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NCCN Guidelines Panel: Acute Myeloid Leukemia (AML)

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:**
 - MYLOTARG [prescribing information]. Philadelphia, PA: Pfizer Inc; 2017.
 - Castaigne S, Pautas C, Terre C, et al. Effect of gemtuzumab ozogamicin on survival of adult patients with de-novo acute myeloid leukaemia (ALFA-0701): a randomised, open-label, phase 3 study. *Lancet*. 2012;379(9825):1508-16.
 - Castaigne S, Pautas C, Terré C, et al; Acute Leukemia French Association. Final analysis of the ALFA 0701 Study. *Blood*. 2014;124(21):376.
 - Amadori S, Succi S, Selleslag D et al. Gemtuzumab Ozogamicin Versus Best Supportive Care in Older Patients With Newly Diagnosed Acute Myeloid Leukemia Unsuitable for Intensive Chemotherapy: Results of the Randomized Phase III EORTC-GIMEMA AML-19 Trial. *J Clin Oncol*. 2016;34(9):972-979.
 - Taksin AL, Legrand O, Raffoux E, et al. High efficacy and safety profile of fractionated doses of Mylotarg as induction therapy in patients with relapsed acute myeloblastic leukemia: a prospective study of the alfa group. *Leukemia*. 2007;21(1):66-71.

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,

A handwritten signature in black ink, appearing to read 'CH', with a long horizontal stroke extending to the right.

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