Clinical trial results:
GOAL trial: Rescue treatment with the monoclonal anti CD20-antibody Obinutuzumab (GA101) in combination with PixantrOne for the treatment of patients with relapsed Aggressive B-cell Lymphoma

Summary

EudraCT number	2014-004780-21
Trial protocol	DE
Global end of trial date	02 January 2022

Results information

Result version number	v1 (current)
This version publication date	22 June 2023
First version publication date	22 June 2023

Trial information

Trial identification

Sponsor protocol code	ETN-1-GOAL

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University Medical Center of the Johannes Gutenberg
Sponsor organisation address	Langenbeckstr 2, Mainz, Germany, 55131
Public contact	Georg Hess, University Medical Center of the Johannes Gutenberg, 0049 6131175040, ruckes@izks-mainz.de
Scientific contact	Georg Hess, University Medical Center of the Johannes Gutenberg, 6131179919 6131175040, ruckes@izks-mainz.de

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	02 May 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 May 2021
Global end of trial reached?	Yes
Global end of trial date	02 January 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To evaluate the overall response rate (ORR) of the combination after completion or termination of trial treatment

Protection of trial subjects:

Ethics approval, authority approval

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 July 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 70
Worldwide total number of subjects	70
EEA total number of subjects	70

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)	19
From 65 to 84 years	50
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

70 patients were enrolled
68 patients were analyzed for efficacy and safety
60 patients were analyzed mITT (available tumor assessment)
42 patients were analyzed within GCB evaluation

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	70
Number of subjects completed	68

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Did not receive stdy medication: 2

Period 1

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

Blinding implementation details:

Not applicable, single-arm trial

Arms

Arm title	Obinutuzumab+Pixantrone

Arm description:

Patients received 1000 mg of Obinutuzumab on days 1, 8 and 15 (first cycle) or day 1 of any following cycle in combination with 50 mg/m2 Pixantrone on days 1, 8 and 15 of a 28-day cycle for up to six cycles.

Arm type	Experimental
Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	
Other name	Gazyvaro
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1000 mg of Obinutuzumab on days 1, 8 and 15 (first cycle) or day 1 of any following cycle

Investigational medicinal product name	Pixantrone
Investigational medicinal product code	
Other name	Pixuvri
Pharmaceutical forms	Infusion
Routes of administration	Infusion

Dosage and administration details:

50 mg/m2 Pixantrone on days 1, 8 and 15 of a 28-day cycle

Number of subjects in period 1[1]	Obinutuzumab+Pixantrone
Started	68
Completed	20
Not completed	48
Adverse event, serious fatal	3
Consent withdrawn by subject	2
Adverse event, non-fatal	10
Unspecified	2
Disease Progression	31

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Only the number of patients receiving study medication were analyzed.

Baseline characteristics

Reporting groups

Reporting group title	Treatment Period

Reporting group description: -

Reporting group values	Treatment Period	Total	
Number of subjects	68	68	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	70.49		
standard deviation	± 11.67	-	
Gender categorical Units: Subjects			
Female	37	37	
Male	31	31	
Current Lymphoma Stage Units: Subjects			
Stage I	8	8	
Stage II	13	13	
Stage III	14	14	
Stage IV	32	32	
Missing	1	1	
Histologically proven type of lymphoma Units: Subjects			
Diffuse large B-cell lymphoma	49	49	
Follicular lymphoma grade IIIB	1	1	
Follicular lymphoma grade IIIA	3	3	
Follicular lymphoma grade II	3	3	
Follicular lymphoma grade I	4	4	
Other	8	8	
Histologically proven type of lymphoma			
Histologically proven type of lymphoma at screening			
Units: Subjects			
Diffeuse large B-cell lymphoma	52	52	
Follicular lymphoma grade IIIB	2	2	

Transformed to DLBCL	8	8	
Transformed to FL3B	1	1	
Transformed to burkitt-like lymphoma	1	1	
Other	4	4	
Prior lymphoma treatment - chemotherapies Units: Subjects			
=1	19	19	
=2	27	27	
=3	13	13	
>3	9	9	
Prior lymphoma treatment - antibodies Units: Subjects			
=1	16	16	
=2	17	17	
>2	35	35	
Prior lymphoma treatment - novel agents Units: Subjects			
None	64	64	
=1	4	4	
Prior lymphoma treatment - consolidation Units: Subjects			
None	56	56	
=1	11	11	
=2	1	1	
Best response to most recent prior therapy Units: Subjects			
CR	14	14	
CRu	1	1	
PR	14	14	
SD	3	3	
PD	31	31	
Discontinued	2	2	
Unknown	3	3	

End points

End points reporting groups

Reporting group title	Obinutuzumab+Pixantrone

Reporting group description:

Patients received 1000 mg of Obinutuzumab on days 1, 8 and 15 (first cycle) or day 1 of any following cycle in combination with 50 mg/m2 Pixantrone on days 1, 8 and 15 of a 28-day cycle for up to six cycles.

