

HOVON 68 WC MEETING October 9 2008: Minutes

Attendees: Mars van't Veer, Rien van Oers, Tomas Kozak, Eva Kimby, Jesper Jurlander, Jan Walewsky, Christian Geisler.

Excuses: Fokje Spoelstra, Kari Remes, Geir Tönnfjord, Aaron Polliack.

1. Accrual:

166 patients accrued at present. Netherlands + Belgium has delivered half the patients (Fig 1 and 2).

Fig.1

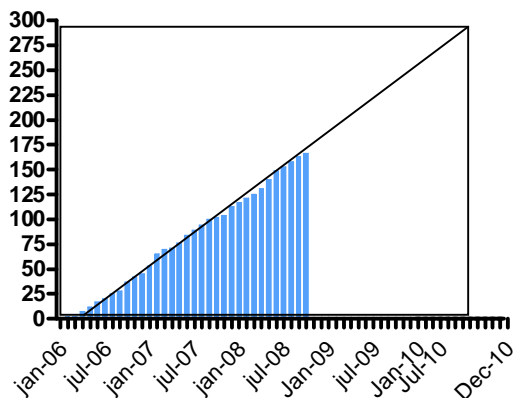
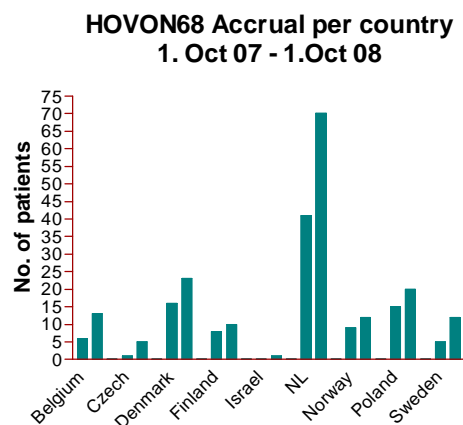


Fig.2.



Denmark: Patients in pipeline. Initial tempo high due to pool. 3 active centres.

Netherlands/Belgium: Steady accrual, a bit slow early 2008. There are several threats: GCLLSG 8, will probably be used to promote RFC as first treatment.

Czech republic: 1 active center, 3 underway.

Finland (not present): Maija Itälla on leave for 1 year. Stand-in: Kari Remes, same department.

Israel (not present): 1 patient from Haifa, IgVh sequencing in Copenhagen.

Norway (not present): Slow

Poland: A period of slow down, now going faster. 5 centres, one not doing well (Krakow).

Sweden: Gaining momentum. 6 active centres.

General aspects: 200 will be accrued by spring 2009, so efficacy interim analysis can be made by fall 2009. By then we may recalculate length of observation period. A folder/newsletter in early 2009, and again following 200 patients, is probably more effective than an investigators meeting. A newsletter has been distributed in Netherlands and Bayer have proposed to sponsor one in English.

2. Safety.

Annual safety report of 2008 has been submitted in Denmark, and will be distributed. Christian reviewed a Bayer/Scheering meeting held in conjunction with the Lugano meeting, and proceeded to review the safety data at present. Ammendments 2008 due to safety:

- q HBV and HCV excluded
- q PJP prophylaxis extended to 6 months post-Tx
- q Pts admitted to other hospitals, must be consulted by specialist in Hematology/Infectious diseases.
- q All investigators highly vigilant for opportunistic infections.

We plan to compare the incidence of infections in GCLLSG 4 and 8 trials. Also, most of the seven deaths were associated with either severe bone marrow failure and/or PD. It was decided to present the safety data at the HOVON meeting in three weeks (power point presentation enclosed to these minutes).

3. Economy.

Instalments are 225.000 + 3x142.500 + 247.500 in the period up to final study report. We have now received the 225.000 and first of the three 142.500 instalments. Because of this schedule, we can never pay more than 70% of the 3000 Euros, until the study has been completed (See enclosed Powerpoint presentation (Budget Oct. 08)).

Insurance: The Polish insurance must be extended, this will be covered as a decentral cost.

Table 1 summarizes the scheduled refunds by now.:

Table 1. Scheduled Refunds October 2008

Balance October 1 2008: 212,241 €						
Country	Accr.	3000 € per patient	70%	Previous payments	To be paid now	Transfer details
Czech Rep.	5	15,000	10,500	0	10,500	
Denmark	23	69,000	48,300	26,862	21,438	
Finland	10	30,000	21,000	5,625	13.275	
Israel	1	3,000	2,100	0	2,100	
NL + B	83	249,000	174,300	96,631	57.600	
Norway	12	36,000	25,200	16,844	2.079	
Poland	20	60,000	42,000	24,966	17,004	
Sweden	12	36,000	25,200	3,082	15.818	
Total, decentral costs	166	486,000	279,300	142,799	148,214	
HOVON Central costs 525€/patient				80,000	20,000	
Total payment					159,814	
Balance 01.10.2008					212,241	
Balance after payments					52,427	

Investigators are

Next instalment of 172.000 euros is due when we reach 200 accrued patients, probably early 2009.

Investigators are urged to contact CG as soon as possible to get their refunds. For that purpose, CG needs this information from each investigator:

- Name of recipient
- name and address of bank,
- IBAN No.
- SWIFT code
- Referral to the research account to which the money should go from the bank.

4. Amendments.

The CRFs have been corrected following amendment 2, which is accepted in Denmark and the Netherlands, and under approval in the other countries.

5. Lab. Questions.

- a) Pharmacokinetics: Jesper will negotiate further with Geoff Hale, either cooperation or commercial pharmacokinetics and alemtuzumab antibodies.
- b) MRD: Jesper has seen molecular remissions in Copenhagen.

6. Activities next few months.

Newsletter as under item 1. Christian Geisler, Rien van Oers and Mars van't Veer will review the first 100 CRF's in January.

7. Relapse study.

A proposal to perform an investigator driven phase III relapse study, +/- ofatumumab maintenance, was discussed. It was agreed to pursue the possibility. Rien van Oers will distribute a protocol draft, and continue negotiations with GSK. There may be an industry competitor with lenalidomide.

8. Other business.

9. Next meeting.

Tuesday 28/4 2009 in Amsterdam.

Jesper Jurlander

Christian Geisler