Clinical trial results:
An Open Label, Multicenter Study Investigating the Safety and Efficacy of Ofatumumab Therapy versus Physicians' Choice in Patients with Bulky Fludarabine Refractory Chronic Lymphocytic Leukemia (CLL)

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/CtrdWeb/home.novfor complete trial results.

Summary

EudraCT number	2010-023066-52
Trial protocol	SE GB HU FR IE CZ DE SK AT IT BE
Global end of trial date	24 April 2017

Results information

Result version number	v1 (current)
This version publication date	27 October 2018
First version publication date	27 October 2018

Trial information

Trial identification

Sponsor protocol code	COMB157A2302/114242

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01313689
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma, AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma, AG, 41 613241111, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma, AG, 41 613241111, novartis.email@novartis.com

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	24 April 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 April 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate improvement in progression-free survival (PFS), defined as the time from randomization to the date of disease progression or death due to any cause, in patients with bulky fludarabine refractory (BFR) CLL receiving ofatumumab (OFA) compared to physicians' choice (PC) of treatment.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 April 2011
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	Bulgaria: 4
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Germany: 11
Country: Number of subjects enrolled	Hungary: 12
Country: Number of subjects enrolled	Israel: 2
Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	Poland: 10
Country: Number of subjects enrolled	Russian Federation: 14
Country: Number of subjects enrolled	Singapore: 1
Country: Number of subjects enrolled	Slovakia: 5
Country: Number of subjects enrolled	Sweden: 14
Country: Number of subjects enrolled	Ukraine: 26
Country: Number of subjects enrolled	United Kingdom: 5
Country: Number of subjects enrolled	Austria: 9

Worldwide total number of subjects	122
EEA total number of subjects	79

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)	70
From 65 to 84 years	52
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Note: The 'Total Participants' in the Baseline Characteristics Table and in most of the Efficacy results Tables should be either Any OFA + Physician's Choice or OFA extended + OFA observation + OFA + Physician's Choice instead of the automatic calculated Total number indicated.

Pre-assignment

Screening details:

Participants(par) were randomized to receive an Open-Label treatment(trt) of ofatumumab(OFA) or a physicians choice(PC) trt for up to 24 weeks. OFA par without progressive disease(PD) underwent a second randomization to receive an additional 24 weeks of OFA or no further trt. PC par who developed PD had the option to receive OFA salvage therapy.

Period 1

Period 1 title	24-Week Randomization 1
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Any Ofatumumab

Arm description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Arm type	Experimental
Investigational medicinal product name	Ofatumumab
Investigational medicinal product code	OMB157
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

OFA was infused intravenously with an initial dose of 300 mg, followed 1 week later with 2000 mg once weekly for 7 weeks, followed 4 weeks later by one infusion of 2000 mg every 4 weeks for 4 infusions, for a total of 12 infusions over 24 weeks.

Arm title	Physician's Choice (PC)

Arm description:

Par. randomized to receive PC trt during Randomization 1 were admin. treatments approved for Chronic Lymphocytic Leukaemia (CLL) & well-established standards of care as prescribed with standard dose & route. Experimental therapies or any doses beyond approved/standard of care dose ranges were not allowed. Par. who developed PD during PC trt or Follow-up had the option to receive (single-agent) OFA salvage trt. Par. received an initial IV dose of OFA 300 mg. One week later, par. received OFA 2000 mg followed by 7 weekly infusions of OFA 2000 mg, followed by infusions of OFA 2000 mg every 4 weeks until Week 48, for max. trt duration of 48 weeks. Par. entered Follow-up after OFA salvage trt until withdrawal or the end of study (60 months). Par. entered SFU if demonstrating PD during OFA salvage trt. Only the survival status & anti-cancer therapy information was collected in the SFU. Par. did not receive OFA salvage trt & demonstrated PD, entered SFU.Of 43 par 22 went to OFA salvage arm.

Arm type	Active comparator

Investigational medicinal product name	Various PC therapies that were approved for CLL at the time of the study
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

PC therapies were infused intravenously with an initial dose of 300 mg, followed 1 week later with 2000 mg once weekly for 7 weeks, followed 4 weeks later by one infusion of 2000 mg every 4 weeks for 4 infusions, for a total of 12 infusions over 24 weeks.

Number of subjects in period 1	Any Ofatumumab	Physician's Choice (PC)
Started	79	43
Completed	60	33
Not completed	19	10
Physician decision	4	5
Consent withdrawn by subject	5	-
Adverse event, non-fatal	10	5

Period 2

Period 2 title	24-Week Randomization 2
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Ofatumumab Extended (OFA Ext)

Arm description:

Par. randomized to receive OFA at Randomization 1 and at Randomization 2. Only the par. who did not demonstrate PD during the first 24 weeks of OFA therapy entered Randomization 2. At Randomization 1, par. were initially administered OFA 300 mg IV. Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Par. randomized to Randomization 2 continued to receive OFA 2000 mg IV every 4 weeks for another 24 weeks. Par. entered Follow-up after the treatment period until withdrawal or the end of study (60 months). Par. entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Arm type	Experimental
Investigational medicinal product name	Ofatumumab
Investigational medicinal product code	OMB157
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

OFA was infused intravenously with an initial dose of 300 mg, followed 1 week later with 2000 mg once weekly for 7 weeks, followed 4 weeks later by one infusion of 2000 mg every 4 weeks for 4 infusions,

for a total of 12 infusions over 24 weeks.

Arm title	Ofatumumab Observation (OFA Observ.)

Arm description:

Par. randomized to receive OFA at Randomization 1 and receiving no treatment at Randomization 2. Only the par. who did not demonstrate PD during the first 24 weeks of OFA therapy entered Randomization 2. At Randomization 1, par. were initially administered OFA 300 mg IV. Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Par. randomized to Randomization 2 received no treatment for another 24 weeks. Par. entered Follow-up after the treatment period until withdrawal or at end of study (60 months). Par. entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Arm type	Experimental
Investigational medicinal product name	Ofatumumab
Investigational medicinal product code	OMB157
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

OFA was infused intravenously with an initial dose of 300 mg, followed 1 week later with 2000 mg once weekly for 7 weeks, followed 4 weeks later by one infusion of 2000 mg every 4 weeks for 4 infusions, for a total of 12 infusions over 24 weeks.

Arm title	OFA first Randomization Only (OFA FRO)

Arm description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. These participants were only randomized once and did not get make it to the second randomization. Par. entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Arm type	Experimental
Investigational medicinal product name	Ofatumumab
Investigational medicinal product code	OMB157
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

OFA was infused intravenously with an initial dose of 300 mg, followed 1 week later with 2000 mg once weekly for 7 weeks, followed 4 weeks later by one infusion of 2000 mg every 4 weeks for 4 infusions, for a total of 12 infusions over 24 weeks.

Number of subjects in period 2[1]	Ofatumumab Extended (OFA Ext)	Ofatumumab Observation (OFA Observ.)	OFA first Randomization Only (OFA FRO)
Started	24	13	42
Completed	21	12	27
Not completed	3	1	15
Consent withdrawn by subject	1	1	3
Physician decision	-	-	4

Adverse event, non-fatal	2	-	8

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: This is correct as per results in CSR

Baseline characteristics

Reporting groups	
Reporting group title	Any Ofatumumab

Reporting group description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Reporting group title	Physician's Choice (PC)

Reporting group description:

Par. randomized to receive PC trt during Randomization 1 were admin. treatments approved for Chronic Lymphocytic Leukaemia (CLL) & well-established standards of care as prescribed with standard dose & route. Experimental therapies or any doses beyond approved/standard of care dose ranges were not allowed. Par. who developed PD during PC trt or Follow-up had the option to receive (single-agent) OFA salvage trt. Par. received an initial IV dose of OFA 300 mg. One week later, par. received OFA 2000 mg followed by 7 weekly infusions of OFA 2000 mg, followed by infusions of OFA 2000 mg every 4 weeks until Week 48, for max. trt duration of 48 weeks. Par. entered Follow-up after OFA salvage trt until withdrawal or the end of study (60 months). Par. entered SFU if demonstrating PD during OFA salvage trt. Only the survival status & anti-cancer therapy information was collected in the SFU. Par. did not receive OFA salvage trt & demonstrated PD, entered SFU.Of 43 par 22 went to OFA salvage arm.

Reporting group values	Any Ofatumumab	Physician's Choice (PC)	Total
Number of subjects	79	43	43
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	46	24	70
From 65-84 years	33	19	52
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean		61.8	
standard deviation	±	± 9.87	-
Sex: Female, Male Units: Subjects			
Female		14	14
Male		29	29
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino|		0	0

Not Hispanic or Latino|		43	43

Subject analysis sets

Subject analysis set title	Any Ofatumumab (OFA)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Any Ofatumumab (OFA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Any Ofatumumab (OFA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Any Ofatumumab (OFA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Any Ofatumumab (OFA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Any Ofatumumab (OFA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	OFA Salvage
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The participants in this arm are from the Physician's Choice (PC) arm. Par. who developed PD during PC trt or Follow-up had the option to receive (single-agent) OFA salvage trt. Par. received an initial IV dose of OFA 300 mg. One week later, par. received OFA 2000 mg followed by 7 weekly infusions of OFA 2000 mg, followed by infusions of OFA 2000 mg every 4 weeks until Week 48, for the maximum trt duration of 48 weeks. Par. entered Follow-up after the OFA salvage trt until withdrawal or the end of study (60 months). Par. entered SFU if demonstrating PD during OFA salvage trt. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Ofatumumab Extended (OFA Ext)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Par. randomized to receive OFA at Randomization 1 and at Randomization 2. Only the par. who did not demonstrate PD during the first 24 weeks of OFA therapy entered Randomization 2. At Randomization 1, par. were initially administered OFA 300 mg IV. Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Par. randomized to Randomization 2 continued to receive OFA 2000 mg IV every 4 weeks for another 24 weeks. Par. entered Follow-up after the treatment period until withdrawal or the end of study (60 months). Par. entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Ofatumumab Observation (OFA Observ.)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Par. randomized to receive OFA at Randomization 1 and receiving no treatment at Randomization 2. Only the par. who did not demonstrate PD during the first 24 weeks of OFA therapy entered Randomization 2. At Randomization 1, par. were initially administered OFA 300 mg IV. Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Par. randomized to Randomization 2 received no treatment for another 24 weeks. Par. entered Follow-up after the treatment period until withdrawal or at end of study (60 months). Par. entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	OFA first Randomization Only (OFA FRO)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. These participants were only randomized once and did

not get make it to the second randomization. Par. entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Reporting group values	Any Ofatumumab (OFA)	Any Ofatumumab (OFA)	Any Ofatumumab (OFA)
Number of subjects	79	56	44
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: years			
arithmetic mean	63.3		
standard deviation	±	±	±
Sex: Female, Male			
Units: Subjects			
Female	24		
Male	55		
Race/Ethnicity, Customized			
Units: Subjects			
Hispanic or Latino|	1		
Not Hispanic or Latino|	78		

Reporting group values	Any Ofatumumab (OFA)	Any Ofatumumab (OFA)	Any Ofatumumab (OFA)
Number of subjects	30	23	78
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±

Sex: Female, Male Units: Subjects			
Female Male			
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino| Not Hispanic or Latino|			

Reporting group values	OFA Salvage	Ofatumumab Extended (OFA Ext)	Ofatumumab Observation (OFA Observ.)
Number of subjects	22	24	13
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
arithmetic mean		61.7	66.7
standard deviation	±	±	±
Sex: Female, Male Units: Subjects			
Female		9	2
Male		15	11
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino|		0	0
Not Hispanic or Latino|		24	13

Reporting group values	OFA first Randomization Only (OFA FRO)		
Number of subjects	42		
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years)			

From 65-84 years 85 years and over			

Age Continuous Units: years arithmetic mean standard deviation	 63.2 ±		
Sex: Female, Male Units: Subjects			
Female Male	13 29		
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino| Not Hispanic or Latino|	1 41		

End points

End points reporting groups

Reporting group title	Any Ofatumumab

Reporting group description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Reporting group title	Physician's Choice (PC)

Reporting group description:

Par. randomized to receive PC trt during Randomization 1 were admin. treatments approved for Chronic Lymphocytic Leukaemia (CLL) & well-established standards of care as prescribed with standard dose & route. Experimental therapies or any doses beyond approved/standard of care dose ranges were not allowed. Par. who developed PD during PC trt or Follow-up had the option to receive (single-agent) OFA salvage trt. Par. received an initial IV dose of OFA 300 mg. One week later, par. received OFA 2000 mg followed by 7 weekly infusions of OFA 2000 mg, followed by infusions of OFA 2000 mg every 4 weeks until Week 48, for max. trt duration of 48 weeks. Par. entered Follow-up after OFA salvage trt until withdrawal or the end of study (60 months). Par. entered SFU if demonstrating PD during OFA salvage trt. Only the survival status & anti-cancer therapy information was collected in the SFU. Par. did not receive OFA salvage trt & demonstrated PD, entered SFU.Of 43 par 22 went to OFA salvage arm.

