

# HOVON 87 - NMSG 18

RCT comparing

MP-Thalidomide (MP-Thal) followed by thalidomide maintenance

versus

MP-Lenalidomide (MP-Len) followed by lenalidomide maintenance

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



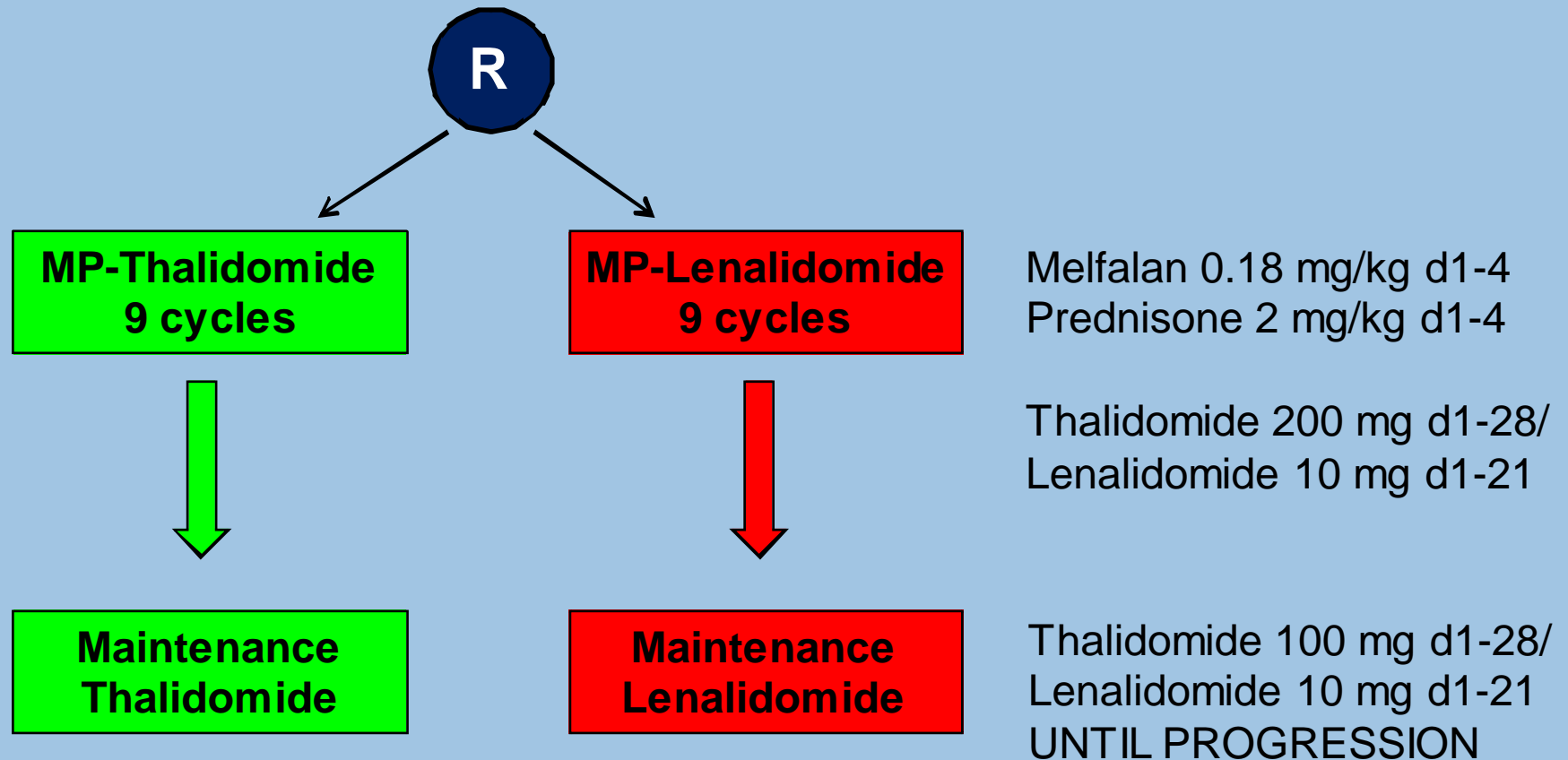
Sponsored by HOVON



# Background

- With MPT a considerable number of patients develop relapse or progressive disease in relatively short time
- Mean PFS ~2 years
  - Lenalidomide superior to Thalidomide?
  - Maintenance therapy?

# Study design



Thrombosis prophylaxis aspirin, LMWH in case of previous VTE

In case of ANC < 0.5 or febrile neutropenia PEG-GCSF on day 5 next cycle

# Primary objectives

- To compare progression free survival
- To compare complete and very good partial response
- **Secondary objectives**
  - Effect of maintenance therapy in terms of improvement of response
  - Time from relapse/progression to death
  - Overall survival
  - Quality of life

# Statistical considerations

- Improvement in PFS in the MPLenaldomide arm with a relative hazard of 0.67
- $\alpha=0.05$  and 80% power
- Accrual period of 3 years
- 452 patients have to be included

# Update April 2011

- Target number of patients required 452
- Patients registered 344
- First patient March 12, 2009
- Last patient (expected) January 2012
  
- Number of participating centers:
  - Netherlands 45
  - Belgium 2
  - Norway 12
  - Denmark 3
  - Sweden 11

# Patient characteristics

	A: MP+Thal	B: MP+Len	Total
Total	166	166	332
Age (median, range)	72 (60-87)	72 (64-87)	72 (60-87)
Gender (M/F, %M)	94/72 (56.6%)	93/73 (56.0%)	187/145 (56.3%)
ISS stage			
I	27%	26%	26%
II	46%	43%	45%
III	27%	31%	29%

