap set at ■■■% of the estimated blinatumomab eligible population with a ■■■% rebate to apply beyond the cap. The cap would be set at an agreed estimate of average number of vials per eligible patient.</p> <p>PBAC Comment: Expenditure caps should reflect the estimate of less than 42 vials and reflect the estimated treated population with a ■■■% rebate to the Commonwealth for use beyond these expenditure caps.</p>	Agreed to cap at estimated patient numbers if restriction to be age specific.

Public Summary Document – November 2016 PBAC Meeting

Component	July 2016 resubmission	Current resubmission
Managed entry scheme	<p>A managed entry scheme proposal using the Phase III TOWER trial was presented.</p> <p>PBAC Comment: The PBAC recommended a managed entry scheme modified from that proposed in the submission to address the primary uncertainty over the incremental proportion of patients alive two years after starting blinatumomab or standard care chemotherapy.</p> <p>Initial price based on weighted historical control data from patients diagnosed post-2000 to maintain an ICER of \$45,000 - \$75,000 per QALY.</p> <p>The incremental proportion of patients alive two years (or 25 months) after starting blinatumomab or standard care chemotherapy, based on the intent-to-treat analysis, will be used as inputs into the current economic model. Extrapolation modelling then applied on both arms whereby patients alive at two years (or 25 months) have normal life expectancy for the remainder of the 20 year model. No other inputs should change.</p> <p>The price of blinatumomab at the end of the MES will either be maintained or reduced to maintain an ICER of \$45,000 - \$75,000 per QALY. If the price is reduced, the sponsor would rebate the Commonwealth.</p>	<p>The model is populated with 12 months of TOWER data and extrapolated from this time point assuming normal life expectancy.</p> <p>Vial price has been reduced further to \$██████ to maintain the recommended ICER.</p> <p>As no further data will become available, there is no need for an interim price or a MES.</p>
PBAC decision	Recommended	-

Source: Compiled during preparation of the overview

ALL = acute lymphoblastic leukaemia; EFC = efficient funding of chemotherapy; ICER = incremental cost-effectiveness ratio; HR = hazard ratio; OS = overall survival; QALY = quality adjusted life year; SC = standard care

- 3.6 Table 2 presents the recommendation forming the basis of the MES, as proposed by the PBAC in July 2016, and how the minor resubmission addressed the recommendations.

Table 2: PBAC recommendations for the MES and approach in the current resubmission

Recommendations forming basis of MES as proposed by PBAC (July 2016 PBAC PSD)	How the resubmission addresses the recommendation (November 2016)
<p>Initial price: \$ [REDACTED] (effective dispensed price; paragraph 6.60) Based on respecifying base case to use only weighted historical control data from patients diagnosed post-2000 for the comparator.</p>	<p>Not applicable</p>
<p>Modelled economic evaluation (paragraphs 6.67 and 6.68):</p> <ul style="list-style-type: none"> • estimate the incremental OS for the two arms of the model up to <u>two years</u> based directly on the observed OS Kaplan-Meier curves (intent-to-treat analysis with no censoring for transplant) • estimate the incremental proportion of patients alive at <u>two years</u> (or 25 months) across the two Kaplan-Meier curves from the clinical evaluation • extrapolation modelling on both arms for the OS curves from this time point, whereby patients still alive at <u>two years</u> (or 25 months) have normal life expectancy for the remainder of the 20-year model • blinatumomab cost based on 42 vials (1.64 cycles) 	<p>Model presented in minor resubmission:</p> <ul style="list-style-type: none"> • incremental OS for the two arms of the model up to <u>one year</u> based directly on the observed OS Kaplan-Meier curves (intent-to-treat analysis with no censoring for transplant) • estimate the incremental proportion of patients alive at <u>one year</u> across the two Kaplan-Meier curves from the clinical evaluation • extrapolation modelling on both arms for the OS curves from this time point, whereby patients still alive at <u>one year</u> have normal life expectancy for the remainder of the 20-year model • blinatumomab cost based on 42 vials (1.64 cycles)
<p>Revised price based on MES (paragraphs 6.61 and 6.62) Back-calculate blinatumomab price to obtain an ICER of \$45,000 - \$75,000 per QALY gained using the model specified above.</p>	<p>Proposed price: \$ [REDACTED] (effective dispensed price) Blinatumomab price back calculated to obtain an ICER of \$45,000 - \$75,000 per QALY gained using the model in the minor resubmission as specified above.</p>
<p>Financial forecasts (paragraphs 6.74-6.75)</p> <ul style="list-style-type: none"> • Expenditure caps reflect 42 vials • Expenditure caps reflect estimated treated population (less than 10,000 adults) • [REDACTED]% rebate to the Commonwealth should apply beyond expenditure caps 	<p>As the recommended restriction wording is silent on the age of the patient, the resubmission suggested that the caps should be revised (p11-12).</p>