Reporting group title	Ofatumumab Extended (OFA Ext)

Reporting group description:

Par. randomized to receive OFA at Randomization 1 and at Randomization 2. Only the par. who did not demonstrate PD during the first 24 weeks of OFA therapy entered Randomization 2. At Randomization 1, par. were initially administered OFA 300 mg IV. Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Par. randomized to Randomization 2 continued to receive OFA 2000 mg IV every 4 weeks for another 24 weeks. Par. entered Follow-up after the treatment period until withdrawal or the end of study (60 months). Par. entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Reporting group title	Ofatumumab Observation (OFA Observ.)

Reporting group description:

Par. randomized to receive OFA at Randomization 1 and receiving no treatment at Randomization 2. Only the par. who did not demonstrate PD during the first 24 weeks of OFA therapy entered Randomization 2. At Randomization 1, par. were initially administered OFA 300 mg IV. Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Par. randomized to Randomization 2 received no treatment for another 24 weeks. Par. entered Follow-up after the treatment period until withdrawal or at end of study (60 months). Par. entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Reporting group title	OFA first Randomization Only (OFA FRO)

Reporting group description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. These participants were only randomized once and did not get make it to the second randomization. Par. entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Any Ofatumumab (OFA)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4

weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Any Ofatumumab (OFA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Any Ofatumumab (OFA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Any Ofatumumab (OFA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Any Ofatumumab (OFA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Any Ofatumumab (OFA)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were

initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Following Randomization 1, par. not demonstrating PD entered Randomization 2 (OFA Extended or OFA Observation); or par. entered Survival Follow-up (SFU) if demonstrating progressive disease (PD). During Randomization 2, par. either received another 24 weeks of OFA 2000 mg every 4 weeks (OFA Extension) or received no further treatment (trt) (OFA Observation). Par. entered Follow-up until withdrawal or the end of study (60 months). Par only entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	OFA Salvage
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The participants in this arm are from the Physician's Choice (PC) arm. Par. who developed PD during PC trt or Follow-up had the option to receive (single-agent) OFA salvage trt. Par. received an initial IV dose of OFA 300 mg. One week later, par. received OFA 2000 mg followed by 7 weekly infusions of OFA 2000 mg, followed by infusions of OFA 2000 mg every 4 weeks until Week 48, for the maximum trt duration of 48 weeks. Par. entered Follow-up after the OFA salvage trt until withdrawal or the end of study (60 months). Par. entered SFU if demonstrating PD during OFA salvage trt. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Ofatumumab Extended (OFA Ext)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Par. randomized to receive OFA at Randomization 1 and at Randomization 2. Only the par. who did not demonstrate PD during the first 24 weeks of OFA therapy entered Randomization 2. At Randomization 1, par. were initially administered OFA 300 mg IV. Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Par. randomized to Randomization 2 continued to receive OFA 2000 mg IV every 4 weeks for another 24 weeks. Par. entered Follow-up after the treatment period until withdrawal or the end of study (60 months). Par. entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	Ofatumumab Observation (OFA Observ.)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Par. randomized to receive OFA at Randomization 1 and receiving no treatment at Randomization 2. Only the par. who did not demonstrate PD during the first 24 weeks of OFA therapy entered Randomization 2. At Randomization 1, par. were initially administered OFA 300 mg IV. Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. Par. randomized to Randomization 2 received no treatment for another 24 weeks. Par. entered Follow-up after the treatment period until withdrawal or at end of study (60 months). Par. entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Subject analysis set title	OFA first Randomization Only (OFA FRO)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants (par.) were randomized to receive ofatumumab (OFA) at Randomization 1. Par. were initially administered OFA 300 milligrams (mg) intravenously (IV). Beginning at Week 2, par. were administered OFA 2000 mg once weekly for 7 weeks, followed by 4 infusions of OFA 2000 mg every 4 weeks for a total of 12 infusions over 24 weeks. These participants were only randomized once and did not get make it to the second randomization. Par. entered SFU if demonstrating PD during the study. Only the survival status and anti-cancer therapy information was collected in the SFU.

Primary: Progression-free Survival (PFS) as assessed by Independent Review Committee (IRC)

End point title	Progression-free Survival (PFS) as assessed by Independent Review Committee (IRC)

End point description:

PFS is the interval of time between the date of first randomization to the date of disease progression (PD) or death due to any reason, whichever occurred first. The date of PD was defined as the first occurrence of any criteria of progression. PD criteria requires at least one of the following: progression of lymphadenopathy, >=50% increase in liver or spleen size, >=50% increase in number of lymphocytes per microliter, more aggressive histology, occurence of cytopenia after treatment attributable to CLL. Disease progression was determined according to the 2008 International Workshop for Chronic Lymphocytic Leukaemia (IWCLL) update of the National Cancer Institute-sponsored Working

Group CLL Guidelines for Response (NCI-WG). PFS was censored at the time of the last follow up for participants who have neither progressed or died.

End point type	Primary

End point timeframe:

From the randomization date up to 60 months post the randomization date.

End point values	Any Ofatumumab	Physician's Choice (PC)	Ofatumumab Extended (OFA Ext)	Ofatumumab Observation (OFA Observ.)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	79	43	24	13
Units: Months				
median (confidence interval 95%)	5.36 (4.30 to 6.97)	3.61 (1.87 to 6.74)	10.05 (7.23 to 13.80)	7.16 (5.36 to 9.49)

Statistical analyses

Statistical analysis title	Any OFA vs PC (IRC)
Comparison groups	Physician's Choice (PC) v Any Ofatumumab
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2677
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.24

Statistical analysis title	OFA Ext. vs OFA Observ.
Comparison groups	Ofatumumab Extended (OFA Ext) v Ofatumumab Observation (OFA Observ.)
Number of subjects included in analysis	37
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0837
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.54

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.19
upper limit	1.53

Secondary: Progression-free Survival (PFS) as assessed by Investigator

End point title	Progression-free Survival (PFS) as assessed by Investigator

End point description:

PFS is the interval of time between the date of first randomization to the date of disease progression (PD) or death due to any reason, whichever occurred first. The date of PD was defined as the first occurrence of any criteria of progression. PD criteria requires at least one of the following: progression of lymphadenopathy, >=50% increase in liver or spleen size, >=50% increase in number of lymphocytes per microliter, more aggressive histology, occurence of cytopenia after treatment attributable to CLL. Disease progression was determined according to the 2008 International Workshop for Chronic Lymphocytic Leukaemia (IWCLL) update of the National Cancer Institute-sponsored Working Group CLL Guidelines for Response (NCI-WG). PFS was censored at the time of the last follow up for participants who have neither progressed or died.

End point type	Secondary

End point timeframe:

From the randomization date up to 60 months post the randomization date.

End point values	Any Ofatumumab	Physician's Choice (PC)	Ofatumumab Extended (OFA Ext)	Ofatumumab Observation (OFA Observ.)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	79	43	24	13
Units: Months				
median (confidence interval 95%)	7.00 (5.42 to 8.25)	4.50 (1.97 to 5.62)	12.68 (10.09 to 14.29)	9.49 (7.00 to 12.12)

Statistical analyses

Statistical analysis title	OFA Ext vs OFA Observ (by Investigator)
Comparison groups	Ofatumumab Extended (OFA Ext) v Ofatumumab Observation (OFA Observ.)
Number of subjects included in analysis	37
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0262
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.49

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.21
upper limit	1.17

Statistical analysis title	Any OFA vs PC Choice (by Investigator)
Comparison groups	Physician's Choice (PC) v Any Ofatumumab
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.35
upper limit	0.87

Secondary: Overall response rate (ORR) as assessed by the IRC

End point title	Overall response rate (ORR) as assessed by the IRC

End point description:

ORR is defined as the number of participants achieving either complete response (CR) or partial response (PR). ORR was measured using the IWCLL updated NCI-WG guidelines 2008. CR requires all of the following criteria: no lymphadenopathy(Ly)/ hepatomegaly, splenomegaly, constitutional symptoms; neutrophils >1500 per microliter(µL), platelets(PL) >100,000/µL, hemoglobin(Hb) >11 grams/deciliter(g/dL), lymphocytes(LC) <4000/µL, bone marrow(BM) sample must be normocellular for age, <30% LC and no lymphoid nodules. PR requires the following criteria for at least 2 months: >=50% decrease in LC, reduction in Ly (i.e., >=50% decrease in lymph node size or no increase or new lymph nodes), >=50% decrease in the size of liver and spleen and at least one of the following results: PL >100,000/µL or 50% improvement over Baseline(BL), Hb >11 g/dL or 50% improvement over BL, neutrophils>1500/µL. Nodular PR (nPR) indicates persistent nodules in the BM.

End point type	Secondary

End point timeframe:

From the randomization date up to 60 months post the randomization date.

End point values	Any Ofatumumab	Physician's Choice (PC)	Ofatumumab Extended (OFA Ext)	Ofatumumab Observation (OFA Observ.)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	79	43	24	13
Units: Participants				
CR|	0	0	0	0
PR|	30	7	18	8
nPR|	0	0	0	0

Stable Disease|	36	22	5	5
Progressive Disease|	9	8	1	0
Not Evaluable|	4	6	0	0
Missing|	0	0	0	0

Statistical analyses

Statistical analysis title	ORR by IRC: Any OFA vs PC (ORR)
Comparison groups	Physician's Choice (PC) v Any Ofatumumab
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0223
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.942
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.166
upper limit	7.424

Statistical analysis title	ORR by IRC: OFA Ext. vs OFA Observ.
Comparison groups	Ofatumumab Extended (OFA Ext) v Ofatumumab Observation (OFA Observ.)
Number of subjects included in analysis	37
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9985
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	999.999
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.001
upper limit	999.999

Secondary: Overall response rate (ORR) as assessed by the Investigator

End point title	Overall response rate (ORR) as assessed by the Investigator

End point description:

ORR is defined as the number of participants achieving either complete response (CR) or partial response (PR). Overall response was measured using the IWCLL updated NCI-WG guidelines 2008. CR requires all of the following criteria: no lymphadenopathy(Ly)/ hepatomegaly, splenomegaly, constitutional symptoms; neutrophils >1500 per microliter(µL), platelets(PL) >100,000/µL, hemoglobin

(Hb) >11 grams/deciliter(g/dL), lymphocytes(LC) <4000/µL, bone marrow(BM) sample must be normocellular for age, <30% LC and no lymphoid nodules. PR requires the following criteria for at least 2 months: >=50% decrease in LC, reduction in Ly (i.e., >=50% decrease in lymph node size or no increase or new lymph nodes), >=50% decrease in the size of liver and spleen and at least one of the following results: PL >100,000/µL or 50% improvement over Baseline(BL), Hb >11 g/dL or 50% improvement over BL, neutrophils>1500/µL. Nodular PR (nPR) indicates persistent nodules in the BM.

