

8th Meeting of the EWALL June, 7, 2007 - Vienna Minutes

Participants

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Part I: Status of the planned trials in Ph-positive ALL

P. Rousselot Status of the Dasatinib trial

PR presented the current status of the trial with Dasatinib in Elderly Ph+ ALL. The study is upon activation in France. The budget is fixed. All study documents were distributed to the different participating countries for activation.



O.G. Ottmann Status of the Nilotinib trial

The negotiations with Novartis regarding a similar trial with Nilotinib were successful. The only difference will be the continuous application of Nilotinib throughout the cycles. The first steps for activation of the study will be done beginning of July.

Part II: Standardisation of methods for lab analysis in the trials for Ph-positve ALL

Renato Bassan introduced the topic by mentioning that standardised methods are an important prerequisite to obtain comparable results in an European intergroup trial.

The different groups gave an overview on their approach.

| O. Spinelli | BCR-ABL determinations an dreporting and mutation analysis in the NILG group |
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| S. Soverini | ABL Kinase domain mutation analysis by D-HPLC of Ph+ ALL patients Italian |
| | experience |
| I. lacobucci | Identification of a novel mechanism of tesistance to Imatinib and Dasatinib in Ph+ |
| | ALL overexpression of aberrantly-splicid oncogenic IKAROS isoforms |
| E. McIntyre | BCR-ABL determination and mutation screening in the GRALL group |
| H. Pfeifer | Procedure in the GMALL and proposal for standardisation |

H. Pfeifer summarized the open questions and points of discussion and presented the results of a questionnaire regarding the methods applied in the different countries for BCR-ABL analysis and mutation analysis.

The group agreed on the following points:

- Basic standardisation is required since quantitative BCR-ABL status is an important endpoint of the study as well as the appearance of mutations
- The questionnaire on methods should be completed by all groups (including those not involved so far i.e. Spain, Poland).
- The result will be circulated in order to identify relevant differences.
- The group will agree then on European standard protocols for BCR-ABL analysis.
- For mutation analysis probably sequencing will be the basic standard.
- The question whether lab rounds should be done will be addressed later in collaboration with cooperative groups for MRD analysis.

Frankfurt, July 23, 2007

Dr.Nicola Gökbuget