Clinical trial results:
An open-labeled, randomized, two-dose, parallel group trial of ofatumumab, a fully human monoclonal anti-CD20 antibody, in combination with CHOP, in patients with previously untreated Follicular Lymphoma

Summary

EudraCT number	2007-000244-27
Trial protocol	DE DK SE CZ
Global end of trial date	09 January 2014

Results information

Result version number	v1 (current)
This version publication date	02 May 2016
First version publication date	14 March 2015

Trial information

Trial identification

Sponsor protocol code	Hx-CD20-409

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,

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	07 February 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 January 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the efficacy in two dose regimens of ofatumumab in combination with CHOP in previously untreated patients with FL.

Protection of trial subjects:

Not Applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 June 2007
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	60 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 59
Worldwide total number of subjects	59
EEA total number of subjects	0

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)	49
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants (par.) were randomized to one of two ofatumumab dose treatment groups as soon as the participant was evaluated and considered eligible for the study. A total of 59 par. were randomized and 58 par. entered the treatment period. The 58 par. are represented in the Subject disposition and Baseline characteristics sections of this summary.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	500 mg Ofatumumab + CHOP

Arm description:

Ofatumumab was given on Day 1 and CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) on Day 3 of each 21-day cycle, with 300 milligrams (mg) in Cycle 1 and 500 mg in Cycles 2 to 6. Participants were followed up for 15 weeks during the Treatment period; then every 3 months for 24 months in the Follow-up period; then every 6 months until Month 60 or withdrawal from the study.

Arm type	Experimental
Investigational medicinal product name	Ofatumumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

During the treatment period each patient will receive a total of 6 infusions of ofatumumab in combination with CHOP every 3 weeks. The first infusion in both arms will be 300 mg, followed by 5 infusions of 500 or 1000 mg.

Investigational medicinal product name	cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

750 mg/m2 iv x 1 for one day 24-48 hrs post-ofatumumab infusion started

Investigational medicinal product name	doxorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

50 mg/m2 iv x 1 for one day 24-48 hrs post-ofatumumab infusion started

Investigational medicinal product name	vincristine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion

Routes of administration	Intravenous use

Dosage and administration details:

1.4 mg/m2 iv (to a maximum of 2mg) x 1 for one day 24-48 hrs post-ofatumumab infusion started

Investigational medicinal product name	prednisolone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg p.o. x 1 daily for 5 days 24-48 hrs post-ofatumumab infusion started

Arm title	1000 mg Ofatumumab + CHOP

Arm description:

Ofatumumab was given on Day 1 and CHOP on Day 3 of each 21-day cycle, with 300 mg in Cycle 1 and 1000 mg in Cycles 2 to 6. Participants were followed up for 15 weeks during the Treatment period; then every 3 months for 24 months in the Follow-up period; then every 6 months until Month 60 or withdrawal from the study.

Arm type	Experimental
Investigational medicinal product name	Ofatumumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

During the treatment period each patient will receive a total of 6 infusions of ofatumumab in combination with CHOP every 3 weeks. The first infusion in both arms will be 300 mg, followed by 5 infusions of 500 or 1000 mg.

Investigational medicinal product name	cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

750 mg/m2 iv x 1 for one day 24-48 hrs post-ofatumumab infusion started

Investigational medicinal product name	doxorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

50 mg/m2 iv x 1 for one day 24-48 hrs post-ofatumumab infusion started

Investigational medicinal product name	vincristine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

1.4 mg/m2 iv (to a maximum of 2mg) x 1 for one day 24-48 hrs post-ofatumumab infusion started

Investigational medicinal product name	prednisolone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg p.o. x 1 daily for 5 days 24-48 hrs post-ofatumumab infusion started

Number of subjects in period 1[1]	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP
Started	29	29
Completed	18	17
Not completed	11	12
Progression of Study Disease	7	8
Insurance Issues	-	1
Adverse event, non-fatal	1	-
Residual Tumour Mass	-	1
Non-compliance	1	-
New Treatment	2	2

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: Baseline characteristics were collected in the Full Analysis Set (FAS), comprised of all participants who were exposed to trial drug irrespective of their compliance to the planned course of treatment. One participant was enrolled and randomized to receive 1000 mg Ofatumumab + CHOP, but withdrew prior to initiation of therapy.

Baseline characteristics

Reporting groups	
Reporting group title	500 mg Ofatumumab + CHOP
Reporting group description:	
Ofatumumab was given on Day 1 and CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) on Day 3 of each 21-day cycle, with 300 milligrams (mg) in Cycle 1 and 500 mg in Cycles 2 to 6. Participants were followed up for 15 weeks during the Treatment period; then every 3 months for 24 months in the Follow-up period; then every 6 months until Month 60 or withdrawal from the study.	
Reporting group title	1000 mg Ofatumumab + CHOP
Reporting group description:	
Ofatumumab was given on Day 1 and CHOP on Day 3 of each 21-day cycle, with 300 mg in Cycle 1 and 1000 mg in Cycles 2 to 6. Participants were followed up for 15 weeks during the Treatment period; then every 3 months for 24 months in the Follow-up period; then every 6 months until Month 60 or withdrawal from the study.	

