16th Congress of EHA

in London, June 9-12, 2011

Summary

The 16th EHA Congress took place from 9 to 12 June 2011 in London, UK. In this context, the WP meetings of the European LeukemiaNet were held on June 8-9, 2011 in the ExCel conference center in London. The WP meetings were financially supported by the ESF-ELN research networking programme.
One major goal of the WP meetings was to get the members of all ELN WPs face-to-face together and to have the opportunity to discuss new studies, ongoing studies and recommendations to common European trials.

Scientific content of and discussion at the congress

WP4 EURO-SKI (EURO-**S**top**K**inase**I**nhibitors**)**

Main topic of this session was the discussion of a new study protocol on stopping tyrosine kinase inhibitor treatment in patients with CML. With regard to the statistical background of the EURO-SKI project, Markus Pfirrmann introduced the background for hypotheses testing after the inclusion of the first 200 patients ready for analyses and after the inclusion of all intended 500 patients. Andreas Hochhaus explained the definition of MR^4 within the protocol and the need for standardization.
The analyses of the primary endpoint were discussed, also with regard to multiple modelling.
Predictive factors for multiple analyses were suggested.
Secondary endpoints were named.
Susanne Saußele gave an overview on the actual synopsis of the study.

Results of and conclusions from the discussion:

a) Before the inclusion of a patient into the study, the patient and his physician should be aware and ready to accept that the situation of a longer period being in MMR and not any longer in CMR (4-log reduction) could happen.
   If possible, both should be ready to tolerate this (with monthly visits, as long as no prior ill-feeling occurs).
b) For the main endpoint "loss of MMR", the proceeding in analysis for those patients who receive treatment despite a lacking loss of MMR needs to be further discussed
c) It is important to define a dataset of core variables where no missing values are allowed (inclusion / exclusion variables)
d) Further variables have to be define for whom information should be available
e) Some explanations and details will be further outlined

WP5

First topic of this meeting was the discussion on possibilities for an European study on AML in the elderly. Therefore the experiences and results of elderly AML patients of different countries were discussed

- German experience (Utz Krug)
- MRC experience (Nigel Russel)
- French experience (Herve Dombret)
- Swedish experience (Soren L)
- Dutch experience (Gert Ossenkoppele)

Second topic was the registry of AML patients. R. Schlenk presented the experiences within Germany at the meeting. Additionally, Z. Berneman from Belgium introduced the audience into a current dendritic cell vaccination trial.

WP14

Within this meeting main topic was the discussion on the study HCT vs. CT in elderly AML.

Actual recruitment numbers are (Current status 16th May 2011):

Overall recruitment		
registered patients	randomised patients	observation arm
45	23	7

Further discussion points were amendments, site initiation visits, documentation and the annual safety report.

WP9 MPD

Within this meeting main topic was the discussion on recommendations
The rationale of this project is that the selection of best variables for measuring benefits or harms of new interventions in Philadelphia negative classic MPNs is a complex and open to debate task. There is a major need to develop clearly defined end-points to support claims of efficacy of therapies for MPNs. These endpoints need to be developed and utilized by investigators leading clinical trials in MPNs. The goal of this project is to provide guidance in the definition of clinically relevant end-points that can expedite new drug approvals for MPNs in the appropriate trial design settings.
The overall methodology of the project will be that of group discussion. For this aim a panel has been elected. The panel is composed of people with clinical or pathological experience in MPNs. In particular the panel will be asked to give judgment on three different issues:

1. Provide a judgment on the available “assessments of response” for MPNs. This judgment will be requested following the FDA reported guidance in using “response”

as an end-point in clinical trials for cancer.

2. List the relevant “therapeutic key questions” in MPNs that may be addressed by hypothetical trials.
3. Recommend the most clinically relevant end-points for each of the relevant therapeutic key questions.

The recommendations produced by the panel will be presented for discussion to FDA and EMA representatives, and pharmaceutical companies representatives, and after the critical comments from these agencies, the recommendations will be published in a scientific journal.

At this first meeting the results of the questionnaires already sent to the panel before were discussed. A new round of questionnaire will be prepared right after this meeting.

Annex 1: Program

European LeukemiaNet

WP4 meeting

Thursday, June 9, 2011
16:15 – 18:15

South Gallery 2, ExCeL London
Royal Victoria Dock, 1 Western Gateway,
London, E16 1XL

Agenda

1.	**EURO-SKI (an ELN sponsored study)**	**S. Saussele** **M. Pfirrmann**
2.	**Relevant definitions for future analyses in CML**	**J. Guillhot**
3.	**Other items**	
4.	**Next WP4 meeting**	

European LeukemiaNet

WP5/14 meeting

Thursday, June 9, 2011
16:15 – 18:15

ExCel London
South Gallery 5

Agenda

1. AML in the elderly: possibilities for an European study
   - German experience (Utz Krug
   - MRC experience (Nigel Russel)
   - French experience (Herve Dombret)
   - Swedish experience (Soren L)
   - Dutch experience (Gert Ossenkoppele)

Discussion on this topic

2. AML Registry (Richard Schlenk)

3. Dendritic cell vaccination trial (Zwi Berneman)

European LeukemiaNet

WP9 meeting

Thursday, June 9, 2011
13:30 – 15:30

ExCel London
South Gallery 2

Agenda

Introduction (T. Barbui)

Update of ongoing clinical studies in MPN in Europe:

- EXELS
- CytoPV
- Vorinostat
- Interferon
- Others…
-

Ongoing projects:

- Consensus on the outcome measures for clinical trials in MPNs ; Definition of clinically relevant end points for new drug approvals in MPNs (G. Barosi, T. Barbui)
- Project: Consensus definition of accelerated phase in myelofibrosis (A. Vannucchi)
- oral contraception and hormonal replacement in MPN patients
- frequency and risk factors of tumors arising in MPN patients
- booklet for MPN patients

Update of the MPN/MPNr-EuroNet working group activities (S. Hermouet)

Closing remarks (J.J. Kiladjian)

European LeukemiaNet

WP14 meeting

Thursday, June 9, 2011
16:15 – 18-15

ExCel London
South Gallery 5
90 theatre style; EHA London

Agenda

HCT vs. CT in elderly AML – Meeting

EHA-Meeting London

1. **Recruitment**

Overall recruitment		
registered patients	**randomised patients**	**observation arm**
45	23	7

Current status 16th May 2011

2. **Amendments**

3. **Site initiation visits**

4. **Documentation**

5. **Annual Safety Report**

6. **Others**