

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 GELA-RC Team wishes you a Happy New Year
and all the Best for our collaboration in the PRIMA Study !!!

ADMINISTRATIVE NEWS

- ✓ 1st PRIMA Monitoring Workshop will be held on the 27th and 28th February, 2007 in Madrid.
 - One monitor per country will participate to this important meeting
- ✓ CT scan collection will be organized by Bio Imaging. The compangny will contact directly each country.
- ✓ The additional CRF booklets have been sent in December for all previously registered patients. We remind you that all these patients should sign the additional informed consent form.
- ✓ The new CRFs are sent to the local coordinator after reception in the GELARC of the 3rd amendment approval.
- ✓ New contracts - including new fees - will be sent for approval during January

MEDICAL NEWS

- ✓ To track the events, in case of **progression or death** in maintenance period, please could you fax immediatly to the GELARC (+33 4 72 66 93 71) the CRF pages (page 47, 47-2 or 49).
- ✓ We remind you that it is important to have a **histological and/or cytological documentation** in case of progression /relapse.
- ✓ If an Infectious or suspected Serious Adverse Event occur during the maintenance period, we recommend to verify the immunological status by performing 1) a dosage of serum Ig classes (IgM, IgG, IgA) and 2) a determination of circulating immune cells (B-, T-, and NK- cells populations)
- ✓ During Maintenance period **with or without rituximab**, patient must have clinical visit **every 2 months. It is critical to maintain this evaluation as planned in the protocol to avoid any biases between the 2 arms.**

ACTIVE COUNTRIES AFTER THE 3rd AMENDMENT

Australia, Belgium, China, Colombia, Croatia, Denmark, Finland, France, Israel, New-Zealand, Portugal, Thailand, United Kingdom and Venezuela.

Status: 1003 patients registered on 31/12/2006

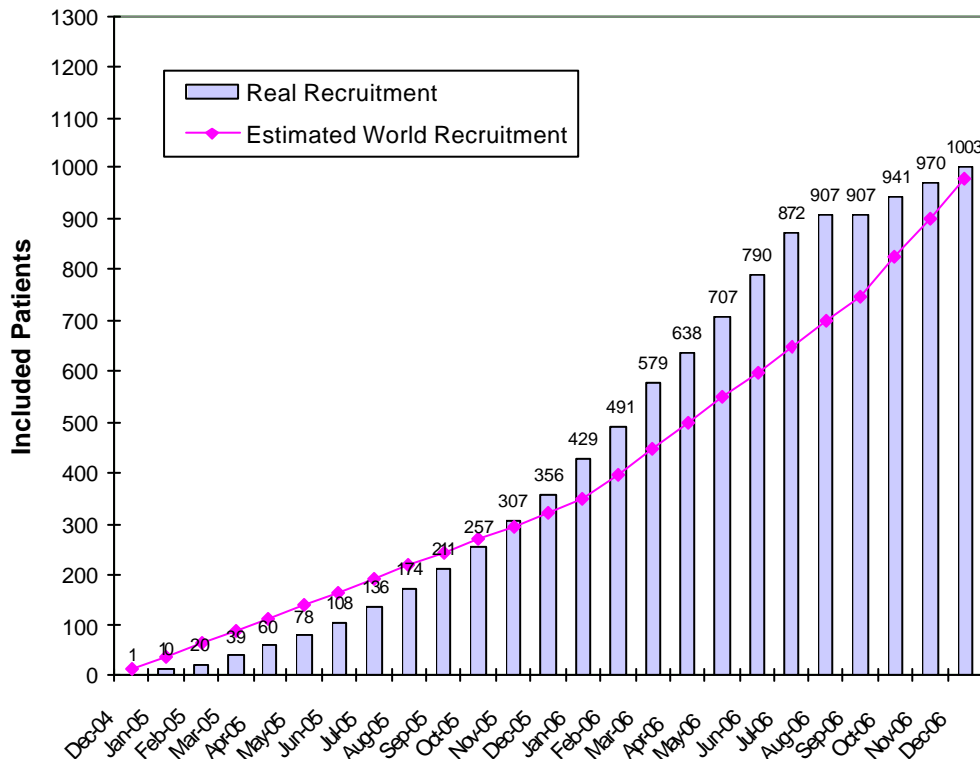
Induction treatment allocation :

- R-CHOP : 742 patients
- R-CVP : 225 patients
- R-FCM : 36 patients

Randomized: 653 patients

- Maintenance with Rituximab : 321 patients
- Observation : 332 patients

Global World Recruitment - PRIMA Study



For administrative information
 To download the protocol or other documents
 For a regular update of patients accrual
 To download the investigator meeting presentations

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

CRF RECEPTION STATUS

CRF STATUS AND NEWS

- * Do not forget to complete, monitor and send **Additional CRF Booklets** for patients registered before 3rd amendment.
- * We have actually received 91.7 % of complete baseline CRF parts for the 907 patients registered before the 3rd amendment: we need to get 100% of them before end of February.
- * **Updated monitoring guidelines** (for current and new CRFs) will be sent during January. Do not hesitate to contact us for any question.
- * Monitoring Frequency will be increased with **a monitoring visit every 2 months** during the first term of 2007.

	Included Patients on 31/8/06	Randomized Patients on 31/12/06	% of complete Baseline	% of incomplete Baseline	% of missing Baseline	% of complete Induction	% of incomplete Induction	% of missing Induction
TOTAL	907	652	91,84	1,43	6,73	51,05	11,25	37,71
Argentina	15	10	80	20	0	33,33	40	26,67
Australia	110	82	91,82	0	8,18	20	15,45	64,55
Belgium	58	48	94,83	3,45	1,72	65,52	10,34	24,14
Brazil	5	4	100	0	0	60	0	40
China	2	1	100	0	0	0	0	100
Colombia	8	3	12,5	0	87,5	0	12,5	87,5
Croatia	7	4	100	0	0	57,14	0	42,86
Czech Republic	36	25	100	0	0	58,33	13,89	27,78
Denmark	35	28	100	0	0	68,57	0	31,43
Finland	12	9	100	0	0	16,67	83,33	0
France	442	337	97,51	0,45	2,04	61,31	9,05	29,64
India	14	8	100	0	0	71,43	14,29	14,29
Israel	5	1	40	0	60	20	20	60
Mexico	15	7	86,67	0	13,33	13,33	0	86,67
Netherlands	17	10	5,88	17,65	76,47	5,88	17,65	76,47
New Zealand	16	11	100	0	0	31,25	0	68,75
Peru	10	8	100	0	0	0	50	50
Portugal	12	11	91,67	0	8,33	91,67	0	8,33
Serbia	7	4	71,43	0	28,57	0	0	100
Spain	42	22	61,90	7,14	30,95	47,62	7,14	45,24
Thailand	15	8	100	0	0	66,67	6,67	26,67
Turkey	7	4	100	0	0	71,43	14,29	14,29
UK	6	NA	100	0	0	0	0	100
Uruguay	2	NA	100	0	0	0	50	50
Venezuela	9	7	88,89	0	11,11	88,89	0	11,11