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Abstract 4044 Bendamustine, Bortezomib and Dexamethasone (BVD) in Elderly Patients with Multiple Myeloma in First Relapse: Updated Results of the Intergroupe Francophone Du Myelome (IFM) 2009-01 Trial

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Background: Prognosis of relapse is severe in elderly multiple myeloma (MM). In recent studies, median survival at progression after 1st line therapy was between 9 and 13

months (T. Facon, Lancet 2007; C. Hulin, J Clin Oncol 2009). Bortezomib (V) plus dexamethasone (D) is a major regimen in the treatment of relapses. Bendamustine (B) demonstrated to be highly active in advanced MM. The IFM 2009-01 trial evaluates the combination of B, V and D in elderly patients with progressive MM on or after 1stline treatment.

Methods: Phase 2 IFM 2009-01 trial was dedicated to patients older than 65 years in 1st relapse or refractory to 1st line therapy. Inclusion criteria were measurable disease, PS ECOG 0-2, ANC > 1.5x109/l, platelets > 100x109/l, serum creatinine level < 250 mcmol/l, AST and ALT < 3xULN. Pts with prior exposure to bortezomib were excluded. Treatment regimen was B 70 mg/m2 D1-8, V 1.3 mg/m2 D1-8-15-22 and D 20 mg D1-8-15-22 every 28 days. 6 cycles were administered. Responders were assigned to receive maintenance treatment with 6 additional cycles administered 1 month out of 2. Response was evaluated according to IMWG criteria. Response rate was the primary objective. Progression-free survival (PFS), overall survival (OS) and toxicity were secondary end-points.

Results: The present analysis is restricted to the 6 monthly cycles. From 03/2010 to 07/2011, 73 pts were included. Median age was 75.8 years (range 66-86). Median time from diagnosis to inclusion was 29 months. All pts received only 1 prior line of therapy: melphalan-prednisone (MP) in 12, MP-Thalidomide in 44, Lenalidomide-Dexamethasone (LD) in 14, other IMiD-based regimen in 3. 49 pts (67.1%) achieved at least partial response [best response CR: 9 pts (12.3%), VGPR: 12 pts (16.5%), PR: 28 pts (38.3%), MR: 6 pts (8.2%), SD: 4 pts (5.5%), progression: 13 pts (17.8%), early discontinuation: 1 pt (1.3%)]. Adverse prognostic factors for response were 1st line regimen with IMiD (p=0.006) and del17p (p=0.036). At 6 months, PFS was 67.1% and OS 80.8%. Cause of death was MM in 9 pts, sepsis in 4 pts and renal failure in 1 pt. Grade 3-4 adverse events were neutropenia: 16 pts (21.9%), thrombocytopenia: 7 pts (9.6%), sepsis: 14 pts (19.2%), gastro-intestinal: 9 pts (12.3%), anaphylaxis: 1 pt (1.3%). Grade 2 peripheral neuropathy occurred in 10 pts (13.6%) and grade 3 in 2 pts (2.7%). At 6 months, treatment was discontinued in 33 pts (45.2%). Cause of discontinuation was progressive MM in 18 pts (24.6%), failure to achieve PR in 5 pts (6.8%), adverse event in 8 pts (10.9%), patient refusal or lost to follow-up 1 pt (1.3%) each.

Conclusion: In this elderly population with poor prognosis MM, BVD combination provides a high overall response rate and manageable toxicity. These results compare favorably with those achieved with VD or LD.

Disclosures: Hulin: *celgene:* Honoraria, Membership on an entity's Board of Directors or advisory committees; *janssen:* Membership on an entity's Board of Directors or advisory committees. **Kolb:** *janssen:* Honoraria; *celgene:* Honoraria. **Roussel:** *celgene:* Honoraria; *janssen:* Honoraria.

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