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Abstract 4035 Preliminary Experience of the Spanish Compassionate Use Registry of Bendamustine in Patients with Relapsed and/or Refractory Multiple Myeloma

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Introduction: Bendamustine is a dual alkylating agent with demonstrated efficacy in de novo multiple myeloma (MM) and in relapsed/refractory (R/R MM). We present the preliminary results from the experience of Spanish compassionate use registry of this agent in different treatment schedules of R/R MM, promoted by the GEM / PETHEMA Group (Benda-MMRR-11). This study has been approved by local ethical committee, CEIC, HUP, Madrid, Spain.

Patients and Methods: 72 patients, 42 males and 30 females, with advanced R/R MM after several lines of previous treatment received a schedule containing Bendamustine (Levact[®], Mundipharma, UK). Median age was 66 (35-86), with a median of 4 previous salvage lines (1-11). Bendamustine dose used ranged between 60 and 120 mg/m² iv on days 1 and 2 for each 28 days cycle. The median of cycles was 2 (1-9). The combinations used were: Bendamustine + Prednisone in 27 patients, Bendamustine + Thalidomide +

Prednisone in 11 cases, Bendamustine + Dexamethasone in 14 patients, Bendamustine + Bortezomib + Dexamethasone in 7 patients, Bendamustine + Bortezomib + Prednisone in 3 patients, Bendamustine + Thalidomide + Dexamethasone in 2 cases, Bendamustine monotherapy in 5 patients, Bendamustine + Thalidomide in 1 case, Bendamustine with Caelyx in 1 case and Bendamustine with Rituximab in 1 case.

Results: In the 69 evaluable patients, the response was: overall response rate (ORR) 30.24%, with complete response (CR) 11.5%, partial response (PR) 13.04%. Minimal response (MR) was 5.7%, and stable disease (SD) was 17.39%. Progression was documented in 52.1% of patients. In general, treatment was well tolerated; the most common adverse effect was hematological toxicity with grade 3-4 neutropenia in 31.8%, grade 3-4 thrombocytopenia in 30.4% and grade 3-4 anemia in 17.3%. Other toxicities included grade 3-4 infections in 27% of patients and grade 3-4 asthenia in 11.5%. Clinical results will be updated with more details regarding TTP, OS and efficacy and toxicity with each schedule.

Comments: Bendamustine is an effective salvage therapy in patients with advanced R/R MM. Our results are consistent with previous published data in larger series of patients. More experience is needed with this agent to define the best combination and to assess its grade of efficacy that will be probably superior in earlier stages of myeloma evolution.

Disclosures: Off Label Use: compassionate use.

* *signifies non-member of ASH*