



## Clinical trial results:

### A Phase Ib/II study of OBINUTUZUMAB combined with LENALIDOMIDE for the treatment of relapsed/refractory follicular and Aggressive (DLBCL and MCL) B-cell Lymphoma.

#### Summary

EudraCT number	2011-005150-62
Trial protocol	FR BE
Global end of trial date	20 May 2022

#### Results information

Result version number	v1 (current)
This version publication date	28 October 2023
First version publication date	28 October 2023

#### Trial information

##### Trial identification

Sponsor protocol code	GALEN
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01582776
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	LYSARC
Sponsor organisation address	Centre Hospitalier Lyon-Sud Bâtiment 2D, PIERRE-BÉNITE Cedex, France, 69495
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Notes:

#### Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 January 2023
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	20 May 2022
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

Phase IB: to determine the recommended dose (RD) of lenalinomide (Revlimid) when administered in association with obinutuzumab by escalation approach (3+3 dosing).

Phase II: to assess the efficacy of the association of the recommended dose of lenalidomide in combination with obinutuzumab, as measured by the overall response rate (ORR) at the end of 6 cycles (end of induction) in 3 different populations of patients with lymphoma disease: relapsed/refractory follicular lymphoma , relapsed/refractory aggressive lymphoma [aNHL] (Diffuse large B-cell and Mantle cell lymphoma) and untreated follicular lymphoma

Protection of trial subjects:

No rescue treatment in this study

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 June 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 47
Country: Number of subjects enrolled	France: 265
Worldwide total number of subjects	312
EEA total number of subjects	312

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	151
From 65 to 84 years	159

85 years and over	2
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## Subject disposition

### Recruitment

Recruitment details:

Subjects were recruited between october 2012 and January 2018

### Pre-assignment

Screening details:

Phase Ib : 21 patients were screened and 20 were included

Phase II : 310 patients were screened and 297 were included

### Period 1

Period 1 title	Treatment (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

### Arms

Arm title	Experimental
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Arm description:

Patients who received combination of lenalidomide plus obinutuzumab.

Arm type	Experimental
Investigational medicinal product name	Lenalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Lenalidomide treatment in Phase I part:

Cycle 1 D1 to D21 depending on dose level: 10 mg, 15mg, 20mg or 25mg

For cycles 2 to 6, lenalidomide will be given on day 2 to day 22

Treatment in Phase II part:

Induction: Oral lenalidomide will be given once daily at 20 mg on days 1-21 of a 28-day cycle for the first cycle and on days 2-22 of a 28-day cycle for cycles 2 to 6. Maintenance: If after cycle 6, the patient has achieved at least a PR, he will be eligible for maintenance treatment. First year of maintenance (12 cycles of 28 days), 10mg on days 2-22 of a 28-day cycle during a maximum of 12 cycles as tolerated, or until

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Injection

Dosage and administration details:

Treatment in Phase I part:

D8, D15, D22 (cycle 1) and D1 (cycles 2 to 6) : 1000mg

Treatment in Phase II part:

1000mg on D8, D15, and D22 of the first cycle and at D1 of cycles 2 to 6 days (total of 8 infusions) During the first year of maintenance (12 cycles of 28 days), patient will received obinutuzumab (6 infusions of 1000mg every 2 cycles: C7, C9, C11, C13, C15 and C17) as tolerated, or until disease progression.

During the second year of maintenance (6 cycles of 56 days), patient will received obinutuzumab (6 infusions of 1000mg every 56 days).

<b>Number of subjects in period 1</b>	Experimental
Started	312
Completed	166
Not completed	146
Adverse event, serious fatal	10
Consent withdrawn by subject	2
Adverse event, non-fatal	23
Progression	95
Concurrent illness	6
other	4
Lack of efficacy	4
Protocol deviation	2

## Baseline characteristics

### Reporting groups

Reporting group title	Experimental
Reporting group description:	
Patients who received combination of lenalidomide plus obinutuzumab.	

