

7062 General Poster Session (Board #M19)  
Sat, 8:00 AM - 12:00 PM

Sub-category: Leukemia  
Category: Leukemia, Myelodysplasia, and Transplantation  
Meeting: 2009 ASCO Annual Meeting

Citation: J Clin Oncol 27:15s, 2009 (suppl; abstr 7062)

Abstract No: 7062

**Updated remission duration and survival results of single-agent clofarabine in previously untreated older adult patients with acute myelogenous leukemia (AML) unlikely to benefit from standard induction chemotherapy due to unfavorable baseline risk factor(s).**

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**Background:** The CLASSIC II trial has previously reported an independently confirmed overall remission rate of 46% (38% CR and 8% CRp) and 30- and 60-day mortality rates of 9.8% and 16.1%, respectively (Blood 112:558, 2008). We now report updated duration of remission (DOR), disease-free survival (DFS), and overall survival (OS). **Methods:** Single arm, multi-center, phase II, open-label, 2-stage study of patients with untreated AML,  $\geq 60$  years old, and at least one adverse prognostic factor: age  $\geq 70$  years, antecedent hematologic disorder (AHD), PS  $\geq 2$ , and/or intermediate/unfavorable risk karyotype. Clofarabine (CLO) administered days 1–5 at 30 mg/m<sup>2</sup> during induction and 20 mg/m<sup>2</sup> during re-induction/consolidation for maximum 6 cycles. Patients were followed for at least 6 months past remission (CR/CRp). **Results:** 116 patients enrolled and 112 in full analysis set. Median age 71 years. Median DOR (censored at alternative therapy) for CR/CRp was 56 weeks (95% CI, 33 weeks - not yet estimable [n/e]) and for CR 65 weeks (95% CI, 41 weeks - n/e). Median DFS (not censored at alternative therapy) for CR/CRp was 34 weeks (95% CI, 24 - 65 weeks). Median OS was 41 weeks (95% CI 28 - 53 weeks), for CR/CRp 59 weeks (95% CI, 50 weeks - n/e), and for CR was 72 weeks (95% CI, 53 weeks - n/e) after median follow-up of 36 weeks (range, 1 - 85 weeks). Thirty-day mortality was 9.8% for all patients with 4.7% and 13% for age  $\geq 70$  and age  $< 70$  years, respectively. **Conclusions:** These data expand on the previously reported efficacy and safety data of single agent CLO in adult AML. Complete remissions appear durable (median  $\geq 1$  yr), and DFS and OS compare favorably to historical experience, particularly in patients with these adverse prognostic factors. These results suggest that single agent CLO is an effective and tolerable treatment option for older adult patients with untreated AML and 1 or more unfavorable baseline prognostic factor(s).