End point type	Secondary

End point timeframe:

From the randomization date up to 60 months post the randomization date.

End point values	Any Ofatumumab	Physician's Choice (PC)	Ofatumumab Extended (OFA Ext)	Ofatumumab Observation (OFA Observ.)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	79	43	24	13
Units: Participants				
CR|	2	2	1	1
PR|	36	12	17	7
nPR|	1	2	0	1
Stable Disease|	34	14	6	4
Progressive Disease|	2	10	0	0
Not Evaluable|	0	0	0	0
Missing|	4	3	0	0

End point values	OFA first Randomization Only (OFA FRO)			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: Participants				
CR|	0			
PR|	12			
nPR|	0			
Stable Disease|	24			
Progressive Disease|	2			
Not Evaluable|	0			
Missing|	4			

Statistical analyses

Statistical analysis title	ORR per Inv: Any OFA vs PC
Comparison groups	Physician's Choice (PC) v Any Ofatumumab

Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4159 [1]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.366
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.644
upper limit	2.899

Notes:

[1] - Odds ratios and p-value are based on conditional logistic regression with interval and pooled stratum included in the Strata statement

Statistical analysis title	ORR per Inv: OFA Ext. vs OFA Observ.
Comparison groups	Ofatumumab Observation (OFA Observ.) v Ofatumumab Extended (OFA Ext)
Number of subjects included in analysis	37
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8866
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.225
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.076
upper limit	19.862

Secondary: Overall Survival

End point title	Overall Survival

End point description:

Overall survival (OS) is defined as the time from randomization to death due to any cause. Kaplan-Meier plots were used to estimate the reported median OS time.

End point type	Secondary

End point timeframe:

From the randomization date up to 60 months post the randomization date.

End point values	Any Ofatumumab	Physician's Choice (PC)	Ofatumumab Extended (OFA Ext)	Ofatumumab Observation (OFA Observ.)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	79	43	24	13
Units: Months				
median (confidence interval 95%)	19.19 (12.19 to 29.11)	14.52 (8.94 to 24.97)	31.54 (19.19 to 51.25)	45.50 (14.69 to 999)

End point values	OFA first Randomization Only (OFA FRO)			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: Months				
median (confidence interval 95%)	8.57 (4.93 to 16.76)			

Statistical analyses

Statistical analysis title	OS: Any OFA vs PC
Comparison groups	Any Ofatumumab v Physician's Choice (PC)
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1732
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	1.17

Statistical analysis title	O: OFA Ext. vs OFA Observ.
Comparison groups	Ofatumumab Extended (OFA Ext) v Ofatumumab Observation (OFA Observ.)
Number of subjects included in analysis	37
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8128
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.11

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	2.68

Secondary: Time to progression as assessed by IRC

End point title	Time to progression as assessed by IRC[2]

End point description:

Time to progression is defined as the time from the date of randomization to disease progression (PD). PD requires at least one of the following: lymphadenopathy, appearance of any new lesion such as enlarged lymph nodes (>1.5 cm) spleen or liver or other infiltrates or an increase by 50% or more in the greatest diameter of any previous site; an increase by 50% or more in the previously noted enlargement of the liver or spleen, an increase by 50% or more in the numbers of blood lymphocytes with at least 5000 lymphocytes per microliter, transformation to a more aggressive histology, or occurrence of cytopenia attributable to chronic lymphocytic leukaemia. Participants who were alive and had not progressed at the time of analysis or if a progression event occurred after extensive lost-to-follow-up time were censored at the date of the last visit with adequate assessment.

End point type	Secondary

End point timeframe:

From the randomization date up to 60 months post the randomization date.

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was done for this endpoint.

End point values	Physician's Choice (PC)	Any Ofatumumab (OFA)	Ofatumumab Extended (OFA Ext)	Ofatumumab Observation (OFA Observ.)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	56	19	11
Units: Months				
median (confidence interval 95%)	5.32 (2.14 to 8.08)	6.31 (4.83 to 7.33)	10.05 (7.23 to 13.80)	7.16 (5.36 to 9.49)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to next anti-cancer therapy by Investigator

End point title	Time to next anti-cancer therapy by Investigator[3]

End point description:

Time to next therapy is defined as the time from randomization until the start of the next line of treatment.

End point type	Secondary

End point timeframe:

From the randomization date up to 60 months post the randomization date.

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was done for this endpoint.

End point values	Physician's Choice (PC)	Any Ofatumumab (OFA)	Ofatumumab Extended (OFA Ext)	Ofatumumab Observation (OFA Observ.)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	44	12	12
Units: Months				
median (confidence interval 95%)	6.54 (2.66 to 8.08)	11.50 (8.51 to 13.80)	15.47 (11.86 to 99.99)	9.00 (8.08 to 14.16)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to response as assessed by the IRC

End point title	Time to response as assessed by the IRC[4]

End point description:

Time to response is defined as the time from randomization to the first response (Complete Remission[CR], Complete Remission with incomplete bone marrow recovery[CRi], partial response[PR], or nodular PR[nPR]). CR(all the criteria at least 2 months after last treatment): no lymphadenopathy(Ly) > 1.5 cm/ hepatomegaly/ splenomegaly/ constitutional symptoms; neutrophils >1500 per microliter(µL), platelets(PL) >100,000/µL, hemoglobin(Hb) >11 grams/deciliter(g/dL), lymphocytes(LC) <4000/µL, bone marrow(BM) sample must be normocellular for age, <30% LC, no lymphoid nodule. CRi: CR criteria, persistent anemia/thrombocytopenia/neutropenia unrelated to CLL but related to drug toxicity. PR: >=50% decrease in LC, Ly, size of liver and spleen and at least one of the following results: PL >100,000/µL or 50% improvement over Baseline(BL), Hb >11 g/dL or 50% improvement over BL. nPR: persistent nodules BM. Participants with unknown or missing responses were considered as non-responders.

End point type	Secondary

End point timeframe:

From the randomization date up to 60 months post the randomization date.

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was done for this endpoint.

End point values	Physician's Choice (PC)	Any Ofatumumab (OFA)	Ofatumumab Extended (OFA Ext)	Ofatumumab Observation (OFA Observ.)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	30	18	8
Units: Months				
median (confidence interval 95%)	2.56 (0.76 to 3.48)	1.17 (1.02 to 1.91)	1.86 (1.05 to 1.94)	1.15 (0.92 to 1.94)

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response as assessed by the IRC

End point title	Duration of response as assessed by the IRC[5]

End point description:

DOR is defined as the time from the initial response (CR, CRi, nPR, or PR) to the first documented sign of PD or death due to any cause. PD requires at least one of the following: lymphadenopathy, appearance of any new lesion such as enlarged lymph nodes (>1.5 cm) spleen or liver or other infiltrates or an increase by 50% or more in the greatest diameter of any previous site; an increase by 50% or more in the previously noted enlargement of the liver or spleen, an increase by 50% or more in the numbers of blood lymphocytes with at least 5000 lymphocytes per microliter, transformation to a more aggressive histology, or occurrence of cytopenia attributable to chronic lymphocytic leukaemia. Par. who were alive and had not progressed at the time of analysis or if a progression event occurred after extensive lost-to-follow-up time (>= 12 weeks) were censored at the date of the last visit with adequate assessment. Par. with unknown or missing responses were considered as non-responders.

End point type	Secondary

End point timeframe:

From the randomization date up to 60 months post the randomization date.

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: No statistical analysis was done for this endpoint.

End point values	Physician's Choice (PC)	Any Ofatumumab (OFA)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	5	23		
Units: Months				
median (confidence interval 95%)	6.95 (4.47 to 9.99)	6.24 (5.32 to 12.22)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any adverse event (AE), any serious adverse event (SAE), any fatal serious adverse event (FSAE), or deaths

End point title	Number of participants with any adverse event (AE), any serious adverse event (SAE), any fatal serious adverse event (FSAE), or deaths[6]

End point description:

An AE is defined as any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. A SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability or incapacity, is a congenital anomaly or birth defect.

End point type	Secondary

End point timeframe:

From the first dose of study medication to 60 days after the last dose of study medication and until follow-up for SAEs unless initiation of subsequent anti-CLL therapy

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: No statistical analysis was done for this endpoint.

End point values	Physician's Choice (PC)	Any Ofatumumab (OFA)	OFA Salvage	Ofatumumab Extended (OFA Ext)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	78	22	24
Units: Participants				
Any AE|	37	71	20	22
Any SAE|	23	43	10	12
Any FSAE|	6	14	5	2
Deaths|	0	1	0	0

End point values	Ofatumumab Observation (OFA Observ.)	OFA first Randomization Only (OFA FRO)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13	41		
Units: Participants				
Any AE|	10	39		
Any SAE|	5	26		
Any FSAE|	3	9		
Deaths|	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any adverse event (AE) of special interest

End point title	Number of participants with any adverse event (AE) of special interest[7]

End point description:

AEs of special interest included cytopenias (neutropenia [decreased neutrophil count], anaemia [decreased hemoglobin], and thrombocytopenia [decreased platelet count]), autoimmune haematologic complications (autoimmune haemolytic anaemia and haemolytic anaemia), infusion reactions, infections, mucocutaneous reactions, Tumour Lysis Syndrome (TLS), cardiovascular events, and small bowel obstruction.

End point type	Secondary

End point timeframe:

From the first dose of study medication to 60 days after the last dose of study medication and until follow-up for SAEs unless initiation of subsequent anti-CLL therapy

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was done for this endpoint.

End point values	Physician's Choice (PC)	Any Ofatumumab (OFA)	Ofatumumab Extended (OFA Ext)	Ofatumumab Observation (OFA Observ.)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	43	78	24	13
Units: Participants				
Any AE of decreased neutrophil count|	15	23	11	2
Any AE of decreased hemoglobin|	9	9	3	2
Any AE of decreased platelet count|	5	10	3	1
Any AE of autoimmune haemolytic anaemia|	2	0	0	0
Any AE of haemolytic anaemia|	0	1	1	0
Any infusion related AE|	11	33	8	4
Any AE of Infection|	24	46	16	8
Any AE of mucocutaneous reaction|	4	20	6	3
Any AE of TLS|	1	1	0	0
Any AE of cardiovascular events|	3	13	6	0
Any AE of small bowel obstruction|	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Immunoglobulin (Ig) antibodies IgA, IgG, and IgM over time

End point title	Mean Immunoglobulin (Ig) antibodies IgA, IgG, and IgM over time

End point description:

Immunoglobulins or antibodies are large proteins used by the immune system to identify and neutralize foreign particles such as bacteria and viruses. Their normal blood levels indicate proper immune status. Low levels indicate immuno-suppression. IgA, IgG, and IgM were measured in the blood samples of the participants. Immunoglobulin testing was performed at Screening (SCR), Cycle 3 Week 4 (C3W4), Cycle 7 Week 4 (C3W4) ,Cycle 9 Week 4 (C3W4), 6 Month Follow-up Visit (6M FU), 9 Month Follow-up (9M FU), 12 Month Follow-up (12M FU), 18 Month Follow-up (18M FU), 24 Month Follow-up (24M FU), 30 Month Follow-up (30M FU), 36 Month Follow-up (36M FU), 42 Month Follow-up (42M FU). A cycle is defined as the time between one round of treatment until the start of the next round.