Reporting group values	Experimental	Total	
Number of subjects	312	312	
Age categorical			
Units: Subjects			
Adults (18-64 years)	151	151	
From 65-84 years	159	159	
85 years and over	2	2	
Age continuous			
Units: years			
arithmetic mean	63.3		
standard deviation	± 10.7	-	
Gender categorical			
Units: Subjects			
Female	134	134	
Male	178	178	

### Subject analysis sets

Subject analysis set title	Cohort 1 : Relapsed/refractory aggressive patients
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Cohort 1 : Relapsed/refractory aggressive patients	
Subject analysis set title	Cohort 2 : Relapsed/refractory follicular patients
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Cohort 2 : Relapsed/refractory follicular patients	
Subject analysis set title	Cohort 3 : Untreated follicular lymphoma
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Cohort 3 : Untreated follicular lymphoma	
Subject analysis set title	DLT set
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Phase Ib	
Subject analysis set title	Cohorte 4
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Untreated follicular lymphoma	

<b>Reporting group values</b>	Cohort 1 : Relapsed/refractory aggressive patients	Cohort 2 : Relapsed/refractory follicular patients	Cohort 3 : Untreated follicular lymphoma
Number of subjects	85	86	100
Age categorical Units: Subjects			
Adults (18-64 years)	20	44	61
From 65-84 years	65	41	38
85 years and over	0	1	1
Age continuous Units: years			
arithmetic mean	68.26	63.29	60.30
standard deviation	± 8.2	± 10.7	± 11.1
Gender categorical Units: Subjects			
Female	30	32	55
Male	55	54	45

<b>Reporting group values</b>	DLT set	Cohorte 4	
Number of subjects	19	17	
Age categorical Units: Subjects			
Adults (18-64 years)	10	12	
From 65-84 years	8	5	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	62.11	60.9	
standard deviation	± 11.8	± 8.7	
Gender categorical Units: Subjects			
Female	9	6	
Male	9	11	

## End points

### End points reporting groups

Reporting group title	Experimental
Reporting group description: Patients who received combination of lenalidomide plus obinutuzumab.	
Subject analysis set title	Cohort 1 : Relapsed/refractory aggressive patients
Subject analysis set type	Sub-group analysis
Subject analysis set description: Cohort 1 : Relapsed/refractory aggressive patients	
Subject analysis set title	Cohort 2 : Relapsed/refractory follicular patients
Subject analysis set type	Sub-group analysis
Subject analysis set description: Cohort 2 : Relapsed/refractory follicular patients	
Subject analysis set title	Cohort 3 : Untreated follicular lymphoma
Subject analysis set type	Sub-group analysis
Subject analysis set description: Cohort 3 : Untreated follicular lymphoma	
Subject analysis set title	DLT set
Subject analysis set type	Sub-group analysis
Subject analysis set description: Phase Ib	
Subject analysis set title	Cohorte 4
Subject analysis set type	Sub-group analysis
Subject analysis set description: Untreated follicular lymphoma	

### Primary: DLT - recommended dose

End point title	DLT - recommended dose <sup>[1]</sup>
End point description: Therefore, primary analysis will be based on safety parameters and particularly on incidence of DLTs as defined in section 8.3. Frequency of patients with DLT only during the first cycle of GALEN study will be reported by dose level. Safety data (adverse events, laboratory data, vital signs and ECOG performance status) will be summarized overall and at each cycle. Definition of DLTs : - DLT 1 : 10 mg - DLT 2 : 15 mg - DLT 3 : 20 mg - DLT 4 : 25 mg	
End point type	Primary
End point timeframe: First six cycles of treatment	

#### Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: GALEN is a phase-II study. There was no statistical tests because no comparison have been made with an another group.



End point values	DLT set			
Subject group type	Subject analysis set			
Number of subjects analysed	19 <sup>[2]</sup>			
Units: Patients				
DLT 1 : 10 mg	2			
DLT 2 : 15 mg	0			
DLT 3 : 20 mg	5			
DLT 4 : 25 mg	3			

Notes:

[2] - 10 patients with at least one DLT after cycle 1

## Statistical analyses

No statistical analyses for this end point

## Primary: Response rate

End point title	Response rate <sup>[3]</sup>
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End point description:

End point type	Primary
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End point timeframe:

At the end of induction (after 6 cycles)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: GALEN is a phase-II study. There was no statistical tests because no comparison have been made with an another group.