Reporting group values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP	Total
Number of subjects	29	29	58
Age categorical Units: Subjects			
Age continuous			
Baseline characteristics were collected in the Full Analysis Set (FAS), comprised of all participants who were exposed to trial drug irrespective of their compliance to the planned course of treatment. One participant was enrolled and randomized to receive 1000 mg Ofatumumab + CHOP, but withdrew prior to initiation of therapy. The age was recorded as missing for 1 participant; therefore, this participant is not included in the "Subjects enrolled per age group" section.			
Units: years			
arithmetic mean	54.1	53.7	
standard deviation	± 11.4	± 9.14	-
Gender categorical Units: Subjects			
Female	14	21	35
Male	15	8	23
Race Units: Subjects			
White	29	27	56
Hispanic or Latino	0	2	2

End points

End points reporting groups

Reporting group title	500 mg Ofatumumab + CHOP

Reporting group description:

Ofatumumab was given on Day 1 and CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) on Day 3 of each 21-day cycle, with 300 milligrams (mg) in Cycle 1 and 500 mg in Cycles 2 to 6. Participants were followed up for 15 weeks during the Treatment period; then every 3 months for 24 months in the Follow-up period; then every 6 months until Month 60 or withdrawal from the study.

Reporting group title	1000 mg Ofatumumab + CHOP

Reporting group description:

Ofatumumab was given on Day 1 and CHOP on Day 3 of each 21-day cycle, with 300 mg in Cycle 1 and 1000 mg in Cycles 2 to 6. Participants were followed up for 15 weeks during the Treatment period; then every 3 months for 24 months in the Follow-up period; then every 6 months until Month 60 or withdrawal from the study.

Primary: Number of participants with the indicated overall best response (OBR) at Visit 26 (3 months after the last infusion of Ofatumumab)

End point title	Number of participants with the indicated overall best response (OBR) at Visit 26 (3 months after the last infusion of Ofatumumab)[1]

End point description:

Based on standardized response criteria for NHL, responders included participants with CR (complete disappearance of all detectable clinical and radiographic evidence of disease), CRu (more than a 75% decrease in LN size compared to baseline), and PR (>=50% decrease in LN size and evidence of new lesions). Non-responders included participants with stable disease (SD; <50% decrease in LN size from baseline) and progressive disease (PD; >=50% increase in LN size and evidence of new lesions).

End point type	Primary

End point timeframe:

Maximum of 23 months after the start 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: Statistical analysis is not available for this primary endpoint.

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[2]	29[3]		
Units: Participants				
Responder, CR	6	9		
Responder, CRu	10	7		
Responder, PR	10	13		
Non-Responder, SD	2	0		
Non-Responder, PD	1	0		

Notes:

[2] - FAS

[3] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with complete remission (CR) at Visit 26

End point title	Number of participants with complete remission (CR) at Visit 26

End point description:

Participants were evaluated for response by an Independent Endpoint Review Committee in accordance with the standardized response criteria for NHL. Participants with CR were defined as those with the complete disappearance of all detectable clinical and radiographic evidence of disease.

End point type	Secondary

End point timeframe:

Maximum of 23 months after the start of treatment

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[4]	29[5]		
Units: Participants	6	9		

Notes:

[4] - FAS

[5] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: Median percent change from Visit 1 (Screening, Week -2) in tumor size at Visit 33 (24 months after the last infusion of Ofatumumab)

End point title	Median percent change from Visit 1 (Screening, Week -2) in tumor size at Visit 33 (24 months after the last infusion of Ofatumumab)

End point description:

The tumor size for a participant was computed as the sum of product of diameters (SPD) for the indicator lesions. Reduction in tumor size was calculated as percent change from Visit 1 until Visit 33, separately by radiologist 1 and radiologist 2. Percent change from Visit 1 (Screening, Week -2) = (value at Visit 33 minus value at Visit 1 divided by value at Visit 1) * 100.

End point type	Secondary

End point timeframe:

Maximum of 24 months after the last infusion of Ofatumumab (Visit 33; median of 33.8 months)

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17[6]	16[7]		
Units: Percent change in tumor size				
median (full range (min-max))				
Radiologist 1	-100 (-100 to 17)	-100 (-100 to -80)		

Radiologist 2	-100 (-100 to -25)	-100 (-100 to -79)		

Notes:

[6] - FAS. Participants were withdrawn from the study between Visits 1 and 33.

