

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.

Last patient has been randomized on November 22nd, 2007.
1030 out of 1217 registered patients have been randomised.
 Thank you all for your work and support!

Status: 1217 patients registered

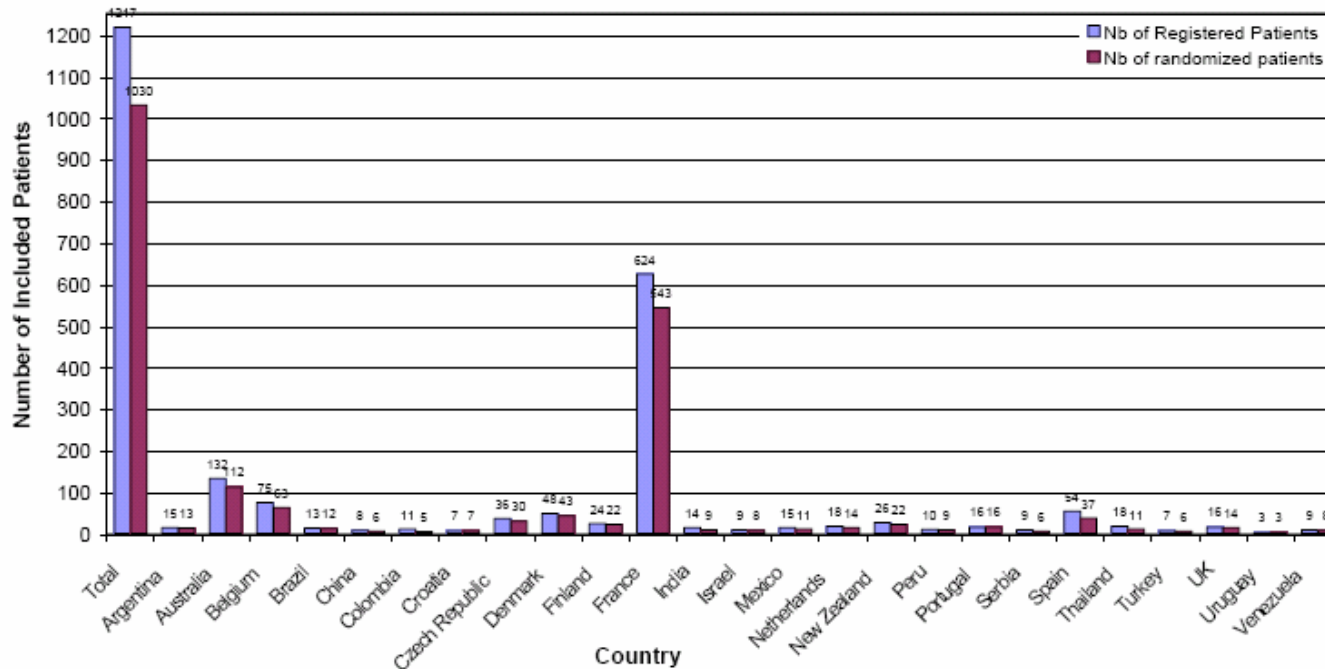
Induction treatment allocation :

- R-CHOP: 900 patients
- R-CVP: 272 patients
- R-FCM: 45 patients

Randomized: 1030 patients

- Maintenance with Rituximab: 513 patients
- Observation: 517 patients

Country Recruitment - PRIMA study



DSMC Meeting

The PRIMA Data Safety Monitoring Committee (DSMC) has met on **December 2007** during the ASH Congress. Demographic and Safety data of the PRIMA Trial has been reviewed and evaluated during this meeting. An official communication from this meeting will be distributed soon by GELARC.

Next DSMC meeting is planned for June 2008.

Importance of Immediate Event Reporting

Death or Progression/Relapse pages (pages 47, 47-2, 48 and 49), if applicable to the patient - need to be faxed to GELARC (**FAX +33 4 72 66 93 71**) IMMEDIATELY after the Investigator is informed of the event.