End point values	Cohort 1 : Relapsed/refractory aggressive patients	Cohort 2 : Relapsed/refractory follicular patients	Cohort 3 : Untreated follicular lymphoma	Cohorte 4
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	85	86	100	17
Units: percent				
number (confidence interval 95%)	36.5 (26.3 to 47.6)	79.1 (68.9 to 87.1)	92.0 (84.8 to 96.5)	100 (80.5 to 100)

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

from the date of informed consent signature to end of treatment evaluation (28 days after last drug administration)

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	25
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### Reporting groups

Reporting group title	Adverse event
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Reporting group description: -

Serious adverse events	Adverse event		
Total subjects affected by serious adverse events			
subjects affected / exposed	120 / 312 (38.46%)		
number of deaths (all causes)	99		
number of deaths resulting from adverse events	6		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm			
subjects affected / exposed	33 / 312 (10.58%)		
occurrences causally related to treatment / all	22 / 48		
deaths causally related to treatment / all	9 / 9		
Vascular disorders			
vascular disorder			
subjects affected / exposed	3 / 312 (0.96%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			
subjects affected / exposed	7 / 312 (2.24%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Immune system disorder			

subjects affected / exposed	3 / 312 (0.96%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
social circumstances			
subjects affected / exposed	1 / 312 (0.32%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Respiratory, thoracic and mediastinal disorders			
subjects affected / exposed	15 / 312 (4.81%)		
occurrences causally related to treatment / all	8 / 15		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Injury, poisoning and procedural complications			
subjects affected / exposed	20 / 312 (6.41%)		
occurrences causally related to treatment / all	5 / 20		
deaths causally related to treatment / all	1 / 1		
Cardiac disorders			
Cardiac disorder			
subjects affected / exposed	7 / 312 (2.24%)		
occurrences causally related to treatment / all	3 / 8		
deaths causally related to treatment / all	1 / 1		
Nervous system disorders			
nervous system disorder			
subjects affected / exposed	7 / 312 (2.24%)		
occurrences causally related to treatment / all	4 / 9		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
BLOOD AND LYMPHATIC SYSTEM DISORDERS			
subjects affected / exposed	9 / 312 (2.88%)		
occurrences causally related to treatment / all	7 / 9		
deaths causally related to treatment / all	1 / 1		

Gastrointestinal disorders GASTROINTESTINAL DISORDERS subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	  9 / 312 (2.88%) 2 / 14 0 / 0		
Hepatobiliary disorders hepatobiliary disorder subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	  3 / 312 (0.96%) 1 / 5 0 / 0		
Skin and subcutaneous tissue disorders Skin and subcutaneous tissue disorders subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	  4 / 312 (1.28%) 3 / 5 0 / 0		
Renal and urinary disorders renal and urinary disorders subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	  5 / 312 (1.60%) 2 / 5 0 / 0		
Endocrine disorders Endocrine disorder subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	  2 / 312 (0.64%) 1 / 2 0 / 0		
Musculoskeletal and connective tissue disorders MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	  4 / 312 (1.28%) 1 / 5 0 / 0		
Infections and infestations INFECTIOUS AND INFESTATIONS subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	  41 / 312 (13.14%) 22 / 49 2 / 5		

Metabolism and nutrition disorders			
metabolism and nutrition disorder			
subjects affected / exposed	4 / 312 (1.28%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

<b>Non-serious adverse events</b>	Adverse event		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	304 / 312 (97.44%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm			
subjects affected / exposed	18 / 312 (5.77%)		
occurrences (all)	18		
Vascular disorders			
Vascular disorder			
subjects affected / exposed	39 / 312 (12.50%)		
occurrences (all)	46		
Surgical and medical procedures			
surgical and medical procedures			
subjects affected / exposed	7 / 312 (2.24%)		
occurrences (all)	8		
General disorders and administration site conditions			
General disorders and administration site conditions			
subjects affected / exposed	204 / 312 (65.38%)		
occurrences (all)	372		
Immune system disorders			
Immune system disorder			
subjects affected / exposed	30 / 312 (9.62%)		
occurrences (all)	33		
Reproductive system and breast disorders			
reproductive system and breast disorders			
subjects affected / exposed	16 / 312 (5.13%)		
occurrences (all)	18		
Respiratory, thoracic and mediastinal			

disorders respratory, thoracic and mediastinal disorders subjects affected / exposed occurrences (all)	151 / 312 (48.40%) 274		
Psychiatric disorders psychiatric disorder subjects affected / exposed occurrences (all)	46 / 312 (14.74%) 55		
Investigations Investigations subjects affected / exposed occurrences (all)	85 / 312 (27.24%) 108		
Injury, poisoning and procedural complications injury, poisoning and procedural complications subjects affected / exposed occurrences (all)	65 / 312 (20.83%) 75		
Congenital, familial and genetic disorders congenital, familial and genetic disorders subjects affected / exposed occurrences (all)	1 / 312 (0.32%) 1		
Cardiac disorders Cardiac disorder subjects affected / exposed occurrences (all)	12 / 312 (3.85%) 14		
Nervous system disorders Nervous system disorder subjects affected / exposed occurrences (all)	113 / 312 (36.22%) 176		
Blood and lymphatic system disorders Blood and lymphatic system disorders subjects affected / exposed occurrences (all)	175 / 312 (56.09%) 542		
Ear and labyrinth disorders ear and labyrinth disorders subjects affected / exposed occurrences (all)	20 / 312 (6.41%) 22		