End point type	Secondary

End point timeframe:

Screening and every 3 months during treatment, every 6 months after last treatment until PD or until 42 Month Follow-up Visit

End point values	Any Ofatumumab	Physician's Choice (PC)	OFA Salvage	Ofatumumab Extended (OFA Ext)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	79	43	22	24
Units: Gram per liter				
arithmetic mean (standard deviation)				
IgA, SCR, n= 78, 41, 24, 13, 41, 0|	0.793 (± 0.6680)	0.685 (± 0.5518)	999 (± 999)	0.807 (± 0.7426)
IgG, SCR, n=78, 41, 24, 13, 41, 0|	6.909 (± 4.6836)	8.615 (± 12.1625)	999 (± 999)	6.270 (± 3.8573)

IgM, SCR, n=77,41, 24, 13, 40, 0|	0.800 (± 1.3154)	0.601 (± 0.7061)	999 (± 999)	0.800 (± 1.6649)
IgA, C3W4, n=61, 23, 24, 12, 25, 17|	0.721 (± 0.6355)	0.675 (± 0.4819)	0.486 (± 0.3868)	0.808 (± 0.7931)
IgG, C3W4, n=61, 23, 24, 12, 25, 17|	5.925 (± 3.5059)	5.481 (± 2.1226)	5.974 (± 2.7992)	5.949 (± 3.4089)
IgM, C3W4, n=61, 23, 24, 12, 25, 17|	0.692 (± 1.3420)	0.485 (± 0.4929)	0.488 (± 0.4816)	0.882 (± 1.9833)
IgA, C7W4, n=38, 0, 24, 12, 2, 10|	0.793 (± 0.6608)	999 (± 999)	0.537 (± 0.4356)	0.723 (± 0.6730)
IgG, C7W4, n=38,0, 24, 12, 2, 10|	6.250 (± 3.5225)	999 (± 999)	5.135 (± 2.6309)	5.817 (± 3.4944)
IgM, C7W4, n=38, 0, 24, 12, 2, 10|	0.762 (± 1.7523)	999 (± 999)	0.447 (± 0.4732)	0.844 (± 2.1136)
IgA, C9W4, n=29, 0, 21, 8, 0, 7|	0.719 (± 0.6336)	999 (± 999)	0.567 (± 0.3968)	0.630 (± 0.6005)
IgG, C9W4, n=29, 0, 21, 8, 0, 7|	6.164 (± 3.5886)	999 (± 999)	5.709 (± 2.1629)	5.553 (± 3.0792)
IgM, C9W4, n=29, 0, 21, 8, 0, 7|	0.853 (± 2.3484)	999 (± 999)	0.484 (± 0.4493)	0.973 (± 2.7574)
IgA, 6M FU, n=0, 1, 0, 0, 0|	999 (± 999)	0.880 (± 999)	999 (± 999)	999 (± 999)
IgG, 6M FU, n=0, 1, 0, 0, 0, 0|	999 (± 999)	8.670 (± 999)	999 (± 999)	999 (± 999)
IgM, 6M FU, n=0, 1, 0, 0, 0, 0|	999 (± 999)	0.200 (± 999)	999 (± 999)	999 (± 999)
IgA, 9M FU, n=2, 5, 2, 0, 0, 0|	0.890 (± 0.0849)	0.510 (± 0.4585)	999 (± 999)	0.890 (± 0.0849)
IgG, 9M FU, n=2, 5, 2, 0, 0, 0|	7.695 (± 0.9263)	5.016 (± 2.4292)	999 (± 999)	7.695 (± 0.9263)
IgM, 9M FU, n=2, 5, 2, 0, 0, 0|	0.375 (± 0.1061)	0.246 (± 0.0706)	999 (± 999)	0.375 (± 0.1061)
IgA, 12M FU, n=10, 3, 7, 3, 0, 2|	0.721 (± 0.8339)	0.983 (± 0.6029)	0.300 (± 0.00)	0.826 (± 0.9960)
IgG, 12M FU, n=10, 3, 7, 3, 0, 2|	6.423 (± 3.5390)	7.497 (± 1.5550)	4.935 (± 0.8273)	7.621 (± 3.3834)
IgM, 12M FU, n=10, 3, 7, 3, 0, 2|	0.384 (± 0.3463)	0.487 (± 0.2743)	0.240 (± 0.0566)	0.3334 (± 0.2833)
IgA, 18M FU, n=8, 2, 7, 1, 0, 2|	0.520 (± 0.2803)	1.095 (± 0.2616)	0.300 (± 0.000)	0.500 (± 0.2965)
IgG, 18M FU, n=8, 2, 7, 1, 0, 2|	4.513 (± 2.0789)	6.620 (± 2.3759)	4.265 (± 1.1384)	4.206 (± 2.0405)
IgM, 18M FU, n=8, 2, 7, 1, 0, 2|	0.417 (± 3.3156)	0.640 (± 0.2687)	0.240 (± 0.566)	0.317 (± 0.1490)
IgA, 24M FU, n=5, 1, 4, 1, 0, 0|	0.540 (± 0.2667)	1.540 (± 999)	999 (± 999)	0.480 (± 0.2662)
IgG, 24M FU, n=5, 1, 4, 1, 0, 0|	5.634 (± 2.4734)	10.900 (± 999)	999 (± 999)	5.098 (± 2.4977)
IgM, 24M FU, n=5, 1, 4, 1, 0, 0|	0.490 (± 0.6321)	1.710 (± 999)	999 (± 999)	0.333 (± 0.0971)
IgA, 30M FU, n=2, 1, 2, 0, 0, 0|	0.505 (± 0.2900)	1.380 (± 999)	999 (± 999)	0.505 (± 0.2900)
IgG, 30M FU, n=2,1, 2, 0, 0, 0|	3.460 (± 1.8809)	11.100 (± 999)	999 (± 999)	3.460 (± 1.8809)
IgM, 30M FU, n=2, 1, 2, 0, 0, 0,|	0.400 (± 0.1131)	0.770 (± 999)	999 (± 999)	0.400 (± 0.1131)
IgA, 36M FU, n=2, 1, 2, 0, 0, 0|	0.550 (± 0.3111)	1.680 (± 999)	999 (± 999)	0.550 (± 0.3111)
IgG, 36M FU, n=2,1, 2, 0, 0, 0|	4.320 (± 2.2486)	13.600 (± 999)	999 (± 999)	4.320 (± 2.2486)
IgM, 36M FU, n=2, 1, 2, 0, 0, 0,|	1.175 (± 0.2899)	0.720 (± 999)	999 (± 999)	1.175 (± 0.2899)
IgA, 42M FU, n=2, 1, 2, 0, 0, 0|	0.545 (± 0.2051)	1.410 (± 999)	999 (± 999)	0.545 (± 0.2051)

IgG, 42M FU, n=2,1, 2, 0, 0, 0|	4.425 (± 3.5143)	11.500 (± 999)	999 (± 999)	4.425 (± 3.5143)
IgM, 42M FU, n=2, 1, 2, 0, 0, 0|	2.155 (± 0.8697)	0.470 (± 999)	999 (± 999)	2.155 (± 0.8697)

End point values	Ofatumumab Observation (OFA Observ.)	OFA first Randomization Only (OFA FRO)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13	41		
Units: Gram per liter				
arithmetic mean (standard deviation)				
IgA, SCR, n= 78, 41, 24, 13, 41, 0|	1.095 (± 0.7535)	0.688 (± 0.5749)		
IgG, SCR, n=78, 41, 24, 13, 41, 0|	8.128 (± 4.7569)	6.898 (± 5.1142)		
IgM, SCR, n=77,41, 24, 13, 40, 0|	0.468 (± 0.3801)	0.907 (± 1.2822)		
IgA, C3W4, n=61, 23, 24, 12, 25, 17|	0.977 (± 0.6458)	0.214 (± 0.3621)		
IgG, C3W4, n=61, 23, 24, 12, 25, 17|	7.232 (± 4.0103)	5.276 (± 3.3056)		
IgM, C3W4, n=61, 23, 24, 12, 25, 17|	0.429 (± 0.3497)	0.636 (± 0.7764)		
IgA, C7W4, n=38, 0, 24, 12, 2, 10|	0.945 (± 0.6724)	0.725 (± 0.6011)		
IgG, C7W4, n=38,0, 24, 12, 2, 10|	7.254 (± 3.7588)	5.420 (± 2.2062)		
IgM, C7W4, n=38, 0, 24, 12, 2, 10|	0.414 (± 0.3400)	1.865 (± 2.3547)		
IgA, C9W4, n=29, 0, 21, 8, 0, 7|	0.952 (± 0.6997)	999 (± 999)		
IgG, C9W4, n=29, 0, 21, 8, 0, 7|	7.768 (± 4.5126)	999 (± 999)		
IgM, C9W4, n=29, 0, 21, 8, 0, 7|	0.536 (± 0.4209)	999 (± 999)		
IgA, 6M FU, n=0, 1, 0, 0, 0|	999 (± 999)	999 (± 999)		
IgG, 6M FU, n=0, 1, 0, 0, 0, 0|	999 (± 999)	999 (± 999)		
IgM, 6M FU, n=0, 1, 0, 0, 0, 0|	999 (± 999)	999 (± 999)		
IgA, 9M FU, n=2, 5, 2, 0, 0, 0|	999 (± 999)	999 (± 999)		
IgG, 9M FU, n=2, 5, 2, 0, 0, 0|	999 (± 999)	999 (± 999)		
IgM, 9M FU, n=2, 5, 2, 0, 0, 0|	999 (± 999)	999 (± 999)		
IgA, 12M FU, n=10, 3, 7, 3, 0, 2|	0.477 (± 0.1595)	999 (± 999)		
IgG, 12M FU, n=10, 3, 7, 3, 0, 2|	3.627 (± 2.2938)	999 (± 999)		
IgM, 12M FU, n=10, 3, 7, 3, 0, 2|	0.500 (± 0.5197)	999 (± 999)		
IgA, 18M FU, n=8, 2, 7, 1, 0, 2|	0.660 (± 999)	999 (± 999)		
IgG, 18M FU, n=8, 2, 7, 1, 0, 2|	6.660 (± 999)	999 (± 999)		
IgM, 18M FU, n=8, 2, 7, 1, 0, 2|	1.120 (± 999)	999 (± 999)		
IgA, 24M FU, n=5, 1, 4, 1, 0, 0|	0.780 (± 999)	999 (± 999)		
IgG, 24M FU, n=5, 1, 4, 1, 0, 0|	7.780 (± 999)	999 (± 999)		
IgM, 24M FU, n=5, 1, 4, 1, 0, 0|	1.120 (± 999)	999 (± 999)		

IgA, 30M FU, n=2, 1, 2, 0, 0, 0|	0.505 (± 0.2900)	999 (± 999)		
IgG, 30M FU, n=2,1, 2, 0, 0, 0|	999 (± 999)	999 (± 999)		
IgM, 30M FU, n=2, 1, 2, 0, 0, 0,|	999 (± 999)	999 (± 999)		
IgA, 36M FU, n=2, 1, 2, 0, 0, 0|	999 (± 999)	999 (± 999)		
IgG, 36M FU, n=2,1, 2, 0, 0, 0|	999 (± 999)	999 (± 999)		
IgM, 36M FU, n=2, 1, 2, 0, 0, 0,|	999 (± 999)	999 (± 999)		
IgA, 42M FU, n=2, 1, 2, 0, 0, 0|	999 (± 999)	999 (± 999)		
IgG, 42M FU, n=2,1, 2, 0, 0, 0|	999 (± 999)	999 (± 999)		
IgM, 42M FU, n=2, 1, 2, 0, 0, 0|	999 (± 999)	999 (± 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants who were positive or negative for Human Anti-Human Antibodies (HAHA) post-OFA therapy

End point title	Number of participants who were positive or negative for Human Anti-Human Antibodies (HAHA) post-OFA therapy

End point description:

The presence of HAHA in human serum was determined using a validated electrochemiluminescent assay in a multi-tier assay format. All samples were first assessed in a screening (SCR) assay, and the potential positive (Pos) samples were further tested in the confirmation (CNF) assays. Confirmed positives were reported as HAHA positive and titer was determined for each positive sample. The drug tolerance of the HAHA assay is 200 microgram/milliliter (µg/mL); thus, samples that tested negative in the assay and had ofatumumab concentrations no more than 200 µg/mL were considered as conclusive negative (Neg) results.