These pages must be SDVed and collected during the next monitoring visit.

PLEASE REMEMBER

1. During Maintenance period with or without Rituximab, patient must have clinical visits every 8 weeks. It is critical to maintain this evaluation as planned in the protocol to avoid any biases between the 2 arms.
2. After 24 months maintenance period the Evaluation at the End of Treatment forms (CRF pages 34, 35, 36) need to be completed independently of how many visits have been done.
3. If a patient is withdrawn due to Treatment Toxicity (AE or SAE) the withdrawal page needs to be completed as soon as possible, with reason due to toxicity.

THANK YOU FOR YOUR CONTINUOUS SUPPORT AND COMMITMENT

If you have any questions or comments about any aspect of the study, please contact your CRA, your Country Study Contact or GELARC (Delphine Germain or Prof. Gilles Salles)

Safety Reporting and Safety Queries

Please be reminded that all information submitted to GELARC Safety Desk in a SAE report must be also reflected in the corresponding CRF page and in the Medical Charts of the patient. If your answer to a query related to an SAE report would affect the information reported in the CRF, please ensure this document is amended accordingly and the CRA is informed.

Please refer to the PRIMA SAE reporting guideline distributed during the last week of November 2008, for detailed information on how to fill in the SAE report forms. Below, you can find the most important points to be considered:

1. Only a single diagnosis must be recorded per report.
2. All the PRIMA study drugs must be listed as study trial medication for both induction and maintenance. Start date is the date of the patient's 1st cycle during induction. Last date before SAE is the date of the last drugs administration before SAE occurred.
3. Relationship to study drugs should always be filled for all study drugs for both induction and maintenance for the SAE to be processed (relationship can always be changed at a later time point with an updated report).
4. All new information is to be updated on a SAE Follow-up form - corresponding CRF AE page must be updated. Be careful to tick off "follow up" for the follow up reports, and "initial" for the initial reports.
5. When you require cancellation of an SAE report, the report must be crossed-out, dated and signed by the investigator, and a reason for cancellation must be given (comment).
6. All the relevant medical information (e.g., medical history, concomitant condition, laboratory results, clinical course of the event) must be indicated in the "comments". Note: Only information entered on an SAE form is processed, attached hospital/lab reports are not considered.

Following items must be equal in both the AE CRF Page and in the SAE report: Patient Number, Date of Birth, Diagnose (Verbatim), AE Onset Date, Outcome, & Relationship to Study Drug (the worse relationship from the SAE report must be recorded on the AE corresponding page)

CT Scan Collection Update by Bio-Imaging

The CT Data Collection for the Roche/GELA PRIMA study is well under way! Bio-Imaging is asking you for your continued assistance as we continue our efforts towards collecting all available CT data.

Prospective CT Scan collection will be started as per January, 2008.

Our team at Bio-Imaging is here to assist you with the data collection. Please let us know how we can assist and we will ensure that your needs are met.

FAQ:

Q: What type of digital data is acceptable at Bio-Imaging?

A: Any digital data should be submitted in uncompressed DICOM format. This is the most widely used format of imaging data. (JPEG and Tiff format can NOT be used!)

Q: Only film data is available for a patient. How do I submit these data?

A: Film data can be submitted to Bio-Imaging. Upon receipt the data will be digitalized by Bio-Imaging. If only original film data is available and this needs to be returned to the site please tick the "Check box only if films need to be copied and returned to your site" on the Data Transmittal Form. The films will be copied and returned as soon as possible.

Q: I can not locate a randomized patient on the outstanding data spreadsheet. Can I submit the collected data?

A: The outstanding data spreadsheet is updated on a monthly basis and the patient will probably appear on the next list. However, the data can be submitted to Bio-Imaging as long as you make sure that the randomized patient has signed ICF versions 2.0/2.1 and the site has approved protocol amendment 3.