Subject analysis set title	GEP-profiling
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects who took part in the gene expression profiling (GEP).
Recent gene expression profiling studies supported the view that DLBCL is heterogeneous, as two major molecular
DLBCL subtypes, termed germinal center B-cell-like (GCB) DLBCL and activated B-cell-like (ABC) DLBCL, could be distinguished.

Primary: Objective Response Rate

End point title	Objective Response Rate[1]

End point description:

End point type	Primary

End point timeframe:

44 weeks

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: This is only a single arm trial.

End point values	Obinutuzumab +Pixantrone	GEP-profiling		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	68	42		
Units: Patients				
Response	24	13		
Non-response	36	29		
Not recorded	8	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free survival

End point title	Progression-free survival

End point description:

Time from first medication intake to first documentation of objective tumor progression or to death due to any cause, whichever occurs first.

End point type	Secondary

End point timeframe:

44 months

End point values	Obinutuzumab +Pixantrone			
Subject group type	Reporting group			
Number of subjects analysed	68			
Units: months				
median (confidence interval 95%)	2.8 (2.0 to 6.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival

End point title	Overall Survival

End point description:

End point type	Secondary

End point timeframe:

44 months

End point values	Obinutuzumab +Pixantrone			
Subject group type	Reporting group			
Number of subjects analysed	68			
Units: months				
median (confidence interval 95%)	8.0 (4.8 to 12.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free survival GCB

End point title	Progression-free survival GCB

End point description:

Progression-free survival for the GCB cohort

End point type	Secondary

End point timeframe:

44 months

End point values	GEP-profiling			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: month				
median (confidence interval 95%)	1.8 (1.0 to 6.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free survival non-GCB

End point title	Progression-free survival non-GCB

End point description:

End point type	Secondary

End point timeframe:

44 months

End point values	GEP-profiling			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: month				
median (confidence interval 95%)	6.5 (2.3 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival GCB

End point title	Overall Survival GCB

End point description:

End point type	Secondary

End point timeframe:

44 months

End point values	GEP-profiling			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: month				
median (confidence interval 95%)	5.2 (1.8 to 10.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival non-GCB

End point title	Overall Survival non-GCB

End point description:

End point type	Secondary

End point timeframe:

44 months

End point values	GEP-profiling			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: month				
median (confidence interval 95%)	99 (7.2 to 999)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

24 weeks (6 treatment cycles)

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups

Reporting group title	Obinutuzumab+Pixantrone

Reporting group description: -

Serious adverse events	Obinutuzumab+Pixantrone		
Total subjects affected by serious adverse events			
subjects affected / exposed	58 / 68 (85.29%)		
number of deaths (all causes)	45		
number of deaths resulting from adverse events	16		
Investigations			
Amylase decreased			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Lipase increased			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neutrophil count decreased			
subjects affected / exposed	2 / 68 (2.94%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Platelet count decreased			

subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
White blood cell count decreased			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	2 / 68 (2.94%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	1 / 1		
Lung neoplasm malignant			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Non-Hodgkin's lymphoma			
subjects affected / exposed	7 / 68 (10.29%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 7		
Injury, poisoning and procedural complications			
Ulna fracture			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Bicytopenia			

subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				
subjects affected / exposed	3 / 68 (4.41%)			
occurrences causally related to treatment / all	1 / 4			
deaths causally related to treatment / all	0 / 0			
Granulocytopenia				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Leukopenia				
subjects affected / exposed	22 / 68 (32.35%)			
occurrences causally related to treatment / all	1 / 29			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	31 / 68 (45.59%)			
occurrences causally related to treatment / all	1 / 37			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	8 / 68 (11.76%)			
occurrences causally related to treatment / all	1 / 12			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Disease progression				
subjects affected / exposed	4 / 68 (5.88%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 4			
Fatigue				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				

subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malaise			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	3 / 68 (4.41%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Subileus			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			

