# Errata to the FDA Briefing Document

## Oncologic Drugs Advisory Committee Meeting (ODAC)

July 11, 2017

BLA 761060

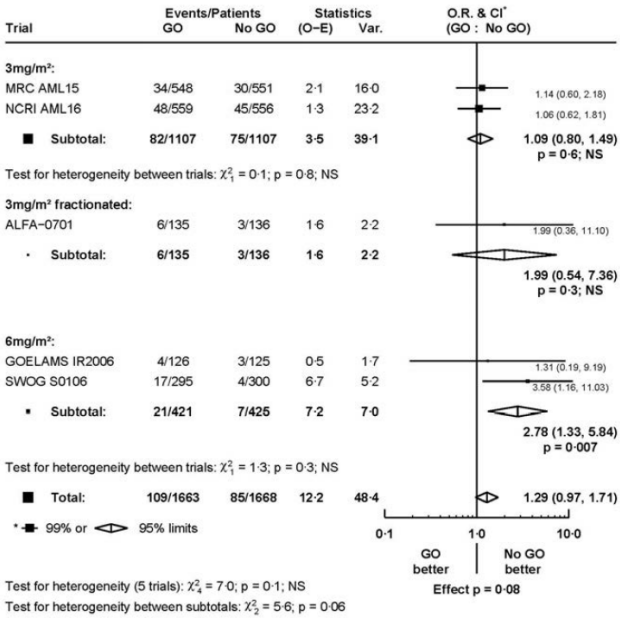
Mylotarg (gemtuzumab ozogamicin)

Applicant: Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.

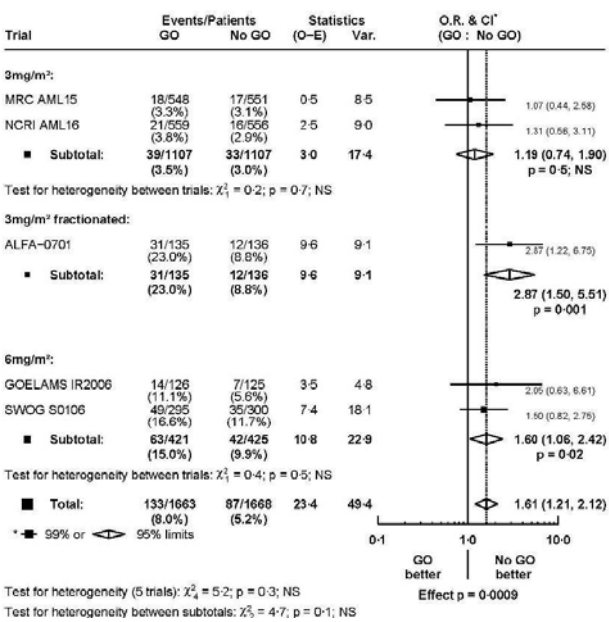
1. On page 36, Figure 9 was changed **from**:

**Figure 1: IPD Meta-Analysis - Grade 3-4 Hemorrhage**

(a) Induction; all sources




b) All-safety period; all sources

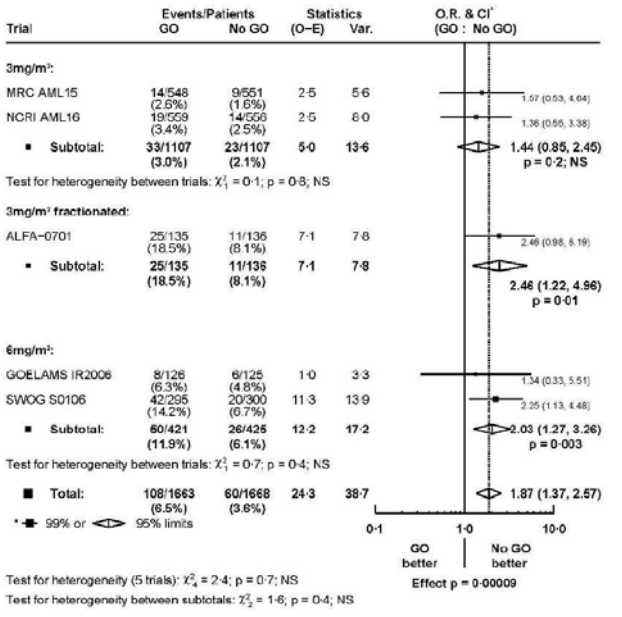



Source: Applicant's IPD meta-analysis report Figures 181 and 183

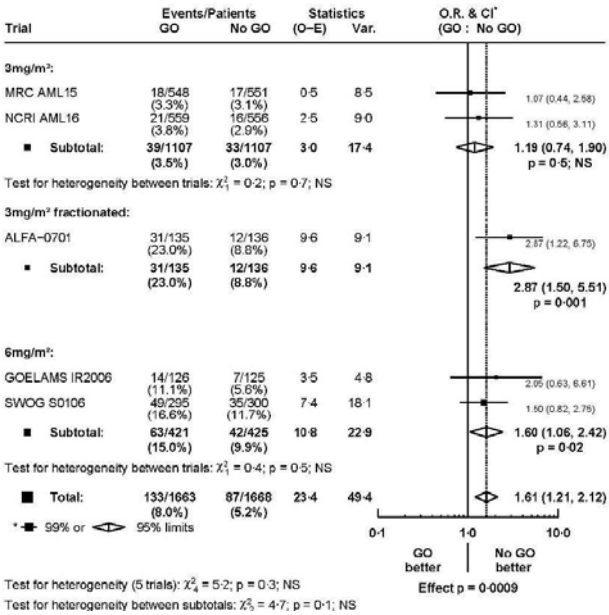
**To**:

**Figure 2: IPD Meta-Analysis - Grade 3-4 Hemorrhage**

(a) Induction; all sources




b) All-safety period; all sources




Source: Applicant's IPD meta-analysis report Figures 181 and 183

2. On page 35, the first paragraph was changed **from:**

Overall and during each phase of treatment, the incidence of hemorrhage events was greater for those patients treated with GO + DA than with DA alone as treated in ALFA-701 (Table 19). Grade ≥ 3 hemorrhage also occurred more frequently in patients treated with GO (23% vs 7% in Induction 1, 13% vs 2% in Consolidation 1, and 6% vs <1% in consolidation 2). Fatal treatment-related hemorrhage was reported for four patients on GO + DA vs none on DA alone.

**To**:

Overall and during each phase of treatment, the incidence of hemorrhage events was greater for those patients treated with GO + DA than with DA alone as treated in ALFA-701 (Table 19). Grade ≥ 3 hemorrhage also occurred more frequently in patients treated with GO (18% vs 9% in Induction 1, 5% vs 0% in Consolidation 1, and 6% vs 0% in consolidation 2). Fatal treatment-related hemorrhage was reported for four patients on GO + DA vs none on DA alone.