Questions or concerns: Please contact Ryan Cella (rcella@bioimaging.com), Marieke van der Kooi (mvdkooi@bioimaging.com), Rianne Vincenten (rvincenten@bioimaging.com), and/or Karen Kubacke (kkubacke@bioimaging.com).

CRF RECEPTION STATUS (23/01/2008)

	Patients	Rando	Complete Baseline	Partial Baseline	Missing baseline	p1-2 Missing	Complete Induction	Partial Induction	Missing Induction	p10-2, 12-2 Missing	Complete V1-V4	Partial V1-V4	Missing V1-V4	Complete V5-V8	Partial V5-V8	Missing V5-V8	Complete V9-V12	Partial V9-V12	Missing V9-V12
	%	84.6	99.8	0.2	0	11.3	95.0	2.4	2.0	5.3	69.4	24.4	6.2	44.7	27.4	27.9	27.3	16.4	56.4
TOTAL	1217	1030	1215	2	0	138	1156	29	24	64	845	297	75	544	333	340	332	199	686
Argentina	15	13	15	0	0	0	15	0	0	0	11	4	0	8	7	0	3	5	7
Australia	132	112	132	0	0	23	113	4	15	28	80	27	25	47	36	49	27	16	89
Belgium	75	63	75	0	0	3	73	2	0	0	61	13	1	42	19	14	29	13	33
Brazil	13	12	13	0	0	0	10	1	2	2	6	5	2	2	4	7	1	0	12
China	8	6	8	0	0	0	6	1	1	1	2	4	2	1	1	6	1	0	7
Colombia	11	5	11	0	0	1	11	0	0	0	8	3	0	10	0	1	7	1	3
Croatia	7	7	7	0	0	0	7	0	0	0	7	0	0	0	7	0	0	0	7
Czech Rep.	36	30	36	0	0	0	34	2	0	3	33	1	2	14	20	2	4	8	24
Denmark	48	43	48	0	0	1	48	0	0	0	33	13	2	20	14	14	10	11	27
Finland	24	22	24	0	0	0	21	1	2	2	15	5	4	6	8	10	4	2	18
France	624	543	624	0	0	85	603	10	3	7	426	178	20	293	150	181	181	117	326
India	14	9	14	0	0	2	14	0	0	2	14	0	0	13	1	0	7	5	2
Israel	9	8	9	0	0	0	8	1	0	0	5	3	1	1	4	4	1	0	8
Mexico	15	11	15	0	0	15	15	0	0	15	13	2	0	7	7	1	7	0	8
Netherlands	18	14	16	2	0	4	17	0	1	2	8	6	4	5	5	8	4	0	14
New Zealand	26	22	26	0	0	1	24	2	0	0	16	8	2	10	7	9	5	6	15
Peru	10	9	10	0	0	0	8	2	0	2	8	1	1	5	4	1	4	1	5
Portugal	16	16	16	0	0	1	16	0	0	0	12	0	4	6	5	5	0	4	12
Serbia	9	6	9	0	0	2	9	0	0	0	3	4	2	1	2	6	0	0	9
Spain	54	37	54	0	0	0	54	0	0	0	47	7	0	32	15	7	24	4	26
Thailand	18	11	18	0	0	0	18	0	0	0	16	2	0	13	3	2	9	4	5
Turkey	7	6	7	0	0	0	7	0	0	0	7	0	0	5	2	0	1	2	4
UK	16	14	16	0	0	0	13	3	0	0	5	9	2	1	5	10	1	0	15
Uruguay	3	3	3	0	0	0	3	0	0	0	2	1	0	2	0	1	2	0	1
Venezuela	9	8	9	0	0	0	9	0	0	0	7	1	1	0	7	2	0	0	9

Please be reminded that all queries should be solved within few days after arrival, in order to allow the CRA to perform Source Data Verification and to collect them during the next Monitoring Visit.