Source: Compiled during the preparation of the overview

ICER = incremental cost-effectiveness ratio; MES = managed entry scheme; OS = overall survival; QALY = quality adjusted life years

4 Clinical place for the proposed therapy

4.1 As for the previous submissions, the minor resubmission proposed that blinatumomab be used in the treatment of relapsed or refractory Ph-B-precursor ALL patients.

5 Comparator

5.1 The comparator was unchanged from the previous submissions. The PBAC previously accepted the comparator as standard care chemotherapy, including FLAG with or without anthracycline, high dose methotrexate in combination with pegylated-asparaginase, vinca alkaloids, steroids, etoposide or alkylating agents, and high-dose cytarabine (HiDAC) base chemotherapy.

6 Consideration of the evidence

Sponsor hearing

6.1 There was no hearing for this item as it was a minor submission.

Consumer comments

6.2 The PBAC noted and welcomed the input from individuals (13) and organisations (2) via the Consumer Comments facility on the PBS website. The comments described a range of benefits of treatment with blinatumomab compared with standard care chemotherapy, including fewer side effects, improvements in quality of life, and reduced time spent in hospital for treatment.

6.3 The PBAC noted the advice received from the Leukaemia Foundation and Rare Cancers Australia clarifying the likely use of blinatumomab in clinical practice. The PBAC specifically noted the advice that the use of blinatumomab may provide significant benefits compared with current standard chemotherapy, including reduced side effects and improvements in patient outcomes, including overall survival and quality of life. The PBAC noted that this advice was supportive of the evidence provided in the submission.

Clinical trials

6.4 Overall survival data from the TOWER trial were presented in the minor resubmission and were used to populate the economic model. The median follow-up was 11.7 months in the blinatumomab arm and 11.8 months in the standard care arm. In the blinatumomab arm 27.7% (74/267) of patients received other cancer therapy during the follow-up compared with 38.5% (42/109) of patients in the standard care arm. Of the standard care patients receiving another cancer treatment, 17% (7/42) received blinatumomab.

Table 3: Key features of the TOWER trial

Study	N	Design/ duration	Risk of bias	Patient population	Outcomes	Used in MES?
TOWER	383	Phase III, R, OL Up to 19 months	Unknown	- Adult; - > 5% blasts in bone marrow; - Refractory disease; - Relapsed disease (1 st remission < 12 months; after 1 st salvage therapy; or at any time after allogeneic HSCT) - Received intensive combination chemotherapy - ECOG performance status ≤ 2	OS; CR/CRh*/CRi; allogeneic HSCT rate; 100 day mortality following HSCT	Yes