Eye disorders Eye disorder subjects affected / exposed occurrences (all)	25 / 312 (8.01%) 39		
Gastrointestinal disorders Gastrointestinal disorder subjects affected / exposed occurrences (all)	231 / 312 (74.04%) 337		
Hepatobiliary disorders Hepatobiliary disorders subjects affected / exposed occurrences (all)	11 / 312 (3.53%) 11		
Skin and subcutaneous tissue disorders skin and subcutaneous tissue disorders subjects affected / exposed occurrences (all)	148 / 312 (47.44%) 383		
Renal and urinary disorders Renal and urinary disorders subjects affected / exposed occurrences (all)	33 / 312 (10.58%) 37		
Endocrine disorders endocrine disorders subjects affected / exposed occurrences (all)	3 / 312 (0.96%) 3		
Musculoskeletal and connective tissue disorders musculoskeletal and connective tissue disorders subjects affected / exposed occurrences (all)	152 / 312 (48.72%) 297		
Infections and infestations infestations and infestations subjects affected / exposed occurrences (all)	203 / 312 (65.06%) 612		
Metabolism and nutrition disorders Metabolism and nutrition disorder subjects affected / exposed occurrences (all)	54 / 312 (17.31%) 62		





## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 October 2012	<p>1. Addition of an exclusion criterion : Patients with a history of PML cannot be included in the study. The exclusion criterion "Prior history of Progressive Multifocal Leukoencephalopathy (PML)" is added.</p> <p>- 2 Addition of a neurological examination during clinical examinations A neurological examination must be performed at every clinical examination, during the treatment and follow-up phases, in order to detect any neurological signs suggestive of neurological signs suggestive of potential PML.</p> <p>- 3 Indications on what to do if PML is suspected: symptoms, diagnosis, treatment with anti-CD20 drugs In the event of symptoms suggestive of PML, investigations should be carried out: consultation with a neurologist, brain MRI, testing for JC virus in cerebrospinal fluid, etc. cerebro-spinal fluid... Treatment with Rituximab or Obinutuzumab should be suspended during these investigations, and stopped permanently if the diagnosis of PML is confirmed.</p>
19 April 2013	<p>- For biological studies, the theoretical sampling time "C1J8 1h after end of infusion" has been changed to "C1J8 just after end of infusion".</p> <p>- Exclusion criterion 8 has been modified to include patients with a history of non-melanoma skin tumours (basal cell carcinoma or squamous cell carcinoma of the skin) or surgically removed carcinoma of any grade 0 (in situ) in phase I, which does not include maintenance treatment with lenalidomide.</p> <p>- Following recommendations made by the study's DSMC at the organizational meeting, an electrocardiogram was added to the list of tests to be performed during patient screening.</p> <p>- Certain clarifications have been made concerning the rules for reporting adverse events</p>

