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Supplemental Appendix for:
FDA Approval Summary: Mylotarg for Treatment of Patients with Relapsed or Refractory CD33-Positive Acute Myeloid Leukemia
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Literature Search Methods: The literature search included OVID MEDLINE (1946-7/1/2015), OVID MEDLINE In-Process, BIOSIS Previews (1969-2015, week 31), Embase Daily Alerts (5/4/2015-7/1/2015), and Embase (1974-7/1/2015) using terms "cma-676," mylotarg," gemtuzumab ozogamicin," or "gemtuzumab." Published papers and meeting abstracts must have included the following: 1) GO as a single agent in patients with R/R AML; 2) unfractionated dosing regimens of 6 or 9 mg/m^2 14 days apart or the fractionated dosing regimen of 3 mg/m^2 days 1, 4, and 7; 3) at least 10 patients total; and 4) information on CR rate or VOD incidence by dose. Review articles, preclinical studies, meta-analyses, case reports, and papers focusing on APL were excluded.

Meta-Analysis Methods: Pooled estimates for VOD incidence rates and CR rates by dose-schedule were determined by taking a weighted average of the rates from independent studies of the same dose-schedule. The weight given to each study was the inverse of variance of the study-specific rate. Considering that many studies had a small number of events, an arcsine transformation was applied to study-specific rates and their variances before pooling. The pooled estimates and confidence intervals were then back-transformed to original scale for reporting. The confidence intervals for the pooled estimates were computed using the exact or Clopper-Pearson method.