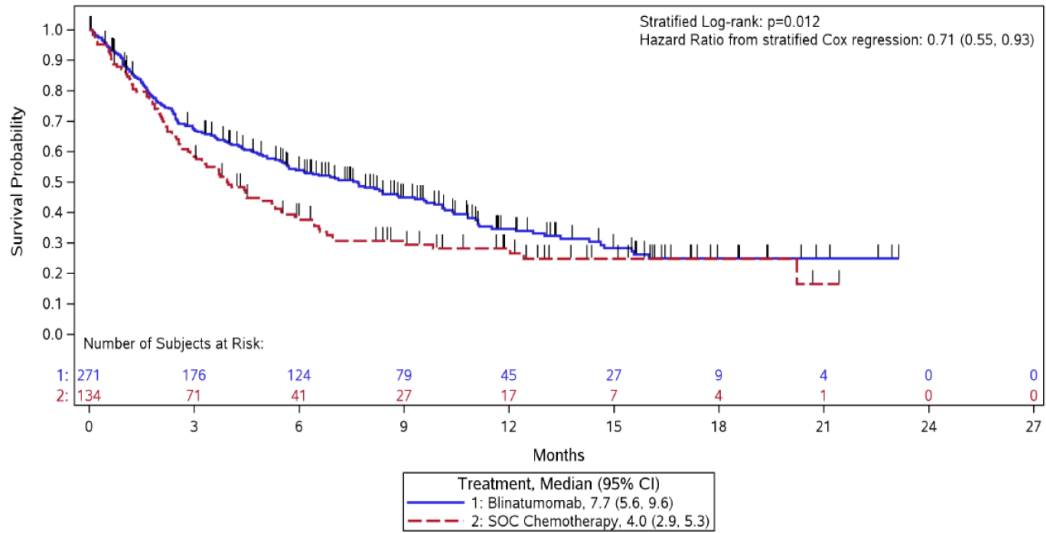
Source: July 2016 PBAC PSD, Table 2

CR = complete remission; CRh* = complete remission with partial haematological recovery; CRi = complete remission with incomplete haematological recovery; ECOG = Eastern Cooperative Oncology Group; HSCT = haematopoietic stem cell transplant; MES = managed entry scheme; OL = open-label; OS = overall survival; R = randomised

Comparative effectiveness

6.5 The Kaplan-Meier plots for overall survival from the TOWER trial are presented in Figure 1. Median overall survival observed was 7.8 months (95%CI: 5.6, 9.6) for blinatumomab and 4.0 months (95%CI: 2.9, 5.4) for standard care (hazard ratio=0.71; stratified log-rank test p=0.012, surpassing the pre-specified O’Brien-Fleming boundary p value of 0.0183).

Figure 1: Overall survival results from the TOWER trial (Full analysis set)



Source: Minor submission, Figure 1

Comparative harms

6.6 The safety results for each arm in the TOWER trial are presented in Table 4.

Table 4: Safety results from TOWER trial

	Blinatumomab (N = 267) n (%)	SC chemotherapy (N = 109) n (%)
All treatment related emergent adverse events	214 (80.1)	92 (84.4)
≥ Grade 2	195 (73.0)	89 (81.7)
≥ Grade 3	143 (53.6)	78 (71.6)
≥ Grade 4	57 (21.3)	51 (46.8)

Source: July 2016 PBAC PSD, Table 2

SC = standard care

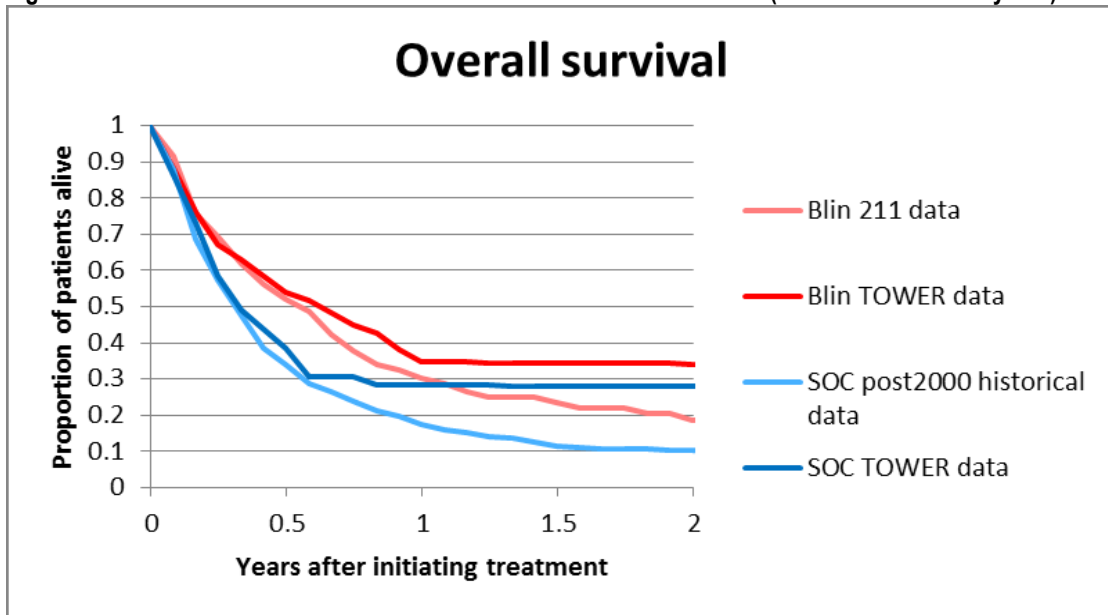
Clinical claim

6.7 The minor resubmission did not propose a change the clinical claim from the July 2016 resubmission. In July 2016, the PBAC considered that the claim of superior comparative effectiveness was reasonable in light of the preliminary results provided from the TOWER trial. The PBAC considered that the claim of superior comparative safety was reasonable.

