Minutes of the ELN breakfast meeting at ASH, Orlando, December 5, 2010

During the general session the MDS WP 8 presented 3 topics:

1. EU-MDS Registry MDS: 3 poster presentations at ASH based on the interim analyses of the first 800 patients
* Alex Smith and David Bowen. **Population based real world of low risk MDS**.

14 countries are participating to the registry: France, Spain, UK and Greece are major contributors.

Cytogenetic data are available in 93% of the patients.

Epo levels low in majority of patients: <100U/l in 68% of the patients. The basal EPO-levels have no significant relationship to Hb-levels.

* Reinhard Stauder: **Quality of Life at base line**. The Hb-levels show no correlation with age in contrast to nonMDS elderly people. Patients having problems with daily activities have a decreased median Hb-level: 9.5 vs 10.4 g/dl when no problems with daily activities. The Sorror score (co-morbidity index) showed a clear relationship with EQ-5D Visual Analogue scale
* L ouise de Swart: **Disease management during the first 18 months:** About 35% of the patients have received EPO with or without G-CSF. 303/800 Patients were transfusion dependent. Transfusion dependency and high ferritin levels in transfusion dependent patients were independent prognostic factors for survival and progression-free survival.

The plans for the EU-MDS registry are to increase follow-up from 2 to 5 years, to increase the number of patients to 2000 and to involve more countries. Additional studies will evaluate the value of ESA and iron chelation treatment.

1. Arjan van der Loosdrecht presented the results of the third ELN Flowcytometry meeting in London, November 5-7, 2010. Also participants from Australia, Japan and the United States participated to this meeting. The Minimal Flow cytometry criteria have been defined and have been published in Haematologica (2009). The Flow Score has been developed as a prognostic tool. Guidelines for the Flow Score Flow will be defined and described in 2 consensus documents to be submitted in first months of 2011 . Next meeting will be in Pavia 2011.
2. Luca Malcovati gave an update of the treatment guidelines. The guidelines have been developed by a European expert panel and a systemic review of literature. Consensus was achieved for key clinical questions and a list of treatment indications. The treatment guidelines will include a summary of the diagnostic guidelines. The final manuscript will be submitted to Blood in 2011. The following version will include international, nonEuropean experts as well. Scenario analysis of more than 50 scenarios have been developed and reviewed by the expert panels. The recommendations for the 50 scenarios are available at the website of Haematologica.

MDS working package continued after the general session with 8 members from the MDS WP ( Pierre Fenaux, Lionel Ades, Michael Lübbert, Arjan van der Loosdrecht, Moshe Mittelmann, Luca Malcovati, Petra Muus, and Theo de Witte)

1. EHA MDS Working Group: coordinators Pierre Fenaux en Eva Hellström-Lindbergh. January 17 is deadline for program submission. Pierre Fenaux will make proposal for the programme and circulate it to the coordinators after ASH. Eva will step down as co-chair. Uwe Platzbecker is proposed to replace her. We shall aim at joining the ELN WP8 and the EHA MDS WP into one MDS WP active both in EHA and in ELN, like several other disease oriented WPs of ELN and EHA.
2. **Platform** for international studies (**platform studies**): it is hardly possible to organize multinational European studies academic studies because of bureaucratic and financial hurdles. The alternative is to develop national identical trials with national (academic) sponsors and ethical approval. The may be facilitated by international randomization and analysis with coordination at ELN level. Pierre Fenaux and Moshe Mittelmann will make proposal for the backbone of the organization of these academic studies. Decitabine studies seem to be an attractive target, may be in combination with bortezomib). We shall put this topic on the agenda of the ELN meeting at Mannheim (to be prepared by Pierre Fenaux). We shall also invite relevant Pharma to Mannheim to discuss common studies with them.
3. Therapeutic guidelines (Luca Malcovati): The addition of nonEuropean experts will further delay the submission of the manuscript; furthermore the practices in Europe and the USA differ substantially because different drugs have been registries in different countries and parts of the world. We shall add a list of drugs and an overview of the countries with approved drugs.
4. Junior members steering committee: areas of interest. Arjan van der Loosdrecht: flowcytometry and diagnostics (shared with Eva H-L), Uwe Platzberger: new regimes/trials for SCT; Wolfgang-Karsten Hofmann: translational studies (together with Joop Jansen); Ades Lionel: clinical trials (together with Pierre Fenaux).
5. Translational research in the international setting of the registry. Joop Jansen will prepare proposal for logistics of collecting cellular samples (viable cells, RNA, DNA). Novartis interested in sponsoring.
6. FCM (Arjan van der Loosdrecht): overview of action from London meeting. The use of the FCM guidelines as a prognostic tool might be incorporated in the MDS registry study (next cohort)
7. Funding: nonrestricted funding is not easily available. Theo de Witte will investigate if EU frame projects would fit for our MDS Registry. An EU FP grant has been obtained for Myeloproliferative disorders. Restricted funding may come from Novartis based on new studies to be developed within the EU MDS registry: e.g. early iron chelation in transfusion dependent patients.
8. Impact of epo treatment: about 1/3 of the patients in the EU-MDS registry receive ESA’s. We observed that the percentage of transfusion dependent patients in the EU-MDS registry did not increase in contrast to what most experts would expect. Early start of ESA’s may decrease or delay transfusions, delay progression and improve survival. We may develop a platform study through ELN together with Jansen Cilag/J&J? Pierre Fenaux will prepare a proposal.
9. Margot Reeker is the new project manager of ELN WP8 MDS. She has replaced Olga Huber.
10. International MDS meeting in Edinborough, 18-21 May 2011. Submission of abstracts from the MDS Registry is planned. We plan a Steering committee meeting in Edinborough . Pierre Fenaux has been elected in Executive Board of the board of the MDS Foundation. The collaboration with ELN MDS WP8 and the MDS Foundation is at low level until now, but we plan to improve cooperation.

Reporter: Dr Petra Muus, Orlando, 05-12-2010.