Bortezomib before and after autologous stem cell transplantation overcomes the negative prognostic impact of renal impairment in newly diagnosed multiple myeloma: a subgroup analysis from the HOVON-65/GMMG-HD4 trial

Christof Scheid,1 Pieter Sonneveld,2 Ingo G.H. Schmidt-Wolf,3 Bronno van der Holt,2 Laila el Jarari,2 Uta Bertsch,4 Hans Salwender,3 Sonja Zweegman,2 Igor Wolfgang Blau,3 Edo Vellenga,2 Katja Weisel,7 Michael Pfreundschuh3, Kon-Siong Jie,2 Kai Neben,4 Helgi van de Velde,5 Ulrich Duehrsen,3 M. Ron Schaafsma,2 Walter Lindemann,3 Marie José Kersten,2 Norma Peter,2 Mathias Hänel,3 Sandra Croockewit,2 Hans Martin,3 Shulamiet Wittebol,2 Gerard MJ Bos,2 Marinus van Marwijk-Kooy,2 Pierre Wijermans,2 Hartmut Goldschmidt,4 and Henk M. Lokhorst2

1GMMG and University Hospital, Cologne, Germany; 2HOVON, The Netherlands; 3GMMG, Germany; 4GMMG and University Hospital and National Center for Tumor Diseases, Heidelberg, Germany; and 5Janssen Research & Development, Beerse, Belgium

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Correspondence: c.scheid@uni-koeln.de
Response assessments and end points

Evaluation of response was performed according to modified European Group for Blood and Marrow Transplantation (EBMT) criteria. Near CR (nCR) and Very Good Partial Response (VGPR) were added as additional response categories. nCR was defined as CR with positive or missing immunofixation, while VGPR was defined as ≥ 90% reduction of serum M-protein. CR required negative serum/urine immunofixation and bone marrow evaluation with <5% plasma cells.

Adverse events were graded according to the NCI Common Terminology Criteria for Adverse Events, CTCAE version 3.0. Assessment of cytogenetic risk factors was performed by FISH on CD138-selected bone marrow cells as previously described (Neben et al. Blood 2012 119:940-8).

Progression free survival (PFS) was calculated from randomization until progression, relapse or death, whichever came first. Patients who received a reduced-intensity allogeneic SCT after HDM were censored for PFS, at the date of AlloSCT. Overall survival (OS) was measured from randomization until death from any cause. Patients still alive at the date of last contact were censored.
Screened 833

Ineligible:
- Stage I myeloma 1
- NHL 1
- Non-secretory MM 4

Randomised 827

Arm A 414
- BLC < 2 mg/dl 369
- BLC ≥2 mg/dl 45
- Death 4
- Progression 2
- Toxicity 7
- Other 0

Arm B 413
- BLC < 2 mg/dl 377
- BLC ≥2 mg/dl 36
- Death 2
- Progression 0
- Toxicity 2
- Other 1

Completed induction 32
- Death 1
- Perf. status 1
- Toxicity 0
- Other 1

Received HDM1 29
(RReceived HDM2, GMMG only 15)

Started maintenance 20