Economic analysis

6.8 Overall survival for the first 2 years (the model time horizon is 20 years) for the July 2016 and current models is presented in Figure 2. In the July 2016 model, overall survival was based on single arm studies. Data from the historical controls informed survival for 5 years for the standard care arm. Data from study MT103-211 informed survival for blinatumomab for 2 years, and between 2 and 5 years the rate of survival for blinatumomab was assumed to be the same as for the standard care arm. Beyond 5 years normal life expectancy was assumed for both arms. In the minor resubmission model, overall survival was estimated using data from TOWER up to 1 year for both arms; beyond this normal life expectancy was assumed.

Figure 2: Modelled overall survival from the revised economic evaluation (x axis truncated at 2 years)



Source: Blinatumomab minor resubmission, Figure 4.2-1

6.9 The economic model in the July 2016 submission assumed a normal life expectancy from 5 years for 11.9% of blinatumomab patients and 6.4% of standard care patients. The current model assumed normal life expectancy from 1 year for 34% and 28% of patients respectively. The incremental gain in life years (LYs) was 1.25 years in the July 2016 model (of which 0.81 years were for the period 5-20 years). This compares with 1.26 LYs gained (0.89 in the period 5-20 years) in the current model. Although the current model assumed substantially more patients are cured both with blinatumomab and standard care, the difference between the groups is similar and thus the gain in overall survival is similar.

6.10 The results of the previous and current economic models are presented in Table 5. The vial price of blinatumomab has been decreased from \$ [redacted] in the July submission to \$ [redacted] in the current submission to achieve an incremental cost per QALY gained of \$45,000 - \$75,000 with the revised model based on the TOWER survival data.

Table 5: Comparison of the results of the economic evaluation in each submission and the PBAC recommendation from July 2016

	November 2015 submission	July 2016 resubmission	July 2016 PBAC recommendation	Minor resubmission November 2016
Source of blinatumomab data	MT103-211 study	MT103-211 study	MT103-211 study	TOWER data (to 12 months)
Source of SOC data	Historical control	Historical control	Historical control restricted to post-2000	TOWER data (to 12 months)
Extrapolation method ^a	Historical control 25-60 months, Aus death rate 5-20 years	Historical control 25-60 months, Aus death rate 5-20 years	Historical control 25-60 months, Aus death rate 5-20 years	Aus death rate from 1-20 years
QALYs blinatumomab	1.679	1.679	1.627	3.673
QALYs SOC	0.746	0.746	0.894	2.959
Incremental QALYs	0.934	0.934	0.733	0.713
Costs blinatumomab	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Costs SOC	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Incremental costs	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
ICER per QALY	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Blinatumomab vial price ^b	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Average course of treatment cost ^c	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]

Source: Blinatumomab minor resubmission, Table 4.3-1

Abbreviations: Aus = Australian; m = month; SOC = standard of care

a. As the historical control was used for the SOC arm in the November 2015, July 2016 submission and the PBAC recommendation from July 2016, the extrapolation described here was only required for the blinatumomab arm. For the current submission, both the blinatumomab arm and the SOC arm are extrapolated following the TOWER data using Australian death rates as laid out in the July 2016 PBAC meeting PSD and advised at the post-PBAC meeting.

b. Derived by fixing the ICER at \$ [REDACTED] and back calculating the vial price

c. November 2015 submission based on 46 vials which was revised down to 42 for all subsequent time-points.

6.11 Compared with the model in the July 2016 submission, the incremental difference in QALYs reduced 3% from 0.733 to 0.713. Fixing the ICER at \$45,000 - \$75,000 against this slightly reduced incremental QALY difference and back calculating the blinatumomab vial price leads to a 1.3% reduction in the vial price to \$ [REDACTED]. The minor resubmission noted the reason for the QALY reduction and price reduction not being proportional is that in adjusting survival in both arms of the model, there are indirect effects on other parameters as a result of different proportions of patients being alive, such as some follow up costs and palliative care costs.