End point type	Secondary

End point timeframe:

From the randomization date up to 60 months post the randomization date.

End point values	Any Ofatumumab (OFA)	OFA Salvage	Ofatumumab Extended (OFA Ext)	Ofatumumab Observation (OFA Observ.)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	78[8]	22[9]	24	13
Units: Participants				
CNF Pos|	0	0	0	0
Neg and no OFA concentration <200 ug/mL|	12	4	1	1
Neg and at least one OFA concentration <200 ug/mL|	57	15	23	12

Notes:

[8] - n = (69, 69, 69)

[9] - n = (19, 19, 19)

End point values	OFA first Randomization Only (OFA FRO)			

Subject group type	Subject analysis set			
Number of subjects analysed	41[10]			
Units: Participants				
CNF Pos|	0			
Neg and no OFA concentration <200 ug/mL|	10			
Neg and at least one OFA concentration <200 ug/mL|	22			

Notes:

[10] - n = (32, 32, 32)

Statistical analyses

No statistical analyses for this end point

Secondary: Changes from Baseline in European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire, Chronic Lymphocytic Leukaemia 16 item module (EORTC QLQ-CLL 16)

End point title	Changes from Baseline in European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire, Chronic Lymphocytic Leukaemia 16 item module (EORTC QLQ-CLL 16)

End point description:

The EORTC QLQ-CLL16 is comprised of 16 questions that address 5 domains of health-related quality of life (HRQoL) important in CLL. There are 4 multi-item scales – fatigue (2 items), treatment side effects ([TSE], 4 items), disease symptoms (disease effects scale [DES], 4 items), and infection (4 items) – and single item scales (social activities [Social Problems (SP) Scale] and future health worries[Future Health (FH) Scale].). These are measured on a four point scale where 1 = not at all and 4 = very much. These scores are transformed to give a rating from 0 – 100, where 0 =no symptoms or problems and 100 = a severe symptoms or problems. EORTC QLQ-CLL16 was assessed at Screening; Week (W) 12 (W4 of Cycle[C] 3), W24 (W4C6), W36 (W4C9), W48 (W4C13); during Follow-up which was every month for Months (M) 1-6, every 8 weeks for M7-12 and every 3 months up to M60; and then at PD.

End point type	Secondary

End point timeframe:

From the randomization date up to 60 months post the randomization date.

End point values	Any Ofatumumab	Physician's Choice (PC)	Ofatumumab Extended (OFA Ext)	Ofatumumab Observation (OFA Observ.)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	79	43	24	13
Units: unit on a scale				
arithmetic mean (standard deviation)				
DES, C3W4, n=59,21, 24,12|	-10.3 (± 17.60)	-6.3 (± 16.22)	-9.7 (± 12.20)	-10.4 (± 17.09)
DES, C6W4, n=44,13, 24,11|	-8.5 (± 15.82)	-6.4 (± 16.37)	-8.3 (± 14.95)	-9.8 (± 18.19)
DES, C9W4, n=28, 0, 20, 8|	-11 (± 17.72)	999 (± 999)	-7.5 (± 17.91)	-19.8 (± 14.73)
DES, C12W4, n=15, 0, 15, 0|	-3.3 (± 21.78)	999 (± 999)	-3.3 (± 21.78)	999 (± 999)
DES, 3MFU, n=0, 0, 0, 0|	999 (± 999)	999 (± 999)	999 (± 999)	999 (± 999)
DES, 5MFU, n=0, 1, 0, 0|	999 (± 999)	0 (± 999)	999 (± 999)	999 (± 999)
DES, 6MFU, n=0, 1, 0, 0|	999 (± 999)	0 (± 999)	999 (± 999)	999 (± 999)
DES, 7MFU, n=0, 8, 0, 0|	999 (± 999)	-14.6 (± 16.52)	999 (± 999)	999 (± 999)
DES, 9MFU, n=2, 6, 2, 0|	0 (± 23.57)	-9.7 (± 9.74)	0 (± 23.57)	999 (± 999)

DES, 11MFU, n=1, 5, 1, 0|	-25 (± 999)	-6.7 (± 18.07)	-2.5 (± 999)	999 (± 999)
DES, 12MFU, n=10, 3, 8, 2|	-10.8 (± 14.19)	-2.8 (± 20.97)	-10.4 (± 14.6)	-12.5 (± 17.68)
DES, 15MFU, n=7, 3, 7, 0|	-4.8 (± 13.49)	-5.6 (± 17.35)	-4.8 (± 13.49)	999 (± 999)
DES, 18MFU, n=5, 2, 5, 0|	-3.3 (± 13.94)	-20.8 (± 17.68)	-3.3 (± 13.94)	999 (± 999)
DES, 21MFU, n=3, 2, 3, 0|	5.6 (± 20.97)	-12.5 (± 5.89)	5.6 (± 20.97)	999 (± 999)
DES, 24MFU, n=2, 1, 2, 0|	4.2 (± 5.89)	0 (± 999)	4.2 (± 5.89)	999 (± 999)
DES, 27MFU, n=1, 0, 1, 0|	0 (± 999)	999 (± 999)	0 (± 999)	999 (± 999)
DES, 30MFU, n=1, 0, 1, 0|	0 (± 999)	999 (± 999)	0 (± 999)	999 (± 999)
Fatigue Scale, C3W4, n=59, 21, 24, 12|	-4 (± 24.04)	2.4 (± 21.91)	-2.1 (± 19.23)	-12.5 (± 24.75)
Fatigue Scale, C6W4, n=44, 13, 24, 11|	-5.7 (± 19.99)	12.8 (± 29.78)	-0.7 (± 16.65)	-13.6 (± 19.46)
Fatigue Scale, C9W4, n=28, 0, 20, 8|	-4.2 (± 25.1)	999 (± 999)	0 (± 24.78)	-14.6 (± 24.3)
Fatigue Scale, C12W4, n=15, 0, 15, 0|	7.8 (± 33.85)	999 (± 999)	7.8 (± 33.85)	999 (± 999)
Fatigue Scale, 3MFU, n=0, 0, 0, 0|	999 (± 999)	999 (± 999)	999 (± 999)	999 (± 999)
Fatigue Scale, 5MFU, n=0, 1, 0, 0|	999 (± 999)	16.7 (± 999)	999 (± 999)	999 (± 999)
Fatigue Scale, 6MFU, n=0, 1, 0, 0|	999 (± 999)	16.7 (± 999)	999 (± 999)	999 (± 999)
Fatigue Scale, 7MFU, n=0, 8, 0, 0|	999 (± 999)	-14.6 (± 18.77)	999 (± 999)	999 (± 999)
Fatigue Scale, 9MFU, n=2, 6, 2, 0|	41.7 (± 82.5)	-8.3 (± 22.97)	41.7 (± 82.5)	999 (± 999)
Fatigue Scale, 11MFU, n=1, 5, 1, 0|	16.7 (± 999)	-6.7 (± 19)	-16.7 (± 999)	999 (± 999)
Fatigue Scale,12MFU, n=10, 3, 8, 2|	5 (± 20.86)	-22.2 (± 9.62)	6.3 (± 21.71)	0 (± 23.57)
Fatigue Scale, 15MFU, n=7, 3, 7, 0|	2.4 (± 22.42)	0 (± 16.67)	2.4 (± 22.42)	999 (± 999)
Fatigue Scale, 18MFU, n=5, 2, 5, 0|	3.3 (± 21.73)	0 (± 0)	3.3 (± 21.73)	999 (± 999)
Fatigue Scale, 21MFU, n=3, 2, 3, 0|	16.7 (± 28.87)	0 (± 23.57)	16.7 (± 28.87)	999 (± 999)
Fatigue Scale, 24MFU, n=2, 1, 2, 0|	41.7 (± 58.93)	16.7 (± 999)	41.7 (± 58.93)	999 (± 999)
Fatigue Scale, 27MFU, n=1, 0, 1, 0|	0 (± 999)	999 (± 999)	0 (± 999)	999 (± 999)
Fatigue Scale, 30MFU, n=1, 0, 1, 0|	0 (± 999)	999 (± 999)	0 (± 999)	999 (± 999)
Future Health Scale, C3W4, n=58, 21,24, 11|	-6.9 (± 27.04)	-7.9 (± 31.46)	-4.2 (± 22.66)	-6.1 (± 29.13)
Future Health Scale, C6W4, n=44, 13, 24, 11|	-12.9 (± 29.83)	-5.1 (± 18.49)	-11.1 (± 25.38)	-24.2 (± 39.7)
Future Health Scale, C9W4, n=28, 0, 20, 8|	-14.3 (± 27.86)	999 (± 999)	-11.7 (± 27.09)	-20.8 (± 30.54)
Future Health Scale, C12W4, n=15, 0, 15, 0|	-4.4 (± 39.57)	999 (± 999)	-4.4 (± 39.57)	999 (± 999)
Future Health Scale, 3MFU, n=0, 0, 0, 0|	999 (± 999)	999 (± 999)	999 (± 999)	999 (± 999)
Future Health Scale, 5MFU, n=0, 1, 0, 0|	999 (± 999)	0 (± 999)	999 (± 999)	999 (± 999)
Future Health Scale, 6MFU, n=0, 1, 0, 0|	999 (± 999)	33.3 (± 999)	999 (± 999)	999 (± 999)
Future Health Scale, 7MFU, n=0, 8, 0, 0|	999 (± 999)	-12.5 (± 24.8)	999 (± 999)	999 (± 999)
Future Health Scale, 9MFU, n=2, 6, 2, 0|	0 (± 47.14)	-22.2 (± 40.37)	0 (± 47.14)	999 (± 999)
Future Health Scale, 11MFU, n=1, 5, 1, 0|	0 (± 999)	-13.3 (± 18.26)	0 (± 999)	999 (± 999)
Future Health Scale, 12MFU, n=10, 3, 8, 2|	-10 (± 31.62)	-11.1 (± 19.25)	-4.2 (± 33.03)	-33.3 (± 0)
Future Health Scale, 15MFU, n=7, 3, 7, 0|	19 (± 17.82)	-11.1 (± 19.25)	19 (± 17.82)	999 (± 999)
Future Health Scale, 18MFU, n=5, 2, 5, 0,|	20 (± 18.26)	-16.7 (± 23.57)	20 (± 18.26)	999 (± 999)
Future Health Scale, 21MFU, n=3, 2, 3, 0|	22.2 (± 19.25)	-16.7 (± 23.57)	22.2 (± 19.25)	999 (± 999)