Erysipelas			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Escherichia sepsis			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	3 / 68 (4.41%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 1		
Influenza			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pharyngitis			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	6 / 68 (8.82%)		
occurrences causally related to treatment / all	1 / 6		
deaths causally related to treatment / all	0 / 1		
Sepsis			
subjects affected / exposed	2 / 68 (2.94%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 1		
Urinary tract infection			

subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Obinutuzumab+Pixantrone		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	68 / 68 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Non-Hodgkin's lymphoma			
subjects affected / exposed	7 / 68 (10.29%)		
occurrences (all)	7		
Vascular disorders			
Hypertension			
subjects affected / exposed	5 / 68 (7.35%)		
occurrences (all)	5		
Hypotension			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	4		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	19 / 68 (27.94%)		
occurrences (all)	22		
General physical health deterioration			

subjects affected / exposed	5 / 68 (7.35%)		
occurrences (all)	5		
Oedema peripheral			
subjects affected / exposed	9 / 68 (13.24%)		
occurrences (all)	14		
Pain			
subjects affected / exposed	6 / 68 (8.82%)		
occurrences (all)	7		
Pyrexia			
subjects affected / exposed	8 / 68 (11.76%)		
occurrences (all)	8		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	10 / 68 (14.71%)		
occurrences (all)	11		
Dysphonia			
subjects affected / exposed	5 / 68 (7.35%)		
occurrences (all)	5		
Dyspnoea			
subjects affected / exposed	12 / 68 (17.65%)		
occurrences (all)	14		
Oropharyngeal pain			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	4		
Pleural effusion			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	4		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	4		
Investigations			
Blood creatine increased			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	5		
Gamma-glutamyltransferase increased			

subjects affected / exposed	5 / 68 (7.35%)		
occurrences (all)	11		
Neutrophil count decreased			
subjects affected / exposed	14 / 68 (20.59%)		
occurrences (all)	45		
Platelet count decreased			
subjects affected / exposed	6 / 68 (8.82%)		
occurrences (all)	11		
Troponin I increased			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	4		
Weight decreased			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	4		
White blood cell count decreased			
subjects affected / exposed	13 / 68 (19.12%)		
occurrences (all)	48		
Cardiac disorders			
Tachycardia			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	5		
Nervous system disorders			
Polyneuropathy			
subjects affected / exposed	5 / 68 (7.35%)		
occurrences (all)	6		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	17 / 68 (25.00%)		
occurrences (all)	29		
Leukopenia			
subjects affected / exposed	46 / 68 (67.65%)		
occurrences (all)	86		
Neutropenia			
subjects affected / exposed	46 / 68 (67.65%)		
occurrences (all)	93		
Thrombocytopenia			

subjects affected / exposed	15 / 68 (22.06%)		
occurrences (all)	34		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	5		
Constipation			
subjects affected / exposed	12 / 68 (17.65%)		
occurrences (all)	13		
Diarrhoea			
subjects affected / exposed	15 / 68 (22.06%)		
occurrences (all)	15		
Nausea			
subjects affected / exposed	14 / 68 (20.59%)		
occurrences (all)	24		
Stomatitis			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	6		
Vomiting			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	6		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	12 / 68 (17.65%)		
occurrences (all)	12		
Pruritus			
subjects affected / exposed	5 / 68 (7.35%)		
occurrences (all)	5		
Rash			
subjects affected / exposed	7 / 68 (10.29%)		
occurrences (all)	9		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 68 (7.35%)		
occurrences (all)	5		
Muscle spasms			

subjects affected / exposed	5 / 68 (7.35%)		
occurrences (all)	6		
Pain in extremity			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	4		
Infections and infestations			
Infection			
subjects affected / exposed	6 / 68 (8.82%)		
occurrences (all)	6		
Nasopharyngitis			
subjects affected / exposed	5 / 68 (7.35%)		
occurrences (all)	5		
Oral herpes			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	4		
Pneumonia			
subjects affected / exposed	6 / 68 (8.82%)		
occurrences (all)	6		
Sinusitis			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	4		
Urinary tract infection			
subjects affected / exposed	7 / 68 (10.29%)		
occurrences (all)	11		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	4		
Hypokalaemia			
subjects affected / exposed	5 / 68 (7.35%)		
occurrences (all)	7		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 June 2016	- Inclusion criteria: Removal of CD20 positive disease. - Inclusion criteria: Change from "LVEF>= 45% and normal serum troponin" to "-Adequate cardiac reserve: Serum Troponin level must be consistent with no significant acute or chronic myocardial damage and there should be no evidence of symptomatic". - Clarification of reconstitution process of Pixantrone. - Addition of frequently observed adverse drug reactions of Obinutuzumab and Pixantrone. - Reference to IB-Addendum Number 1, March 2016 of Obinutuzumab concerning precautions for patients considered at risk for Tumor Lysis Syndrome was added. - Observation period for concomitant treatments and adverse events prolonged to 42 days after last administration of trial medication or until the start of a new antineoplastic therapy. - Minor typographic and editorial corrections or clarifications.
06 November 2017	- Change of manufacturer of Pixantrone. - Addition of frequently observed adverse drug reactions of Obinutuzumab and Pixantrone. - Addition of documentation and reporting of special situations. - Minor typographic and editorial corrections or clarifications.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported