



Errata to the FDA Briefing Document

Oncologic Drugs Advisory Committee Meeting (ODAC) March 7, 2018

BLA 125557

Blincyto (blinatumomab)

Applicant: Amgen, Inc.

1. On page 16, Table 5:

Philadelphia chromosome		
• Positive	5 (4)	0 (0)
• Negative	108 (96)	87 (100)

Corrected to read:

Philadelphia chromosome		
• Positive	5 (4)	1 (1)
• Negative	108 (96)	86 (99)

2. On page 16, text below Table 6:

“Also, FDA noted that approximately 45% of the MRD-responders underwent HSCT compared with 15% in MRD-nonresponders. However, due to the small sample sizes, a quantitative interaction of MRD response status and HSCT was not found.”

Corrected to read:

“Also, FDA noted that approximately 45% of **RFS events occurred** in the MRD-responders **who** underwent HSCT compared with 15% in MRD-nonresponders. However, due to the small sample sizes, a quantitative interaction of MRD response status and HSCT was not found.”

3. On page 17, text above Table 7:

“Using the FDA efficacy analysis set, the 18-month RFS was 56%.”

Corrected to read:

“Using the FDA efficacy analysis set, the 18-month RFS was **58.5%**.”

4. On page 19, text above Table 9:

“Adding a criterion of minimal 14 days between MRD measurement and start of blinatumomab further reduced the sample size from Study MT103-203 from n=113 in PE FAS to n=73 in the Primary Analysis Set (33% reduction).”

Corrected to read:

“**Restricting the population to only patients in CR1** reduced the sample size from Study MT103-203 from N=113 in PE FAS to N=73 in the propensity score subset (35% reduction).”

5. On page 23, text above Figure 6:

“The estimated median OS time was 76.1 months (95% CI: 26.23, NE) for the blinatumomab group and 30.59 months (95% CI: 22.45, NE) for the control group.”

Corrected to read:

“The estimated median OS time was 76.1 months (95% CI: 26.23, NE) for the **control group** and 30.59 months (95% CI: 22.45, NE) for the **blinatumomab group**.”

6. On page 24, Table 10:

OS	No HSCT	0.61 (0.40, 0.94)
	HSCT	1.62 (0.61, 4.3)

Corrected to read:

OS	No HSCT	0.61 (0.40, 0.94)
	HSCT	1.04 (0.61,1.76)

7. On page 24, text below Table 10:

“It is not clear whether the lack of effect of blinatumomab on RFS (or worsen effect on OS) with HSCT was due to disease-related events or transplant-related mortality”

Corrected to read:

“It is not clear whether the lack of effect of blinatumomab on RFS (**or OS**) with HSCT was due to disease-related events or transplant-related mortality.”