Future Health Scale, 24MFU, n=2, 1, 2, 0|	0 (± 999)	0 (± 999)	33.3 (± 47.14)	999 (± 999)
Future Health Scale, 27MFU, n=1, 0, 1, 0|	0 (± 999)	999 (± 999)	0 (± 999)	999 (± 999)
Future Health Scale, 30MFU, n=1, 0, 1, 0|	0 (± 999)	999 (± 999)	0 (± 999)	999 (± 999)
Infection Scale, C3W4, n=59, 21, 24, 12|	2.1 (± 23.6)	3.2 (± 19.63)	-1 (± 20.01)	-5.6 (± 12.48)
Infection Scale, C6W4, n=44, 13, 24, 11|	-3.7 (± 22.66)	12.2 (± 25.6)	-5.6 (± 19.91)	-6.8 (± 19.3)
Infection Scale,C9W4, n=28, 0, 20, 8|	-7.4 (± 18.61)	999 (± 999)	-7.5 (± 16.86)	-7.3 (± 23.75)
Infection Scale, C12W4, n=15, 0, 15, 0|	-11.7 (± 14.02)	999 (± 999)	-11.7 (± 14.02)	999 (± 999)
Infection Scale, 3MFU, n=0, 0, 0, 0|	999 (± 999)	999 (± 999)	999 (± 999)	999 (± 999)
Infection Scale, 5MFU, n=0, 1, 0, 0|	999 (± 999)	0 (± 999)	999 (± 999)	999 (± 999)
Infection Scale, 6MFU, n=0, 1, 0, 0|	999 (± 999)	8.3 (± 999)	999 (± 999)	999 (± 999)
Infection Scale, 7MFU, n=0, 8, 0, 0|	999 (± 999)	-9.4 (± 12.15)	999 (± 999)	999 (± 999)
Infection Scale, 9MFU, n=2, 6, 2, 0|	16.7 (± 23.57)	0 (± 13.94)	16.7 (± 23.57)	999 (± 999)
Infection Scale, 11MFU, n=1, 5, 1, 0|	0 (± 999)	-6.7 (± 12.36)	0 (± 999)	999 (± 999)
Infection Scale, 12MFU, n=10, 3, 8, 2|	-7.5 (± 20.58)	2.8 (± 12.73)	-6.2 (± 20.29)	-12.5 (± 29.46)
Infection Scale, 15MFU, n=7, 3, 7, 0|	-2.4 (± 17.82)	-2.8 (± 20.97)	-2.4 (± 17.82)	999 (± 999)
Infection Scale, 18MFU, n=5, 2, 5, 0|	5 (± 12.64)	-8.3 (± 11.79)	5 (± 12.64)	999 (± 999)
Infection Scale, 21MFU, n=3, 2, 3, 0|	2.8 (± 12.73)	8.3 (± 0)	2.8 (± 12.73)	999 (± 999)
Infection Scale, 24MFU, n=2, 1, 2, 0|	0 (± 0)	8.3 (± 999)	0 (± 0)	999 (± 999)
Infection Scale, 27MFU, n=1, 0, 1, 0|	0 (± 999)	999 (± 999)	0 (± 999)	999 (± 999)
Infection Scale, 30MFU, n=1, 0, 1, 0|	0 (± 999)	999 (± 999)	0 (± 999)	999 (± 999)
SP Scale, C3W4, n=59, 21, 24, 12|	-9 (± 27.56)	3.2 (± 36.37)	-11.1 (± 23.4)	-13.9 (± 30.01)
SP Scale, C6W4, n=44, 13, 24, 11|	-10.6 (± 27.63)	10.3 (± 31.58)	-9.7 (± 25.02)	-15.2 (± 31.14)
SP Scale, C9W4, n=28, 0, 20, 8|	-13.1 (± 27.72)	999 (± 999)	-11.7 (± 29.17)	-16.7 (± 25.2)
SP Scale, C12W4, n=15, 0, 15, 0|	-11.1 (± 37.09)	999 (± 999)	-11.1 (± 37.09)	999 (± 999)
SP Scale, 3MFU, n=0, 0, 0, 0|	999 (± 999)	999 (± 999)	999 (± 999)	999 (± 999)
SP Scale, 5MFU, n=0, 1, 0, 0|	999 (± 999)	-33.3 (± 999)	999 (± 999)	999 (± 999)
SP Scale, 6MFU, n=0, 1, 0, 0|	999 (± 999)	-66.7 (± 999)	999 (± 999)	999 (± 999)
SP Scale, 7MFU, n=0, 8, 0, 0|	999 (± 999)	-16.7 (± 25.2)	999 (± 999)	999 (± 999)
SP Scale, 9MFU, n=2, 6, 2, 0|	16.7 (± 70.71)	-5.6 (± 32.77)	16.7 (± 70.71)	999 (± 999)
SP Scale, 11MFU, n=1, 5, 1, 0|	-33.3 (± 999)	-6.7 (± 36.51)	-33.3 (± 999)	999 (± 999)
SP Scale, 12MFU, n=10, 3, 8, 2|	-16.7 (± 23.57)	-22.2 (± 19.25)	-16.7 (± 25.2)	-16.7 (± 23.57)
SP Scale, 15MFU, n=7, 3, 7, 0|	-9.5 (± 37.09)	-11.1 (± 19.25)	-9.5 (± 37.09)	999 (± 999)
SP Scale, 18MFU, n=5, 2, 5, 0|	0 (± 23.57)	-16.7 (± 23.57)	0 (± 23.57)	999 (± 999)
SP Scale, 21MFU, n=3, 2, 3, 0|	-22.2 (± 38.49)	-16.7 (± 23.57)	-22.2 (± 38.49)	999 (± 999)
SP Scale, 24MFU, n=2, 1, 2, 0|	33.3 (± 47.14)	0 (± 999)	33.3 (± 47.14)	999 (± 999)
SP Scale, 27MFU, n=1, 0, 1, 0|	0 (± 999)	999 (± 999)	0 (± 999)	999 (± 999)
SP Scale, 30MFU, n=1, 0, 1, 0|	0 (± 999)	999 (± 999)	0 (± 999)	999 (± 999)
TSE Scale, C3W4, n=59, 21, 24, 12|	-4.8 (± 15.33)	-1.5 (± 16.82)	-2.4 (± 10.85)	-8.3 (± 13.76)
TSE Scale, C6W4, n=44, 13, 24, 11|	-4.2 (± 14.33)	3.2 (± 12.52)	-0.2 (± 11.32)	-9.1 (± 16.44)
TSE Scale, C9W4, n=28, 0, 20, 8|	-5.4 (± 15.75)	999 (± 999)	-3.7 (± 13.91)	-9.4 (± 20.14)
TSE Scale, C12W4, n=15, 0, 15, 0|	-2.8 (± 14.66)	999 (± 999)	-2.8 (± 14.66)	999 (± 999)
TSE Scale, 3MFU, n=0, 0, 0, 0|	0 (± 0)	0 (± 0)	999 (± 999)	999 (± 999)

TSE Scale, 5MFU, n=0, 1, 0, 0|	999 (± 999)	16.7 (± 999)	999 (± 999)	999 (± 999)
TSE Scale, 6MFU, n=0, 1, 0, 0|	999 (± 999)	16.7 (± 999)	999 (± 999)	999 (± 999)
TSE Scale, 7MFU, n=0, 8, 0, 0|	999 (± 999)	-8.3 (± 17.82)	999 (± 999)	999 (± 999)
TSE Scale, 9MFU, n=2, 6, 2, 0|	8.3 (± 11.79)	-1.4 (± 9.74)	8.3 (± 11.79)	999 (± 999)
TSE Scale, 11MFU, n=1, 5, 1, 0|	0 (± 999)	-1.7 (± 14.91)	0 (± 999)	999 (± 999)
TSE Scale, 12MFU, n=10, 3, 8, 2|	-4.2 (± 19.74)	2.8 (± 12.73)	0 (± 12.6)	-20.8 (± 41.25)
TSE Scale, 15MFU, n=7, 3, 7, 0|	-8.3 (± 12.73)	2.8 (± 9.62)	-8.3 (± 12.73)	999 (± 999)
TSE Scale, 18MFU, n=5, 2, 5, 0|	6.7 (± 16.03)	0 (± 11.79)	6.7 (± 16.03)	999 (± 999)
TSE Scale, 21MFU, n=3, 2, 3, 0|	8.3 (± 22.05)	0 (± 0)	8.3 (± 22.05)	999 (± 999)
TSE Scale, 24MFU, n=2, 1, 2, 0|	4.2 (± 5.89)	0 (± 999)	4.2 (± 5.89)	999 (± 999)
TSE Scale, 27MFU, n=1, 0, 1, 0|	8.3 (± 999)	999 (± 999)	8.3 (± 999)	999 (± 999)
TSE Scale, 30MFU, n=1, 0, 1, 0|	0 (± 999)	999 (± 999)	0 (± 999)	999 (± 999)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Health Change Questionnaire (HCQ) score

End point title	Mean Health Change Questionnaire (HCQ) score

End point description:

The HCQ consists of a single question in which the participant is asked if he/she has experienced any change in his/her health overall since beginning the study. For HCQ, values from 1 to 9 were assigned to the 9 responses in the HCQ questionnaire, ranging from 1 for 'my health is a great deal better' to 9 for 'my health is a great deal worse' since the beginning of the study. A score of 3 or less indicates improvement from Baseline. HCQ was assessed at Screening; Week (W) 12 (W4 of Cycle[C] 3), W24 (W4C6), W36 (W4C9), W48 (W4C13); during follow-up which was every month for Months 1-6, every 8 weeks for M7-12 and every 3 months up to M60; and then at PD..

End point type	Secondary

End point timeframe:

From the randomization date up to 60 months post the randomization date.

End point values	Any Ofatumumab	Physician's Choice (PC)	OFA Salvage	Ofatumumab Extended (OFA Ext)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	79	43	22	24
Units: Unit on a scale				
arithmetic mean (standard deviation)				
C3W4, n=60, 21, 24, 12, 24, 17|	2.8 (± 1.57)	3.9 (± 2.01)	3.1 (± 1.92)	2.5 (± 1.44)
C6W4, n=44, 13, 24, 11, 9, 12|	3.2 (± 2.04)	3.5 (± 2.37)	3.0 (± 2.00)	2.7 (± 1.66)
C9W4, n=28, 0, 20, 8, 0, 7|	2.08 (± 1.60)	999 (± 999)	3.1 (± 2.48)	2.5 (± 1.36)
C12W4, n=14, 0, 14, 0, 0, 4|	2.6 (± 1.99)	999 (± 999)	3.0 (± 1.83)	2.6 (± 1.99)
3MFU, n=0, 0, 0, 0, 0, 1|	999 (± 999)	999 (± 999)	3.0 (± 999)	999 (± 999)
5MFU, n=0, 1, 0, 0, 0, 0|	999 (± 999)	5.0 (± 999)	999 (± 999)	999 (± 999)
6MFU, n=0, 1, 0, 0, 0, 0|	999 (± 999)	3.0 (± 999)	999 (± 999)	999 (± 999)
7MFU, n=0, 8, 0, 0, 0, 0|	999 (± 999)	2.4 (± 1.30)	999 (± 999)	999 (± 999)
9MFU, n=2, 6, 2, 0, 0, 0|	6.5 (± 2.12)	3.5 (± 2.07)	999 (± 999)	6.5 (± 2.12)
11MFU, n=1, 5, 1, 0, 0, 0|	5.0 (± 999)	3.0 (± 2.35)	999 (± 999)	5.0 (± 999)

12MFU, n=10, 3, 8, 2, 0, 2|	3.4 (± 2.07)	2.3 (± 1.53)	2.0 (± 1.41)	3.5 (± 2.27)
15MFU, n=10, 3, 9, 1, 0, 3|	3.5 (± 2.27)	3.7 (± 1.53)	2.0 (± 1.00)	3.7 (± 2.35)
18MFU, n=7, 2, 6, 1, 0, 2|	2.6 (± 2.15)	4.5 (± 0.71)	4.0 (± 4.24)	2.8 (± 2.23)
21MFU, n=5, 2, 4, 1, 0, 0|	2.0 (± 1.22)	6.0 (± 1.41)	999 (± 999)	2.3 (± 1.26)
24MFU, n=4, 1, 3, 1, 0, 0|	2.5 (± 3.00)	4.0 (± 999)	999 (± 999)	3.0 (± 3.46)
27MFU, n=3, 1, 2, 0, 0, 0|	2.7 (± 2.89)	5.0 (± 999)	999 (± 999)	3.5 (± 3.54)
30MFU, n=1, 1, 1, 0, 0, 0|	1.0 (± 999)	5.0 (± 999)	999 (± 999)	1.0 (± 999)
33MFU, n=2, 1, 2, 0, 0, 0|	3.0 (± 2.83)	5.0 (± 999)	999 (± 999)	3.0 (± 2.83)
36MFU, n=2, 1, 2, 0, 0, 0|	3.0 (± 2.83)	5.0 (± 999)	999 (± 999)	3.0 (± 2.83)
39MFU, n=2, 1, 2, 0, 0, 0|	4.0 (± 4.24)	7.0 (± 999)	999 (± 999)	4.0 (± 4.24)
42MFU, n=2, 1, 2, 0, 0, 0|	3.0 (± 2.83)	5.0 (± 999)	999 (± 999)	3.0 (± 2.83)
45MFU, n=1, 1, 1, 0, 0, 0|	1.0 (± 999)	7.0 (± 999)	999 (± 999)	1.0 (± 999)

