Date: June 20, 2012/nst

European LeukemiaNet Workpackage Meetings
at 17th Congress of EHA

Amsterdam, June 14-17, 2012

Coordinator: Prof. Dr. Rüdiger Hehlmann

Summary

The 17th EHA Congress took place from 14 to 17 June 2012 in Amsterdam, The Netherlands. In this context, the WP meetings of the European LeukemiaNet were held on June 14, 2012 in the RAI conference center in Amsterdam. The WP meetings were financially supported by the ESF-ELN research networking program. The ELN is grateful for the support.
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 workshops

On 14 June, each ELN-Workpackage had their meeting. Challenges and new directions in leukemia and related disease entities were highlighted during the workpackage meeting. Trials were presented and discussed. Each WP reported on the different projects and discussed future objectives and partially recommendations.

AML/Diagnostic Platform/MRD/SCT (WP5/WP10/WP12/WP14)

WP5, WP10, WP12 and WP14 have held their meeting together. *Schuurhuis* gave an introduction on FCM MRD. At the moment it is not wise to choose assessment in a multiple center approach for MRD. Improvement and alternatives have been shown, e.g. new discovery of MRD marker or MRD in peripheral blood which is more specific. *Grimwade* showed methods to detect MRD in AML. The issues here were development of standardized RT-qPCR assays for detection of WT1 transcripts and of optimized MRD monitoring schedules for AML (also in terms of clinical utilities and cost effectiveness). Afterwards the progress of MRD implementation in AML at different trials was

shown. *Amadori* is engaged in the GIMEMA study. He talked about the improving risk stratification in AML and the integrated risk-score. *Hills* presented the MRD monitoring experiences in the UK. Prognostic vs. predictive biomarkers in term of monitoring were illustrated. *Ossenkoppele* talked about the HOVON/SAKK 42a study. The study is international and prospective and it is a multicenter study. The topics here were intermediate risk group, combination of MRD positivity and negativity after first and second induction cycle and relationship between molecular and immunophenotype MRD. The conclusion was that MRD can be used for risk stratification. Béné gave an update on the ALFA/GOELAM study in relation to WP10 and the GOELAMS. Further, *Schlenk* presented the AMLSG trial. He talked about the implementation of minimal residual disease measurements in clinical trials. Current implemented targets were shown.

ELN RECOMMENDATIONS FOR CML

30 members of the ELN recommendations for CML discussed the upcoming recommendations. It is expected to provide new recommendations in January 2013. The session was by invitation only and confidential.

CLL (WP7)

First, *Montserrat* gave an introduction and update of the membership. Now there are 366 members from 36 countries involved in ERIC. *Stamatopoulos* talked about the accreditation programme for IGHV gene analysis. The focus was on external quality assessment in diagnostic laboratories and how to provide certificates (every 2 years). The components were introduced: Informatics, Reference Lab, Bioinformatics, Evaluated Lab and ERIC Review Board. Afterwards, *Moreno* introduced the ERIC Phase IV trial on Ofatumumab in CLL therapy. Currently 100 patients from 10 countries are included, 130 patients are possible. The data collection was explained in more detail. The issue here are the difference in the various countries. *Del Giudice* gave an update on the international CLL registry for spontaneous regression in CLL. He illustrated the online registration. *Moreno* talked about the CLL clinical data form. The aims of the project were shown such as to facilitate studies in ERIC. Patient and disease characteristics and laboratory and biological data at diagnosis for minimal data set were discussed. Recently, *Ghia* explained the rules and regulations in the ERIC studies and programmes. Completed and on-going projects are shared on the website www.ericll.org. There rules and regulations are:

- Only members can present new projects (is welcome)
- Submit new projects any time to the board
- Every member can join an existing project

CML (WP4)

Saussele gave an update on the EURO-SKI trial and the status in various countries. *Richter* discussed a proposal for an amendment to the protocol that retreatment after MMR loss should start with 2nd gen. TKI in patient on imatinib prior to stopping. It was agreed that the group works on a detailed plan after discussion with the statisticians. *Hehlmann* presented the status of the New EU Clinical Trial Directive and the associated measures taken by the ELN to support academic clinical trials. Afterwards, *Hochhaus*, *Rosti and Hjorth-Hansen* gave updates on new studies in their countries: status, experiences, mutual help and European strategy. Last, *Mueller* showed data on 3 month landmark analyses demonstrating this time point as crucial.

MPD (WP9)

The member of WP 9 discussed new recommendations. The topic was "*Clinically relevant end-points in contemporary trials for Ph-neg classical MPNs. A project of the ELN and IWG-MRT Groups. Where we are with the revised response criteria for ET and PV*". The session was by invitation only and confidential.

Assessment of results and impact of the workshops on the future direction of the field

The European LeukemiaNet Workpackage Meetings at 17th Congress of EHA highlighted upfront European research in leukemia. European clinical trials are important to gain a broad patient collective, to discuss and compare results and offer optimal treatment for patients. Important activities include consensus decisions in clinical study endpoints, the setup of patient registries for all leukemias, common standardisation procedures and classification systems in diagnosis and follow up (molecular monitoring, cytogenetics, minimal residual disease assessment) but also harmonisation in data evaluation and reporting. The publication and continuous revision of recommendations is an important aspect in patients' healthcare. Cooperative research is the only way to cure leukemia.

Final Programme

Assignment of groups and rooms
17th Congress of the EHA, Amsterdam, Thursday, June 14, 2012

TIME THURSDAY JUNE 14	D201	D204	
8:00 – 10:00	ELN RECOMMENDATIONS FOR CML	AML/Diagnostic Platform/MRD/SCT (WP5/WP10/WP12/WP14)	
Coffee break 10:00 – 10:45			
10:45 – 12:45	ELN RECOMMENDATIONS FOR CML	AML/Diagnostic Platform/MRD/SCT (WP5/WP10/WP12/WP14)	
Lunch break 12:45 – 13:30			
13:30 – 15:30	IACRLRD	CLL (WP7)	
Coffee break 15:30 – 16:15			
16:15 – 18:15	CML (WP4)	MPD (WP9)	
Official EHA Scientific Working Groups			
From 18:30			EWALL (WP6) CLL (WP7) MDS (WP8)

ADDRESS: Amsterdam RAI, Europaplein 22, 1078 GZ, Amsterdam, The Netherlands

Combined meeting of WP5, 12, 10 and 14

Thursday, June 14, 2012
8:00 – 11:00

Room: Elicium D204
Amsterdam RAI, Europaplein 22, 1078 GZ,
Amsterdam, The Netherlands

Chairs: David Grimwade, Gert Ossenkoppele

Agenda

1. Introduction on FCM MRD — *Schuurhuis (10-15 min)*
2. Introduction on molecular MRD — *Grimwade (10-15 min)*
3. MRD implementation in AML how far are we?:
   - in GIMEMA studies — *Venditti/Amadori (5-10 min)*
   - in MRC — *Burnett/ R.Hills/ Grimwade(5-10 min)*
   - in HOVON — *Ossenkoppele (5 min)*
   - in ALFA/GOELAM — *Dombret/Bene (5-10 min)*
   - in German AMLSG — *Schlenk (5-10 min)*
   - in CETLAM — *Sierra (5-10 min)*
   - in CELL (Czech republic) — *Racil/Mayer(5-10 min)*
   - in Pethema — *Sanz (5-10 min)*
   - MRD in SCT — *Niederwieser/Cornelissen (5-10 min)*
4. Discussion (already time for a position paper?, content, ,writing committee)

ELN WP7 / CLL at the 17th Annual Congress of the European Hematology Association

29th General Meeting of ERIC Members

Date: Thursday 14th June 2012
Time: 13.30-15.30

Venue: Room D204, Amsterdam RAI, Europaplein 22, 1078 GZ, Amsterdam, The Netherlands

Agenda

- Introduction and membership update – *E. Montserrat, E. Kimby*
- Accreditation programme for IGHV gene analysis – *K. Stamatopoulos*
- Update of the 8 color MRD study – *A. Rawstron*
- ERIC Phase IV trial on Ofatumumab in CLL therapy – *C. Moreno, C. Bradley*
- An International CLL registry for spontaneous regression in CLL – *I. Del Giudice*
- CLL clinical data form – *F. Cymbalista, E. Kimby, C. Moreno*
- ERIC studies and programmes: rules and regulations – *P.Ghia*
- Queries and answers, plus concluding remarks - *E. Montserrat*

WP4 meeting

Thursday, June 14, 2012
16:15 – 18:15

Room D201, Amsterdam RAI
Europaplein 22, 1078 GZ, Amsterdam

Agenda

1.	EURO-SKI: Status in various countries. Treatment after relapse.	*Saussele, Mahon* *Richter (60 min)*
2.	New EU Clinical Trial Directive. Present status. Measures taken by the ELN to support academic clinical trials.	*Hehlmann (10 min)*
3.	Update on new IFN combination studies. Status, experiences, mutual help, European strategy.	*Hochhaus, Guilhot,* *Hjorth-Hansen (40 min)*
4.	Is the 3 month endpoint becoming a standard?	*Mueller (10 min)*
5.	Next meeting	

WP9 (MPD) meeting

Thursday, June 14, 2012
16:15 – 18:15

Room D204
Amsterdam RAI, Europaplein 22, 1078 GZ,
Amsterdam, The Netherlands

Agenda

- The ELN project of end-points for clinical trials in MPNs