20.3 months (range: 2.9 – 81.2). Relapse was treated with single agent ATO in 22 (59.5%), with ATO+ATRA in 5(13.5%) and with ATO+ATRA+anthracycline in 10 (27%). Thirty five (94.5%) achieved CR (two early deaths). After remission induction, a consolidation course of the same agents used in induction was administered (ATO and ATRA were administered for 28 days), 34 (92%) achieved molecular remission after this course. All patients who achieved molecular remission were offered an autologous SCT. Fourteen patients opted to have an autologous SCT and the remaining patients were scheduled to receive monthly cycles of ATO as a single agent (n = 14) or ATO+ATRA (n = 7) for 6 months. The age, sex, duration of first CR, induction and consolidation regimen used to treat relapse was comparable between the patients that underwent an autologous SCT and the remaining patients. Patients who underwent an autologous SCT were conditioned with a conventional Bu/Cy regimen and received PBSC graft with a median cell dose of 5.3×10^6 CD34/Kg (range: 3.54 – 9.24). There were no treatment related deaths following the autologous SCT, one patient had an isolated CNS relapse 6 months post transplant. There were no other relapses or deaths in this group. Among the remaining patients who achieved CR but did not have an autologous SCT (n = 21), 16 relapsed and all except one of these patients eventually died of progressive disease at median period of 1.6 months from second relapse (range: 0 – 42.6). At a median follow up of 24 months, the 3-year Kaplan-Meier estimate of EFS among those who received an autologous SCT vs. those that did not was 92.8±6.8 vs. 28.7±9.7 (log rank: P = 0.003). Following remission induction with ATO based regimens in patients with relapsed APL, consolidation with an autologous SCT is associated with a significantly superior clinical outcome in comparison to alternative ATO / ATRA based maintenance regimens.

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EFFECT OF PLERIXAFOR (AMD 3100) PLUS G-CSF ON TUMOR CELL MOBILIZATION AMONG PATIENTS WITH LYMPHOMA

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Introduction: Plerixafor used with G-CSF has been shown to rapidly and predictably increase peripheral blood CD34+ cells. This report evaluates the effect of G-CSF with or without plerixafor on tumor cell mobilization in patients with lymphoma.

Methods: This is a retrospective evaluation of apheresis samples from patients with a diagnosis of BCL-2 positive non-Hodgkins lymphoma that were enrolled in either a pivotal Phase III (3101) or Phase II (2101) study assessing the safety and efficacy of plerixafor in hematopoietic stem cell mobilization. To assess tumor cell mobilization, samples from apheresis products were assayed by real-time quantitative polymerase chain reaction (PCR) to quantify major breakpoint region (MBR) translocation of the BCL-2 gene and normalized to B-actin. Standard curves for the BCL-2 rearrangement and B-actin were generated to quantify DNA levels within each sample. A result of undetectable levels of the t(14;18) translocated BCL-2 gene indicated an absence of mobilized tumor cells.

Results: Apheresis samples from 11 BCL-2 positive lymphoma patients, 8/ 298 patients enrolled in 3101 and 3/25 patients enrolled in 2101, were evaluated for evidence of tumor cell mobilization. The age of patients ranged from 47 to 66 years and majority of the patients were women (8/11 patients). Six patients were diagnosed with follicular lymphoma while the remainder had diffuse large cell lymphoma. Five patients received G-CSF alone and 6 patients received a combination of G-CSF and plerixafor. Between 0.70×10^6 CD34+ cells/kg and 10.12×10^6 CD34+ cells/kg were mobilized within four apheresis days. Quantification by real-time PCR demonstrated that 10 of the 11 patients had undetectable levels of translocated BCL-2 in the leukapheresis product. One patient who was treated with G-CSF alone had detectable levels of the BCL-2 translocation.

Conclusions: These findings are consistent with other phase II clinical studies, which reported negligible tumor cell mobilization after plerixafor treatment.

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PLERIXAFOR CAN PREDICTABLY MOBILIZE HEMATOPOIETIC STEM CELLS IN PATIENTS WITH MULTIPLE MYELOMA PREVIOUSLY TREATED WITH LENALIDOMIDE

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Introduction: Emerging literature suggests that lenalidomide negatively affects the ability to collect CD34+ cells in patients with multiple myeloma (MM) undergoing hematopoietic stem cell transplantation. The aim of this retrospective subgroup analysis is to examine the efficacy of mobilization with plerixafor + G-CSF (P+G) among patients previously treated with lenalidomide.

Methods: Patients with MM who participated in a phase III study (3102) assessing the safety and efficacy of plerixafor in hematopoietic stem cell mobilization or in a compassionate use program (CUP) who received P+G and that had complete data on number of cycles of lenalidomide and total CD34 + cells collected were analyzed. Trial designs of the aforementioned studies have been described previously (DiPersio ASH 2007, Calandra BMT 2007). Briefly, in study 3102, patients received P+G as a first line mobilization regimen, whereas patients in the CUP received P+G as rescue therapy after failing other mobilization regimens.

Results: Of the 148 patients randomized to P+G in 3102, seven patients were previously treated with lenalidomide. In the CUP database, 60/708 patients were previously treated with lenalidomide. Complete data on number of cycles of lenalidomide and total CD34+ cells collected was available for 27 patients; five from 3102 and 22 from CUP. The mean age was 61.2±7.9 years and 14/27 (52%) of the patients were men. The median number of lenalidomide cycles prior to mobilization was four (range 1–20). Administration of P+G resulted in a median collection of 4.3×10^6 $CD34^+$ cells/kg. A total of 20/27 (74%) of the patients collected $\geq 2 \times 10^6$ $CD34^+$ cells/kg in a median of two apheresis sessions. All the patients in 3102 collected $\geq 2 \times 10^6$ $CD34^+$ cells/kg compared to 15/22 (68%) of the patients in CUP. Overall, 22 (81.5%) patients proceeded to transplant. Median time to neutrophil and platelet engraftment was 11.5 days and 18 days, respectively.

	Study 3102 (n=5)	CUP (n=22)	Pooled Data from 3102 and CUP (n=27)
Median Number of Lenalidomide Cycles (Range)	4 (1–5)	4.5 (2–20)	4 (1–20)
Median Collection of CD 34+ ($\times 10^6$ cells/kg) (Range)	14.8 (4.6–22.2)	3.29 (0.45–13.53)	4.3 (0.45–22.2)
Percent of Patients that Collected $\geq 5 \times 10^6$ CD34+ cells/kg	4/5 (80%)	7/22 (32%)	11/27 (41%)
Percent of Patients that Collected $\geq 2 \times 10^6$ CD34+ cells/kg	5/5 (100%)	15/22 (68%)	20/27 (74%)
Median Time (in days) to Neutrophil Engraftment (Range)	12 (11–13)	11 (10–16)	11.5 (10–16)
Median Time (in days) to Platelet Engraftment (Range)	18 (13–22)	18.5 (11–42)	18 (11–42)

Conclusions: These preliminary results suggest that the majority of patients with MM pretreated with lenalidomide can be successfully mobilized ($\geq 2 \times 10^6$ $CD34^+$ cells/kg) with P+G.