# Efficacy data

URSULA SCHULZ-DORNBURG  
ARCHITECTUREN DES WARTENS  
ARCHITECTURES OF WAITING  
PHOTOGRAPHS





# Incidence of SAE's

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Nr of patients with at least one SAE	155 (47%)
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Number of SAE per person

# 1 SAE	91 (27%)
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# 2 SAE	43 (13%)
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# 3-7 SAE	21 (7%)
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# General causes of SAE's

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## Reason SAE

Death	8 (5%)
Life threatening	7 (5%)
Hospitalisation	128 (83%)
Disability	5 (3%)
Other	7 (5%)
≤1st cycle	107
Total	155

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**DSMB no reason for amendments  
No difference <75 versus ≥75 years**

# Side studies

## Molecular characterization

Biological diversity - Prognostic value - Predictive value

## Imaging studies

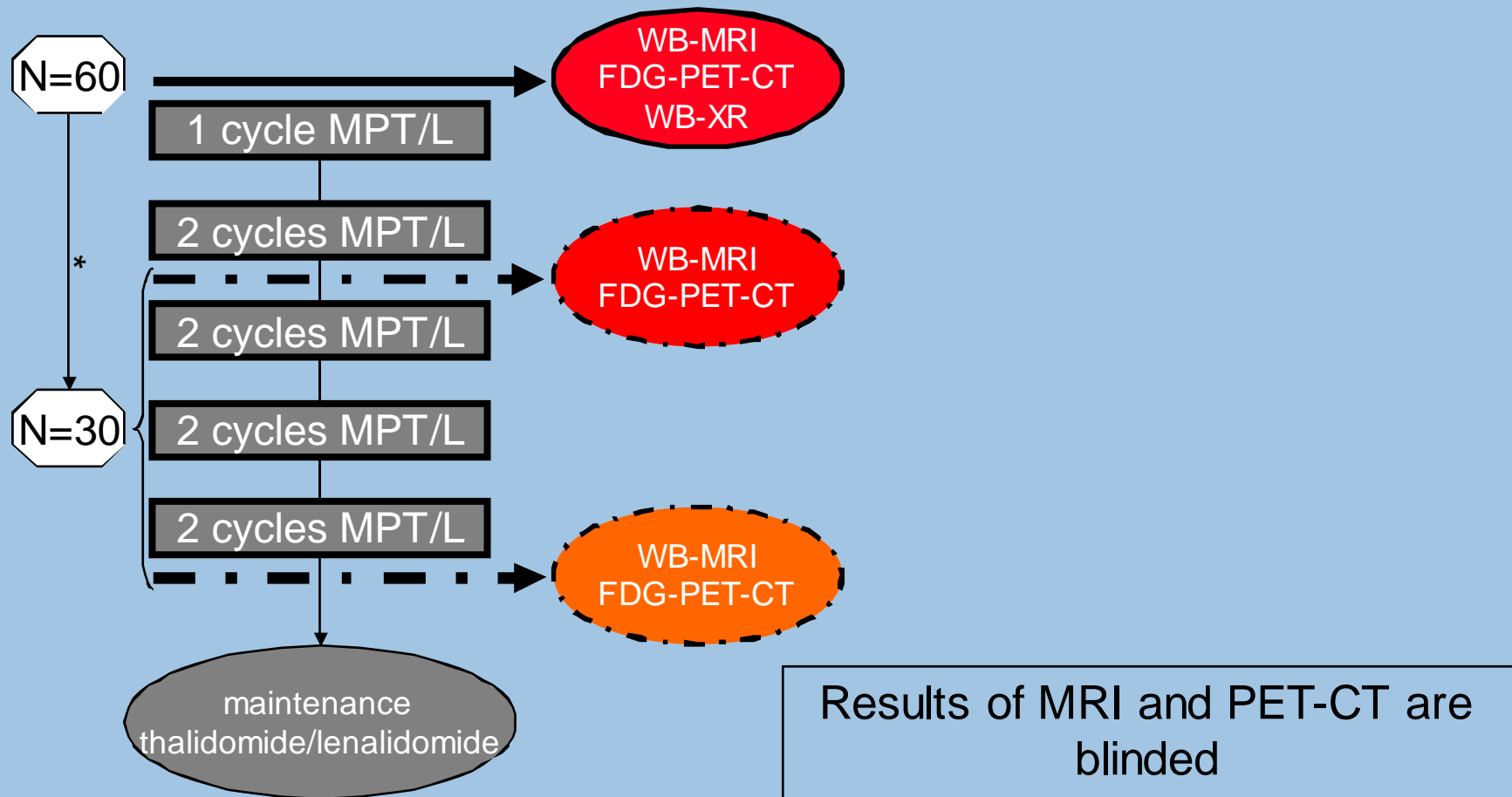
Monitoring therapy response

# Molecular characterization

- Gene Expression Profiling
- Single Nucleotide Polymorphism analysis
- Investigating variation in gene expression and in genes representing cellular functions and pathways that determine
  - Biology of the disease
  - Course of the disease
  - Treatment efficacy
  - Treatment related toxicity

# Imaging studies

Prognostic value of different imaging techniques at diagnosis  
Conversion rate of PET in non-intensively treated patients



# Acknowledgments

## **PARTICIPATING CENTERS**

### **Co-investigators HOVON**

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Pieter Sonneveld, Netherlands

### **Co-investigators NMSG**

Anders Waage, Norway

Ulf Henrik Mellqvist, Sweden

Morton Salomo, Denmark

## **NMSG and HOVON DATA CENTER**

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