ADD MYLOTARG TO

FOR LONGER REMISSION[1]

MYLOTARG added to chemotherapy in *de novo* AML offers:

- A significantly prolonged EFS by reducing risk of induction failure, relapse, and death vs chemotherapy alone[1,2]
- A significantly prolonged first remission, more than doubling median RFS vs chemotherapy alone[1]
- An acceptable safety profile using a fractionated 3, 3, 3 schedule[1,3]
  - Rate of infection (Grade ≥ 3) was similar between treatment arms: MYLOTARG + chemotherapy, 77.9% versus chemotherapy alone, 77.4%[1]
  - The overall rate of VOD in the MYLOTARG arm was 4.6%[1]

Click here for
MYLOTARG SmPC

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.

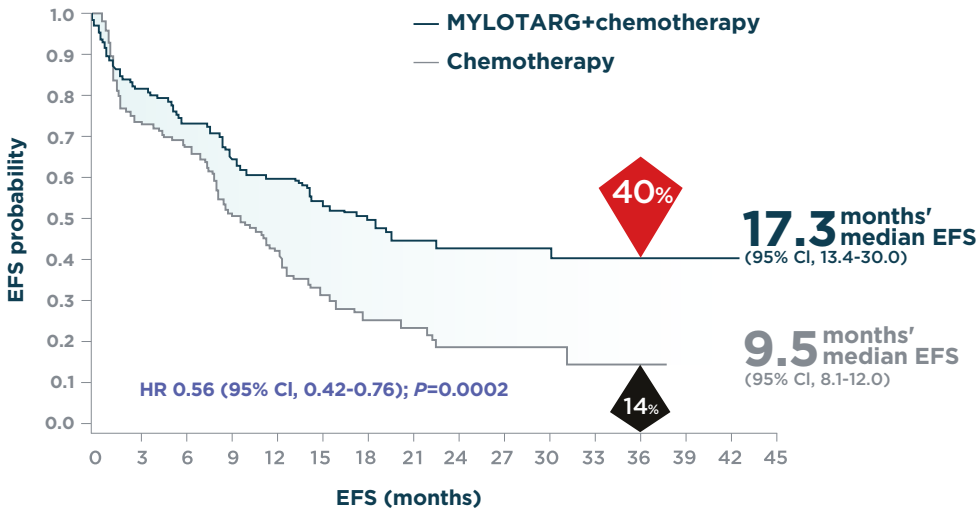
Indication: MYLOTARG is indicated for combination therapy with daunorubicin (DNR) and cytarabine (AraC) for the treatment of patients aged 15 years and above with previously untreated, *de novo* CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL).

Pfizer

MYLOTARG™ ▼
(gemtuzumab ozogamicin) INJECTION FOR IV INFUSION

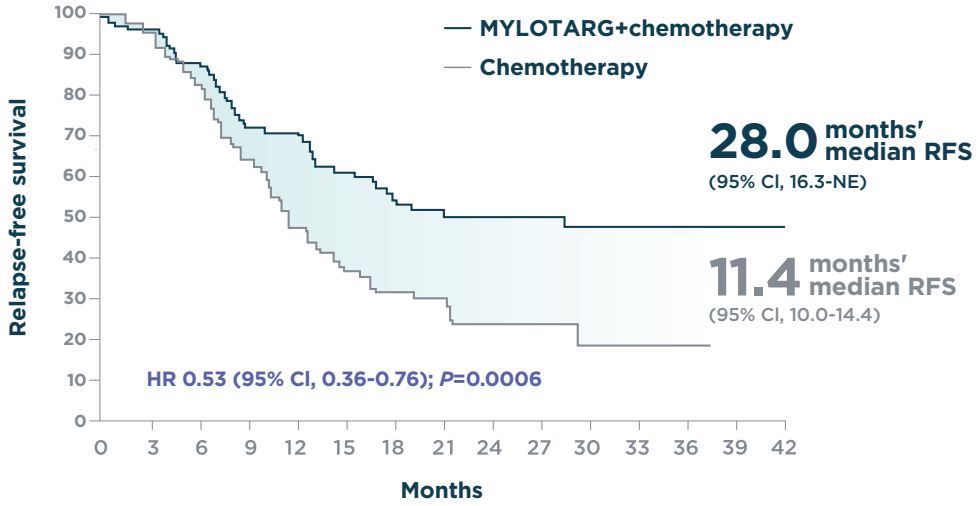
POWER UP YOUR 7+3 TREATMENT FOR AML

Prolonged survival in first remission[1,2]



- Median EFS nearly doubled with MYLOTARG plus induction chemotherapy vs chemotherapy alone[2]
- 40% of patients in the MYLOTARG+chemotherapy arm are still alive in first remission at 3 years[2]
- 44% reduction in the risk of induction failure, relapse, or death for patients in the MYLOTARG arm compared with the chemotherapy arm[1]

Prolonged remission[3]



- In the ALFA-0701 study, median RFS more than doubled with MYLOTARG+chemotherapy vs chemotherapy alone[2]
- The addition of MYLOTARG to chemotherapy resulted in a 47% reduction in the risk of relapse or death vs chemotherapy alone[1]

MYLOTARG+chemotherapy is well tolerated, with a manageable safety profile[1-3]

- The most common grade 3/4 adverse events among patients receiving MYLOTARG plus induction chemotherapy were haematologic, including persistent thrombocytopenia (20.4%) and haemorrhage (20.6%)
- Rate of infection (Grade ≥ 3) was similar between treatment arms: MYLOTARG+chemotherapy, 77.9% versus chemotherapy alone, 77.4%[1]
- The overall rate of VOD in the MYLOTARG arm was 4.6%[1]

Fractionated dosing induction regimen[2]

- MYLOTARG dosing is fractionated at a dosage of 3 mg/m^2, capped at one 5-mg vial, on days 1, 4, and 7 (3, 3, 3 schedule)

Please see the SmPC for more information on adverse events.

CI=confidence interval; EFS=event-free survival; HR=hazard ratio; NE=not evaluable; RFS=relapse-free survival; SmPC=Summary of Product Characteristics.

References: 1. Lambert J, Pautas C, Terré C, et al. Gemtuzumab ozogamicin for *de novo* acute myeloid leukemia: final efficacy and safety updates from the open-label, phase III ALFA-0701 trial. Haematologica. 2019;104(1):113-119. **2.** Mylotarg [summary of product characteristics]. Brussels, Belgium: Pfizer; 2020. **3.** Lambert J, Pautas C, Terré C, et al. Gemtuzumab ozogamicin for *de novo* acute myeloid leukemia: final efficacy and safety updates from the open-label, phase III ALFA-0701 trial. Haematologica. 2019;104(1):113-119, Supplemental Appendix. http://www.haematologica.org/content/104/1/113.figures-only. Accessed April 29, 2021.

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PP-MYL-GLB-0067

May 2021