

## **HOVON 87 – NMSG 18**

Randomized phase III trial in elderly patients with previously untreated symptomatic Multiple Myeloma comparing MP-Thalidomide (MP-Thal) followed by thalidomide maintenance versus MP-Lenalidomide (MP-Len) followed by maintenance with lenalidomide

A joint study of the HOVON and the Nordic Myeloma Study Group

Principal Investigator : S. Zweegman (HOVON)

Principal Investigator NMSG : A. Waage (NMSG)

Study Coordinators : P. Sonneveld (HOVON)

G.M.J. Bos (HOVON)

U-H. Mellqvist (NMSG)

M. Salomo (NMSG)

Sponsor : HOVON

### **Synopsis**

Study phase Randomized phase III

### **Study objectives**

- ☒ To compare progression free survival with MP+Thalidomide (MP-Thal) followed by maintenance with thalidomide versus MP+Lenalidomide (MP-Len) followed by maintenance with lenalidomide
- ☒ To compare (stringent) complete and very good partial response with MP-Thal versus MP-Len
- ☒ To compare overall survival with MP-Thal versus MP-Len
- ☒ To assess and compare overall response and time-toresponse with MP-Thal versus MP-Len
- ☒ To assess the effect of maintenance therapy with thalidomide alone following MP-Thal induction or lenalidomide alone following MP-Len induction
- ☒ To assess and compare the time from relapse/progression (after initial response) to death in patients having been treated with MP-Thal versus MPLen
- ☒ To assess the quality of life with these regimens
- ☒ To assess the safety and toxicity of both regimens

### **Patient population**

Previously untreated symptomatic patients with MM  
Age > 65 or ☒ 65 and patient ineligible for high dose therapy and peripheral stem cell transplantation

### **Study design**

Prospective, multicenter, randomized

### **Duration of treatment**

Expected duration of induction treatment: 9 months  
Maintenance therapy with lenalidomide or thalidomide will be given until relapse/progression. All patients will be

followed until 10 years after registration

Number of patients 668 eligible patients

Adverse events

Adverse events will be documented if observed, mentioned during open questioning, or when spontaneously reported.

Planned start and end of recruitment

Start of recruitment: I 2009

End of recruitment: I 2013