Drug cost/patient/treatment: \$ [REDACTED]

6.12 The minor resubmission estimated that the cost per blinatumomab treatment would be \$ [REDACTED], assuming an average total dose of 1,156 µg (1.64 cycles and 42 vials). This compares with \$ [REDACTED] per treatment in the July 2016 submission.

Estimated PBS usage & financial implications

6.13 The minor submission updated the financial implications to the PBS to account for the revised cost of an average course of treatment with blinatumomab. The redacted table below shows that at year 5 the estimated number of patients was less than

10,000 per year and the net cost to the PBS/RPBS would be less than \$10 million per year.

Table 6: Estimated use and financial implications of listing blinatumomab on the PBS/RPBS

	Year 1	Year 2	Year 3	Year 4	Year 5
Estimated extent of use					
Number treated					
Viials*					
July 2016 PBAC recommendation (based on a price of \$ [redacted] per vial)					
Net cost to PBS/RPBS	\$ [redacted]	\$ [redacted]	\$ [redacted]	\$ [redacted]	\$ [redacted]
Current minor resubmission (based on a price of \$ [redacted] per vial)					
Net cost to PBS/RPBS	\$ [redacted]	\$ [redacted]	\$ [redacted]	\$ [redacted]	\$ [redacted]

Source: Blinatumomab minor resubmission, Table 5.1-1

* based on an adult population (≥18 years of age), [redacted]% uptake rate and an average of 42 vials (1.64 cycles) per patient

Financial Management – Risk Sharing Arrangements

- 6.14 The July 2016 resubmission proposed a financial cap set at [redacted]% of the estimated blinatumomab eligible population with a [redacted]% rebate to apply beyond the cap. The cap would be set at an agreed estimate of average number of vials per eligible patient.
- 6.15 In July 2016, the PBAC recommended that:
- the expenditure caps reflect the estimate of 42 vials (1.64 cycles);
 - the caps should reflect the estimated treated population (less than 10,000 adults), rather than [redacted]% of the estimated eligible population (less than 10,000 adults); and
 - a [redacted]% rebate to the Commonwealth should apply beyond the corresponding expenditure caps.
- 6.16 The minor resubmission stated that if the recommended restriction wording was to be age-specific, the sponsor would accept the placement of the cap relative to the estimated patient numbers based on an adult population (≥18 years of age). However, the decision to remain silent on age has a direct impact on the number of patients expected to receive blinatumomab, not just on the estimated uptake rate, but the entire eligible patient population.
- 6.17 In its consideration of the current resubmission, the PBAC recommended that the Risk Sharing Arrangements outlined in the July 2016 PBAC PSD should apply (see paragraph 6.15). The PBAC reaffirmed that the restriction should remain silent on age. However, given the significant uncertainty around several aspects of the estimates and the high ICER, the PBAC did not consider that this was sufficient grounds for any upward revision of the expenditure cap.

For more detail on PBAC’s view, see section 7 “PBAC outcome”

7 PBAC Outcome

- 7.1 The PBAC recommended the listing of blinatumomab for relapsed or refractory Ph B-precursor ALL on the basis of the previous recommendation in July 2016, with the revised price proposed in the minor submission and removal of the recommended

Managed Entry Scheme (MES). The PBAC reaffirmed that its recommendation was on the basis that blinatumomab should be available only under special arrangements under Section 100 (Efficient Funding of Chemotherapy).

- 7.2 The PBAC noted that the key input for the proposed MES was the proportion of patients alive two years after starting blinatumomab or standard care from the TOWER clinical trial; however, as patients in the TOWER trial will not be followed for survival for two years the required data will not be collected.
- 7.3 The PBAC noted that the ICER calculated using the revised price, the 12 month survival data from the TOWER trial and the previously evaluated economic model was \$45,000 - \$75,000 per QALY gained. In July 2016, the PBAC considered that this ICER was high but acceptable in this patient population.
- 7.4 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

8 Recommended listing

- 8.1 Add new item: Blinatumomab, Injection 38.5 microgram [1 vial] and inert substance solution [10 mL vial], 1 pack

Restriction to be finalised.

9 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

10 Sponsor's Comment

Amgen is pleased with the PBAC's recommendation and recognition of the clinical need for an effective treatment in this patient population. Amgen are committed to working with the PBAC to achieve PBS listing of blinatumomab for all appropriate patients at the earliest opportunity.