

## [Abstract 49]

### VELCADE IN WALDENSTRÖM'S MACROGLOBULINEMIA

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**Background:** Velcade is a novel agent approved for the treatment of relapsed/refractory multiple myeloma which targets the ubiquitin-proteasome pathway. The efficacy of Velcade has been examined by us for *in vitro* efficacy against WM cells. These studies demonstrated that Velcade induced cell death of WM-WSU tumor cells, as well as tumor cells taken from 4 of 5 WM patients at pharmacologically relevant dose ranges.

**Study design:** WM patients who failed at least one first line regimen (i.e. an alkylator agent, nucleoside analogue or rituximab) are eligible for this study. Up to 30 patients will be enrolled in this open-label Phase II study. Velcade will be administered at a dose of 1.3 mg/m<sup>2</sup>/dose as an intravenous (IV) push over 3 to 5 seconds followed by a standard saline flush. Doses are to be administered twice a week (e.g., Monday and Thursday) for two consecutive weeks (Days 1, 4, 8, and 11) followed by a 10-day rest period. At least 72 hours must separate each VELCADE dose. Patients will be evaluated after Cycles 2, 4, and 6 to determine their response to therapy. If patients demonstrate a response or have stable disease at the end of cycles 2, 4, or 6 then they will continue to receive therapy. If the patient demonstrates evidence of progressive disease at the end of cycles 2, 4, or 6, then the patient will be removed from study. Patients are to receive a maximum of eight treatment cycles in this study.

**Results:** As of October 1, 2004, 8 patients with relapsed/refractory WM have been enrolled on this study. Tolerance to therapy has been good. Three patients completed the intended therapy, and are evaluable for response. Two of these patients attained a minor response, and one patient a major response.