8014 **Oral Abstract Session, Sun, 8:00 AM-11:00 AM**

Bendamustine, bortezomib, and dexamethasone (BVD) in elderly patients with relapsed/refractory multiple myeloma (RRMM): The Intergroupe Francophone du Myélome (IFM) 2009-01 protocol.

Philippe Rodon, Cyrille Hulin, Brigitte Pegourie, Mourad Tiab, Bruno Anglaret, Lotfi Benboubker, Henry Jardel, Olivier Decaux, Brigitte Kolb, Murielle Roussel, Laurent Garderet, Xavier Leleu, Olivier Fitoussi, Carine Chaleteix, Philippe Casassus, Pascal Lenain, Philippe Moreau, Marie-Odile Petillon, Claire Mathiot, Herve Avet-Loiseau; Hematology, General Hospital, Blois, France; Hematology Department, University Hospital, Nancy, France; University Hospital, Grenoble, France; Hematology Department, University Hospital, La Roche Sur Yon, France; General Hospital, Valence, France; CHU Tours-Hopital Bretonneau, Tours, France; General Hospital, Vannes, France; University Hospital, Rennes, France; University Hospital, Reims, France; Hematology Department, CHU Purpan, Toulouse, France; Hematology Department, University Hospital, Paris, France; Service des Maladies du Sang, Hôpital Claude Huriez, Lille, France; Service d'Oncologie Médicale, Polyclinique Bordeaux Nord Aquitaine, Bordeaux, France; University Hospital, Clermont-Ferrand, France; Avicenne Hospital, Bobigny, France; CAC, Rouen, France; Hematology Department, University Hospital, Nantes, France; CHRU, Lille, France; Hematology Laboratory, Institut Curie, Paris, France; University Hospital, Nantes, France

Background: Bortezomib (V) plus dexamethasone (D) is a treatment of choice of RRMM. In small series, the addition of an alkylator was beneficial. Bendamustine (B) showed a high activity in advanced MM. The IFM 2009-01 trial evaluates the combination of B, V and D in elderly pts with MM progressive on or after 1st line therapy. **Methods:** We conducted a phase 2 trial combining B 70 mg/m^2 D1-8, V 1.3 mg/m^2 D1-8-15-22 and D 20 mg D1-8-15-22 every 28 days. 4 cycles were administered. In responders (PR or better), 2 additional cycles were provided followed by a maintenance phase with 6 cycles given every 2 months. Inclusion criteria were progression on or after 1 prior line of therapy, measurable disease, PS ECOG <3, ANC $> 1.5x10^9$/l, platelets $> 100x10^9$/l, creatinine < 250 mcmol/l, AST and ALT < 3xULN. Pts with prior exposure to bortezomib were excluded. Response was evaluated according to IMWG criteria. Primary end point was response at end of cycle 4, secondary objectives overall response rate (ORR), progression-free survival (PFS), overall survival (OS) and toxicity. **Results:** The present analysis was restricted to the first 4 cycles. From 03/2010 to 07/2011, 73 pts were included, median age 75.8 years (range 66-86). Median time from diagnosis to inclusion was 29 months. All pts received only 1 prior therapy: MP in 12, MP-thalidomide in 44, lenalidomide-dexamethasone (LD) in 14, other in 3. 42 pts (57.5%) were responders at end of cycle 4 [CR: 8 (10.9%), VGPR: 9 (12.3%), PR: 25 (34.2%), SD: 10 (13.6%), progression: 11 (15%), early discontinuation: 10 (13.6%)]. 6pts/10 were in PR and 1pt/10 in VGPR at time of discontinuation. ORR was 67.1% (49/73 pts). 11 pts died (MM: 6, sepsis: 4, renal failure: 1). Adverse events grade 3-4 were neutropenia: 16 pts, thrombocytopenia: 7 pts, sepsis: 12 pts, gastro-intestinal: 8 pts, anaphylaxis: 1 pt. 2 pts had DVT. Peripheral neuropathy grade>1 occurred in 9 pts, all grade 2. Treatment was stopped in 20 pts (lack of efficacy: 11, toxicity: 9). **Conclusions:** These results compare favorably with those achieved with VD or LD. The triplet BVD combination is very effective and tolerable in elderly pts with MM in 1st progression.