

[Abstract 43]

CAMPATH-1H IN WALDENSTROM'S MACROGLOBULINEMIA

Daniel Ditzel Santos^{1,2}, **Zachary R Hunter**¹, **Andrew R Branagan**¹ and **Steven P Treon**^{1,2}. ¹Bing Program for Waldenstrom's Macroglobulinemia, Dana Farber Cancer Institute and ²Harvard Medical School, Boston, MA, 02115, USA.

Campath-1H is a humanized monoclonal antibody that targets CD52, a commonly expressed antigen in WM (Treon *et al*, *Semin Oncology* 30:248). We therefore initiated this two-stage Phase II study of single agent Campath-1H in patients with WM. WM patients who failed at least one first line regimen (i.e. an alkylator agent, nucleoside analogue or rituximab) were eligible and received Campath-1H by IV for one week on a gradual dose escalation schedule (Day 1, 3 mg; Day 3, 10 mg; Day 5, 30 mg) followed by up to 12 weeks of therapy (30 mg IV TIW) provided therapy was tolerated and patients did not progress. All patients received acyclovir and bactrim prophylaxis while on therapy and for 2 months thereafter. Seven subjects with a median age of 59 (range 43-68) years and 2 (range 1-4) prior therapies have been enrolled, 4 and 7 of whom were relapsed/refractory to nucleoside analogues and rituximab, respectively. Five patients completed the intended therapy. Responses to date are as follows: Partial Response (n=3); Minor Response (n=3); SD (n=1). With a median follow-up of 7 months, no responding patient has progressed. Hematological but not infectious toxicities occurred with reversible grade IV neutropenia (n=3) and thrombocytopenia (n=2), and prolonged pancytopenia (n=1) in a patient with systemic amyloidosis. These studies demonstrate that Campath-1H is active in patients with relapsed/refractory WM, with sufficient activity to continue enrollment in this two-stage study.