



+Date: July 15, 2013

**European LeukemiaNet Workpackage Meetings  
at 18<sup>th</sup> Congress of EHA**

**Stockholm, June 13-16, 2013**

Coordinator: Prof. Dr. Rüdiger Hehlmann

### Summary

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The 18<sup>th</sup> EHA Congress took place from 13 to 16 June 2013 in Stockholm, Sweden. In this context, the WP meetings of the European LeukemiaNet were held on June 13, 2013 in the Stockholmsmässan in Stockholm. 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

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On 13 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.

#### **EURO-SKI Investigators meeting**

By 31. May 2013, 196 patients were preregistered, 180 had a confirmed MR4 and 159 are finally included. A total of 24 centers in 8 countries are activated. The formation of an official Steering Committee consisting of at least one representative per country/study group, statisticians and a representative of the molecular monitoring group has been proposed. The eCRF is started and some functions have been explained. Recommendations for diagnosis and treatment for all investigators are planned. There is general interest to open a separate study (EURO-SKI2). As the study is recruiting fast, it was agreed to send an abstract to ASH 2013 with demographic data on the first 200 patients.



### CLL (WP7)

First, *Montserrat* gave an introduction and general information as well as information concerning ERIC publications in CLL. The second speaker, *Rosenquist* spoke about ERIC project on CLL mutations such as NOTCH1, SF3B1, BIRC3, MYD88 and their prognostic relevance as well as the published data of 2013. Protocols that should be used were also discussed. Afterwards, *Moreno* gave the final results on the ERIC Phase IV trial on Ofatumumab in CLL therapy and informed that a manuscript is in preparation. She also talked about ERIC questionnaire on prognostic and predictive markers in clinical practice.

*Popsilova* gave an update on TP53 harmonization and reference laboratories.

Lastly the audience was invited to register as members, if they are not already members.

### CML (WP4)

*Saussele* gave a short update on the EURO-SKI study and the investigator meeting. *Steegmann* and *Saussele* on behalf of Larsson reported on the planned committees on pharmaco-economic and on adverse events issues.

*Abbruzzese* gave a lecture on the observational study of conception/pregnancy in adult patients with CML treated with tyrosine kinase inhibitors (GIMEMA CML 1012). An electronic data base will be used for this study.

Afterwards, *Chelysheva* and *Kulikov* presented the CML Pregnancy Registry project of the Hematology Research Center of Federal State Institution of Ministry of Healthcare, Moscow, Russian Federation.

*Pfirschmann* on behalf of the ELN committee on statistical methods with inclusion of ideas of J. Hasford and J. Guilhot presented current statistical challenges arising from efficacy endpoints in chronic myeloid leukaemia, especially new primary endpoints, inconsistent approaches, surrogate endpoints, recommendations and spread of statistical standards.

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

The European LeukemiaNet Workpackage Meetings at 18<sup>th</sup> 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  
18<sup>th</sup> Congress of the EHA, Stockholm, Thursday, June 13, 2013**

<b>TIME THURSDAY JUNE 13</b>	<b>B7</b>	<b>B8</b>	
<b>Lunch 12:45 – 13:30</b>			
<b>13:30 – 15:30</b>	<b>EURO-SKI Investigators meeting</b>	<b>CLL (WP7)</b>	
<b>Coffee 15:30 – 16:15</b>			
<b>16:15 – 18:15</b>	<b>CML (WP4)</b>	<b>CLL (WP7)</b>	
<b>Official EHA Scientific Working Groups</b>			
<b>From 18:30</b>			<b>EWALL (WP6) CLL (WP7) MDS (WP8) Diagnostics (WP10)</b>

**ADDRESS:** Stockholmsmässan, Mässvägen 1, Älvsjö (Stockholm), Sweden



## **EuroSKI Investigator Meeting**

**Thursday, June 13, 2013**

**13:30 – 15:30**

Room: B7

Stockholmsmässan, Mässvägen 1, Älvsjö (Stockholm)

### **Agenda**

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|---|-------------------------------|
| 1. Recruitment and active centers                                     | <i>S. Sauße</i>               |
| 2. Formation of a steering committee for the EURO-SKI study           | <i>F. X. Mahon</i>            |
| 3. E-CRF  | <i>J. Richter</i>             |
| 4. 2nd Stop Study Amendment proposal                                  | <i>J. Richter</i>             |
| 5. Sweden experience, musculoskeletal side effects after stopping TKI | <i>J. Richter</i>             |
| 6. Nordic Immunology substudy   | <i>S. Mustjoki</i>            |
| 7. Future plans   | <i>S. Sauße / F. X. Mahon</i> |
| 8. Discussion   | <i>All participants</i>       |



## **WP4 meeting (CML)**

**Thursday, June 13, 2013**

**16:15 – 18:15**

Room: B7

Stockholmsmässan, Mässvägen 1, Älvsjö (Stockholm)

## **Agenda**

1. EURO-SKI. Short update *Mahon, J.Guilhot, Saussel (10 min)*
2. Pregnancy registry *Abruzzeze, Chelysheva (20 min)*
3. ELN committee on recommendations on AE *Clark, Steegmann (20 min)*
4. ELN committee on pharmaco-economic and ethic issues *Larson, Saussele (10 min)*
5. Permanent committee on statistical methods *Hasford, J.Guilhot (20 min)*
6. Committee for European sub-studies *(Hochhaus) (20 min)*
7. Next WP4 meeting
8. Other topics



**WP7 meeting (CLL)  
32th General Meeting of ERIC Members, Session 1**

**Thursday, June 13, 2013  
13:30 – 15:30**

Room: B8  
Stockholmsmässan, Mässvägen 1, Älvsjö (Stockholm)

## **Agenda**

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|---|----------------------------------|
| 1. General information                            | <i>E. Montserrat</i>             |
| 2. Novel mutation project                         | <i>R. Rosenquist</i>             |
| 3. Final results of the Phase IV Ofatumumab study | <i>C. Moreno,<br/>C. Bradley</i> |
| 4. Update of ongoing projects                     |                                  |