End point values	Ofatumumab Observation (OFA Observ.)	OFA first Randomization Only (OFA FRO)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13	41		
Units: Unit on a scale				
arithmetic mean (standard deviation)				
C3W4, n=60, 21, 24, 12, 24, 17|	2.8 (± 0.97)	3.2 (± 1.90)		
C6W4, n=44, 13, 24, 11, 9, 12|	2.9 (± 1.76)	5.1 (± 2.37)		
C9W4, n=28, 0, 20, 8, 0, 7|	3.5 (± 2.00)	999 (± 999)		
C12W4, n=14, 0, 14, 0, 0, 4|	999 (± 999)	999 (± 999)		
3MFU, n=0, 0, 0, 0, 0, 1|	999 (± 999)	999 (± 999)		
5MFU, n=0, 1, 0, 0, 0, 0|	999 (± 999)	999 (± 999)		
6MFU, n=0, 1, 0, 0, 0, 0|	999 (± 9999)	999 (± 999)		
7MFU, n=0, 8, 0, 0, 0, 0|	999 (± 999)	999 (± 999)		
9MFU, n=2, 6, 2, 0, 0, 0|	999 (± 999)	999 (± 999)		
11MFU, n=1, 5, 1, 0, 0, 0|	999 (± 999)	999 (± 999)		
12MFU, n=10, 3, 8, 2, 0, 2|	3.0 (± 1.41)	999 (± 999)		
15MFU, n=10, 3, 9, 1, 0, 3|	2.0 (± 999)	999 (± 999)		
18MFU, n=7, 2, 6, 1, 0, 2|	1.0 (± 999)	999 (± 999)		
21MFU, n=5, 2, 4, 1, 0, 0|	1.0 (± 999)	999 (± 999)		
24MFU, n=4, 1, 3, 1, 0, 0|	1.0 (± 999)	999 (± 999)		
27MFU, n=3, 1, 2, 0, 0, 0|	1.0 (± 999)	999 (± 999)		
30MFU, n=1, 1, 1, 0, 0, 0|	999 (± 999)	999 (± 999)		
33MFU, n=2, 1, 2, 0, 0, 0|	3.0 (± 2.83)	999 (± 999)		
36MFU, n=2, 1, 2, 0, 0, 0|	3.0 (± 2.83)	999 (± 999)		
39MFU, n=2, 1, 2, 0, 0, 0|	4.0 (± 4.24)	999 (± 999)		
42MFU, n=2, 1, 2, 0, 0, 0|	3.0 (± 3.83)	999 (± 999)		
45MFU, n=1, 1, 1, 0, 0, 0|	1.0 (± 999)	999 (± 999)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs & AEs were collected from 1st dose to 60 days after last dose of study medication & until end of FU period for SAEs unless initiation of subsequent anti-CLL therapy. AEs reported in this record - from date of FP First Treatment until LPLV

Adverse event reporting additional description:

Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Any Ofatumumab
Reporting group description:	
Any Ofatumumab	
Reporting group title	Ofatumumab extended
Reporting group description:	
Ofatumumab extended	
Reporting group title	Ofatumumab observation
Reporting group description:	
Ofatumumab observation	
Reporting group title	Ofatumumab
Reporting group description:	
Ofatumumab	
Reporting group title	Physicians choice
Reporting group description:	
Physicians choice	
Reporting group title	Ofatumumab salvage
Reporting group description:	
Ofatumumab salvage	

Serious adverse events	Any Ofatumumab	Ofatumumab extended	Ofatumumab observation
Total subjects affected by serious adverse events			
subjects affected / exposed	43 / 78 (55.13%)	12 / 24 (50.00%)	5 / 13 (38.46%)
number of deaths (all causes)	13	1	1
number of deaths resulting from adverse events	5	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Large cell lung cancer			

subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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			
Hypotension			
subjects affected / exposed	2 / 78 (2.56%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
General disorders and administration site conditions			
Chills			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Death			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 78 (1.28%)	1 / 24 (4.17%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	1 / 1	0 / 0
Oedema peripheral			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Pyrexia			
subjects affected / exposed	4 / 78 (5.13%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	6 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Bronchospasm			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 78 (1.28%)	1 / 24 (4.17%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Hydrothorax			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Lung disorder			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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

Obstructive airways disorder			
subjects affected / exposed	1 / 78 (1.28%)	1 / 24 (4.17%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Pneumonitis			
subjects affected / exposed	2 / 78 (2.56%)	1 / 24 (4.17%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Pulmonary oedema			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Investigations			
Blood pressure decreased			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
C-reactive protein increased			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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

Thoracic vertebral fracture			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	2 / 78 (2.56%)	0 / 24 (0.00%)	0 / 13 (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
Cardiac arrest			
subjects affected / exposed	2 / 78 (2.56%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	2 / 78 (2.56%)	1 / 24 (4.17%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Cardiovascular insufficiency			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Myocardial infarction			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Ventricular tachycardia			

subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Nervous system disorders			
Chorea			
subjects affected / exposed	1 / 78 (1.28%)	1 / 24 (4.17%)	0 / 13 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 78 (2.56%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Febrile neutropenia			
subjects affected / exposed	7 / 78 (8.97%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	5 / 8	0 / 0	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Neutropenia			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Thrombocytopenia			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Eye disorders			

Chorioretinal atrophy			
subjects affected / exposed	1 / 78 (1.28%)	1 / 24 (4.17%)	0 / 13 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Diarrhoea			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 78 (1.28%)	1 / 24 (4.17%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Hepatitis toxic			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Hepatotoxicity			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Hydronephrosis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Renal failure			
subjects affected / exposed	2 / 78 (2.56%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Endocrine disorders			
Hypercalcaemia of malignancy			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Infections and infestations			
Abscess neck			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Acute sinusitis			
subjects affected / exposed	1 / 78 (1.28%)	1 / 24 (4.17%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 78 (1.28%)	1 / 24 (4.17%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Device related infection			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Empyema			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Enterocolitis infectious			
subjects affected / exposed	1 / 78 (1.28%)	1 / 24 (4.17%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal fungal infection			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Hepatitis B			
subjects affected / exposed	1 / 78 (1.28%)	1 / 24 (4.17%)	0 / 13 (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
Hepatitis E			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Lower respiratory tract infection			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			

subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Meningitis			
subjects affected / exposed	2 / 78 (2.56%)	1 / 24 (4.17%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis aseptic			
subjects affected / exposed	1 / 78 (1.28%)	1 / 24 (4.17%)	0 / 13 (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
Neutropenic sepsis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Otosalpingitis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Pneumonia			
subjects affected / exposed	9 / 78 (11.54%)	3 / 24 (12.50%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	3 / 10	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Progressive multifocal leukoencephalopathy			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	1 / 1
Pseudomembranous colitis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Sepsis			

subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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 infection			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	2 / 78 (2.56%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Viral infection			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Viral tonsillitis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Hypoalbuminaemia			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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
Malnutrition			

subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (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
Tumour lysis syndrome			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (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

Serious adverse events	Ofatumumab	Physicians choice	Ofatumumab salvage
Total subjects affected by serious adverse events			
subjects affected / exposed	26 / 41 (63.41%)	23 / 43 (53.49%)	10 / 22 (45.45%)
number of deaths (all causes)	11	8	3
number of deaths resulting from adverse events	3	5	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Large cell lung cancer			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vascular disorders			
Hypotension			
subjects affected / exposed	2 / 41 (4.88%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
General disorders and administration site conditions			
Chills			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Death			

subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Oedema peripheral			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Pyrexia			
subjects affected / exposed	4 / 41 (9.76%)	3 / 43 (6.98%)	2 / 22 (9.09%)
occurrences causally related to treatment / all	6 / 7	2 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (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
Bronchospasm			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (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
Dyspnoea			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			

subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (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
Hydrothorax			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (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
Lung disorder			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (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
Lung infiltration			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Obstructive airways disorder			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (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
Pleural effusion			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	1 / 41 (2.44%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			

subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Investigations			
Blood pressure decreased			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
C-reactive protein increased			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (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
Thoracic vertebral fracture			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	2 / 41 (4.88%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	2 / 41 (4.88%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 41 (2.44%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 0

Cardiac failure acute			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	2 / 22 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiovascular insufficiency			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Myocardial infarction			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Ventricular tachycardia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Nervous system disorders			
Chorea			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 41 (2.44%)	4 / 43 (9.30%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	1 / 1	2 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 41 (0.00%)	2 / 43 (4.65%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Febrile neutropenia			
subjects affected / exposed	6 / 41 (14.63%)	4 / 43 (9.30%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	4 / 7	6 / 6	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (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
Neutropenia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Thrombocytopenia			
subjects affected / exposed	1 / 41 (2.44%)	1 / 43 (2.33%)	0 / 22 (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
Eye disorders			
Chorioretinal atrophy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Diarrhoea			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Hepatobiliary disorders			
Cholelithiasis			

subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (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
Drug-induced liver injury			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (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
Hepatitis toxic			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Hepatotoxicity			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Hydronephrosis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Renal failure			
subjects affected / exposed	2 / 41 (4.88%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Endocrine disorders			

Hypercalcaemia of malignancy			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Infections and infestations			
Abscess neck			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Acute sinusitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (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
Bronchitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (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
Cellulitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Device related infection			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (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
Empyema			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (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
Gastrointestinal fungal infection			

subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Hepatitis B			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis E			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (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
Lung infection			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Meningitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Meningitis aseptic			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (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
Neutropenic sepsis			
subjects affected / exposed	1 / 41 (2.44%)	2 / 43 (4.65%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	2 / 2	0 / 0
Otosalpingitis			

subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	6 / 41 (14.63%)	7 / 43 (16.28%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	3 / 6	2 / 8	0 / 1
deaths causally related to treatment / all	0 / 2	1 / 1	0 / 0
Progressive multifocal leukoencephalopathy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (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
Pseudomembranous colitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Sepsis			
subjects affected / exposed	0 / 41 (0.00%)	4 / 43 (9.30%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (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
Upper respiratory tract infection			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Urinary tract infection			
subjects affected / exposed	1 / 41 (2.44%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral tonsillitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (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
Hypoalbuminaemia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (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
Malnutrition			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (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
Tumour lysis syndrome			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0

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

Non-serious adverse events	Any Ofatumumab	Ofatumumab extended	Ofatumumab observation
Total subjects affected by non-serious adverse events			
subjects affected / exposed	62 / 78 (79.49%)	20 / 24 (83.33%)	9 / 13 (69.23%)
Vascular disorders			
Flushing			
subjects affected / exposed	3 / 78 (3.85%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	6	0	1

Hypertension			
subjects affected / exposed	5 / 78 (6.41%)	2 / 24 (8.33%)	0 / 13 (0.00%)
occurrences (all)	5	2	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 78 (3.85%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Chills			
subjects affected / exposed	9 / 78 (11.54%)	1 / 24 (4.17%)	2 / 13 (15.38%)
occurrences (all)	18	1	3
Fatigue			
subjects affected / exposed	3 / 78 (3.85%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	3	0	1
Oedema peripheral			
subjects affected / exposed	2 / 78 (2.56%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Peripheral swelling			
subjects affected / exposed	4 / 78 (5.13%)	1 / 24 (4.17%)	0 / 13 (0.00%)
occurrences (all)	4	1	0
Pyrexia			
subjects affected / exposed	8 / 78 (10.26%)	2 / 24 (8.33%)	1 / 13 (7.69%)
occurrences (all)	14	3	2
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	11 / 78 (14.10%)	3 / 24 (12.50%)	2 / 13 (15.38%)
occurrences (all)	14	4	2
Dyspnoea			
subjects affected / exposed	3 / 78 (3.85%)	1 / 24 (4.17%)	1 / 13 (7.69%)
occurrences (all)	3	1	1
Nasal obstruction			

subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Productive cough			
subjects affected / exposed	4 / 78 (5.13%)	0 / 24 (0.00%)	2 / 13 (15.38%)
occurrences (all)	4	0	2
Psychiatric disorders			
Depressed mood			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	4 / 78 (5.13%)	1 / 24 (4.17%)	1 / 13 (7.69%)
occurrences (all)	6	1	3
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 78 (3.85%)	1 / 24 (4.17%)	1 / 13 (7.69%)
occurrences (all)	5	1	3
Blood bilirubin increased			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Haemoglobin decreased			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Lymphocyte count decreased			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Neutrophil count decreased			
subjects affected / exposed	2 / 78 (2.56%)	1 / 24 (4.17%)	1 / 13 (7.69%)
occurrences (all)	4	3	1
Weight decreased			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Weight increased			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Injury, poisoning and procedural complications			

