Summary

Primary endpoint: In the PP population, an increase in ORR above 67% could not be shown: the observed ORR was 0.7879 with lower confidence limit 0.6495 and p-value of the one-sided binomial test of 0.0876.
Secondary endpoint: Likewise, an increase in ORR above 67% could not be shown in the ITT population: the observed ORR was 0.7111 with lower confidence limit 0.5899 and p-value of the one-sided binomial test of 0.3304.
Secondary endpoint: Out of 19 patients with impaired renal function at baseline, recovery or improvement of renal function was found in 11 (57.9%) of patients in the ITT population (2nd objective).
The overall number of adverse events was 152.
Three most common AEs: neutropenia (11 (6.9% of all AEs); 4 with CTC 4), leukopenia (6 (3.8%); 1 with CTC 4), and thrombocytopenia (6 (3.8%))
7 (15.2%) patients experienced at least one AE of CTC grade 4
AEs classified as being related to:
-Bortezomib: neutropenia, platelet count decreased, pnp, white blood cell decreased
-Bendamustine: anaemia, exanthem, leukopenia, neutropenia, platelet count decreased, thrombocytopenia, dry skin, white blood cell decreased
-Prednisone: hypertensive crisis, pneumonia
11 (23.9%) patients had one SAE, 10 (21.7%) patients had 2 SAEs, one patient had three SAEs, one patient had 4 SAEs.
Most common SAE: pneumonia (4 (10.5%))
Seven deaths were observed during and after treatment; two fatal AEs were observed during or within 30 days after treatment: Reasons for death were abscess in the area of the malleo lateralis and pneumonia.