

A multicentre phase III open-label randomized study in patients with advanced follicular lymphoma evaluating the benefit of maintenance therapy with rituximab after induction of response with chemotherapy plus rituximab in comparison with no maintenance therapy.

**PRIMA Results presented at the Annual ASCO Meeting and the EHA Congress were received with great interest and enthusiasm!**

### Topics

- Submission to EU and USA Authorities
- Results presented at ASCO and EHA
- Next Steps
- Adverse Events Reporting
- Time Window for last Protocol Visit

### Submission of PRIMA Results to EU and USA Authorities

As mentioned in the previous Newsletter and following the DSMC recommendations, the results of the positive Interim Analysis were submitted to the EU and US regulatory authorities in March 2010.

The PRIMA Team wants to acknowledge and thank you all for your commitment and support of the study. Without you, it would not have been possible to achieve this milestone!

MANY THANKS!

### Results presented at ASCO and EHA

Prima results have been present at the Annual ASCO Meeting (5<sup>th</sup> of June 2010 in Chicago, USA) and at the 15<sup>th</sup> Congress of the European Hematology Association (12<sup>th</sup> of June 2010 in Barcelona, Spain). PRIMA has been a great success in both congresses and the results have been received with great enthusiasm and interest.

### Adverse Events Reporting Reminder

- Please do not forget to send an updated Follow-up of all AEs still persisting during last evaluation (pages 58 to 61 of CRF)
- Adverse events should be reported up to 6 months after the last treatment dose or last observation visit or until progression, the start of a new cancer therapy or death.
- Treatment related SAEs have to be reported at any time beyond 30 days after the last dose of induction therapy.

### Next Steps

Please be reminded that:

- **The PRIMA Study is still ongoing and patients continue to be followed-up as per the protocol.**
- Current Monitoring Frequency will be on average every 3 months with at least 3 visits per year, from April 2010 until December 2012. This will be changed to an average of every 6 months with at least 2 visits per year during 2013 and 2014. Some sites will need more frequent visits during a certain period of time and other sites may need less frequent visits. However, regular phone contact will be kept by the CRA, in order to ensure that no data/events stay unattended for long periods of time.
- **CT Scan collection has been stopped. Please do not send any CT Scans to BioClinica anymore.**
- It is highly important to have all original Query Forms and completed CRF pages SDVed and collected by the CRAs, and sent to GELARC for further processing.
- Some patients in the PRIMA study are starting to approach the end of the follow-up period. In order to help you preparing for the last patient visit, the CRAs will be provided with a list of patients approaching the end of study. (see text box below)
- **It is highly important to continue with the completion and collection of the QoL questionnaires on a yearly basis during the Follow-up visits, starting after End of Treatment.**
- **Page 48-2 should be collected only for patients who reached a progression and who did not receive any treatment following progression (page 48 collected with “no therapy”) or who received only a treatment without chemotherapy.**

### Time Window for last Protocol Visit

Depending on the latest ICF signed by each patient, visits are scheduled every 6 months during follow-up years 3 to 5. Consequently it was decided that the last protocol visit should fall within 6 months of the planned final visit. This 6 month time-window will allow some degree of flexibility and convenience for scheduling the final patient visit and evaluation. An additional 1 month time window will provide further flexibility for this final visit whilst ensuring the total study duration corresponds to the original 5 year follow-up planned for the study

A tracker including the information for those patients that are approaching the end of study as per protocol, will be produced and distributed to all CRAs every two months. This tracker will include the time window during which the last FUP visit should take place, in order to help the investigators in the planning of their next patient visit.

The CRA will review this tracker and identify patients for which the last FUP visit needs to be planned. Each CRA will be in charge of his/her sites and will communicate with the PI as required, in order to ensure that the last FUP visit takes place during the above mentioned time frame.

**It is highly important to be compliant with the provided time frame for last FUP.** Last FUP should not take place after the official length of the study (as per protocol).

**IN CASE OF QUESTIONS****Medical questions: please contact**

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**THANK YOU FOR YOUR CONTINUOUS SUPPORT AND COMMITMENT!**