

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 definitive recruitment: 1217 patients' around the world
Many Thanks for your participation!!!

Status: 1217 patients registered

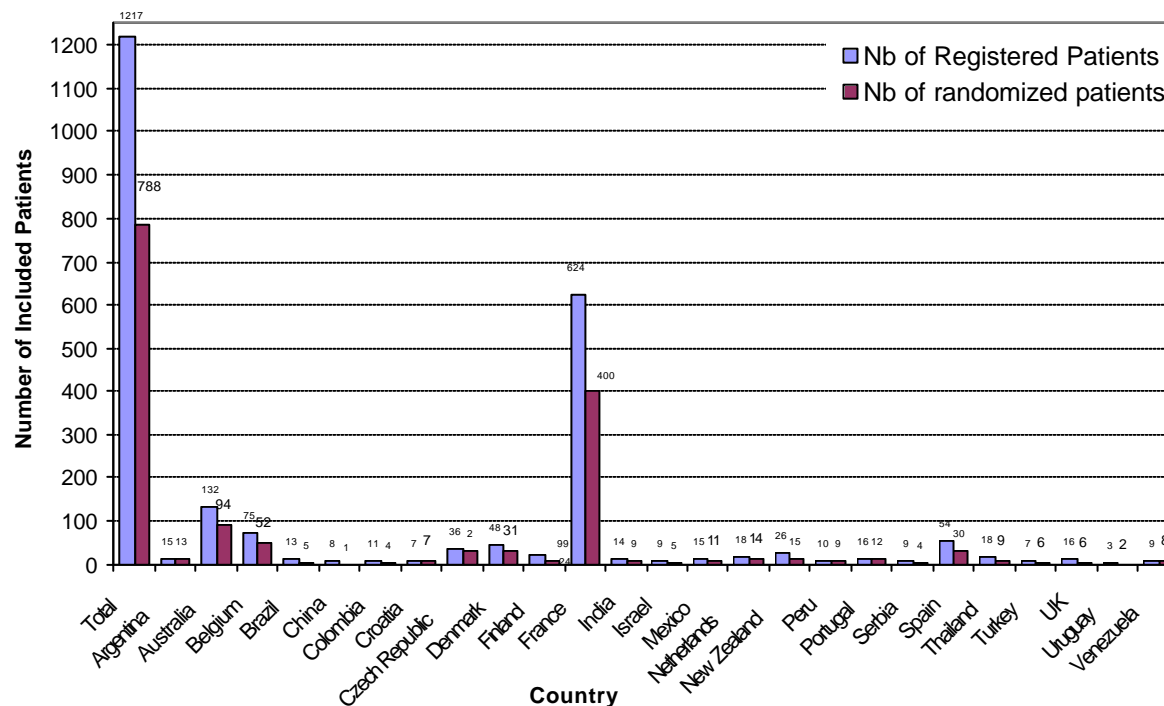
Induction treatment allocation :

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

Randomized: 788 patients

- Maintenance with Rituximab : 394 patients
- Observation : 394 patients

Country Recruitment - PRIMA study



CT SCAN COLLECTION - NEWS

- ↪ CT scan collection, organized by Bio Imaging Technologies will start in countries where the 3rd protocol amendment has been approved.
- ↪ Collection of CT scan (and/or MRI if applicable) will involve only patients :
 - **Randomized for maintenance period** (whatever the arm).
 - **Who have signed the new ICF or the additional one** according to the 3rd protocol amendment.
- ↪ Collection will start with the “retrospective part” first and we need to collect all CT scans for those patients:
 - Baseline CT scan
 - Middle induction CT scan
 - Post induction CT scan used for the evaluation of the response before randomization
 - CT scan done during maintenance/observation period (every 6 months)
 - CT scan used for evaluation at the end of treatment (end of maintenance period or at withdrawal)
 - CT scan in case done at progression/relapse if applicable
 - CT scan done during follow-up period
- ↪ Bio Imaging will contact first Local Coordinators to organize CT scan collection in each country.

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COUNTRIES WITH THE 3rd AMENDMENT APPROVAL

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

All countries need to have this approval!

CRF RECEPTION STATUS (on 30/04/2007)

	Patients		Baseline (p1-p9)			Induction (p10-p18)			Maintenance V1-V4			Maintenance V5-V8			Nb 10-2, 12-2 Full
	Included	randomized (included before 3rd amd)	Full	Partial	Missing	Full	Partial	Missing	Full	Partial	Missing	Full	Partial	Missing	
TOTAL	1217	766	1007	31	179	698	126	392	182	299	285	44	121	601	407
Argentina	15	13	12	3	0	7	6	2	0	5	8	0	1	12	0
Australia	132	94	106	1	25	48	9	75	1	11	82	1	1	92	6
Belgium	75	49	67	1	7	57	2	16	26	21	2	10	16	23	52
Brazil	13	5	8	0	5	5	0	8	0	5	0	0	0	5	3
China	8	1	2	0	6	0	0	8	0	0	1	0	0	1	0
Colombia	11	4	5	3	3	3	3	5	0	1	3	0	0	4	0
Croatia	7	7	7	0	0	4	0	3	0	0	7	0	0	7	0
Czech Republic	36	30	36	0	0	31	4	1	3	22	5	0	0	30	0
Denmark	48	31	44	1	3	29	3	16	9	13	9	1	7	23	24
Finland	24	11	18	0	6	12	4	8	0	11	0	0	0	11	2
France	624	381	534	7	83	373	72	178	131	163	87	30	90	261	291
India	14	9	14	0	0	10	2	2	0	5	4	0	0	9	0
Israel	9	5	4	0	5	3	4	2	0	0	5	0	0	5	0
Mexico	15	11	15	0	0	13	1	1	0	6	5	0	0	11	0
Netherlands	18	14	9	5	4	10	4	4	0	6	8	0	0	14	6
New Zealand	26	15	16	0	10	6	0	20	0	0	15	0	0	15	3
Peru	10	9	10	0	0	6	0	4	0	3	6	0	0	9	1
Portugal	16	12	12	1	3	12	0	4	0	2	10	0	0	12	1
Serbia	9	4	6	0	3	3	0	6	0	0	4	0	0	4	0
Spain	54	30	42	8	4	38	9	7	7	19	4	1	3	26	8
Thailand	18	9	15	0	3	11	2	5	3	2	4	1	2	6	9
Turkey	7	6	7	0	0	6	1	0	2	3	1	0	1	5	0
UK	16	6	6	1	9	0	0	16	0	0	6	0	0	6	0
Uruguay	3	2	3	0	0	2	0	1	0	1	1	0	0	2	1
Venezuela	9	8	9	0	0	9	0	0	0	0	8	0	0	8	0

MEDICAL NEWS

- ✓ To track the events, in case of **progression or death** in maintenance period, please could you fax the CRF pages (page 47, 47-2, 49) **immediately** to GELARC (+33 4 72 66 93 71). The number of events will trigger the analysis timepoint!
- ✓ 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.**
- ✓ It is mandatory for **women in age of child bearing potential to take contraceptive** methods during treatment or maintenance.
- ✓ **SAE completion rule's** : we would remind you that **during induction phase**
 - Severe haematological (anemia, neutropenia, leucopenia, thrombopenia) toxicity requiring hospitalization for less than 8 days
 - Nausea or vomiting grade 4 requiring hospitalization for less than 8 days
 - Alopecia grade 4

These cases must be recorded on toxicity page but not as serious adverse event unless life threatening or fatal.

NEXT INVESTIGATOR'S MEETING

During 12th congress of European Hematology Association

Vienna, Austria
Prima Meeting

Thursday, 7th June, 2007
19.00 – 21.00

Hilton Stadtpark, Vienna
Room Anton Bruckner

You can register on the website:

<http://www.investigate-event.com/prima/>

Login: prima

Password: amirp