6607 **General Poster Session (Board #23B), Mon, 1:15 PM-5:15 PM**

Interim results of a phase I/II randomized study of clofarabine, idarubicin, and cytarabine (CIA) versus fludarabine, idarubicin, and cytarabine (FIA) for newly diagnosed or relapsed patients (pts) with acute myeloid leukemia (AML).

Michael Mathisen, Hagop Kantarjian, Stefan Faderl, Guillermo Garcia-Manero, Farhad Ravandi, Tapan M. Kadia, Naval Guastad Daver, Susan Mary O'Brien, Stephan Joseph Dorkhom, Sherry Pierce, Cynthia Lira, Jorge E. Cortes, Elias Jabbour; University of Texas M. D. Anderson Cancer Center, Houston, TX

Background: Outcomes of pts with AML remain suboptimal. The addition of cladribine to 3+7 has been shown to improve complete remission (CR) rates and 3-year survival. The aim of this study was to assess the efficacy and safety of idarubicin + cytarabine (IA, idarubicin 10 mg/m^2 on days 1-3, cytarabine 1 g/m^2 on days 1-5) combined with two other nucleoside analogs, clofarabine (C) or fludarabine (F), in pts with newly diagnosed and relapsed/refractory (RR) AML. **Methods:** Pts with newly diagnosed or RR non-M3 AML with normal organ function were eligible. Pts with RR disease were treated in the phase I portion defining the MTD of C. The starting dose of C was 15 mg/m^2 with doses escalating to 25 mg/m^2 on days 1-5 in subsequent cohorts. During phase II, patients were randomized in a Bayesian design to C at the MTD with IA or fludarabine (F) at 30 mg/m^2 on days 1-5 with IA. Up to 6 consolidation cycles were planned according to an attenuated schedule using the same drugs. Dose adjustments were made for elderly pts or pts with poor PS. **Results:** 9 pts were enrolled in the phase I portion. The overall response rate (ORR) in this group was 44%. DLT were observed at C 20 mg/m^2 and included hand/foot syndrome (HFS), elevated bilirubin, and prolonged myelosuppression. The MTD was 15 mg/m^2 on days 1-5. 50 evaluable pts were enrolled (16 newly diagnosed, 34 RR) in the phase II. In the frontline cohort, median age was similar in both groups (C 56, F 55), as were the cytogenetic profiles. The CR rate was 100% in both groups (9 CIA, 7 FIA). Detailed efficacy information can be found in the Table. More than half of the RR cohort were receiving therapy as salvage 2 or higher, and most had short first CR durations. Notable toxicities included elevated liver function tests for both groups, and HFS in the C group. There were 4 deaths on study, though most pts were receiving therapy as second salvage and were over the age of 60. **Conclusions:** CIA and FIA are effective regimens for newly diagnosed or RR AML with manageable toxicity profiles. The ORR were 100% and 32% for newly diagnosed and RR AML pts, respectively, with low early mortality rates. The study is ongoing.