

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.

The primary endpoint for the study was met at the Interim Analysis showing maintenance treatment with Rituximab significantly prolongs PFS compared to observation

Topics

- Interim Analysis and DSMC Feedback
- Next Steps
- Revised Monitoring Frequency
- Investigators Meetings and Submission of Results to ASCO
- Adverse Events and Reminders

Season's Greetings



Interim Analysis and DSMC Feedback

As mentioned in the previous Newsletter, the results of the Interim Analysis were submitted to the DSMC for evaluation at their meeting on September, 15th 2009. The DSMC considered that the PRIMA data was mature enough and agreed that the predefined end-point was met at the interim Analysis. The DSMC recommended that the study results should be fully evaluated and disclosed.

The results of the study will be submitted to the EU and US regulatory authorities in March 2010.

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

MANY THANKS!

Next Steps

Please be reminded that:

- **The PRIMA Study is still ongoing and patients continue to be followed-up as per the protocol.**
- The monitoring frequency will change as described in the box below. The CRAs will inform you of any details related to monitoring frequency.
- Continued CRF collection and query resolution will be key.
- **It is very important to continue reporting PFS events per FAX to GELARC, immediately after they have been detected, as well as collecting all available clinical and safety data on an ongoing basis.**
- CT scan collection with BioClinica has been finalized. **No more CT Scans are required to be sent to BioClinica.**

Revised Monitoring Frequency

The monitoring frequency for the PRIMA Study will be changed as follows:

1. No changes in Monitoring Frequency (every 4 weeks) until the end of March 2010, in order to cover essential document collection for filing and ongoing CRF/DCF collection for supplementary snapshot.
2. Monitoring frequency on average every 3 months with at least 3 visits per year, starting on April 2010 until December 2012.
3. Monitoring frequency on average every 6 months with at least 2 visits per year during 2013 and 2014.
4. All Site Closure Visits to be completed by 2015.

Depending on the patient status and the outstanding data (included but not limited to CRF, DCFs and Essential Documents) at the site, the monitoring frequency can slightly deviate from the scheme explained above. 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.

General Update on Investigators Meetings and Submission of Results to ASCO

Two Investigator Meetings were held (Paris: 26th November 2009; and New Orleans: 7th December 2009) in order to present the positive study results. Due to confidentiality restrictions both meetings were held under a closed environment and only members of the PRIMA team were allowed to attend.

As you may be aware, the results of the PRIMA trial were not presented during the ASH Congress this year. These results will be submitted to ASCO in 2010 for a public presentation. Until this presentation takes place, all data from the PRIMA study needs to be kept as confidential.

Adverse Events Reporting

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.**

PLEASE REMEMBER

After the 24 month maintenance period **it is not possible** to have a reason for premature withdrawal. Also any AE or SAE occurring after the 24 months action with study drug **should not be** ticked *discontinued*.

Other remaining important information to be collected in the follow-up period is : **subsequent treatment (CRF page 48 and 48-2), progression (pages 47 and 47-2) and death (CRF page 49).**

IN CASE OF QUESTIONS

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THANK YOU FOR YOUR CONTINUOUS SUPPORT AND COMMITMENT!