[7] - FAS. Participants were withdrawn from the study between Visits 1 and 33.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response

End point title	Duration of response

End point description:

The duration of response is defined as the time from the initial response (the first visit at which response was observed) to progression or death. There were too few events for the upper limit of the CI to be estimated (system value of 99999 = NA for upper limit of the 95% CI).

End point type	Secondary

End point timeframe:

Followed up to 5 years

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26[8]	29[9]		
Units: months				
median (confidence interval 95%)	21 (13.3 to 26.2)	25 (13.7 to 99999)		

Notes:

[8] - FAS. Only those participants with a response were analyzed.

[9] - FAS. Only those participants with a response were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS)

End point title	Progression-Free Survival (PFS)

End point description:

PFS is defined as the time from randomization until progression or death. There were too few events for the median and upper limit of the CI to be estimated (system value of 99999 = NA for the median and the upper limit of the 95% CI).

End point type	Secondary

End point timeframe:

Followed up to 5 years

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[10]	29[11]		
Units: months				
median (confidence interval 95%)	27.6 (15.1 to 28.3)	99999 (21.3 to 99999)		

Notes:

[10] - FAS

[11] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: Time to new anti-follicular lymphoma (FL) therapy

End point title	Time to new anti-follicular lymphoma (FL) therapy

End point description:

Time to new FL therapy is defined as the time from randomization until the time of first administration of the new FL therapy other than ofatumumab. Time to new FL therapy will be censored if participants are lost to follow-up. The censoring date in such cases will be the date of the last attended visit at which the endpoint was assessed. There were too few participants; therefore, the upper limit of the CI could not be estimated for the 500 mg Ofatumumab + CHOP treatment and because there were too few participants the median and the upper limit of the CI could not be estimated for the 1000 mg Ofatumumab + CHOP treatment (system value of 99999 = NA).

End point type	Secondary

End point timeframe:

Followed up to 5 years

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[12]	29[13]		
Units: months				
median (confidence interval 95%)	47.2 (30.4 to 99999)	99999 (32.2 to 99999)		

Notes:

[12] - FAS

[13] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: Percent change from Visit 1 (Screening) in peripheral CD19+ and CD20+ cell counts at Visit 33 (24 months after the last infusion of Ofatumumab)

End point title	Percent change from Visit 1 (Screening) in peripheral CD19+ and CD20+ cell counts at Visit 33 (24 months after the last infusion of Ofatumumab)

End point description:

The peripheral blood for each participant was collected and analyzed for CD19+ and CD20+ cell counts. CD19+ and CD20+ are B-cell types which are used as an index of a participant's response to treatment.

End point type	Secondary

End point timeframe:

Maximum of 24 months after the last infusion of Ofatumumab (Visit 33; median of 33.8 months)

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17[14]	16[15]		
Units: Percent change in cell counts				
median (full range (min-max))				
CD19+	154.1 (-95 to 748)	307.9 (-51 to 1767)		
CD20+	154.1 (-95 to 520)	307.9 (-51 to 1767)		

Notes:

[14] - FAS. Only those participants who provided samples at Visit 33 were analyzed.

[15] - FAS. Only those participants who provided samples at Visit 33 were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants who experienced any adverse event (AEs) from first treatment to Visit 33 (24 months after last infusion)

End point title	Number of participants who experienced any adverse event (AEs) from first treatment to Visit 33 (24 months after last infusion)

End point description:

An adverse event is defined as any untoward medical occurrence in a participant administered a pharmaceutical product and which did not necessarily have a causal relationship with the treatment. A list of AEs experienced in the study with a frequency threshold of 5% can be found in the AE section.

End point type	Secondary

End point timeframe:

Up to 22 months after study start

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[16]	29[17]		
Units: Participants	29	29		

Notes:

[16] - FAS

[17] - FAS

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with positive human anti-human antibodies (HAHA) at Visits 1, 28, and 33

End point title	Number of participants with positive human anti-human antibodies (HAHA) at Visits 1, 28, and 33

End point description:

HAHA are indicators of immunogenicity to ofatumumab. Blood samples were drawn from participants at Visits 1, 28, and 33 for analysis of HAHA.

End point type	Secondary

End point timeframe:

Visits 1 (Screening), 28 (9 months after last dose), and 33 (24 months after last dose)

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[18]	29[19]		
Units: Participants				
Visit 1, n=29, 29	0	0		
Visit 28, n=18, 21	0	0		
Visit 33, n=16, 16	0	0		

Notes:

[18] - FAS. Particiapants dropped out of the study as the study progressed.

[19] - FAS. Particiapants dropped out of the study as the study progressed.

