

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 patient's accrual gets close to the 1200 patients,
Less than 60 patients before end of recruitment**

ADMINISTRATIVE NEWS

- ✓ 1st PRIMA Monitoring (27 & 28/02/2007) in Madrid => Great success thanks to 42 persons, from many countries involved in Prima !!!! Many thanks to Roche Team for the organization of this very useful workshop.
- ✓ **Pathological Review:**
 - In case of global GELA-P review => send biopsy samples as soon as possible
 - In case of local review => send biopsy samples for 1/3 of registered patients + Pathological review form for the other 2/3 with results of Local pathological review.
- ✓ ***Local coordinator will received an updated status of inclusions every 10 new patients recruited. Please, keep inform all sites regarding end of registrations.***
- ✓ CT scan collection, organized by Bio imaging will start in countries after 3rd amendment approval.

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, Brazil, China, Colombia, Croatia, Denmark, Finland, France, Israel, Netherlands, New-Zealand, Portugal, Serbia, Spain, Thailand, UK and Venezuela.

Status: 1142 patients registered on 08/03/2007

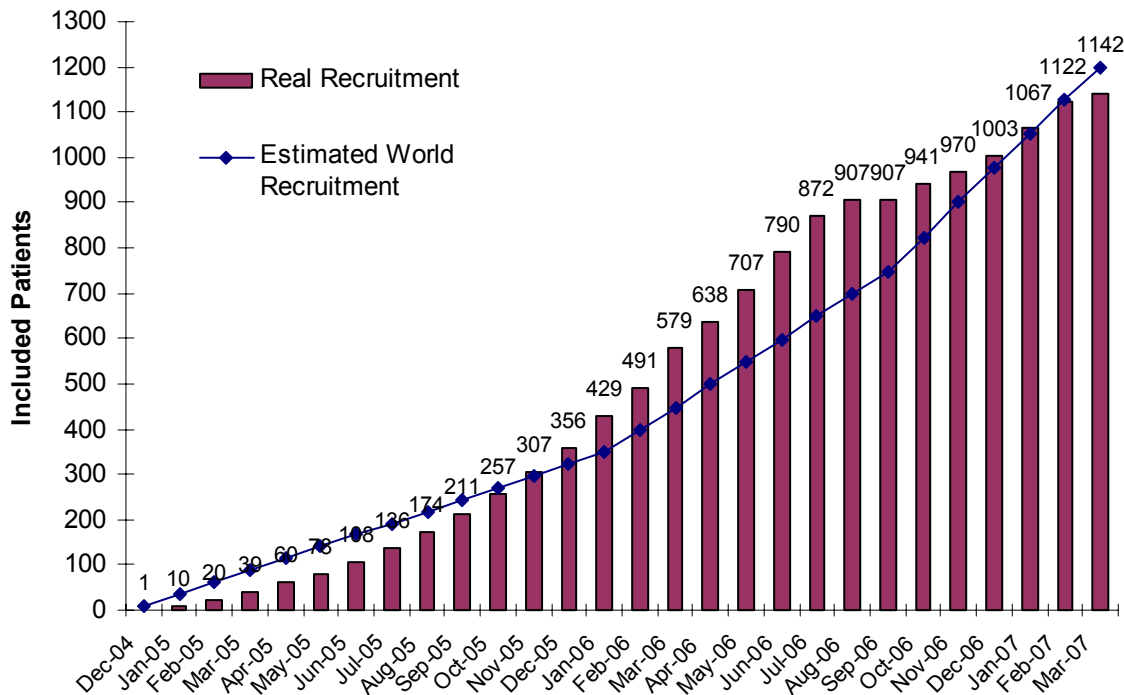
Induction treatment allocation :

- R-CHOP : 842 patients
- R-CVP : 258 patients
- R-FCM : 42 patients

Randomized: 759 patients

- Maintenance with Rituximab : 379 patients
- Observation : 380 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 STATUS AND NEWS

- * Do not forget to complete, monitor and send **Additional CRF Pages** for patients registered before 3rd amendment.
- * *In the last newsletter, we asked to get 100% of complete baseline CRF parts for the 907 patients registered before the 3rd amendment for the end of February: some pages are still missing, **Please send these pages ASAP!!!***
- * **New Monitoring Guidelines + Top Level Monitoring Plan** have been sent (for current and new CRFs) during February. These documents must now be used for each monitoring visit.

CRF RECEPTION STATUS

	Patients included on 31/8/06	Patients randomized	% of complete Baselines	% of incomplete Baselines	% of missing Baseline	% of complete Inductions	% of incomplete Inductions	% of missing Inductions	% of Complete p19-23	% of Incomplete p19-23	% of missing p19-23
TOTAL	907	758	96,5	1,7	1,9	66,4	9,3	24,4	18,3	30,1	51,6
Argentina	15	13	80	20	0	46,7	40	13,3	0	38,5	61,5
Australia	110	92	96,4	0,9	2,7	43,6	8,2	48,2	1	12	87
Belgium	58	49	98,3	1,7	0	86,2	8,6	5,2	44,9	40,8	14,3
Brazil	5	5	100	0	0	60	0	40	0	0	100
China	2	1	100	0	0	0	0	100	0	0	100
Colombia	8	4	62,5	25	12,5	37,5	37,5	25	0	25	75
Croatia	7	7	100	0	0	57,1	0	42,9	0	0	100
Czech Republic	36	29	100	0	0	66,7	5,6	27,8	3,4	51,7	44,8
Denmark	35	31	100	0	0	74,3	0	25,7	16,1	3,2	80,6
Finland	12	11	100	0	0	66,7	33,3	0	0	63,6	36,4
France	442	378	99,8	0,2	0	76,9	5,9	17,2	28,6	39,7	31,7
India	14	9	100	0	0	57,1	28,6	14,3	0	44,4	55,6
Israel	5	5	80	0	20	20	40	40	0	0	100
Mexico	15	11	100	0	0	73,3	6,7	20	0	36,4	63,6
Netherlands	17	12	23,5	35,3	41,2	29,4	29,4	41,2	0	0	100
New Zealand	16	15	100	0	0	31,3	0	68,8	0	0	100
Peru	10	9	100	0	0	0	60	40	0	33,3	66,7
Portugal	12	12	100	0	0	100	0	0	0	0	100
Serbia	7	4	85,7	0	14,3	0	0	100	0	0	100
Spain	42	30	90,5	0	9,5	78,6	11,9	9,5	3,3	3,3	93,3
Thailand	15	9	100	0	0	73,3	13,3	13,3	11,1	33,3	55,6
Turkey	7	6	100	0	0	71,4	14,3	14,3	0	50	50
UK	6	6	100	0	0	0	0	100	0	0	100
Uruguay	2	2	100	0	0	0	100	0	0	0	100
Venezuela	9	8	100	0	0	100	0	0	0	0	100