18 March 2014	<ul style="list-style-type: none"> <li>- The recommended lenalidomide dose of 20 mg for phase II has been added.</li> <li>- The doses of GA101 and lenalidomide for the two years of maintenance have been reformulated.</li> <li>- Corrections have been made to the abstract to reflect the content of the protocol (inclusion criteria, DLT definitions and prophylaxis).</li> <li>- AE and SAE deferrals have been added or clarified for each period. The NCI CTCAE version has been specified (version 4.03).</li> <li>- Following Roche's recommendations in a February DIL, prophylaxis treatments have been adapted. The dose of paracetamol is now 1000mg, and that of antihistamines such as diphenhydramine hydrochloride 100mg. Recommendations have been added for patients with pre-existing heart and lung disease. BSA calculation and B symptom collection were added to the baseline. It was specified that biological analyses could be performed.</li> <li>- During treatment, times for physical and neurological examinations and vital signs were clarified. Weight and BSA were collected only for assessments. CBC was maintained weekly for the 1st cycle, on the 1st day of each cycle for the induction period and at each visit for treatments during maintenance. All other CBCs were eliminated. Optional biological tests were added.</li> <li>- For assessments, appointment "windows" have been specified: for cycle 3 between I C3J21 and C3J28; for cycle 6 between C6J22 and C6J28. Assessments every 6 months during the maintenance period and in the event of premature discharge.- For assessments, only weight (without BSA) will be requested. PET scans are mandatory at the end of cycles 3 and 6 and at the end of treatment, but optional during maintenance.</li> <li>- During the maintenance period, it has been added that the PET scan is optional, bone marrow biopsy is compulsory every 6 months in the event of positive results at the previous assessment, response assessment must be carried out every 6 months as well as baseline assessments.- For biological studies, the theoretical sampling time "C1J8</li> </ul>
15 October 2014	<ul style="list-style-type: none"> <li>o study duration shortened due to earlier inclusion than initially estimated</li> <li>o contraception of women for 18 months after GA101 treatment</li> <li>o withdrawal of the planned 20-patient efficacy/safety analysis, since a DSMC is planned every 6 months.</li> <li>o updated GA101 data.</li> </ul>
19 January 2015	<p>The purpose of this amendment is to present GALEN's ancillary study: GALEN-IM. GALEN-IM is an exploratory, open-label, multicenter immunoPET ancillary study involving 30 GALEN patients with histologically confirmed CD20-positive follicular lymphoma. After signing specific information and consent documents, these patients will receive 0.6 MBq/kg (36-54 MBq) of 89Zr-obinutuzumab, in addition to the 1000 mg dose of obinutuzumab planned in the GALEN study, on Cycle 1 J8 and/or Cycle 2 J1. This administration will enable us to determine the tissue concentration of obinutuzumab in the tumor and in the main organs of interest, and to generate a PK model of obinutuzumab. Secondly, it will enable us to define patient radiation exposure, compare obinutuzumab concentration-time profiles in tumor and normal organs, correlate tissue and plasma PK with tumor burden, and evaluate the 89Zr-obinutuzumab uptake model.</p>
08 June 2015	<p>Addition of a cohort of 100 previously untreated follicular lymphoma patients. Addition of biological studies adapted to this new cohort of 100 patients with previously untreated follicular lymphoma.</p> <p>Addition of biological studies to search for correlations between transcriptomic profile (GCvs ABC) and response to treatment for patients with relapsed or refractory diffuse large relapsed or refractory diffuse large B-cell lymphoma (DLBCL) already included in the phase 2 aggressive lymphoma cohort.</p> <p>Update of the Pregnancy Prevention Plan linked to lenalidomide treatment.</p>
22 November 2016	<p>We would therefore like to complete the enrolment of cohort 3 without offering the GALEN-IM study to patients, to enable analysis of the 100 patients as planned in the protocol, and to add a cohort of 15 patients with 1st-line Follicular Lymphoma solely for the GALEN-IM study (cohort 4). These 15 patients will receive exactly the same treatment as the GALEN patients, with one or two additional doses of 89Zr-obinutuzumab. The data collected will meet the objectives of the GALEN-IM study alone, and will not be included in the analysis of the GALEN study.</p>

28 August 2017	<p>The changes mainly concern the ancillary immunoPET exploratory study. It was initially planned that each patient would receive 0.6 MBq/kg (36-54 MBq) of 89Zr-obinutuzumab, in addition to the GALEN dose.</p> <p>the 1000 mg dose of obinutuzumab planned in the GALEN study, on Cycle 1 D8 and/or Cycle Cycle 2 D1. The first 6 patients finally received a fixed dose of 37 MBq on Cycle 1 D8 and Cycle Cycle 2 J1; subsequent patients will receive the same dose.</p> <p>Analysis of the results obtained from the first six patients shows that immunoPET scans scans performed on Cycle 1 Day 8 appear to be more informative than those performed on Cycle 2 Day 1. The experts therefore decided, for the remaining 9 patients, to carry out a single injection of 89Zr-obinutuzumab at Cycle Cycle 1 Day 8.</p>
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Notes:

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## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported

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## Online references

<http://www.ncbi.nlm.nih.gov/pubmed/30291335>

<http://www.ncbi.nlm.nih.gov/pubmed/30068505>

<http://www.ncbi.nlm.nih.gov/pubmed/31296423>

<http://www.ncbi.nlm.nih.gov/pubmed/34936697>