Statistical analyses

No statistical analyses for this end point

Secondary: Median percent change from Visit 1 (Screening) in serum complement (CH50) levels at Visit 22

End point title	Median percent change from Visit 1 (Screening) in serum complement (CH50) levels at Visit 22

End point description:

The peripheral blood for each participant was collected and analyzed for serum complement CH50 levels. Cluster of Differentiation index 50 (CD50) is a human gene which is used as an index of immune response. CD50Percent change from Visit 1 (Screening, Week -2) = (value at Visit 22 minus value at Visit 1 divided by value at Visit 1) * 100.

End point type	Secondary

End point timeframe:

Visit 1 (Screening, Week -2) and Visit 22 (Week 15)

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24[20]	28[21]		
Units: Percent change in serum complement CH50				
median (full range (min-max))	42 (-36 to 450)	23.2 (-55 to 620)		

Notes:

[20] - FAS. Only those participants who remained in the study at Visit 22 were analyzed.

[21] - FAS. Only those participants who remained in the study at Visit 22 were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax and Ctrough at the sixth infusion (Week 15, Visit 22)

End point title	Cmax and Ctrough at the sixth infusion (Week 15, Visit 22)

End point description:

Cmax is defined as the maximum concentration of drug in plasma samples. Ctrough is defined as the trough plasma concentration (measured concentration at the end of a dosing interval [taken directly before next administration]).

End point type	Secondary

End point timeframe:

Week 15 (Visit 22)

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26[22]	29[23]		
Units: milligrams per liter (mg/L)				
geometric mean (geometric coefficient of variation)				
Cmax	232 (± 0.25)	497 (± 0.26)		
Ctrough	78.5 (± 0.5)	188 (± 0.47)		

Notes:

[22] - FAS. Data were provided for the number of participants who had a value.

[23] - FAS. Data were provided for the number of participants who had a value.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-inf) and AUC(0-504) after the sixth infusion (Week 15, Visit 22)

End point title	AUC(0-inf) and AUC(0-504) after the sixth infusion (Week 15, Visit 22)

End point description:

AUC is defined as the area under the ofatumumab concentration-time curve as a measure of drug exposure. AUC(0-504) is AUC from the start of infusion to 504 hours after the start of the infusion; AUC(0-inf) is AUC from the start of infusion extrapolated to infinity.

End point type	Secondary

End point timeframe:

Week 15 (Visit 22)

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25[24]	29[25]		
Units: Milligrams * hours/liter (mg.h/L)				
geometric mean (geometric coefficient of variation)				
AUC(0-inf), n=20, 28	177133 (± 0.41)	399676 (± 0.47)		
AUC(0-504), n=24, 28	79500 (± 0.26)	168866 (± 0.33)		

Notes:

[24] - FAS. Data were provided for the number of participants for whom the parameter could be calculated.
[25] - FAS. Data were provided for the number of participants for whom the parameter could be calculated.

Statistical analyses

No statistical analyses for this end point

Secondary: Half life (t1/2) of ofatumumab at the sixth infusion (Week 15, Visit 22)

End point title	Half life (t1/2) of ofatumumab at the sixth infusion (Week 15, Visit 22)

End point description:

Half life is defined as the period of time required for the amount of drug in the body to be reduced by half.

End point type	Secondary

End point timeframe:

Week 15 (Visit 22)

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23[26]	29[27]		
Units: Hours				
geometric mean (geometric coefficient of variation)	652 (± 0.57)	644 (± 0.32)		

Notes:

[26] - FAS. Data provided for participants attending each visit for whom the parameter could be calculated.
[27] - FAS. Data provided for participants attending each visit for whom the parameter could be calculated.

Statistical analyses

No statistical analyses for this end point

Secondary: CL after the sixth infusion (Week 15, Visit 22)

End point title	CL after the sixth infusion (Week 15, Visit 22)

End point description:

CL is the clearance of drug from plasma, which is defined as the volume of plasma from which the drug is cleared per unit time.

End point type	Secondary

End point timeframe:

Week 15 (Visit 22)

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26[28]	29[29]		
Units: Milliliters per hour (mL/h)				
geometric mean (geometric coefficient of variation)	6.29 (± 0.26)	5.92 (± 0.33)		

Notes:

[28] - FAS. Data provided for participants attending each visit for whom the parameter could be calculated.
[29] - FAS. Data provided for participants attending each visit for whom the parameter could be calculated.

Statistical analyses

No statistical analyses for this end point

Secondary: Vss at the sixth infusion (Week 15, Visit 22)

End point title	Vss at the sixth infusion (Week 15, Visit 22)

End point description:

Vss is defined as the volume of distribution at steady state of ofatumumab.