Arthropod bite			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Contusion			
subjects affected / exposed	3 / 78 (3.85%)	2 / 24 (8.33%)	1 / 13 (7.69%)
occurrences (all)	3	2	1
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	3 / 78 (3.85%)	2 / 24 (8.33%)	0 / 13 (0.00%)
occurrences (all)	3	2	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	3 / 78 (3.85%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Hypoaesthesia			
subjects affected / exposed	2 / 78 (2.56%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Muscle spasticity			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Paraesthesia			
subjects affected / exposed	3 / 78 (3.85%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	4	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 78 (6.41%)	2 / 24 (8.33%)	0 / 13 (0.00%)
occurrences (all)	5	2	0
Leukopenia			
subjects affected / exposed	2 / 78 (2.56%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	3	0	1
Lymphocytosis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Neutropenia			

subjects affected / exposed	15 / 78 (19.23%)	10 / 24 (41.67%)	1 / 13 (7.69%)
occurrences (all)	33	24	1
Thrombocytopenia			
subjects affected / exposed	8 / 78 (10.26%)	3 / 24 (12.50%)	1 / 13 (7.69%)
occurrences (all)	11	6	1
Ear and labyrinth disorders			
Ear congestion			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Hypoacusis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Vertigo			
subjects affected / exposed	2 / 78 (2.56%)	1 / 24 (4.17%)	1 / 13 (7.69%)
occurrences (all)	3	2	1
Eye disorders			
Visual impairment			
subjects affected / exposed	2 / 78 (2.56%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	4 / 78 (5.13%)	2 / 24 (8.33%)	0 / 13 (0.00%)
occurrences (all)	4	2	0
Constipation			
subjects affected / exposed	3 / 78 (3.85%)	1 / 24 (4.17%)	1 / 13 (7.69%)
occurrences (all)	4	1	1
Diarrhoea			
subjects affected / exposed	5 / 78 (6.41%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences (all)	9	0	0
Nausea			
subjects affected / exposed	8 / 78 (10.26%)	2 / 24 (8.33%)	1 / 13 (7.69%)
occurrences (all)	11	3	1
Vomiting			
subjects affected / exposed	4 / 78 (5.13%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences (all)	4	0	0
Hepatobiliary disorders			

Hyperbilirubinaemia			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	3 / 78 (3.85%)	1 / 24 (4.17%)	1 / 13 (7.69%)
occurrences (all)	4	2	1
Pruritus			
subjects affected / exposed	5 / 78 (6.41%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences (all)	7	0	0
Rash			
subjects affected / exposed	3 / 78 (3.85%)	1 / 24 (4.17%)	1 / 13 (7.69%)
occurrences (all)	3	1	1
Skin lesion			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Urticaria			
subjects affected / exposed	3 / 78 (3.85%)	2 / 24 (8.33%)	1 / 13 (7.69%)
occurrences (all)	4	3	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 78 (2.56%)	0 / 24 (0.00%)	2 / 13 (15.38%)
occurrences (all)	2	0	2
Back pain			
subjects affected / exposed	4 / 78 (5.13%)	1 / 24 (4.17%)	0 / 13 (0.00%)
occurrences (all)	5	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	6 / 78 (7.69%)	4 / 24 (16.67%)	0 / 13 (0.00%)
occurrences (all)	7	4	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	2 / 78 (2.56%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1

Fungal infection			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	2
Gastroenteritis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Nasopharyngitis			
subjects affected / exposed	5 / 78 (6.41%)	3 / 24 (12.50%)	1 / 13 (7.69%)
occurrences (all)	6	4	1
Pneumonia			
subjects affected / exposed	4 / 78 (5.13%)	3 / 24 (12.50%)	0 / 13 (0.00%)
occurrences (all)	4	3	0
Respiratory tract infection			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Sialoadenitis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 24 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Sinusitis			
subjects affected / exposed	3 / 78 (3.85%)	2 / 24 (8.33%)	0 / 13 (0.00%)
occurrences (all)	3	2	0
Upper respiratory tract infection			
subjects affected / exposed	4 / 78 (5.13%)	0 / 24 (0.00%)	2 / 13 (15.38%)
occurrences (all)	4	0	2
Urinary tract infection			
subjects affected / exposed	3 / 78 (3.85%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	3 / 78 (3.85%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 78 (0.00%)	0 / 24 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			

subjects affected / exposed	4 / 78 (5.13%)	1 / 24 (4.17%)	0 / 13 (0.00%)
occurrences (all)	4	1	0
Hyperuricaemia			
subjects affected / exposed	2 / 78 (2.56%)	2 / 24 (8.33%)	0 / 13 (0.00%)
occurrences (all)	3	3	0

Non-serious adverse events	Ofatumumab	Physicians choice	Ofatumumab salvage
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 41 (80.49%)	28 / 43 (65.12%)	13 / 22 (59.09%)
Vascular disorders			
Flushing			
subjects affected / exposed	2 / 41 (4.88%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	5	0	0
Hypertension			
subjects affected / exposed	3 / 41 (7.32%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 41 (7.32%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Chills			
subjects affected / exposed	6 / 41 (14.63%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences (all)	14	1	0
Fatigue			
subjects affected / exposed	2 / 41 (4.88%)	4 / 43 (9.30%)	0 / 22 (0.00%)
occurrences (all)	2	4	0
Oedema peripheral			
subjects affected / exposed	1 / 41 (2.44%)	3 / 43 (6.98%)	0 / 22 (0.00%)
occurrences (all)	1	3	0
Peripheral swelling			
subjects affected / exposed	3 / 41 (7.32%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences (all)	3	1	0
Pyrexia			
subjects affected / exposed	5 / 41 (12.20%)	3 / 43 (6.98%)	1 / 22 (4.55%)
occurrences (all)	9	3	2
Reproductive system and breast disorders			

Erectile dysfunction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	6 / 41 (14.63%)	1 / 43 (2.33%)	2 / 22 (9.09%)
occurrences (all)	8	1	2
Dyspnoea			
subjects affected / exposed	1 / 41 (2.44%)	2 / 43 (4.65%)	1 / 22 (4.55%)
occurrences (all)	1	2	1
Nasal obstruction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	2 / 41 (4.88%)	0 / 43 (0.00%)	1 / 22 (4.55%)
occurrences (all)	2	0	1
Psychiatric disorders			
Depressed mood			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 41 (4.88%)	1 / 43 (2.33%)	1 / 22 (4.55%)
occurrences (all)	2	1	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Neutrophil count decreased			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	1 / 41 (2.44%)	1 / 43 (2.33%)	2 / 22 (9.09%)
occurrences (all)	1	1	2
Weight increased			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	1 / 22 (4.55%)
occurrences (all)	0	1	2
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	2
Headache			
subjects affected / exposed	3 / 41 (7.32%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Muscle spasticity			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	2 / 41 (4.88%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 41 (7.32%)	5 / 43 (11.63%)	1 / 22 (4.55%)
occurrences (all)	3	8	4
Leukopenia			
subjects affected / exposed	1 / 41 (2.44%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences (all)	2	2	0
Lymphocytosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	4 / 41 (9.76%)	8 / 43 (18.60%)	3 / 22 (13.64%)
occurrences (all)	8	9	6
Thrombocytopenia			
subjects affected / exposed	4 / 41 (9.76%)	3 / 43 (6.98%)	1 / 22 (4.55%)
occurrences (all)	4	4	1
Ear and labyrinth disorders			
Ear congestion			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Visual impairment			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	2 / 41 (4.88%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences (all)	2	1	0
Constipation			
subjects affected / exposed	1 / 41 (2.44%)	1 / 43 (2.33%)	1 / 22 (4.55%)
occurrences (all)	2	1	1

Diarrhoea			
subjects affected / exposed	5 / 41 (12.20%)	4 / 43 (9.30%)	2 / 22 (9.09%)
occurrences (all)	9	4	2
Nausea			
subjects affected / exposed	5 / 41 (12.20%)	5 / 43 (11.63%)	1 / 22 (4.55%)
occurrences (all)	7	7	2
Vomiting			
subjects affected / exposed	4 / 41 (9.76%)	3 / 43 (6.98%)	0 / 22 (0.00%)
occurrences (all)	4	3	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	5 / 41 (12.20%)	2 / 43 (4.65%)	0 / 22 (0.00%)
occurrences (all)	7	2	0
Rash			
subjects affected / exposed	1 / 41 (2.44%)	2 / 43 (4.65%)	2 / 22 (9.09%)
occurrences (all)	1	2	2
Skin lesion			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	3 / 41 (7.32%)	1 / 43 (2.33%)	1 / 22 (4.55%)
occurrences (all)	4	1	1

Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 41 (4.88%)	3 / 43 (6.98%)	1 / 22 (4.55%)
occurrences (all)	3	4	1
Cytomegalovirus infection			
subjects affected / exposed	0 / 41 (0.00%)	4 / 43 (9.30%)	0 / 22 (0.00%)
occurrences (all)	0	4	0
Eye infection			
subjects affected / exposed	1 / 41 (2.44%)	0 / 43 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Fungal infection			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 41 (2.44%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Pneumonia			
subjects affected / exposed	1 / 41 (2.44%)	1 / 43 (2.33%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sialoadenitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 41 (2.44%)	1 / 43 (2.33%)	1 / 22 (4.55%)
occurrences (all)	1	1	1
Upper respiratory tract infection			
subjects affected / exposed	2 / 41 (4.88%)	4 / 43 (9.30%)	2 / 22 (9.09%)
occurrences (all)	2	4	3
Urinary tract infection			

subjects affected / exposed	3 / 41 (7.32%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	3 / 41 (7.32%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 43 (2.33%)	2 / 22 (9.09%)
occurrences (all)	0	2	3
Hyperkalaemia			
subjects affected / exposed	3 / 41 (7.32%)	0 / 43 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 41 (0.00%)	2 / 43 (4.65%)	0 / 22 (0.00%)
occurrences (all)	0	2	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 February 2013	Amendment 1 was applicable to all study sites that were required to include information from the Study Procedures Manual
11 December 2013	The main purpose of this amendment was to incorporate the recommendations related to HBV reactivation which were based on the update to internal global safety information for ofatumumab. Recommendations were given on HBV screening, monitoring and management for all subjects who a received ofatumumab and all subjects who completed treatment with ofatumumab in the previous 12 months before the amendment and were in the follow-up phase of the protocol.
25 February 2016	Change in study sponsorship from GSK to Novartis. Other clarifications have been included in this amendment: List of abbreviations from CRO to Clinical Research Organization, change in time Period and Frequency of Detecting AEs and SAEs, Prompt Reporting of Serious Adverse Events and Other Events to Novartis, Pregnancy Reporting, Study and Site Closure, record Retention, Provision of Study Results to Investigators, Posting of Information on Publically Available Clinical Trials Registers and Publication

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/CtrdWeb/home.novfor complete trial results.

Notes: