

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

## Exciting News for PRIMA!!!

Dear Investigators,

**As announced in the previous newsletter (July 2006), an extension for 1200 registered patients has been proposed and now approved by the DSMC, together with other changes.** The Global Amendment n°3 was immediately submitted to the ethics committee in France for these modifications. We will need a new informed consent form. (Extension of patients follow-up for 2 years and 2 additional visits the 2<sup>nd</sup> year after maintenance/observation). Today, this amendment has not yet been approved by the authorities,

**It will then be necessary to suspend the registration for a few weeks,  
As soon as we reach the 900 target number (in the next following days ...!)**

We hope that this interruption will be as short as possible, and that we can resume registration in a delay that will not extend more than 6 weeks. Obviously, we hope to come back soon to the same accrual rate observed in the last few months.

**Randomizations will obviously continue as planned by the protocol.**

Protocol v 4.0 (and other specific documents) will be forwarded soon to the Local Coordinator for submission to your local authorities. We remind you that we will need the approval (from Ethics and Health Authorities) for all amendments (please send us the approvals relating to the Global Amendment n°2 if you haven' done so yet).

**☞ All countries will have to submit the Global Amendment n°3  
in order to start registrations again because the Informed consent is modified.**

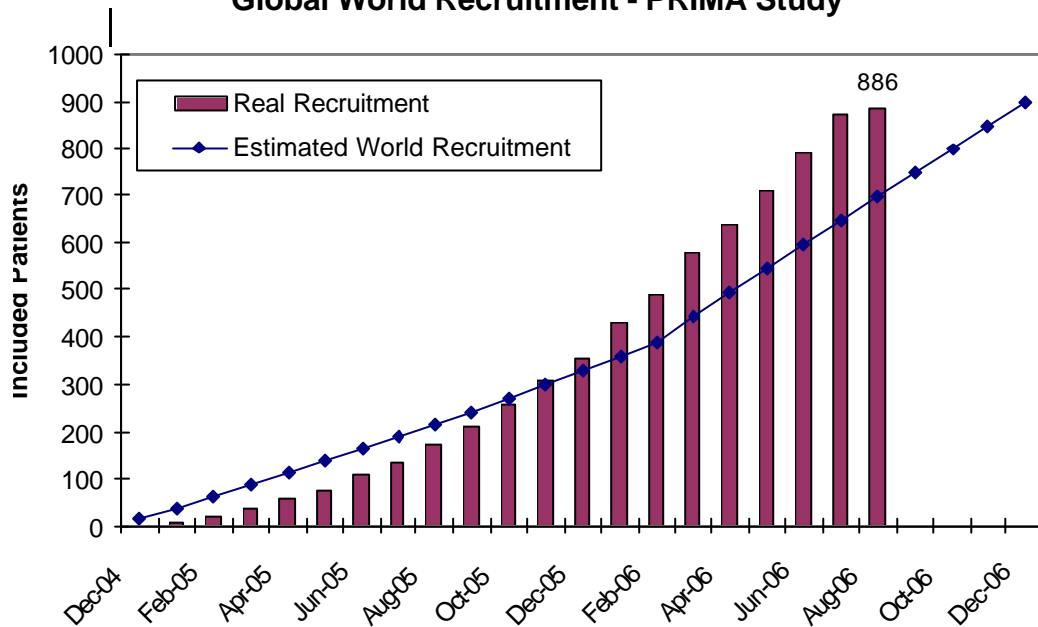
**Thanks for your efforts and participation that allowed PRIMA to be such a fast accruing study!**

**We hope that we will reach this new 1200 target number in the next following months**

**We will not be over, since patients will still be on study for several years**

**And we will need to carefully follow them according to the protocol.**

Global World Recruitment - PRIMA Study



Status

Induction treatment allocation :

- R-CHOP : 643 patients
- R-CVP : 207 patients
- R-FCM : 36 patients

Randomized: 348 patients

- Maintenance with Rituximab : 181 patients
- Observation : 167 patients

CRF received : 527 Complete Baseline (original pages)  
172 Complete Induction Phase

**ACTIVE COUNTRIES**

- Argentina
- Australia
- Belgium
- Brazil
- China
- Colombia
- Croatia
- Czech Republic
- Denmark
- Finland
- France
- India
- Israel
- Mexico
- Netherlands
- New-Zealand
- Peru
- Portugal
- Serbia
- Spain
- Thailand
- Turkey
- United Kingdom
- Uruguay
- Venezuela

Baseline documentation prior randomization

We do need to receive the baseline documentation of the CRF prior to be able to randomize a patient. **So don't forget to fill it in quickly**, to review it locally by your country monitor and to send it to the GELA-RC as soon as possible. This will avoid any delay at the time of randomization.

As data validation has started and a lot of patients are already randomized, Please send us the CRFs pages of Induction part and Randomization sheet (page 10 to 18 included).

For patient randomized in the observation arm (B), please don't forget the regular visits (every two months) and the assessments planned in the protocol.

For administrative information  
To download the protocol or other documents  
For a regular update of patients accrual per country,

Please look at <http://prima.gela.org>