End point type	Secondary

End point timeframe:

Week 15 (Visit 22)

End point values	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23[30]	29[31]		
Units: Liters				
geometric mean (geometric coefficient of variation)	5.15 (± 0.34)	5.32 (± 0.38)		

Notes:

[30] - FAS. Data provided for participants attending each visit for whom the parameter could be calculated.
[31] - FAS. Data provided for participants attending each visit for whom the parameter could be calculated.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Non-serious adverse events (AEs) were collected from the start of study medication until Follow-up (up to 24 months after last treatment). Serious AEs were collected from the start of study medication until study completion (up to 60 months).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups

Reporting group title	500 mg Ofatumumab + CHOP

Reporting group description:

Ofatumumab was given on Day 1 and CHOP on Day 3 of each 21-day cycle, with 300 mg in Cycle 1 and 500 mg in Cycles 2 to 6. Participants were followed up for 15 weeks during the Treatment period; then every 3 months for 24 months in the Follow-up period; then every 6 months until Month 60 or withdrawal from the study.

Reporting group title	1000 mg Ofatumumab + CHOP

Reporting group description:

Ofatumumab was given on Day 1 and CHOP on Day 3 of each 21-day cycle, with 300 mg in Cycle 1 and 1000 mg in Cycles 2 to 6. Participants were followed up for 15 weeks during the Treatment period; then every 3 months for 24 months in the Follow-up period; then every 6 months until Month 60 or withdrawal from the study.

Reporting group title	500 mg Ofatumumab + CHOP: Extended Follow-up

Reporting group description:

Ofatumumab was given on Day 1 and CHOP on Day 3 of each 21-day cycle, with 300 mg in Cycle 1 and 500 mg in Cycles 2 to 6. Participants were followed up for 15 weeks during the Treatment period; then every 3 months for 24 months in the Follow-up period; then every 6 months until Month 60 or withdrawal from the study.

Reporting group title	1000 mg Ofatumumab + CHOP: Extended Follow-up

Reporting group description:

Ofatumumab was given on Day 1 and CHOP on Day 3 of each 21-day cycle, with 300 mg in Cycle 1 and 1000 mg in Cycles 2 to 6. Participants were followed up for 15 weeks during the Treatment period; then every 3 months for 24 months in the Follow-up period; then every 6 months until Month 60 or withdrawal from the study.

Serious adverse events	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP	500 mg Ofatumumab + CHOP: Extended Follow-up
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 29 (44.83%)	11 / 29 (37.93%)	1 / 29 (3.45%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			

subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulval cancer			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Infarction (CNS)			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Ileostomy			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 29 (6.90%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	1 / 29 (3.45%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injection site extravasation			
subjects affected / exposed	1 / 29 (3.45%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 29 (3.45%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytokine release syndrome			
subjects affected / exposed	1 / 29 (3.45%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Weight decreased			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fibula fracture			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Migraine			

subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	5 / 29 (17.24%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 14	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	4 / 29 (13.79%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	2 / 11	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	2 / 29 (6.90%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	1 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			

subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abnorminal hernia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Precancerous skin lesion			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rosacea			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Periostitis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Candidiasis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lung infection			
subjects affected / exposed	1 / 29 (3.45%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 29 (3.45%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	1000 mg Ofatumumab + CHOP: Extended Follow-up		
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 29 (20.69%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian cancer			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			

subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vulval cancer			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Infarction (CNS)			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Ileostomy			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Disease progression			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injection site extravasation			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Hypersensitivity			

subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cytokine release syndrome			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Weight decreased			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fibula fracture			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meniscus injury			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Migraine			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Presyncope			

subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestinal perforation			

subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abnorminal hernia				
subjects affected / exposed	2 / 29 (6.90%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Precancerous skin lesion				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rosacea				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Periostitis				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				
subjects affected / exposed	1 / 29 (3.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Candidiasis				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung infection				
subjects affected / exposed	0 / 29 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Alanine aminotransferase increased			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erysipelas			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	500 mg Ofatumumab + CHOP	1000 mg Ofatumumab + CHOP	500 mg Ofatumumab + CHOP: Extended Follow-up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 29 (100.00%)	28 / 29 (96.55%)	0 / 29 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			
subjects affected / exposed	0 / 29 (0.00%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Vascular disorders			
Flushing			
subjects affected / exposed	1 / 29 (3.45%)	6 / 29 (20.69%)	0 / 29 (0.00%)
occurrences (all)	1	6	0
Hot flush			
subjects affected / exposed	2 / 29 (6.90%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences (all)	2	1	0
Hypertension			
subjects affected / exposed	0 / 29 (0.00%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	0	3	0
Haematoma			

