Dear Ms. McClure,

On behalf of Pfizer Oncology, I respectfully request the NCCN Acute Myeloid Leukemia (AML) Guideline Panel to review and consider the enclosed information on MYLOTARG™ (gemtuzumab ozogamicin) for the treatment of adults with newly diagnosed, relapsed, or refractory CD33-positive AML in NCCN Guidelines in Oncology® for AML Version 4.2017 and the associated Drugs and Biologics Compendium™.

- **Request for NCCN Guidelines Panel to review data for a specific indication(s)**
  - MYLOTARG (gemtuzumab ozogamicin) combined with chemotherapy or as a single agent for newly diagnosed AML and as a single agent for relapsed/refractory (R/R) AML.

- **Specific changes recommended within the NCCN Guidelines (one sentence)**
  - Please include gemtuzumab ozogamicin in combination with standard induction and consolidation therapy as an option for newly diagnosed AML in AML-7, AML-10, AML-11, AML-13, and relevant discussion sections; single agent gemtuzumab ozogamicin as an option for newly diagnosed AML not candidates for intensive remission induction therapy or declines intensive therapy in AML-11, AML-14, and relevant discussion sections; single agent gemtuzumab ozogamicin as an option for R/R AML in AML-15, AML-F, and relevant discussion sections.

- **Statement of whether the submitted use is or is not FDA approved for that indication**
  - The submitted use is approved by the FDA for these indications.

- **Citation of literature support and complete articles supporting recommended change:**
We appreciate the Panel’s thorough consideration of the data supporting the FDA-approved indications for MYLOTARG (gemtuzumab ozogamicin) in adult patients with newly diagnosed and R/R AML.

Sincere regards,

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Director, US Medical Affairs
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