subjects affected / exposed	2 / 29 (6.90%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences (all)	2	0	0
Phlebitis			
subjects affected / exposed	0 / 29 (0.00%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	13 / 29 (44.83%)	13 / 29 (44.83%)	0 / 29 (0.00%)
occurrences (all)	23	17	0
Infusion related reaction			
subjects affected / exposed	7 / 29 (24.14%)	8 / 29 (27.59%)	0 / 29 (0.00%)
occurrences (all)	13	10	0
Oedema peripheral			
subjects affected / exposed	7 / 29 (24.14%)	6 / 29 (20.69%)	0 / 29 (0.00%)
occurrences (all)	8	10	0
Pyrexia			
subjects affected / exposed	5 / 29 (17.24%)	8 / 29 (27.59%)	0 / 29 (0.00%)
occurrences (all)	6	10	0
Oedema			
subjects affected / exposed	3 / 29 (10.34%)	5 / 29 (17.24%)	0 / 29 (0.00%)
occurrences (all)	5	5	0
Chills			
subjects affected / exposed	3 / 29 (10.34%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	4	3	0
Asthenia			
subjects affected / exposed	2 / 29 (6.90%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	3	3	0
Pain			
subjects affected / exposed	2 / 29 (6.90%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	3	3	0
Mucosal inflammation			
subjects affected / exposed	2 / 29 (6.90%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	2	2	0
Chest Pain			

subjects affected / exposed	1 / 29 (3.45%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	1	2	0
Influenza like illness			
subjects affected / exposed	0 / 29 (0.00%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Abdominal distension			
subjects affected / exposed	3 / 29 (10.34%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	3	2	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	6 / 29 (20.69%)	7 / 29 (24.14%)	0 / 29 (0.00%)
occurrences (all)	6	9	0
Oropharyngeal pain			
subjects affected / exposed	8 / 29 (27.59%)	5 / 29 (17.24%)	0 / 29 (0.00%)
occurrences (all)	14	6	0
Nasal congestion			
subjects affected / exposed	2 / 29 (6.90%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	2	3	0
Nasal disorder			
subjects affected / exposed	2 / 29 (6.90%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	4	2	0
Throat irritation			
subjects affected / exposed	1 / 29 (3.45%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	1	4	0
Rhinorrhoea			
subjects affected / exposed	2 / 29 (6.90%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences (all)	2	0	0
Dyspnea			
subjects affected / exposed	9 / 29 (31.03%)	8 / 29 (27.59%)	0 / 29 (0.00%)
occurrences (all)	16	11	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	4 / 29 (13.79%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	5	3	0
Depression			

subjects affected / exposed	2 / 29 (6.90%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	2	3	0
Depressed mood			
subjects affected / exposed	1 / 29 (3.45%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	1	3	0
Sleep disorder			
subjects affected / exposed	0 / 29 (0.00%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Investigations			
Weight increased			
subjects affected / exposed	2 / 29 (6.90%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences (all)	2	1	0
White blood cell count decreased			
subjects affected / exposed	2 / 29 (6.90%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences (all)	2	0	0
Injury, poisoning and procedural complications			
Fungal skin infection			
subjects affected / exposed	0 / 29 (0.00%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	1 / 29 (3.45%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	1	3	0
Arrhythmia			
subjects affected / exposed	2 / 29 (6.90%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
Polyneuropathy			
subjects affected / exposed	8 / 29 (27.59%)	8 / 29 (27.59%)	0 / 29 (0.00%)
occurrences (all)	9	11	0
Headache			
subjects affected / exposed	6 / 29 (20.69%)	7 / 29 (24.14%)	0 / 29 (0.00%)
occurrences (all)	8	12	0
Dizziness			
subjects affected / exposed	4 / 29 (13.79%)	6 / 29 (20.69%)	0 / 29 (0.00%)
occurrences (all)	4	6	0

Dysgeusia			
subjects affected / exposed	2 / 29 (6.90%)	8 / 29 (27.59%)	0 / 29 (0.00%)
occurrences (all)	2	8	0
Neuropathy peripheral			
subjects affected / exposed	3 / 29 (10.34%)	4 / 29 (13.79%)	0 / 29 (0.00%)
occurrences (all)	3	4	0
Paraesthesia			
subjects affected / exposed	4 / 29 (13.79%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	4	3	0
Peripheral sensory neuropathy			
subjects affected / exposed	4 / 29 (13.79%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	4	5	0
Tremor			
subjects affected / exposed	1 / 29 (3.45%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	1	3	0
Hypoaesthesia			
subjects affected / exposed	2 / 29 (6.90%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences (all)	2	0	0
Presyncope			
subjects affected / exposed	0 / 29 (0.00%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	9 / 29 (31.03%)	9 / 29 (31.03%)	0 / 29 (0.00%)
occurrences (all)	32	25	0
Neutropenia			
subjects affected / exposed	7 / 29 (24.14%)	7 / 29 (24.14%)	0 / 29 (0.00%)
occurrences (all)	17	9	0
Anaemia			
subjects affected / exposed	3 / 29 (10.34%)	4 / 29 (13.79%)	0 / 29 (0.00%)
occurrences (all)	3	7	0
Lymphopenia			
subjects affected / exposed	2 / 29 (6.90%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	2	2	0
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	4 / 29 (13.79%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences (all)	5	2	0
Tinnitus			
subjects affected / exposed	0 / 29 (0.00%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
Vision blurred			
subjects affected / exposed	3 / 29 (10.34%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	3	2	0
Keratoconjunctivitis sicca			
subjects affected / exposed	2 / 29 (6.90%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences (all)	2	1	0
Ocular surface disease			
subjects affected / exposed	0 / 29 (0.00%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	0	3	0
Eye irritation			
subjects affected / exposed	2 / 29 (6.90%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences (all)	3	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	11 / 29 (37.93%)	12 / 29 (41.38%)	0 / 29 (0.00%)
occurrences (all)	22	24	0
Constipation			
subjects affected / exposed	9 / 29 (31.03%)	12 / 29 (41.38%)	0 / 29 (0.00%)
occurrences (all)	10	15	0
Diarrhoea			
subjects affected / exposed	8 / 29 (27.59%)	10 / 29 (34.48%)	0 / 29 (0.00%)
occurrences (all)	9	15	0
Dyspepsia			
subjects affected / exposed	6 / 29 (20.69%)	6 / 29 (20.69%)	0 / 29 (0.00%)
occurrences (all)	7	7	0
Vomiting			
subjects affected / exposed	5 / 29 (17.24%)	6 / 29 (20.69%)	0 / 29 (0.00%)
occurrences (all)	7	15	0
Gingivitis			

subjects affected / exposed	5 / 29 (17.24%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	7	3	0
Abdominal pain			
subjects affected / exposed	2 / 29 (6.90%)	4 / 29 (13.79%)	0 / 29 (0.00%)
occurrences (all)	2	5	0
Abdominal pain upper			
subjects affected / exposed	1 / 29 (3.45%)	5 / 29 (17.24%)	0 / 29 (0.00%)
occurrences (all)	1	6	0
Dry mouth			
subjects affected / exposed	2 / 29 (6.90%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	2	3	0
Haemorrhoids			
subjects affected / exposed	1 / 29 (3.45%)	4 / 29 (13.79%)	0 / 29 (0.00%)
occurrences (all)	1	6	0
Aphthous stomatitis			
subjects affected / exposed	1 / 29 (3.45%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	1	2	0
Flatulence			
subjects affected / exposed	1 / 29 (3.45%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	1	3	0
Glossodynia			
subjects affected / exposed	2 / 29 (6.90%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences (all)	2	1	0
Dysphagia			
subjects affected / exposed	0 / 29 (0.00%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Gingival bleeding			
subjects affected / exposed	0 / 29 (0.00%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	17 / 29 (58.62%)	11 / 29 (37.93%)	0 / 29 (0.00%)
occurrences (all)	17	11	0
Urticaria			
subjects affected / exposed	11 / 29 (37.93%)	9 / 29 (31.03%)	0 / 29 (0.00%)
occurrences (all)	19	11	0

Rash			
subjects affected / exposed	11 / 29 (37.93%)	8 / 29 (27.59%)	0 / 29 (0.00%)
occurrences (all)	11	12	0
Pruritus			
subjects affected / exposed	4 / 29 (13.79%)	8 / 29 (27.59%)	0 / 29 (0.00%)
occurrences (all)	4	8	0
Erythema			
subjects affected / exposed	5 / 29 (17.24%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	6	3	0
Hyperhidrosis			
subjects affected / exposed	3 / 29 (10.34%)	5 / 29 (17.24%)	0 / 29 (0.00%)
occurrences (all)	4	5	0
Dry skin			
subjects affected / exposed	2 / 29 (6.90%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	2	4	0
Skin lesion			
subjects affected / exposed	0 / 29 (0.00%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Renal and urinary disorders			
Urinary incontinence			
subjects affected / exposed	0 / 29 (0.00%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	0	4	0
Dysuria			
subjects affected / exposed	2 / 29 (6.90%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences (all)	2	0	0
Incontinence			
subjects affected / exposed	2 / 29 (6.90%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 29 (10.34%)	10 / 29 (34.48%)	0 / 29 (0.00%)
occurrences (all)	3	10	0
Arthralgia			
subjects affected / exposed	6 / 29 (20.69%)	4 / 29 (13.79%)	0 / 29 (0.00%)
occurrences (all)	9	6	0
Bone pain			

subjects affected / exposed	1 / 29 (3.45%)	5 / 29 (17.24%)	0 / 29 (0.00%)
occurrences (all)	1	8	0
Musculoskeletal pain			
subjects affected / exposed	1 / 29 (3.45%)	5 / 29 (17.24%)	0 / 29 (0.00%)
occurrences (all)	1	5	0
Intervertebral disc protrusion			
subjects affected / exposed	3 / 29 (10.34%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences (all)	3	1	0
Pain in extremity			
subjects affected / exposed	4 / 29 (13.79%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences (all)	5	0	0
Joint stiffness			
subjects affected / exposed	0 / 29 (0.00%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal discomfort			
subjects affected / exposed	2 / 29 (6.90%)	0 / 29 (0.00%)	0 / 29 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	4 / 29 (13.79%)	7 / 29 (24.14%)	0 / 29 (0.00%)
occurrences (all)	4	10	0
Cystitis			
subjects affected / exposed	3 / 29 (10.34%)	4 / 29 (13.79%)	0 / 29 (0.00%)
occurrences (all)	3	4	0
Bronchitis			
subjects affected / exposed	3 / 29 (10.34%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	5	2	0
Herpes zoster			
subjects affected / exposed	3 / 29 (10.34%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	3	2	0
Oral herpes			
subjects affected / exposed	3 / 29 (10.34%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	4	3	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 29 (6.90%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	2	3	0

Pharyngitis			
subjects affected / exposed	2 / 29 (6.90%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences (all)	2	1	0
Rhinitis			
subjects affected / exposed	0 / 29 (0.00%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	0	4	0
Sinusitis			
subjects affected / exposed	0 / 29 (0.00%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	0	6	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	5 / 29 (17.24%)	3 / 29 (10.34%)	0 / 29 (0.00%)
occurrences (all)	8	3	0
Hypokalaemia			
subjects affected / exposed	2 / 29 (6.90%)	1 / 29 (3.45%)	0 / 29 (0.00%)
occurrences (all)	5	1	0
Diabetes mellitus			
subjects affected / exposed	0 / 29 (0.00%)	2 / 29 (6.90%)	0 / 29 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	1000 mg Ofatumumab + CHOP: Extended Follow-up		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 29 (0.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Hot flush			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Hypertension			

subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Haematoma			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Phlebitis			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Infusion related reaction			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Oedema			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Asthenia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Mucosal inflammation			

subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Chest Pain subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Influenza like illness subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Abdominal distension subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Nasal congestion subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Nasal disorder subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Throat irritation subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Dyspnea subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Psychiatric disorders			

Insomnia subjects affected / exposed occurrences (all) Depression subjects affected / exposed occurrences (all) Depressed mood subjects affected / exposed occurrences (all) Sleep disorder subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0 0 / 29 (0.00%) 0 0 / 29 (0.00%) 0 0 / 29 (0.00%) 0		
Investigations Weight increased subjects affected / exposed occurrences (all) White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0 0 / 29 (0.00%) 0		
Injury, poisoning and procedural complications Fungal skin infection subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all) Arrhythmia subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0 0 / 29 (0.00%) 0		
Nervous system disorders Polyneuropathy subjects affected / exposed occurrences (all) Headache	0 / 29 (0.00%) 0		

subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Dysgeusia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Neuropathy peripheral			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Anaemia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		

Lymphopenia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Tinnitus			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Keratoconjunctivitis sicca			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Ocular surface disease			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Eye irritation			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Vomiting			

subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Gingivitis			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Dry mouth			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Haemorrhoids			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Aphthous stomatitis			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Flatulence			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Glossodynia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Dysphagia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Gingival bleeding			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		

Urticaria subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Rash subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Pruritus subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Erythema subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Dry skin subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Skin lesion subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Renal and urinary disorders Urinary incontinence subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Dysuria subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Incontinence subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Arthralgia			

subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Bone pain			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Intervertebral disc protrusion			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Joint stiffness			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Musculoskeletal discomfort			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Herpes zoster			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Oral herpes			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		

Upper respiratory tract infection subjects affected / exposed occurrences (all) Pharyngitis subjects affected / exposed occurrences (all) Rhinitis subjects affected / exposed occurrences (all) Sinusitis subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0 0 / 29 (0.00%) 0 0 / 29 (0.00%) 0 0 / 29 (0.00%) 0		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all) Hypokalaemia subjects affected / exposed occurrences (all) Diabetes mellitus subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0 0 / 29 (0.00%) 0 0 / 29 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 March 2010	Amendment No.: 01 Addition of primary efficacy endpoint data and updated safety data
03 August 2010	Amendment No.: 02 Pharmacokinetic data were removed as re-analysis is ongoing

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported