ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 09/19/2013

ClinicalTrials.gov ID: NCT00655824

Study Identification

Unique Protocol ID:	111752
Brief Title:	Long-term Efficacy and Safety of Repeated Ofatumumab Treatment Courses in RA Patients Who Previously Received Ofatumumab or Placebo in Trial Hx-CD20-403
Official Title:	An Open-label, International, Multi-center, Phase II, Extension Trial Investigating Long-term Efficacy and Safety of Repeated Treatment Courses of Ofatumumab, a Fully Human Monoclonal Anti-CD20 Antibody, in Adult Patients With Active Rheumatoid Arthritis Who Previously Received Ofatumumab or Placebo
Secondary IDs:	GEN413 [GENMAB]

Study Status

Record Verification:	September 2013
Overall Status:	Terminated
Study Start:	January 2008
Primary Completion:	May 2011 [Actual]
Study Completion:	March 2013 [Actual]

Sponsor/Collaborators

Sponsor:	GlaxoSmithKline
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 12060 Serial Number: Has Expanded Access? No
Review Board:	Approval Status: Approved Approval Number: LR/07/S0501/90 Board Name: Fife, Forth Valley and Tayside Research Ethics Service Board Affiliation: NHS Tayside. Phone: 01382 740 099 Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	A 3-year open-label trial for patients who previously participated in Trial Hx-CD20-403 and who fulfill the eligibility criteria for this trial (GEN413) . Th e primary purpose of the trial is to evaluate the long-term effectiveness of repeated courses (a maximum of 9 treatment courses) of ofatumumab in RA patients who previously received ofatumumab or placebo in Trial Hx-CD20-403.
Detailed Description:	All patients who fulfill the eligibility criteria for this trial , will initiate at least one treatment course of ofatumumab, and depending of subsequent worsening in disease activity will be eligible to received further treatment through the 156 week treatment period: a maximum of a further 8 treatment courses will be given at individualized time intervals . The interval between each treatment course will be at least 16 weeks with the last treatment course given no later than week 130 after baseline (Visit 2A). After each treatment course the patients will attend their next trial visit 8 weeks after Infusion 1, followed by trial visits every 4 weeks up to Week 24, and subsequently every 8 weeks until the next treatment course. After completing the Treatment Period or after withdrawing from the Treatment Period prematurely patients will be followed every 12 weeks (Follow-up Period) until CD19+ cells &/or IgG levels have returned to baseline or normal levels.

Conditions

Conditions:	Arthritis, Rheumatoid

Keywords:

Study Design

Study Type: Interventional
Primary Purpose: Treatment
Study Phase: Phase 2
Intervention Model: Single Group Assignment
Number of Arms: 1
Masking: Open Label
Allocation: N/A
Endpoint Classification: Safety/Efficacy Study
Enrollment: 124 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Ofatumumab 1000 mL dilution of 35mls ofatumumab in sterile, pyrogen free, 0.9% NaCl	Drug: ofatumumab 1000 mL dilution of 35mls ofatumumab in sterile, pyrogen free, 0.9% NaCl

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years
Maximum Age:
Gender: Both
Accepts Healthy Volunteers?: No
Criteria: Inclusion Criteria:

- Previously received ofatumumab or placebo in Trial Hx-CD20-403.
- Patients on methotrexate therapy (7.5 – 25 mg/week, p.o., i.m., and/or s.c.).
- Oral corticosteroids therapy (≤ 10 mg/day prednisolone or equivalent).
- Active disease at the time of screening as defined by:

- 3 swollen joints (of 28 joints assessed) and ≥ 3 tender joints (of 28 joints assessed), DAS28≥3.2 (based on ESR)

Exclusion Criteria:

- Use of DMARDs other than methotrexate or exposure to other cell depleting therapy, including investigational compounds < 6 months prior to Visit 2 A.
- Patients who have received treatment with any non-marketed drug substance within 4 weeks prior to Visit 1 (screening).
- Breast feeding women or women with a positive pregnancy test at Visit 1 (screening).
- Received anti-cancer therapy, corticosteroids (intra-articular, i.m., or i.v.), or live/attenuated vaccinations, or exposure to cyclophosphamide, nitrogen mustard, chlorambucil or other alkylating agents < 5 years prior to screening.
- Past or current malignancy, except for Cervical carcinoma Stage 1B or less, Non-invasive basal cell and squamous cell skin carcinoma, Malignant melanoma with a complete response of a duration of > 10 years, or other cancer diagnoses with a complete response of a duration of > 5 years.
- Chronic or ongoing active infectious disease requiring systemic treatment.
- Clinically significant cardiac disease, or history of significant cerebrovascular disease.

Significant concurrent, uncontrolled medical conditions, but not limited to, renal, hepatic, hematological, gastrointestinal, endocrine, pulmonary, neurological, cerebral psychiatric disease

- Known or suspected HIV positive, positive serology for hepatitis B (HB), positive test for Hepatitis C, or positive plasma or white cell JC virus (JCV) PCR (either compartment).
- A circulating IgG level <lower limit of normal.
- Known hypersensitivity to components of the investigational medicinal product.
- Patients known or suspected of not being able to comply with a study protocol.
- Women of child bearing potential not will to use adequate contraception during study

Contacts/Locations

Study Officials: GSK Clinical Trials
Study Director
GlaxoSmithKline

Locations: United Kingdom
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References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Participants who previously participated in Study OFA112657 (NCT00291928) and who fulfilled the eligibility criteria were offered participation in this study (111752; NCT00655824).

Pre-Assignment Details	A participant was considered to have completed the study when the Investigator decided that the participant had completed the treatment phase and recorded this in the Case Report Form. Completion was not based on having completed a set number of treatment courses.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course (TC). The remaining TCs were given at individualized time intervals when a clinical response had been achieved following the previous TC and a subsequent worsening in disease activity had been observed. For the remaining TCs, the interval between the TCs was at least 16 weeks from the first infusion in the previous TC irrespective of progression in disease activity. After each TC, participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next TC. A maximum of 9 TCs were allowed. After completing or withdrawing from the Treatment Period, participants were followed up every 12 weeks (for a maximum of 2 years in the Follow-up Period) until CD19+ cells returned to Baseline or normal levels.

Treatment Period

	Ofatumumab 700 mg IV Infusion
Started	92
Completed	8
Not Completed	84
Adverse Event	3
Early Termination of Study by Sponsor	74
Protocol Violation	1
Withdrawal by Subject	4
Deterioration of Trial Disease	2

Follow-up (FU) Period

	Ofatumumab 700 mg IV Infusion
Started	79 [1]
Completed	13
Not Completed	66
Protocol Violation	59
Withdrawal by Subject	4

	Ofatumumab 700 mg IV Infusion
Started Adalimumab Therapy	1
Physician Decision; Low B-cells	1
Did Not Show for Scheduled FU Visit	1

[1] A participant who withdrew from the Treatment Phase could still enter the Follow-up Phase.

Baseline Characteristics

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Baseline Measures

	Ofatumumab 700 mg IV Infusion
Number of Participants	92
Age, Continuous [units: Years] Mean (Standard Deviation)	52.9 (10.73)
Gender, Male/Female [units: Participants]	
Female	84
Male	8

	Ofatumumab 700 mg IV Infusion
Race/Ethnicity, Customized [units: participants]	92

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Time to Treatment Withdrawal
Measure Description	Time to treatment withdrawal was defined as the time from the first infusion of ofatumumab until the date of treatment withdrawal. The sponsor discontinued the intravenous route of administration development program for rheumatoid arthritis (RA), and this study was terminated early; hence, this primary endpoint was not evaluated.
Time Frame	From Baseline up to 144 weeks
Safety Issue?	No

Analysis Population Description

Full Analysis Set (FAS) Population: all participants who were exposed to study drug irrespective of their compliance to the planned course of treatment.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

2. Secondary Outcome Measure:

Measure Title	Minimum Change From Baseline in Disease Activity Score Based on 28 Joints (DAS28) Over the Course of Weeks (Wk) 1 to 24 in Each Treatment Course (TC), Assessed by Erythrocyte Sedimentation Rate (ESR; Rate at Which Red Blood Cells Sediment in 1 Hour)
Measure Description	DAS28(ESR) is a numeric outcome that measures RA activity based on the ESR (a non-specific general indicator of inflammation), tender joint count (JC), swollen JC, and participant's global assessment of disease activity on a 100 millimeter Visual Analog Scale. DAS28 values range from 0 (no activity) and upwards; increasing values indicate increasing activity (there is no upper limit on the scale). Change from baseline (CFB) was calculated at all visits; however, minimum CFB was calculated as the minimum CFB obtained over the course of weeks 1-24 of each treatment cycle.
Time Frame	Baseline (last visit prior to dosing in each TC) and last visit of each TC (8 wk post infusion, then every 4 wk until Wk 24; up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description

FAS Population. One participant withdrew during the first infusion due to adverse events (AEs) of rash and pruritus. Only participants available at the indicated time point were assessed. Minimum change from baseline is defined as the smallest change at any visit over the course of Weeks 1 to 24 of each treatment cycle.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	91
Minimum Change From Baseline in Disease Activity Score Based on 28 Joints (DAS28) Over the Course of Weeks (Wk) 1 to 24 in Each Treatment Course (TC), Assessed by Erythrocyte Sedimentation Rate (ESR; Rate at Which Red Blood Cells Sediment in 1 Hour)	

	Ofatumumab 700 mg IV Infusion
[units: scores on a scale] Mean (Standard Deviation)	
Treatment Course 1, n=91	-1.92 (0.918)
Treatment Course 2, n=71	-1.58 (0.824)
Treatment Course 3, n=53	-1.52 (0.849)
Treatment Course 4, n=20	-1.65 (1.110)
Treatment Course 5, n=8	-2.16 (1.114)
Treatment Course 6, n=4	-0.87 (0.771)
Treatment Course 7, n=2	-2.10 (2.146)

3. Secondary Outcome Measure:

Measure Title	Minimum Change From Baseline in DAS28 Over the Course of Weeks 1 to 24 in Each Treatment Course, Based on C-reactive Protein (CRP)
Measure Description	DAS28(CRP) is a numeric outcome that measures RA activity based on the CRP (used to monitor acute inflammatory phases of RA), tender JC, swollen JC, and participant's global assessment of disease activity on a 100 millimeter Visual Analog Scale. DAS28 values range from 0 (no activity) and upwards; increasing values indicate increasing activity (there is no upper limit on the scale). Change from baseline (CFB) was calculated at all visits; however, minimum CFB was calculated as the minimum CFB obtained over the course of weeks 1-24 of each treatment cycle.
Time Frame	Baseline (last visit prior to dosing in each TC) and last visit of each TC (8 wk post infusion, then every 4 wk until Wk 24; up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description

FAS Population. One participant withdrew during the first infusion due to AEs of rash and pruritis. Only participants available at the indicated time point were assessed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	91
Minimum Change From Baseline in DAS28 Over the Course of Weeks 1 to 24 in Each Treatment Course, Based on C-reactive Protein (CRP) [units: scores on a scale] Mean (Standard Deviation)	
Treatment Course 1, n=91	-1.79 (0.906)
Treatment Course 2, n=71	-1.32 (0.771)
Treatment Course 3, n=53	-1.27 (0.793)
Treatment Course 4, n=20	-1.55 (0.970)
Treatment Course 5, n=8	-1.88 (1.181)
Treatment Course 6, n=4	-0.88 (0.572)
Treatment Course 7, n=2	-2.14 (1.893)

4. Secondary Outcome Measure:

Measure Title	Time to Re-treatment in Each Treatment Course

Measure Description	Time to re-treatment in each treatment course (TC) is defined as the time from the first infusion of ofatumumab until the date of the first infusion of the first re-treatment course. The data presented reflect the time to re-treatment, which is defined as the time in days between the first infusion of each TC and the first infusion of the following TC. For TC 1, time to re-treatment is defined as the time between the first infusion in TC 1 and the first infusion in TC 2; similarly, for TC 2 it is the time between the first infusion of TC 2 and the first infusion of TC 3.
Time Frame	Week 16 to Week 104 of each treatment course (up to 125 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants available at the indicated time point were assessed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	73
Time to Re-treatment in Each Treatment Course [units: days] Mean (Standard Deviation)	
Treatment Course 1, n=73	291.01 (127.367)
Treatment Course 2, n=53	328.83 (122.427)
Treatment Course 3, n=20	235.95 (93.924)
Treatment Course 4, n=8	154.88 (19.172)
Treatment Course 5, n=4	161.75 (22.066)
Treatment Course 6, n=2	120.00 (0.000)

	Ofatumumab 700 mg IV Infusion
Treatment Course 7, n=0	NA (NA) [1]

[1] The study was terminated by the sponsor after Treatment Course 7; therefore, there are no re-treatment data available for Treatment Course 7.

5. Secondary Outcome Measure:

Measure Title	Ofatumumab Serum Concentration
Measure Description	Blood samples of participants were collected for the measurement of ofatumumab concentration in the blood. The blood samples were collected before infusion (BI) (baseline of that particular treatment course) and at the end of infusion (EI) of ofatumumab.
Time Frame	Before infusion and at the end of infusion for each Treatment Course (8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next TC; up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial vi
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at the particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Ofatumumab Serum Concentration [units: Nanograms per milliliter (ng/mL)] Mean (Standard Deviation)	

	Ofatumumab 700 mg IV Infusion
Treatment Course 1, Baseline (BI); n=92	3596.3 (32324.08)
Treatment Course 1, Baseline (EI); n=91	295588.3 (67754.65)
Treatment Course 1, Week 104; n=1	NA (NA) [1]
Treatment Course 2, Baseline (BI); n=73	837.6 (3102.94)
Treatment Course 2, Baseline (EI); n=92	292283.5 (87672.90)
Treatment Course 2, Week 80; n=1	NA (NA) [1]
Treatment Course 3, Baseline (BI); n=53	955.0 (3270.64)
Treatment Course 3, Baseline (EI); n=53	276719.3 (68620.07)
Treatment Course 3, Week 64; n=1	NA (NA) [1]
Treatment Course 4, Baseline (BI); n=20	2070.2 (3329.24)
Treatment Course 4, Baseline (EI); n=20	296305.7 (76863.21)
Treatment Course 4, Week 40; n=1	NA (NA) [1]
Treatment Course 5, Baseline (BI); n=8	6077.8 (5853.91)
Treatment Course 5, Baseline (EI); n=8	244302.0 (115157.71)
Treatment Course 5, Week 24; n=2	6543.5 (1229.66)
Treatment Course 6, Baseline (BI); n=4	5036.5 (3099.45)
Treatment Course 6, Baseline (EI); n=4	305474.8 (79304.73)
Treatment Course 6, Week 16; n=2	16661.5 (11651.00)
Treatment Course 7, Baseline (BI); n=2	13262.0 (9702.92)
Treatment Course 7, Baseline (EI); n=2	277168.5 (25532.92)
Treatment Course 7, Week 8; n=2	73159.5 (19078.45)

[1] The mean cannot be calculated for one participant. For this parameter at this time point, the value was below the lower limit of quantification.

6. Secondary Outcome Measure:

Measure Title	Number of Participants Achieving American College of Rheumatology (ACR)20

Measure Description	ACR20 is achieved if the participant has 20% improvement from Baseline in TJC and SJC and in 3 out of 5 of following assessments (A); participant pain A, participant global A, physician global A on a visual analog scale (VAS: a 10 cm scale ranging from "no pain" to "severe pain"; the distance marked by the participant from the “no pain” end is his joint pain score), participant self-assessed disability, and C-reactive protein. The sponsor discontinued the IV administration development program for RA, and this study was terminated early; hence, this endpoint was not evaluated.
Time Frame	Baseline of each TC and 8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description
FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

7. Secondary Outcome Measure:

Measure Title	Number of Participants Achieving ACR50
Measure Description	ACR50 is achieved if the participant has 50% improvement from Baseline in: TJC and SJC and in 3 out of 5 of following assessment (A) ; participant pain A , participant global A, physician global A on a visual analogue scale (VAS: a 10 cm scale ranges from ‘no pain’ to ‘severe pain’ and the distance marked by the participant from the “no pain” end is his joint pain score).and participant self-assessed disability and C-reactive protein. The sponsor discontinued the IV administration development program for RA, and this study was terminated early; hence, this endpoint was not evaluated.

Time Frame	Baseline of each TCand 8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description
FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

8. Secondary Outcome Measure:

Measure Title	Number of Participants Achieving ACR70
Measure Description	ACR70 is achieved if the participant has 70% improvement from Baseline in: TJC and SJC and in 3 out of 5 of following assessment (A) ; participant pain A , participant global A, physician global A on a visual analogue scale (VAS: a 10 cm scale ranges from ‘no pain’ to ‘severe pain’ and the distance marked by the participant from the “no pain” end is his joint pain score).and participant self-assessed disability and C-reactive protein. The sponsor discontinued the IV administration development program for RA, and this study was terminated early; hence, this endpoint was not evaluated.
Time Frame	Baseline of each TC and 8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description
FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

9. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated European League Against Rheumatism (EULAR) Response
Measure Description	EULAR response is based on the DAS score. EULAR response criterion classifies participants as good or moderate responders and non-responders. Good response: DAS28 score <=3.2 and >1.2 improvement from Baseline (IfB) in DAS28 score, Moderate response: DAS28 score <=3.2 and between >0.6 and <=1.2 IfB; DAS28 score between >3.2 and <=5.1 and >1.2 IfB; DAS28 score between >3.2 and <=5.1 and between >0.6 and <=1.2 IfB; DAS28 score >5.1 and >1.2 IfB. The sponsor discontinued the IV administration development program for RA, and this study was terminated early; hence, this endpoint was not evaluated.
Time Frame	Baseline of each TC and 8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description

FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

10. Secondary Outcome Measure:

Measure Title	Number of Participants in the Indicated Categories of the Health Assessment Questionnaire (HAQ)
Measure Description	The HAQ, a 20-question instrument, assesses the degree of difficulty a person has in accomplishing tasks in eight functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and errands and chores). Responses in each area are scored from 0 (no difficulty) to 3 (inability to perform a task in that area). The index is calculated by adding all scores, then dividing this score by the total number of components answered. The sponsor discontinued the IV administration development program for RA, and this study was terminated early; hence, this endpoint was not evaluated.
Time Frame	Baseline of each TC and 8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description

FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

11. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Global Disease Assessment Using the VAS
Measure Description	The participant and the physician independently used the VAS for overall assessment of the disease. VAS is used to measure the physician's subjective assessment of the participant's RA disease process at the time of the visit. The scale ranged from 0 (extremely well) to 10 (extremely poor). The sponsor discontinued the IV administration development program for RA, and this study was terminated early; hence, this endpoint was not evaluated.
Time Frame	Baseline of each TC and 8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description

FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

12. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Pain Score
Measure Description	The pain score was assessed using the VAS: a 10 cm scale ranging from "no pain" to "severe pain"; the distance marked by the participant from the "no pain" end is his joint pain score. The sponsor discontinued the IV administration development program for RA, and this study was terminated early; hence, this endpoint was not evaluated.
Time Frame	Baseline of each TC and 8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description

FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

13. Secondary Outcome Measure:

Measure Title	Number of Participants With HAHA Response
Measure Description	The host immune response was assessed based on Human Anti-Human Antibodies (HAHA). The serum samples of the participants were collected for the assessment of HAHA. The sponsor discontinued the IV administration development program for RA, and this study was terminated early; hence, this endpoint was not evaluated.
Time Frame	Baseline of each TC and 8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description

FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

14. Secondary Outcome Measure:

Measure Title	Whole Blood Transcriptional Profiles
Measure Description	Blood samples were collected for transcriptomic analysis of messenger ribonucleic acid (mRNA). The sponsor discontinued the IV administration development program for RA, and this study was terminated early; hence, this endpoint was not evaluated.
Time Frame	Baseline (BL) of each TC and 8 wk post infusion (PI), then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description

FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total participants analyzed.

15. Secondary Outcome Measure:

Measure Title	Percentage of Cluster of Differentiation (CD)19+, 4+, 3+, and 8+ B-cell Subsets in the Blood
Measure Description	Blood samples of participants were collected for the evaluation of CD19+, CD4+, CD3+, and CD8+ B-cell subsets. These biomarkers are associated with immune functions. Only CD19+ cells were measured in the Follow-up Period.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then every 12 wk follow-up (up to Study Wk 204). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Percentage of Cluster of Differentiation (CD)19+, 4+, 3+, and 8+ B-cell Subsets in the Blood [units: Percentage of CD19+, 4+, 8+, and 3+ BCSs] Mean (Standard Deviation)	
CD19+, Treatment Course 1, Baseline; n=92	6.4 (4.45)
CD19+, Treatment Course 1, Week 104; n=1	4.0 (NA) [1]
CD19+, Treatment Course 2, Baseline; n=72	1.9 (3.06)
CD19+, Treatment Course 2, Week 80; n=1	2.0 (NA) [1]
CD19+, Treatment Course 3, Baseline; n=53	2.6 (2.99)
CD19+, Treatment Course 3, Week 64; n=1	1.0 (NA) [1]
CD19+, Treatment Course 4, Baseline; n=20	1.7 (2.68)
CD19+, Treatment Course 4, Week 40; n=1	3.0 (NA) [1]
CD19+, Treatment Course 5, Baseline; n=8	0 (NA) [2]
CD19+, Treatment Course 5, Week 24; n=2	0 (NA) [2]
CD19+, Treatment Course 6, Baseline; n=4	0 (NA) [2]
CD19+, Treatment Course 6, Week 12; n=4	0 (NA) [2]
CD19+, Treatment Course 7, Baseline; n=2	0 (NA) [2]

	Ofatumumab 700 mg IV Infusion
CD19+, Treatment Course 7, Week 8; n=2	0 (NA) [2]
CD19+, Follow-up Week 12; n=79	1.8 (2.47)
CD19+, Follow-up Week 120; n=1	6.0 (NA) [1]
CD3+, Treatment Course 1, Baseline; n=92	79.7 (7.87)
CD3+, Treatment Course 1, Week 104; n=1	92.0 (NA) [1]
CD3+, Treatment Course 2, Baseline; n=72	81.9 (9.23)
CD3+, Treatment Course 2, Week 80; n=1	87.0 (NA) [1]
CD3+, Treatment Course 3, Baseline; n=53	81.4 (8.84)
CD3+, Treatment Course 3, Week 64; n=1	77.0 (NA) [1]
CD3+, Treatment Course 4, Baseline; n=20	85.4 (5.09)
CD3+, Treatment Course 4, Week 40; n=1	88.0 (NA) [1]
CD3+, Treatment Course 5, Baseline; n=8	86.5 (5.83)
CD3+, Treatment Course 5, Week 24; n=2	88.5 (0.71)
CD3+, Treatment Course 6, Baseline; n=4	80.8 (4.57)
CD3+, Treatment Course 6, Week 12; n=4	82.8 (5.38)
CD3+, Treatment Course 7, Baseline; n=2	87.0 (0.00)
CD3+, Treatment Course 7, Week 8; n=2	84.5 (3.54)
CD4+, Treatment Course 1, Baseline; n=92	51.8 (11.46)
CD4+, Treatment Course 1, Week 104; n=1	65.0 (NA) [1]
CD4+, Treatment Course 2, Baseline; n=72	53.2 (10.49)
CD4+, Treatment Course 2, Week 80; n=1	59.0 (NA) [1]
CD4+, Treatment Course 3, Baseline; n=53	53.2 (10.72)
CD4+, Treatment Course 3, Week 64; n=1	58.0 (NA) [1]
CD4+, Treatment Course 4, Baseline; n=20	56.6 (13.78)
CD4+, Treatment Course 4, Week 40; n=1	62.0 (NA) [1]

	Ofatumumab 700 mg IV Infusion
CD4+, Treatment Course 5, Baseline; n=8	53.3 (12.87)
CD4+, Treatment Course 5, Week 24; n=2	55.5 (17.68)
CD4+, Treatment Course 6, Baseline; n=4	51.0 (16.06)
CD4+, Treatment Course 6, Week 12; n=4	54.8 (17.75)
CD4+, Treatment Course 7, Baseline; n=2	57.0 (9.90)
CD4+, Treatment Course 7, Week 8; n=2	54.5 (16.26)
CD8+, Treatment Course 1, Baseline; n=92	23.7 (8.61)
CD8+, Treatment Course 1, Week 104; n=1	23.0 (NA) [1]
CD8+, Treatment Course 2, Baseline; n=72	24.2 (7.94)
CD8+, Treatment Course 2, Week 80; n=1	26.0 (NA) [1]
CD8+, Treatment Course 3, Baseline; n=53	24.1 (7.83)
CD8+, Treatment Course 3, Week 64; n=1	18.0 (NA) [1]
CD8+, Treatment Course 4, Baseline; n=20	24.6 (8.24)
CD8+, Treatment Course 4, Week 40; n=1	22.0 (NA) [1]
CD8+, Treatment Course 5, Baseline; n=8	27.5 (9.47)
CD8+, Treatment Course 5, Week 24; n=2	23.5 (7.78)
CD8+, Treatment Course 6, Baseline; n=4	26.0 (10.10)
CD8+, Treatment Course 6, Week 12; n=4	24.3 (11.15)
CD8+, Treatment Course 7, Baseline; n=2	26.0 (8.49)
CD8+, Treatment Course 7, Week 8; n=2	25.5 (10.61)

[1] Standard deviation is not calculated when only one participant was analyzed.
[2] A dispersion cannot be calculated for a mean of 0.

16. Secondary Outcome Measure:

Measure Title	CD19+, CD4+, CD3+, and CD8+ Cell Counts, Measured in mm^3

Measure Description	Blood samples of participants were collected for the evaluation of CD19+, CD4+, CD3+, and CD8+ cell counts. These cells are present on white blood cells and are used as markers to associate cells with immune functions. Only CD19+ cells were measured in the Follow-up Period.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then every 12 wk follow-up (up to Study Wk 204). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
CD19+, CD4+, CD3+, and CD8+ Cell Counts, Measured in mm^3 [units: cells per millimeters cubed (mm^3)] Mean (Standard Deviation)	
CD19+, Treatment Course 1, Baseline; n=92	109.6 (91.12)
CD19+, Treatment Course 1, Week 104; n=1	95.0 (NA) [1]
CD19+, Treatment Course 2, Baseline; n=71	30.0 (49.36)
CD19+, Treatment Course 2, Week 80; n=1	24.0 (NA) [1]
CD19+, Treatment Course 3, Baseline; n=51	43.8 (50.11)
CD19+, Treatment Course 3, Week 64; n=1	16.0 (NA) [1]
CD19+, Treatment Course 4, Baseline; n=20	27.2 (43.75)

	Ofatumumab 700 mg IV Infusion
CD19+, Treatment Course 4, Week 40; n=1	54.0 (NA) [1]
CD19+, Treatment Course 5, Baseline; n=8	0 (NA) [2]
CD19+, Treatment Course 5, Week 24; n=2	0 (NA) [2]
CD19+, Treatment Course 6, Baseline; n=4	0 (NA) [2]
CD19+, Treatment Course 6, Week 12; n=4	0 (NA) [2]
CD19+, Treatment Course 7, Baseline; n=2	0 (NA) [2]
CD19+, Treatment Course 7, Week 8; n=2	0 (NA) [2]
CD19+, Follow-up Week 12; n=78	28.7 (49.48)
CD19+, Follow-up Week 120; n=1	83.0 (NA) [1]
CD3+, Treatment Course 1, Baseline; n=92	1325.3 (467.40)
CD3+, Treatment Course 1, Week 104; n=1	2174.0 (NA) [1]
CD3+, Treatment Course 2, Baseline; n=71	1338.8 (557.04)
CD3+, Treatment Course 2, Week 80; n=1	1051.0 (NA) [1]
CD3+, Treatment Course 3, Baseline; n=51	1325.1 (398.74)
CD3+, Treatment Course 3, Week 64; n=1	1213.0 (NA) [1]
CD3+, Treatment Course 4, Baseline; n=20	1388.3 (502.80)
CD3+, Treatment Course 4, Week 40; n=1	1594.0 (NA) [1]
CD3+, Treatment Course 5, Baseline; n=8	1324.1 (618.65)
CD3+, Treatment Course 5, Week 24; n=2	1218.5 (342.95)
CD3+, Treatment Course 6, Baseline; n=4	1574.3 (553.71)
CD3+, Treatment Course 6, Week 12; n=4	1430.8 (507.31)
CD3+, Treatment Course 7, Baseline; n=2	1062.0 (169.71)
CD3+, Treatment Course 7, Week 8; n=2	1230.0 (373.35)
CD4+, Treatment Course 1, Baseline; n=92	869.2 (386.45)
CD4+, Treatment Course 1, Week 104; n=1	1544.0 (NA) [1]

	Ofatumumab 700 mg IV Infusion
CD4+, Treatment Course 2, Baseline; n=71	877.3 (443.09)
CD4+, Treatment Course 2, Week 80; n=1	715.0 (NA) [1]
CD4+, Treatment Course 3, Baseline; n=51	876.7 (310.96)
CD4+, Treatment Course 3, Week 64; n=1	910.0 (NA) [1]
CD4+, Treatment Course 4, Baseline; n=20	931.8 (451.30)
CD4+, Treatment Course 4, Week 40; n=1	1116.0 (NA) [1]
CD4+, Treatment Course 5, Baseline; n=8	837.3 (499.45)
CD4+, Treatment Course 5, Week 24; n=2	729.0 (18.38)
CD4+, Treatment Course 6, Baseline; n=4	1000.3 (545.33)
CD4+, Treatment Course 6, Week 12; n=4	919.8 (380.08)
CD4+, Treatment Course 7, Baseline; n=2	686.0 (1.41)
CD4+, Treatment Course 7, Week 8; n=2	755.5 (30.41)
CD8+, Treatment Course 1, Baseline; n=92	387.7 (183.18)
CD8+, Treatment Course 1, Week 104; n=1	543.0 (NA) [1]
CD8+, Treatment Course 2, Baseline; n=71	391.0 (193.89)
CD8+, Treatment Course 2, Week 80; n=1	315.0 (NA) [1]
CD8+, Treatment Course 3, Baseline; n=51	383.3 (159.28)
CD8+, Treatment Course 3, Week 64; n=1	279.0 (NA) [1]
CD8+, Treatment Course 4, Baseline; n=20	389.0 (151.22)
CD8+, Treatment Course 4, Week 40; n=1	398.0 (NA) [1]
CD8+, Treatment Course 5, Baseline; n=8	411.0 (198.41)
CD8+, Treatment Course 5, Week 24; n=2	338.5 (202.94)
CD8+, Treatment Course 6, Baseline; n=4	502.3 (234.80)
CD8+, Treatment Course 6, Week 12; n=4	443.8 (298.72)
CD8+, Treatment Course 7, Baseline; n=2	327.0 (155.56)
CD8+, Treatment Course 7, Week 8; n=2	400.0 (278.60)

[1] Standard deviation is not calculated when only one participant was analyzed.
[2] A dispersion cannot be calculated for a mean of 0.

17. Secondary Outcome Measure:

Measure Title	Ratio of CD 4+/CD8+
Measure Description	Blood samples of participants were collected for the evaluation of CD4+ and CD8+ cell counts and the ratio was calculated.
Time Frame	Baseline of each TC and 8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	72
Ratio of CD 4+/CD8+ [units: Ratio of CD 4+/CD8+ cells] Mean (Standard Deviation)	
Treatment Course 1, Baseline; n=72	2.55 (1.295)
Treatment Course 1, Week 48; n=1	5.40 (NA) [1]
Treatment Course 2, Week 24; n=1	4.10 (NA) [1]

	Ofatumumab 700 mg IV Infusion
Treatment Course 2, Week 56; n=1	2.60 (NA) [1]
Treatment Course 3, Baseline; n=1	2.60 (NA) [1]
Treatment Course 3, Week 32; n=2	2.40 (0.424)
Treatment Course 4, Baseline; n=1	1.50 (NA) [1]

[1] Standard deviation is not calculated when only one participant was analyzed.

18. Secondary Outcome Measure:

Measure Title	Number of Participants With Rheumatoid Factor (RA Factor) >13 International Units Per Milliliter
Measure Description	Blood samples of participants were collected for the evaluation of RA factor. RA factor is an antibody found in the blood of participants with rheumatoid arthritis and is used for the diagnosis of rheumatoid arthritis.
Time Frame	Baseline of each TC and 8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92

	Ofatumumab 700 mg IV Infusion
Number of Participants With Rheumatoid Factor (RA Factor) >13 International Units Per Milliliter [units: participants]	
Treatment Course 1, Baseline; n=92	79
Treatment Course 1, Week 104; n=1	1
Treatment Course 1, At any time; n=92	81
Treatment Course 2, Baseline; n=73	60
Treatment Course 2, Week 80; n=1	1
Treatment Course 2, At any time; n=73	63
Treatment Course 3, Baseline; n=53	42
Treatment Course 3, Week 64; n=1	1
Treatment Course 3, At any time; n=53	46
Treatment Course 4, Baseline; n=20	13
Treatment Course 4, Week 40; n=1	1
Treatment Course 4, At any time; n=20	14
Treatment Course 5, Baseline; n=8	4
Treatment Course 5, Week 24; n=2	0
Treatment Course 5, At any time; n=8	4
Treatment Course 6, Baseline; n=4	2
Treatment Course 6, Week 16; n=2	1
Treatment Course 6, At any time; n=4	2
Treatment Course 7, Baseline; n=2	1
Treatment Course 7, Week 8; n=2	1
Treatment Course 7, At any time; n=2	1

19. Secondary Outcome Measure:

Measure Title	Number of Participants With Anti-cyclic Citrullinated Peptide Antibody (CCP) >6.9 International Units Per Liter

Measure Description	Blood samples of participants were collected for the evaluation of Anti-CCP. Anti-CCP plays an important role in immune response and helps assess the disease condition.
Time Frame	Baseline of each TC and 8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Number of Participants With Anti-cyclic Citrullinated Peptide Antibody (CCP) >6.9 International Units Per Liter [units: participants]	
Treatment Course 1, Baseline; n=92	80
Treatment Course 1, Week 104; n=1	1
Treatment Course 1, At any time; n=92	83
Treatment Course 2, Baseline; n=73	66
Treatment Course 2, Week 80; n=1	1
Treatment Course 2, At any time; n=73	67
Treatment Course 3, Baseline; n=53	48
Treatment Course 3, Week 64; n=1	1

	Ofatumumab 700 mg IV Infusion
Treatment Course 3, At any time; n=53	48
Treatment Course 4, Baseline; n=20	15
Treatment Course 4, Week 40; n=1	1
Treatment Course 4, At any time; n=20	15
Treatment Course 5, Baseline; n=8	7
Treatment Course 5, Week 24; n=2	1
Treatment Course 5, At any time; n=8	7
Treatment Course 6, Baseline; n=4	3
Treatment Course 6, Week 16; n=2	1
Treatment Course 6, At any time; n=4	3
Treatment Course 7, Baseline; n=2	1
Treatment Course 7, Week 8; n=2	1
Treatment Course 7, At any time; n=2	1

20. Secondary Outcome Measure:

Measure Title	Number of Participants With B-Lymphocyte Stimulator (BLyS) >2.49 Micrograms Per Liter
Measure Description	Blood samples of participants were collected for the evaluation of BLyS. BLyS is a potent co-stimulator of B lymphocytes, and elevated levels of BLyS are observed in autoimmune diseases. It regulates the immunoglobin (antibody produced by B cells that is used by the immune system to identify bacteria and viruses in the body) secretion of normal B cells (type of cells in the blood).
Time Frame	Baseline of each TC and 8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Number of Participants With B-Lymphocyte Stimulator (BLyS) >2.49 Micrograms Per Liter [units: participants]	
Treatment Course 1, Baseline; n=92	12
Treatment Course 1, Week 104; n=1	0
Treatment Course 1, At any time; n=92	81
Treatment Course 2, Baseline; n=73	38
Treatment Course 2, Week 80; n=1	0
Treatment Course 2, At any time; n=73	65
Treatment Course 3, Baseline; n=53	32
Treatment Course 3, Week 64; n=1	1
Treatment Course 3, At any time; n=53	48
Treatment Course 4, Baseline; n=20	12
Treatment Course 4, Week 40; n=1	1
Treatment Course 4, At any time; n=20	16
Treatment Course 5, Baseline; n=8	7
Treatment Course 5, Week 24; n=2	2
Treatment Course 5, At any time; n=8	7

	Ofatumumab 700 mg IV Infusion
Treatment Course 6, Baseline; n=4	4
Treatment Course 6, Week 16; n=2	2
Treatment Course 6, At any time; n=4	4
Treatment Course 7, Baseline; n=2	2
Treatment Course 7, Week 8; n=2	2
Treatment Course 7, At any time; n=2	2

21. Secondary Outcome Measure:

Measure Title	Number of Participants With Interleukin 6 (IL-6) >11.9 Picograms Per Milliliter
Measure Description	Blood samples of participants were collected for the evaluation of IL-6. IL-6 plays an important role in immune response and helps assess the disease condition.
Time Frame	Baseline of each TC and 8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92

	Ofatumumab 700 mg IV Infusion
Number of Participants With Interleukin 6 (IL-6) >11.9 Picograms Per Milliliter [units: participants]	
Treatment Course 1, Baseline; n=92	40
Treatment Course 1, Week 104; n=1	0
Treatment Course 1, At any time; n=92	47
Treatment Course 2, Baseline; n=73	12
Treatment Course 2, Week 80; n=1	1
Treatment Course 2, At any time; n=73	27
Treatment Course 3, Baseline; n=52	11
Treatment Course 3, Week 64; n=1	0
Treatment Course 3, At any time; n=53	15
Treatment Course 4, Baseline; n=20	3
Treatment Course 4, Week 40; n=1	0
Treatment Course 4, At any time; n=20	4
Treatment Course 5, Baseline; n=8	1
Treatment Course 5, Week 24; n=2	0
Treatment Course 5, At any time; n=8	1
Treatment Course 6, Baseline; n=4	0
Treatment Course 6, Week 16; n=2	0
Treatment Course 6, At any time; n=4	0
Treatment Course 7, Baseline; n=2	0
Treatment Course 7, Week 8; n=2	0
Treatment Course 7, At any time; n=2	0

22. Secondary Outcome Measure:

Measure Title	Assessment of Sodium, Potassium, Chloride, Bicarbonate, Calcium, and Uric Acid

Measure Description	Blood samples of participants were collected for the evaluation of uric acid and electrolytes (sodium, potassium, chloride, and calcium), as increased levels may reflect B-cell lysis due to treatment with ofatumumab.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then Weeks 12 and 24 of follow-up (up to Study Wk 156). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Assessment of Sodium, Potassium, Chloride, Bicarbonate, Calcium, and Uric Acid [units: Millimoles/liter (mmol/L)] Mean (Standard Deviation)	
Sodium, Treatment Course 1, Baseline; n=92	142.1 (2.76)
Sodium, Treatment Course 1, Week 104; n=1	144.0 (NA) [1]
Sodium, Treatment Course 2, Baseline; n=73	142.3 (2.25)
Sodium, Treatment Course 2, Week 80; n=1	145.0 (NA) [1]
Sodium, Treatment Course 3, Baseline; n=53	143.3 (2.26)
Sodium, Treatment Course 3, Week 64; n=1	147.0 (NA) [1]
Sodium, Treatment Course 4, Baseline; n=20	142.8 (2.65)

	Ofatumumab 700 mg IV Infusion
Sodium, Treatment Course 4, Week 40; n=1	145.0 (NA) [1]
Sodium, Treatment Course 5, Baseline; n=8	143.1 (2.30)
Sodium, Treatment Course 5, Week 24; n=2	142.5 (2.12)
Sodium, Treatment Course 6, Baseline; n=4	142.0 (1.83)
Sodium, Treatment Course 6, Week 16; n=2	141.5 (3.54)
Sodium, Treatment Course 7, Baseline; n=2	142.5 (0.71)
Sodium, Treatment Course 7, Week 8; n=2	141.0 (2.83)
Sodium, Follow-up Week 12; n=59	143.3 (2.23)
Sodium, Follow-up Week 24; n=18	142.7 (2.87)
Potassium, Treatment Course 1, Baseline; n=92	4.25 (0.317)
Potassium, Treatment Course 1, Week 104; n=1	3.30 (NA) [1]
Potassium, Treatment Course 2, Baseline; n=73	4.32 (0.386)
Potassium, Treatment Course 2, Week 80; n=1	4.20 (NA) [1]
Potassium, Treatment Course 3, Baseline; n=53	4.25 (0.358)
Potassium, Treatment Course 3, Week 64; n=1	4.60 (NA) [1]
Potassium, Treatment Course 4, Baseline; n=20	4.20 (0.208)
Potassium, Treatment Course 4, Week 40; n=1	4.20 (NA) [1]
Potassium, Treatment Course 5, Baseline; n=8	4.34 (0.220)
Potassium, Treatment Course 5, Week 24; n=2	4.40 (0.283)
Potassium, Treatment Course 6, Baseline; n=4	4.48 (0.377)
Potassium, Treatment Course 6, Week 16; n=2	4.45 (0.495)
Potassium, Treatment Course 7, Baseline; n=2	4.50 (0.707)
Potassium, Treatment Course 7, Week 8; n=2	4.35 (0.495)
Potassium, Follow-up Week 12; n=59	4.34 (0.371)
Potassium, Follow-up Week 24; n=18	4.33 (0.407)
Chloride, Treatment Course 1, Baseline; n=92	105.2 (2.98)

	Ofatumumab 700 mg IV Infusion
Chloride, Treatment Course 1, Week 104; n=1	104.0 (NA) [1]
Chloride Treatment Course 2, Baseline; n=73	105.6 (2.18)
Chloride Treatment Course 2, Week 80; n=1	105.0 (NA) [1]
Chloride, Treatment Course 3, Baseline; n=53	106.0 (2.54)
Chloride, Treatment Course 3, Week 64; n=1	111.0 (NA) [1]
Chloride Treatment Course 4, Baseline; n=20	105.9 (3.56)
Chloride, Treatment Course 4, Week 40; n=1	102.0 (NA) [1]
Chloride Treatment Course 5, Baseline; n=8	104.8 (3.54)
Chloride, Treatment Course 5, Week 24; n=2	105.5 (3.54)
Chloride, Treatment Course 6, Baseline; n=4	105.0 (3.37)
Chloride, Treatment Course 6, Week 16; n=2	105.0 (2.83)
Chloride, Treatment Course 7, Baseline; n=2	104.0 (1.41)
Chloride, Treatment Course 7, Week 8; n=2	105.0 (4.24)
Chloride, Follow-up Week 12; n=59	106.1 (2.66)
Chloride, Follow-up Week 24; n=18	105.3 (3.46)
Bicarbonate, Treatment Course 1, Baseline; n=92	24.67 (2.519)
Bicarbonate, Treatment Course 1, Week 104; n=1	28.40 (NA) [1]
Bicarbonate, Treatment Course 2, Baseline; n=73	25.10 (2.416)
Bicarbonate, Treatment Course 2, Week 80; n=1	22.80 (NA) [1]
Bicarbonate, Treatment Course 3, Baseline; n=53	25.49 (2.299)
Bicarbonate, Treatment Course 3, Week 64; n=1	25.40 (NA) [1]
Bicarbonate, Treatment Course 4, Baseline; n=20	24.61 (2.748)
Bicarbonate, Treatment Course 4, Week 40; n=1	30.00 (NA) [1]
Bicarbonate, Treatment Course 5, Baseline; n=8	26.20 (2.262)
Bicarbonate, Treatment Course 5, Week 24; n=2	27.20 (4.243)
Bicarbonate, , Treatment Course 6, Baseline; n=4	25.00 (0.876)

	Ofatumumab 700 mg IV Infusion
Bicarbonate, Treatment Course 6, Week 16; n=2	24.50 (2.546)
Bicarbonate, Treatment Course 7, Baseline; n=2	24.80 (1.414)
Bicarbonate, Treatment Course 7, Week 8; n=2	23.40 (0.849)
Bicarbonate, Follow-up Week 12; n=59	23.99 (2.042)
Bicarbonate, Follow-up Week 24; n=18	24.06 (2.360)
Calcium, Treatment Course 1, Baseline; n=92	2.324 (0.0965)
Calcium Treatment Course 1, Week 104; n=1	2.250 (NA) [1]
Calcium, Treatment Course 2, Baseline; n=73	2.305 (0.0991)
Calcium, Treatment Course 2, Week 80; n=1	2.200 (NA) [1]
Calcium, Treatment Course 3, Baseline; n=53	2.312 (0.0935)
Calcium, Treatment Course 3, Week 64; n=1	2.300 (NA) [1]
Calcium, Treatment Course 4, Baseline; n=20	2.315 (0.1113)
Calcium, Treatment Course 4, Week 40; n=1	2.400 (NA) [1]
Calcium, Treatment Course 5, Baseline; n=8	2.313 (0.0954)
Calcium, Treatment Course 5, Week 24; n=2	2.275 (0.1061)
Calcium, Treatment Course 6, Baseline; n=4	2.338 (0.1109)
Calcium, Treatment Course 6, Week 16; n=2	2.275 (0.1061)
Calcium, Treatment Course 7, Baseline; n=2	2.375 (0.1768)
Calcium, Treatment Course 7, Week 8; n=2	2.300 (0.0707)
Calcium, Follow-up Week 12; n=59	2.315 (0.0897)
Calcium, Follow-up Week 24; n=18	2.342 (0.0943)
Uric acid, Treatment Course 1, Baseline; n=92	0.259 (0.0684)
Uric acid, Treatment Course 1, Week 104; n=1	0.380 (NA) [1]
Uric acid, Treatment Course 2, Baseline; n=73	0.265 (0.0572)
Uric acid, Treatment Course 2, Week 80; n=1	0.300 (NA) [1]
Uric acid, Treatment Course 3, Baseline; n=53	0.259 (0.0502)

	Ofatumumab 700 mg IV Infusion
Uric acid, Treatment Course 3, Week 64; n=1	0.250 (NA) [1]
Uric acid, Treatment Course 4, Baseline; n=20	0.256 (0.0518)
Uric acid, Treatment Course 4, Week 40; n=1	0.310 (NA) [1]
Uric acid, Treatment Course 5, Baseline; n=8	0.275 (0.0407)
Uric acid, Treatment Course 5, Week 24; n=2	0.245 (0.0354)
Uric acid, Treatment Course 6, Baseline; n=4	0.273 (0.0222)
Uric acid, Treatment Course 6, Week 16; n=2	0.265 (0.0212)
Uric acid, Treatment Course 7, Baseline; n=2	0.250 (0.0424)
Uric acid, Treatment Course 7, Week 8; n=2	0.295 (0.0354)
Uric acid, Follow-up Week 12; n=59	0.271 (0.0573)
Uric acid, Follow-up Week 24; n=18	0.268 (0.0495)

[1] Standard deviation is not calculated when only one participant was analyzed.

23. Secondary Outcome Measure:

Measure Title	Assessment of Total Protein (TP) and Albumin
Measure Description	Blood samples of participants were collected to evaluate TP and albumin. TP can vary depending on auto-immune diseases, and TP and albumin can vary depending on debilitating diseases.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then Weeks 12 and 24 of follow-up (up to Study Wk 156). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Assessment of Total Protein (TP) and Albumin [units: Grams/Liter (g/L)] Mean (Standard Deviation)	
Grams/Liter (g/L)	76.3 (4.97)
TP, Treatment Course 1, Week 104; n=1	72.0 (NA) [1]
TP, Treatment Course 2, Baseline; n=73	76.2 (4.53)
TP, Treatment Course 2, Week 80; n=1	72.0 (NA) [1]
TP, Treatment Course 3, Baseline; n=53	74.7 (4.80)
TP, Treatment Course 3, Week 64; n=1	71.0 (NA) [1]
TP, Treatment Course 4, Baseline; n=20	73.9 (5.44)
TP, Treatment Course 4, Week 40; n=1	78.0 (NA) [1]
TP, Treatment Course 5, Baseline; n=8	75.6 (4.17)
TP, Treatment Course 5, Week 24; n=2	75.0 (5.66)
TP, Treatment Course 6, Baseline; n=4	74.8 (4.50)
TP, Treatment Course 6, Week 16; n=2	77.0 (5.66)
TP, Treatment Course 7, Baseline; n=2	78.5 (6.36)
TP, Treatment Course 7, Week 8; n=2	75.0 (2.83)

	Ofatumumab 700 mg IV Infusion
TP, Follow-up Week 12; n=59	74.0 (4.52)
TP, Follow-up Week 24; n=18	75.4 (4.51)
Albumin, Treatment Course 1, Baseline; n=92	43.50 (3.043)
Albumin, Treatment Course 1, Week 104; n=1	40.80 (NA) [1]
Albumin, Treatment Course 2, Baseline; n=73	44.21 (2.984)
Albumin, Treatment Course 2, Week 80; n=1	39.10 (NA) [1]
Albumin, Treatment Course 3, Baseline; n=53	44.18 (3.332)
Albumin, Treatment Course 3, Week 64; n=1	43.40 (NA) [1]
Albumin, Treatment Course 4, Baseline; n=20	44.34 (3.497)
Albumin, Treatment Course 4, Week 40; n=1	46.20 (NA) [1]
Albumin, Treatment Course 5, Baseline; n=8	46.75 (3.203)
Albumin, Treatment Course 5, Week 24; n=2	45.90 (2.263)
Albumin, Treatment Course 6, Baseline; n=4	45.83 (3.035)
Albumin, Treatment Course 6, Week 16; n=2	46.80 (2.546)
Albumin, Treatment Course 7, Baseline; n=2	48.00 (3.536)
Albumin, Treatment Course 7, Week 8; n=2	45.75 (1.344)
Albumin, Follow-up Week 12; n=59	43.93 (3.002)
Albumin, Follow-up Week 24; n=18	44.66 (3.642)

[1] Standard deviation is not calculated when only one participant was analyzed.

24. Secondary Outcome Measure:

Measure Title	Assessment of Total Bilirubin (TB) and Creatinine
Measure Description	Blood samples of participants were collected to evaluate TB and creatinine levels. TB evaluation is performed to assess the condition of the liver, and possible hemolytic anemia, and the creatinine evaluation is performed to assess the renal condition (condition of the kidneys).

Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then Weeks 12 and 24 of follow-up (up to Study Wk 156). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Assessment of Total Bilirubin (TB) and Creatinine [units: Micromoles per liter (umol/L)] Mean (Standard Deviation)	
TB, Treatment Course 1, Baseline; n=92	7.18 (3.823)
TB, Treatment Course 1, Week 104; n=1	6.30 (NA) [1]
TB, Treatment Course 2, Baseline; n=73	7.91 (4.528)
TB, Treatment Course 2, Week 80; n=1	3.10 (NA) [1]
TB, Treatment Course 3, Baseline; n=53	7.84 (4.501)
TB, Treatment Course 3, Week 64; n=1	8.00 (NA) [1]
TB, Treatment Course 4, Baseline; n=20	7.68 (3.652)
TB, Treatment Course 4, Week 40; n=1	7.50 (NA) [1]
TB, Treatment Course 5, Baseline; n=8	9.20 (5.283)

	Ofatumumab 700 mg IV Infusion
TB, Treatment Course 5, Week 24; n=2	6.40 (2.546)
TB, Treatment Course 6, Baseline; n=4	10.38 (3.779)
TB, Treatment Course 6, Week 16; n=2	9.85 (0.636)
TB, Treatment Course 7, Baseline; n=2	8.95 (1.344)
TB, Treatment Course 7, Week 8; n=2	14.05 (5.586)
TB, Follow-up Week 12; n=59	8.62 (4.796)
TB, Follow-up Week 24; n=18	8.60 (3.281)
Creatinine, Treatment Course 1, Baseline; n=92	64.14 (12.569)
Creatinine, Treatment Course 1, Week 104; n=1	54.80 (NA) [1]
Creatinine, Treatment Course 2, Baseline; n=73	67.82 (14.735)
Creatinine, Treatment Course 2, Week 80; n=1	75.10 (NA) [1]
Creatinine, Treatment Course 3, Baseline; n=53	65.50 (10.871)
Creatinine, Treatment Course 3, Week 64; n=1	68.10 (NA) [1]
Creatinine, Treatment Course 4, Baseline; n=20	65.36 (12.626)
Creatinine, Treatment Course 4, Week 40; n=1	70.70 (NA) [1]
Creatinine, Treatment Course 5, Baseline; n=8	67.75 (7.543)
Creatinine, Treatment Course 5, Week 24; n=2	64.55 (6.293)
Creatinine, Treatment Course 6, Baseline; n=4	67.63 (11.909)
Creatinine, Treatment Course 6, Week 16; n=2	60.55 (8.132)
Creatinine, Treatment Course 7, Baseline; n=2	61.40 (3.111)
Creatinine, Treatment Course 7, Week 8; n=2	59.65 (9.405)
Creatinine, Follow-up Week 12; n=59	69.72 (15.553)
Creatinine, Follow-up Week 24; n=18	74.95 (21.833)

[1] Standard deviation is not calculated when only one participant was analyzed.

25. Secondary Outcome Measure:

Measure Title	Assessment of Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Alkaline Phosphatase (AP), and Gamma Glutamyl-transferase (GGT)
Measure Description	Blood samples of participants were collected for the evaluation of ALT, AST, AP, and GGT. AST, ALT, AP, and GGT are evaluated to assess the condition of the liver.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then Weeks 12 and 24 of follow-up (up to Study Wk 156). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Assessment of Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Alkaline Phosphatase (AP), and Gamma Glutamyl-transferase (GGT) [units: Units per liter (U/L)] Mean (Standard Deviation)	
ALT, Treatment Course 1, Baseline; n=92	20.4 (11.71)
ALT, Treatment Course 1, Week 104; n=1	16.0 (NA) [1]
ALT, Treatment Course 2, Baseline; n=73	21.8 (11.99)

	Ofatumumab 700 mg IV Infusion
ALT, Treatment Course 2, Week 80; n=1	19.0 (NA) [1]
ALT, Treatment Course 3, Baseline; n=53	20.5 (15.40)
ALT, Treatment Course 3, Week 64; n=1	36.0 (NA) [1]
ALT, Treatment Course 4, Baseline; n=20	22.7 (12.39)
ALT, Treatment Course 4, Week 40; n=1	19.0 (NA) [1]
ALT, Treatment Course 5, Baseline; n=8	19.0 (5.04)
ALT, Treatment Course 5, Week 24; n=2	15.0 (1.41)
ALT, Treatment Course 6, Baseline; n=4	23.5 (9.43)
ALT, Treatment Course 6, Week 16; n=2	24.0 (1.41)
ALT, Treatment Course 7, Baseline; n=2	18.5 (2.12)
ALT, Treatment Course 7, Week 8; n=2	22.0 (4.24)
ALT, Follow-up Week 12; n=59	19.8 (8.37)
ALT, Follow-up Week 24; n=18	21.9 (12.54)
AST, Treatment Course 1, Baseline; n=92	21.1 (9.01)
AST, Treatment Course 1, Week 104; n=1	17.0 (NA) [1]
AST, Treatment Course 2, Baseline; n=73	22.8 (8.96)
AST, Treatment Course 2, Week 80; n=1	21.0 (NA) [1]
AST, Treatment Course 3, Baseline; n=53	21.8 (10.83)
AST, Treatment Course 3, Week 64; n=1	21.0 (NA) [1]
AST, Treatment Course 4, Baseline; n=20	21.2 (6.47)
AST, Treatment Course 4, Week 40; n=1	23.0 (NA) [1]
AST, Treatment Course 5, Baseline; n=8	22.4 (7.78)
AST, Treatment Course 5, Week 24; n=2	18.0 (0.00)
AST, Treatment Course 6, Baseline; n=4	25.3 (8.77)
AST, Treatment Course 6, Week 16; n=2	23.5 (3.54)
AST, Treatment Course 7, Baseline; n=2	22.5 (4.95)

	Ofatumumab 700 mg IV Infusion
AST, Treatment Course 7, Week 8; n=2	21.5 (0.71)
AST, Follow-up Week 12; n=59	22.1 (6.95)
AST, Follow-up Week 24; n=18	21.7 (7.24)
AP, Treatment Course 1, Baseline; n=92	79.4 (27.80)
AP, Treatment Course 1, Week 104; n=1	60.0 (NA) [1]
AP, Treatment Course 2, Baseline; n=73	73.3 (23.76)
AP, Treatment Course 2, Week 80; n=1	79.0 (NA) [1]
AP, Treatment Course 3, Baseline; n=53	70.5 (22.18)
AP, Treatment Course 3, Week 64; n=1	61.0 (NA) [1]
AP, Treatment Course 4, Baseline; n=20	66.2 (15.54)
AP, Treatment Course 4, Week 40; n=1	77.0 (NA) [1]
AP, Treatment Course 5, Baseline; n=8	68.0 (25.03)
AP, Treatment Course 5, Week 24; n=2	52.0 (14.14)
AP, Treatment Course 6, Baseline; n=4	59.5 (26.51)
AP, Treatment Course 6, Week 16; n=2	49.0 (1.41)
AP, Treatment Course 7, Baseline; n=2	47.5 (2.12)
AP, Treatment Course 7, Week 8; n=2	45.0 (2.83)
AP, Follow-up Week 12; n=59	64.6 (19.44)
AP, Follow-up Week 24; n=18	68.9 (20.90)
GGT, Treatment Course 1, Baseline; n=92	22.2 (18.51)
GGT, Treatment Course 1, Week 104; n=1	16.0 (NA) [1]
GGT, Treatment Course 2, Baseline; n=73	22.0 (20.88)
GGT, Treatment Course 2, Week 80; n=1	21.0 (NA) [1]
GGT, Treatment Course 3, Baseline; n=53	19.0 (12.78)
GGT, Treatment Course 3, Week 64; n=1	50.0 (NA) [1]
GGT, Treatment Course 4, Baseline; n=20	16.4 (8.41)

	Ofatumumab 700 mg IV Infusion
GGT, Treatment Course 4, Week 40; n=1	12.0 (NA) [1]
GGT, Treatment Course 5, Baseline; n=8	14.4 (2.97)
GGT Treatment Course 5, Week 24; n=2	11.0 (1.41)
GGT, Treatment Course 6, Baseline; n=4	16.5 (7.19)
GGT, Treatment Course 6, Week 16; n=2	14.0 (4.24)
GGT Treatment Course 7, Baseline; n=2	14.0 (4.24)
GGT, Treatment Course 7, Week 8; n=2	14.5 (6.36)
GGT, Follow-up Week 12; n=59	20.5 (18.17)
GGT, Follow-up Week 24; n=18	24.8 (36.99)

[1] Standard deviation is not calculated when only one participant was analyzed.

26. Secondary Outcome Measure:

Measure Title	Assessment of Blood Urea Nitrogen (BUN)
Measure Description	The blood samples of participants were collected to assess the amount of nitrogen (in the form of urea) in the blood. BUN is evaluated to assess the renal function of the participants.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then Weeks 12 and 24 of follow-up (up to Study Wk 156). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Assessment of Blood Urea Nitrogen (BUN) [units: millimoles per liter] Mean (Standard Deviation)	
Treatment Course 1, Baseline; n=92	5.85 (1.767)
Treatment Course 1, Week 104; n=1	6.40 (NA) [1]
Treatment Course 2, Baseline; n=73	6.10 (1.781)
Treatment Course 2, Week 80; n=1	9.60 (NA) [1]
Treatment Course 3, Baseline; n=53	5.78 (1.574)
Treatment Course 3, Week 64; n=1	6.80 (NA) [1]
Treatment Course 4, Baseline; n=20	5.75 (1.257)
Treatment Course 4, Week 40; n=1	4.60 (NA) [1]
Treatment Course 5, Baseline; n=8	5.49 (1.197)
Treatment Course 5, Week 24; n=2	6.05 (0.495)
Treatment Course 6, Baseline; n=4	6.95 (1.700)
Treatment Course 6, Week 16; n=2	7.15 (0.495)
Treatment Course 7, Baseline; n=2	6.60 (0.707)
Treatment Course 7, Week 8; n=2	7.15 (1.061)

	Ofatumumab 700 mg IV Infusion
Follow-up Week 12; n=59	5.79 (1.878)
Follow-up Week 24; n=18	6.04 (2.530)

[1] Standard deviation is not calculated when only one participant was analyzed.

27. Secondary Outcome Measure:

Measure Title	Assessment of Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)
Measure Description	The blood pressure (BP) of the participants was measured before infusion (infu) (BI) and post the first (A) and second (B) infusions (PI) during all 7 treatment courses. Timing for taking BP readings: SBP (BP when the heart is contracting): TC1, 2, 3 (infu A) more than 2 hours PI; TC1, 2 ,3 (infu B) 2 hours PI; TC4, 5, 6, 7 (infu A) 2 hours PI; TC4, 7 (infu B) 2 hours PI; TC5, 6 (infu B) 1 hour PI. For DBP (BP when the heart is resting between beats): TC1, 3 (infu A) more than 2 hours PI; TC2, 4, 5, 6, 7 (infu A) 2 hours PI; TC1, 2, 3, 4, 7 (infu A) 2 hours PI; TC5, 6 (infu B) 1 hour PI.
Time Frame	BI and PI A and B for all TCs (8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course [up to 156 weeks, follow-up phase]). TCs were individualized based on clinical status and may not correlate to trial visits/wk
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92

	Ofatumumab 700 mg IV Infusion
Assessment of Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) [units: Millimeters of mercury (mmHg)] Mean (Standard Deviation)	
SBP, Treatment Course 1, BI-A, n =92	121.7 (18.20)
SBP, Treatment Course 1, PI-A, + >2 Hours, n=2	138.5 (3.54)
SBP, Treatment Course 1, BI-B, n=91	119.9 (18.38)
SBP, Treatment Course 1, PI-B, + 2 Hours, n=48	122.8 (13.32)
SBP, Treatment Course 2, BI-A, n=73	117.3 (16.84)
SBP, Treatment Course 2, PI-A, + 2 Hours, n=71	121.4 (13.86)
SBP, Treatment Course 2, BI-B, n=69	116.8 (16.09)
SBP, Treatment Course 2, PI-B, + 2 Hours, n=36	120.5 (13.52)
SBP, Treatment Course 3, BI-A, n=53	116.8 (15.61)
SBP, Treatment Course 3, PI-A, + >2 Hours, n=1	125.0 (NA) [1]
SBP, Treatment Course 3, BI-B, n=53	120.1 (15.59)
SBP, Treatment Course 3, PI-B, + 2 Hours, n=26	121.2 (9.63)
SBP, Treatment Course 4, BI-A, n=20	114.2 (14.86)
SBP, Treatment Course 4, PI-A, + 2 Hours, n=19	116.0 (12.54)
SBP, Treatment Course 4, BI-B, n=19	111.8 (14.86)
SBP, Treatment Course 4, PI-B, + 2 Hours, n=2	115.0 (15.56)
SBP, Treatment Course 5, BI-A, n=8	116.1 (16.17)
SBP, Treatment Course 5, PI-A, + 2 Hours, n=8	114.0 (11.99)
SBP, Treatment Course 5, BI-B, n=8	102.5 (12.54)
SBP, Treatment Course 5, PI-B, + 1 Hour, n=7	103.6 (14.35)
SBP, Treatment Course 6, BI-A, n=4	123.8 (7.50)
SBP, Treatment Course 6, PI-A, + 2 Hours, n=4	117.5 (12.58)
SBP, Treatment Course 6, BI-B, n=4	118.8 (13.15)
SBP, Treatment Course 6, PI-B, + 1 Hour, n=4	127.5 (2.89)

	Ofatumumab 700 mg IV Infusion
SBP, Treatment Course 7, BI-A, n=2	120.0 (14.14)
SBP, Treatment Course 7, PI-A, + 2 Hours, n=1	125.0 (NA) [1]
SBP, Treatment Course 7, BI-B, n=2	110.0 (0.00)
SBP, Treatment Course 7, PI-B, + 2 Hours, n=1	125.0 (NA) [1]
SBP, Follow-up, n=78	125.9 (14.45)
DBP, Treatment Course 1, BI-A, n=92	76.3 (11.51)
DBP, Treatment Course 1, PI-A, +>2 Hours, n=90	86.5 (6.36)
DBP, Treatment Course 1, BI-B, n=91	74.4 (11.85)
DBP, Treatment Course 1, PI-B, + 2 Hours, n=48	75.5 (8.73)
DBP, Treatment Course 2, BI-A, n=73	73.4 (10.26)
DBP, Treatment Course 2, PI-A, + 2 Hours, n=71	74.8 (8.56)
DBP, Treatment Course 2, BI-B, n=69	72.8 (10.37)
DBP, Treatment Course 2, PI-B, + 2 Hours, n=36	74.0 (7.58)
DBP, Treatment Course 3, BI-A, n=53	72.1 (10.84)
DBP, Treatment Course 3, PI-A, >2 Hours, n=1	75.0 (NA) [1]
DBP, Treatment Course 3, BI-B, n=53	74.7 (10.53)
DBP, Treatment Course 3, PI-B, + 2 Hours, n=26	75.3 (8.02)
DBP, Treatment Course 4, BI-A, n=20	71.7 (11.59)
DBP, Treatment Course 4, PI-A, + 2 Hours, n=19	75.1 (9.79)
DBP, Treatment Course 4, BI-B, n=19	71.7 (10.87)
DBP, Treatment Course 4, PI-B, + 2 Hours, n=2	75.0 (7.07)
DBP, Treatment Course 5, BI-A, n=8	74.6 (12.06)
DBP, Treatment Course 5, PI-A, + 2 Hours, n=8	77.5 (10.00)
DBP, Treatment Course 5, BI-B, n=8	68.4 (6.74)
DBP, Treatment Course 5, PI-B, +1 Hour, n=7	69.7 (10.44)
DBP, Treatment Course 6, BI-A, n=4	77.5 (6.45)
DBP, Treatment Course 6, PI-A, + 2 Hours, n=4	78.8 (4.79)

	Ofatumumab 700 mg IV Infusion
DBP, Treatment Course 6, BI-B, n=4	68.8 (10.31)
DBP, Treatment Course 6, PI-B, 1 Hour, n=4	81.3 (2.50)
DBP, Treatment Course 7, BI-A, n=2	85.0 (7.07)
DBP, Treatment Course 7, PI-A, + 2 Hours, n=1	90.0 (NA) [1]
DBP, Treatment Course 7, BI-B, n=2	75.0 (7.07)
DBP, Treatment Course 7, PI-B, + 2 Hours, n=1	90.0 (NA) [1]
DBP, Follow-up, n=78	76.9 (9.16)

[1] Standard deviation is not calculated when only one participant was analyzed.

28. Secondary Outcome Measure:

Measure Title	Assessment of Heart Rate (HR)
Measure Description	The HR of the participants was measured to assess the condition of the heart. HR was measured BI and post the first (A) and second (B) infusions during all 7 treatment courses. Timing for measuring HR: TC1, 3 (infu A) more than 2 hours PI; TC1, 2 ,3, 4, 7 (infu B) 2 hours PI; TC2, 4, 5, 6, 7 (infu A) 2 hours PI; TC5, 6 (infu B) 1 hour PI.
Time Frame	BI and PI A and B for all TCs (8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course [up to 156 weeks, follow-up phase]). TCs were individualized based on clinical status and may not correlate to trial visits/wk
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Assessment of Heart Rate (HR) [units: Beats per minute (bpm)] Mean (Standard Deviation)	
HR, Treatment Course 1, BI-A, n=92	73.4 (10.10)
HR, Treatment Course 1, PI-A, + >2 Hours, n=2	76.5 (12.02)
HR, Treatment Course 1, BI-B, n=91	71.8 (9.41)
HR, Treatment Course 1, PI-B, + 2 Hours, n=48	74.9 (10.72)
HR, Treatment Course 2, BI-A, n=73	70.9 (7.37)
HR, Treatment Course 2, PI-A, + 2 Hours, n=71	74.3 (7.88)
HR, Treatment Course 2, BI-B, n=69	72.9 (8.02)
HR, Treatment Course 2, PI-B, + 2 Hours, n=36	73.4 (7.53)
HR, Treatment Course 3, BI-A, n=53	72.6 (6.99)
HR, Treatment Course 3, PI-A, + >2 Hours, n= 1	68.0 (NA) [1]
HR, Treatment Course 3, BI-B, n=53	72.2 (8.57)
HR, Treatment Course 3, PI-B, + 2 Hours, n=26	75.6 (6.11)
HR, Treatment Course 4, BI-A, n=20	70.8 (5.77)
HR, Treatment Course 4, PI-A, + 2 Hours, n=19	74.6 (6.50)
HR, Treatment Course 4, BI-B, n=19	70.5 (4.43)

	Ofatumumab 700 mg IV Infusion
HR, Treatment Course 4, PI-B, + 2 Hours, n=2	76.0 (5.66)
HR, Treatment Course 5, BI-A, n=8	70.9 (3.00)
HR, Treatment Course 5, PI-A, + 2 Hours, n=8	72.6 (3.66)
HR, Treatment Course 5, BI-B, n=8	68.9 (4.58)
HR, Treatment Course 5, PI-B, + 1 Hour, n=7	71.7 (4.96)
HR, Treatment Course 6, BI-A, n=4	70.0 (4.00)
HR, Treatment Course 6, PI-A, + 2 Hours, n=4	71.0 (6.00)
HR, Treatment Course 6, BI-B, n=4	68.0 (5.66)
HR, Treatment Course 6, PI-B, + 1 Hour, n=4	72.0 (0.00)
HR, Treatment Course 7, BI-A, n=2	72.0 (0.00)
HR, Treatment Course 7, PI-A, + 2 Hours, n=1	72.0 (NA) [1]
HR, Treatment Course 7, BI-B, n=2	70.0 (2.83)
HR, Treatment Course 7, PI-B, + 2 Hours, n=1	68.0 (NA) [1]
HR, Follow-up, n=78	72.1 (8.05)

[1] Standard deviation is not calculated when only one participant was analyzed.

29. Secondary Outcome Measure:

Measure Title	Assessment of Body Temperature (BT)
Measure Description	The BT of the participants was measured BI and post the first (A) and second (B) infusions (PI) of each cycle to assess the effect of ofatumumab on the BT. The BT of the participants was measured before BI and PI A and B during all 7 treatment courses. Timing for taking BT reading: TC1, 3 (infu A) more than 2 hours PI; TC1, 2 ,3, 4, 7 (infu B) 2 hours PI; TC2, 4, 5, 6, 7 (infu A) 2 hours PI; TC5, 6 (infu B) 1 hour PI.
Time Frame	BI and PI A and B for all TCs (8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course [up to 156 weeks, follow-up phase]). TCs were individualized based on clinical status and may not correlate to trial visits/wk
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Assessment of Body Temperature (BT) [units: Degrees celcius] Mean (Standard Deviation)	
BT, Treatment Course 1, BI-A, n=92	36.50 (0.360)
BT, Treatment Course 1, PI-A, + >2 Hours, n=1	36.50 (NA) [1]
BT, Treatment Course 1, BI-B, n=91	36.46 (0.368)
BT, Treatment Course 1, PI-B, + 2 Hours, n=48	36.53 (0.316)
BT, Treatment Course 2 BI-A, n=73	36.48 (0.313)
BT, Treatment Course 2 PI-A, + 2 Hours, n=71	36.56 (0.261)
BT, Treatment Course 2 BI-B, n=69	36.54 (0.370)
BT, Treatment Course 2 PI-B, + 2 Hours, n=36	36.58 (0.252)
BT, Treatment Course 3 BI-A, n=53	36.46 (0.307)
BT, Treatment Course 3 PI-A, + >2 Hours, n=1	36.60 (NA) [1]
BT, Treatment Course 3, BI-B, n=53	36.45 (0.392)
BT, Treatment Course 3, PI-B, + 2 Hours, n=26	36.59 (0.294)
BT, Treatment Course 4, BI-A, n=20	36.50 (0.381)
BT, Treatment Course 4, PI-A, + 2 Hours, n=19	36.58 (0.242)
BT, Treatment Course 4, BI-B, n=19	36.53 (0.421)

	Ofatumumab 700 mg IV Infusion
BT, Treatment Course 4, PI-B, + 2 Hours, n=2	37.00 (0.283)
BT, Treatment Course 5, BI-A, n=8	36.40 (0.267)
BT, Treatment Course 5, PI-A, + 2 Hours, n=8	36.50 (0.262)
BT, Treatment Course 5, BI-B, n=8	36.41 (0.242)
BT, Treatment Course 5, PI-B, + 1 Hour, n=7	36.49 (0.329)
BT, Treatment Course 6, BI-A, n=4	36.48 (0.126)
BT, Treatment Course 6, PI-A, + 2 Hours, n=4	36.48 (0.250)
BT, Treatment Course 6, BI-B, n=4	36.35 (0.370)
BT, Treatment Course 6, PI-B, + 1 Hour, n=4	36.45 (0.370)
BT, Treatment Course 7, BI-A, n=2	36.55 (0.071)
BT, Treatment Course 7, PI-A, + 2 Hours, n=1	36.60 (NA) [1]
BT, Treatment Course 7, BI-B, n=2	36.65 (0.071)
BT, Treatment Course 7, PI-B, + 2 Hours, n=1	36.60 (NA) [1]
BT, Follow-up, n=78	36.57 (0.323)

[1] Standard deviation is not calculated when only one participant was analyzed.

30. Secondary Outcome Measure:

Measure Title	Assessment of Lactic Dehydrogenase (LDH) and Creatine Phosphokinase (CPK)
Measure Description	Blood samples of participants were collected to assess LDH and CPK. Both tests are performed to evaluate the injury and damage to the body tissue, potentially from B-cell lysis.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then Weeks 12 and 24 of follow-up (up to Study Wk 156). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Assessment of Lactic Dehydrogenase (LDH) and Creatine Phosphokinase (CPK) [units: U/L] Mean (Standard Deviation)	
LDH, Treatment Course 1, Baseline, n=92	189.6 (35.18)
LDH, Treatment Course 1, Week 104, n=1	229.0 (NA) [1]
LDH, Treatment Course 2, Baseline, n=73	198.6 (77.62)
LDH, Treatment Course 2, Week 80, n=1	219.0 (NA) [1]
LDH, Treatment Course 3, Baseline, n=53	186.5 (37.39)
LDH, Treatment Course 3, Week 64, n=1	242.0 (NA) [1]
LDH, Treatment Course 4, Baseline, n=20	184.6 (35.52)
LDH, Treatment Course 4, Week 40, n=1	170.0 (NA) [1]
LDH, Treatment Course 5, Baseline, n=8	179.4 (25.03)
LDH, Treatment Course 5, Week 24, n=2	168.5 (27.58)
LDH, Treatment Course 6, Baseline, n=4	173.3 (15.13)
LDH, Treatment Course 6, Week 16, n=2	234.0 (53.74)
LDH, Treatment Course 7, Baseline, n=2	292.0 (140.01)
LDH, Treatment Course 7, Week 8, n=2	190.0 (25.46)

	Ofatumumab 700 mg IV Infusion
LDH, Follow-up Week 12, n=59	191.3 (34.14)
LDH, Follow-up Week 24, n=18	194.4 (28.56)
CPK, Treatment Course 1, Baseline, n=92	61.4 (29.25)
CPK, Treatment Course 1, Week 104, n=1	127.0 (NA) [1]
CPK, Treatment Course 2, Baseline, n=73	70.5 (31.07)
CPK, Treatment Course 2, Week 80, n=1	61.0 (NA) [1]
CPK, Treatment Course 3, Baseline, n=53	77.7 (50.86)
CPK, Treatment Course 3, Week 64, n=1	81.0 (NA) [1]
CPK, Treatment Course 4, Baseline n=20	85.4 (64.46)
CPK, Treatment Course 4, Week 40, n=1	52.0 (NA) [1]
CPK, Treatment Course 5, Baseline, n=8	157.6 (216.71)
CPK, Treatment Course 5, Week 24, n=2	82.5 (27.58)
CPK, Treatment Course 6, Baseline, n=4	84.8 (23.91)
CPK, Treatment Course 6, Week 16, n=2	100.0 (14.14)
CPK, Treatment Course 7, Baseline, n=2	103.0 (19.80)
CPK, Treatment Course 7, Week 8, n=2	109.0 (15.56)
CPK, Follow-up Week 12, n=59	79.3 (38.73)
CPK, Follow-up Week 24, n=18	77.0 (26.09)

[1] Standard deviation is not calculated when only one participant was analyzed.

31. Secondary Outcome Measure:

Measure Title	Number of Participants With Normal and Abnormal Electrocardiogram Readings
Measure Description	Electrocardiograms of the participants were taken. The abnormal clinically significant (CS) and not clinically significant (NCS) reading, as determined by the Investigator, were recorded.
Time Frame	8 wk post infusion, then every 4 wk until Wk 24, then every 8 wk until next treatment course (up to 144 weeks). TCs were individualized based on clinical status and may not correlate to trial visits or study weeks.

Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Number of Participants With Normal and Abnormal Electrocardiogram Readings [units: participants]	
Treatment Course 1, Week 24, Normal	64
Treatment Course 1, Week 24, Abnormal NCS	9
Treatment Course 1, Week 24, Abnormal CS	0
Treatment Course 1, Week 104, Normal	1
Treatment Course 1, Week 104, Abnormal NCS	0
Treatment Course 1, Week 104, Abnormal NCS	0
Treatment Course 2, Week 24, Normal	43
Treatment Course 2, Week 24, Abnormal NCS	17
Treatment Course 2, Week 24, Abnormal CS	0
Treatment Course 2, Week 80, Normal	1
Treatment Course 2, Week 80, Abnormal NCS	0
Treatment Course 2, Week 80, Abnormal CS	0

	Ofatumumab 700 mg IV Infusion
Treatment Course 3, Week 24, Normal	24
Treatment Course 3, Week 24, Abnormal NCS	4
Treatment Course 3, Week 56, Normal	1
Treatment Course 3, Week 56, Abnormal NCS	1
Treatment Course 3, Week 56, Abnormal CS	0
Treatment Course 4, Week 24, Normal	7
Treatment Course 4, Week 24, Abnormal NCS	0
Treatment Course 4, Week 24, Abnormal CS	0
Treatment Course 4, Week 32, Normal	3
Treatment Course 4, Week 32, Abnormal NCS	0
Treatment Course 4, Week 32, Abnormal CS	0
Treatment Course 5, Week 24, Normal	2
Treatment Course 5, Week 24, Abnormal NCS	0
Treatment Course 5, Week 24, Abnormal CS	0

32. Secondary Outcome Measure:

Measure Title	Number of Participants With Grade 3 and 4 Neutropenia Events (NEs)
Measure Description	Blood samples of participants were collected for the evaluation of absolute neutrophil count. A Grade 3 NE was defined as absolute neutrophil count below the following values: absolute neutrophil count <1000-500/mm^3; <1.0-0.5 x 10^9/L. A Grade 4 NE was defined as absolute neutrophil count below the following values: absolute neutrophil count <500/mm3; <0.5 x 10^9/L. Blood samples of participants were collected for the evaluation of platelet count. Grade 3 thrombocytopenia was defined as platelet counts below the following values: platelet count <50000-25000/mm^3; <50.0-25.0 x 10^9/L. Grade 4 thrombocytopenia was defined as platelet counts below the following values: platelet count <25000/mm^3; <25.0 x 10^9/L.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then every 12 wk follow-up (up to Study Wk 156). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description
FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Number of Participants With Grade 3 and 4 Neutropenia Events (NEs) [units: participants]	
Treatment Course 1, Grade 3 NE	1
Treatment Course 1, Grade 4 NE	2
Treatment Course 2, Grade 3 NE	0
Treatment Course 2, Grade 4 NE	0
Treatment Course 3, Grade 3 NE	0
Treatment Course 3, Grade 4 NE	0
Treatment Course 4, Grade 3 NE	0
Treatment Course 4, Grade 4 NE	0
Treatment Course 5, Grade 3 NE	0
Treatment Course 5, Grade 4 NE	0
Treatment Course 6, Grade 3 NE	0
Treatment Course 6, Grade 4 NE	0
Treatment Course 7, Grade 3 NE	0
Treatment Course 7, Grade 4 NE	0

33. Secondary Outcome Measure:

Measure Title	Number of Participants With Repopulated CD19+ Cell Counts at the Indicated Time Points
Measure Description	Blood samples of participants were collected for the evaluation of the CD19+ B-cell subset. The number of participants with repopulated CD19+ cell counts was determined. A participant was defined as repopulated at a visit if the cell count was >=the lower limit of normal (LLN) or the Baseline value, whichever was lower. Baseline was defined as the Baseline value from Study OFA112657.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then every 12 wk follow-up (up to Study Wk 204). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description
FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Number of Participants With Repopulated CD19+ Cell Counts at the Indicated Time Points [units: participants]	
Treatment Course 1, Week 24	2
Treatment Course 1, Week 32	2
Treatment Course 1, Week 40	1
Treatment Course 1, Week 48	2

	Ofatumumab 700 mg IV Infusion
Treatment Course 1, Week 56	3
Treatment Course 1, Week 64	1
Treatment Course 1, Week 72	1
Treatment Course 1, Week 80	1
Treatment Course 1, Week 88	2
Treatment Course 2, Baseline	5
Treatment Course 2, Week 32	1
Treatment Course 2, Week 40	2
Treatment Course 2, Week 48	5
Treatment Course 2, Week 56	3
Treatment Course 2, Week 64	2
Treatment Course 3, Baseline	9
Treatment Course 3, Week 40	1
Treatment Course 3, Week 48	1
Treatment Course 3, Week 56	2
Treatment Course 4, Baseline	2
Follow-up Week 12	7
Follow-up Week 24	4
Follow-up Week 36	2
Follow-up Week 48	2
Follow-up Week 60	2
Follow-up Week 84	1
Follow-up Week 96	1

34. Secondary Outcome Measure:

Measure Title	Time to CD19+ Repopulation Relative to Baseline

Measure Description	Blood samples of participants were collected for the evaluation of the CD19+ B-cell subset. A participant was defined as repopulated at a visit if the CD19+ cell count was >=the lower limit of normal (LLN) or the Baseline value, whichever was lower. Time to the first repopulation relative to Baseline was calculated as: (the date of the first sample where CD19+ was greater than or equal to the minimum of the LLN and the Baseline value minus the Baseline date + 1) divided by 365.25. Baseline was defined as the Baseline value from Study OFA112657.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then every 12 wk follow-up (up to Study Wk 204). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with repopulated CD19+ cell counts were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Time to CD19+ Repopulation Relative to Baseline [units: years] Mean (Standard Deviation)	
Received 1 Treatment Course, n=7	3.87 (0.804)
Received 2 Treatment Courses, n=4	4.37 (0.706)
Received 3 Treatment Courses, n=10	4.17 (0.543)
Received 4-7 Treatment Courses, n=6	4.01 (0.724)

35. Secondary Outcome Measure:

Measure Title	Time to CD19+ Cell Repopulation From the Time of the Last Ofatumumab Dose
Measure Description	Blood samples of participants were collected for the evaluation of the CD19+ B-cell subset. A participant was defined as repopulated at a visit if the CD19+ cell count was >=the lower limit of normal (LLN) or the Baseline value, whichever was lower. Time to the first repopulation relative to the last ofatumumab treatment was calculated as: (the date of the first sample where CD19+ was greater than or equal to the minimum of the LLN and the Baseline value minus the date of last dose of ofatumumab + 1) divided by 30.4375. Baseline was defined as the Baseline value from Study OFA112657.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then every 12 wk follow-up (up to Study Wk 204). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with repopulated CD19+ cell counts were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Time to CD19+ Cell Repopulation From the Time of the Last Ofatumumab Dose [units: months] Mean (Standard Deviation)	
Received 1 Treatment Course, n=7	15.17 (7.213)
Received 2 Treatment Courses, n=3	12.32 (5.330)
Received 3 Treatment Courses, n=3	9.32 (1.421)
Received 4-7 Treatment Courses, n=1	11.70 (NA) [1]

[1] Standard deviation is not calculated when only one participant was analyzed.

36. Secondary Outcome Measure:

Measure Title	Number of Participants With Postive or Negative Plasma/White Cell John Cunningham Virus (JCV) Polymerase Chain Reaction (PCR) Test Results
Measure Description	Blood samples were collected, and the plasma/white cell JCV PCR test was performed for qualitative analysis of plasma/white cell JCV DeoxyriboNucleic Acid (DNA). Participants with positive results on at least one visit (any visit) are included in the indicated positive category. Positive test results denoted presence of the indicated parameters and Negative test results denoted absence of the indicated parameters.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then every 12 wk follow-up (up to Study Wk 204). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description
FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Number of Participants With Postive or Negative Plasma/White Cell John Cunningham Virus (JCV) Polymerase Chain Reaction (PCR) Test Results [units: participants]	
Positive Plasma JCV DNA	0

	Ofatumumab 700 mg IV Infusion
Negative Plasma JCV DNA	92
Positive White Cell JCV DNA	1
Negative White Cell JCV DNA	91

37. Secondary Outcome Measure:

Measure Title	Number of Participants With Postive or Negative Results of Testing for Anti-HBc, Anti-HBs, and HBsAG
Measure Description	Blood samples were collected, and participants were evaluated for serologic evidence of Hepatitis B (HB) infection based on the results of testing for HBsAg, anti-HBc, and anti-HBs antibodies. Participants with positive results on at least one visit (any visit) are included in the indicated positive category. Positive test results denoted presence of the indicated parameters and Negative test results denoted absence of the indicated parameters.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then every 24 wk follow-up (up to Study Wk 204). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description

FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Number of Participants With Postive or Negative Results of Testing for Anti-HBc, Anti-HBs, and HBsAG	

	Ofatumumab 700 mg IV Infusion
[units: participants]	
Positive Anti-HBc	3
Negative Anti-HBc	89
Positive Anti-HBs	29
Negative Anti-HBs	63
Postive HBsAG	0
Negative HBsAG	92

38. Secondary Outcome Measure:

Measure Title	Number of Participants With Any Signs/Symptoms of Progressive Multifocal Leukoencephalopathy (PML)
Measure Description	A neurological examination to detect any signs or symptoms consistent with a diagnosis of PML was conducted. Signs and symptoms of PML includ visual disturbances, ocular movements, ataxia, and changes in mental status such as disorientation or confusion. Participants with any signs/symptoms of PML on at least one visit (any visit) are included in the "Yes" category.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then every 12 wk follow-up (up to Study Wk 204). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description
FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92
Number of Participants With Any Signs/Symptoms of Progressive Multifocal Leukoencephalopathy (PML) [units: participants]	
Yes	3
No	89

39. Secondary Outcome Measure:

Measure Title	Number of Participants With a Positive or Negative Pregnancy Test Results.
Measure Description	Serum and urine pregnancy testing were performed for women of childbearing potential.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then Weeks 12 and 24 of follow-up (up to Study Wk 156). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description
FAS Population

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92

	Ofatumumab 700 mg IV Infusion
Number of Participants With a Positive or Negative Pregnancy Test Results. [units: participants]	
Postive	0
Negative/Test Not Done	92

40. Secondary Outcome Measure:

Measure Title	Number of Participants With Immunoglobulin A (IgA) <0.7 Grams Per Liter (g/L) or >4 g/L, Immunoglobulin M (IgM) <0.5 g/L or >3 g/L, and Immunoglobulin G (IgG) <6.5 g/L or >16 g/L at the Indicated Time Points
Measure Description	Blood samples of participants were collected for the measurement of IgA, IgG, and IgM.
Time Frame	BL of each TC and 8 wk PI, then every 4 wk until Wk 24, then every 8 wk until next TC, then every 12 wk follow-up (up to Study Wk 204). TCs were individualized based on clinical status and may not correlate to trial visits or study wk
Safety Issue?	No

Analysis Population Description

FAS Population. Only participants with data available at particular time points were analyzed.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treatment course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.

Measured Values

	Ofatumumab 700 mg IV Infusion
Number of Participants Analyzed	92

	Ofatumumab 700 mg IV Infusion
Number of Participants With Immunoglobulin A (IgA) <0.7 Grams Per Liter (g/L) or >4 g/L, Immunoglobulin M (IgM) <0.5 g/L or >3 g/L, and Immunoglobulin G (IgG) <6.5 g/L or >16 g/L at the Indicated Time Points [units: participants]	
IgA <0.7 g/L, Treatment Course 1, Baseline; n=91	1
IgA >4 g/L, Treatment Course 1, Baseline; n=91	14
IgA <0.7 g/L, Treatment Course 1, Week 104; n=1	0
IgA >4 g/L, Treatment Course 1, Week 104; n=1	0
IgA <0.7 g/L, Treatment Course 1,At any time;n=92	2
IgA >4 g/L, Treatment Course 1, At any time; n=92	17
IgA <0.7 g/L, Treatment Course 2, Baseline; n=73	2
IgA >4 g/L, Treatment Course 2, Baseline; n=73	6
IgA <0.7 g/L, Treatment Course 2, Week 80; n=1	0
IgA >4 g/L, Treatment Course 2, Week 80; n=1	0
IgA <0.7 g/L, Treatment Course 2, At any time;n=73	2
IgA >4 g/L, Treatment Course 2, At any time; n=73	9
IgA <0.7 g/L, Treatment Course 3, Baseline; n=53	0
IgA >4 g/L, Treatment Course 3, Baseline; n=53	7
IgA <0.7 g/L, Treatment Course 3, Week 64; n=1	0
IgA >4 g/L, Treatment Course 3, Week 64; n=1	0
IgA <0.7 g/L, Treatment Course 3, At any time;n=53	1
IgA >4 g/L, Treatment Course 3, At any time; n=53	8
IgA <0.7 g/L, Treatment Course 4, Baseline; n=20	0
IgA >4 g/L, Treatment Course 4, Baseline; n=20	2
IgA <0.7 g/L, Treatment Course 4, Week 40; n=1	0
IgA >4 g/L, Treatment Course 4, Week 40; n=1	0
IgA <0.7 g/L, Treatment Course 4, At any time;n=20	0
IgA >4 g/L, Treatment Course 4, At any time; n=20	2

	Ofatumumab 700 mg IV Infusion
IgA <0.7 g/L, Treatment Course 5, Baseline; n=8	0
IgA >4 g/L, Treatment Course 5, Baseline; n=8	1
IgA <0.7 g/L, Treatment Course 5, Week 24; n=2	0
IgA >4 g/L, Treatment Course 5, Week 24; n=2	0
IgA <0.7 g/L, Treatment Course 5, At any time; n=8	0
IgA >4 g/L, Treatment Course 5, At any time; n=8	1
IgA <0.7 g/L, Treatment Course 6, Baseline; n=4	0
IgA >4 g/L, Treatment Course 6, Baseline; n=4	1
IgA <0.7 g/L, Treatment Course 6, Week 12; n=4	0
IgA >4 g/L, Treatment Course 6, Week 12; n=4	0
IgA <0.7 g/L, Treatment Course 6, At any time; n=4	0
IgA >4 g/L, Treatment Course 6, At any time; n=4	1
IgA <0.7 g/L, Treatment Course 7, Baseline; n=2	0
IgA >4 g/L, Treatment Course 7, Baseline; n=2	1
IgA <0.7 g/L, Treatment Course 7, At any time; n=2	0
IgA >4 g/L, Treatment Course 7, At any time; n=2	1
IgA <0.7 g/L, Follow-up Week 12; n=59	0
IgA >4 g/L, Follow-up Week 12; n=59	5
IgA <0.7 g/L, Follow-up Week 120; n=1	0
IgA >4 g/L, Follow-up Week 120; n=1	0
IgA <0.7 g/L, Follow-up, at any time; n=61	0
IgA >4 g/L, Follow-up, at any time; n=61	5
IgM <0.5 g/L, Treatment Course 1, Baseline; n=91	5
IgM >3 g/L, Treatment Course 1, Baseline; n=91	4
IgM <0.5 g/L, Treatment Course 1, Week 104; n=1	0
IgM >3 g/L, Treatment Course 1, Week 104; n=1	0

	Ofatumumab 700 mg IV Infusion
IgM <0.5 g/L, Treatment Course 1, At any time;n=92	20
IgM >3 g/L, Treatment Course 1, At any time; n=92	4
IgM <0.5 g/L, Treatment Course 2, Baseline; n=73	10
IgM >3 g/L, Treatment Course 2, Baseline; n=73	2
IgM <0.5 g/L, Treatment Course 2, Week 80; n=1	1
IgM >3 g/L, Treatment Course 2, Week 80; n=1	0
IgM <0.5 g/L, Treatment Course 2, At any time;n=73	16
IgM >3 g/L, Treatment Course 2, At any time; n=73	2
IgM <0.5 g/L, Treatment Course 3, Baseline; n=53	10
IgM >3 g/L, Treatment Course 3, Baseline; n=53	2
IgM <0.5 g/L, Treatment Course 3, Week 64; n=1	0
IgM >3 g/L, Treatment Course 3, Week 64; n=1	0
IgM <0.5 g/L, Treatment Course 3, At any time;n=53	15
IgM >3 g/L, Treatment Course 3, At any time;n=53	2
IgM <0.5 g/L, Treatment Course 4, Baseline; n=20	2
IgM >3 g/L, Treatment Course 4, Baseline; n=20	2
IgM <0.5 g/L, Treatment Course 4, Week 40; n=1	0
IgM >3 g/L, Treatment Course 4, Week 40; n=1	0
IgM <0.5 g/L, Treatment Course 4, At any time;n=20	3
IgM >3 g/L, Treatment Course 4, At any time; n=20	2
IgM <0.5 g/L, Treatment Course 5, Baseline; n=8	3
IgM >3 g/L, Treatment Course 5, Baseline; n=8	0
IgM <0.5 g/L, Treatment Course 5, Week 24; n=2	0
IgM >3 g/L, Treatment Course 5, Week 24; n=2	0
IgM <0.5 g/L, Treatment Course 5, At any time; n=8	3

	Ofatumumab 700 mg IV Infusion
IgM >3 g/L, Treatment Course 5, At any time; n=8	0
IgM <0.5 g/L, Treatment Course 6, Baseline; n=4	1
IgM >3 g/L, Treatment Course 6, Baseline; n=4	0
IgM <0.5 g/L, Treatment Course 6, Week 12; n=4	2
IgM >3 g/L, Treatment Course 6, Week 12; n=4	0
IgM <0.5 g/L, Treatment Course 6, At any time; n=4	2
IgM >3 g/L, Treatment Course 6, At any time; n=4	0
IgM <0.5 g/L, Treatment Course 7, Baseline; n=2	1
IgM >3 g/L, Treatment Course 7, Baseline; n=2	0
IgM <0.5 g/L, Treatment Course 7, At any time; n=2	1
IgM >3 g/L, Treatment Course 7, At any time; n=2	0
IgM <0.5 g/L, Follow-up Week 12; n=59	17
IgM >3 g/L, Follow-up Week 12; n=59	1
IgM <0.5 g/L, Follow-up Week 120; n=1	1
IgM >3 g/L, Follow-up Week 120; n=1	0
IgM <0.5 g/L, Follow-up, at any time; n=61	19
IgM >3 g/L, Follow-up, at any time; n=61	1
IgG <6.5 g/L, Treatment Course 1, Baseline; n=91	0
IgG >16 g/L, Treatment Course 1, Baseline; n=91	10
IgG <6.5 g/L, Treatment Course 1, Week 104; n=1	0
IgG >16 g/L, Treatment Course 1, Week 104; n=1	0
IgG <6.5 g/L, Treatment Course 1, At any time;n=92	7
IgG >16 g/L, Treatment Course 1, At any time; n=92	13
IgG <6.5 g/L, Treatment Course 2, Baseline; n=73	1
IgG >16 g/L, Treatment Course 2, Baseline; n=73	5
IgG <6.5 g/L, Treatment Course 2, Week 80; n=1	0

	Ofatumumab 700 mg IV Infusion
IgG >16 g/L, Treatment Course 2, Week 80; n=1	0
IgG <6.5 g/L, Treatment Course 2, At any time;n=73	1
IgG >16 g/L, Treatment Course 2, At any time; n=73	7
IgG <6.5 g/L, Treatment Course 3, Baseline; n=53	0
IgG >16 g/L, Treatment Course 3, Baseline; n=53	2
IgG <6.5 g/L, Treatment Course 3, Week 64; n=1	0
IgG >16 g/L, Treatment Course 3, Week 64; n=1	0
IgG <6.5 g/L, Treatment Course 3, At any time;n=53	1
IgG >16 g/L, Treatment Course 3, At any time; n=53	3
IgG <6.5 g/L, Treatment Course 4, Baseline; n=20	0
IgG >16 g/L, Treatment Course 4, Baseline; n=20	0
IgG <6.5 g/L, Treatment Course 4, Week 40; n=1	0
IgG >16 g/L, Treatment Course 4, Week 40; n=1	0
IgG <6.5 g/L, Treatment Course 4, At any time;n=20	1
IgG >16 g/L, Treatment Course 4, At any time; n=20	0
IgG <6.5 g/L, Treatment Course 5, Baseline; n=8	0
IgG >16 g/L, Treatment Course 5, Baseline; n=8	0
IgG <6.5 g/L, Treatment Course 5, Week 24; n=2	0
IgG >16 g/L, Treatment Course 5, Week 24; n=2	0
IgG <6.5 g/L, Treatment Course 5, At any time; n=8	0
IgG >16 g/L, Treatment Course 5, At any time; n=8	0
IgG <6.5 g/L, Treatment Course 6, Baseline; n=4	0
IgG >16 g/L, Treatment Course 6, Baseline; n=4	0

	Ofatumumab 700 mg IV Infusion
IgG <6.5 g/L, Treatment Course 6, Week 16; n=2	0
IgG >16 g/L, Treatment Course 6, Week 16; n=2	0
IgG <6.5 g/L, Treatment Course 6, At any time; n=4	0
IgG >16 g/L, Treatment Course 6, At any time; n=4	0
IgG <6.5 g/L, Treatment Course 7, Baseline; n=2	0
IgG >16 g/L, Treatment Course 7, Baseline; n=2	0
IgG <6.5 g/L, Treatment Course 7, Week 8; n=2	0
IgG >16 g/L, Treatment Course 7, Week 8; n=2	0
IgG <6.5 g/L, Treatment Course 7, At any time; n=2	0
IgG >16 g/L, Treatment Course 7, At any time; n=2	0
IgG <6.5 g/L, Follow-up Week 12; n=67	4
IgG >16 g/L, Follow-up Week 12; n=67	3
IgG <6.5 g/L, Follow-up Week 120; n=1	0
IgG >16 g/L, Follow-up Week 120; n=1	0
IgG <6.5 g/L, Follow-up, at any time; n=70	5
IgG >16 g/L, Follow-up, at any time; n=70	4

Reported Adverse Events

Time Frame	Adverse events (AEs) were collected in the period beginning from the first treatment cycle until the end of the Treatment Period (up to Study Week 144). Only Serious adverse events (SAEs) were collected up to the Follow-up Period (up to Study Week 204).
Additional Description	Although the study was designed such that only SAEs were to be collected for the Follow-up Period, non-serious AEs were recorded for some participants.

Reporting Groups

	Description
Ofatumumab 700 mg IV Infusion: Treatment Period	Ofatumumab was administered in the dose of 700 milligrams (mg) as two intravenous (IV) infusions separated by 2 weeks for the first treament course. The remaining treatment courses were given at individualized time intervals when a clinical response had been achieved following the previous treatment course and a subsequent worsening in disease activity had been observed. For the remaining treatment courses, the interval between the treatment courses was at least 16 weeks from the first infusion in the previous treatment course irrespective of progression in disease activity. After each treatment course, the participants attended their next trial visit 8 weeks after the first infusion of that course, followed by trial visits every 4 weeks up to Week 24, and subsequent visits every 8 weeks until the next treatment course. A maximum of 9 treatment courses were allowed.
Ofatumumab 700 mg IV Infusion: Follow-up Period	After completing or withdrawing from the Treatment Period, participants were followed up every 12 weeks (for a maximum of 2 years in the Follow-up Period) until CD19+ cells returned to Baseline or normal levels.

Serious Adverse Events

	Ofatumumab 700 mg IV Infusion: Treatment Period	Ofatumumab 700 mg IV Infusion: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)
Total	11/92 (11.96%)	2/79 (2.53%)
Cardiac disorders		
Myocardial infarction [A] †	1/92 (1.09%)	1/79 (1.27%)
Eye disorders		
Visual impairment [A] †	1/92 (1.09%)	0/79 (0%)
Gastrointestinal disorders		
Pancreatitis [A] †	1/92 (1.09%)	0/79 (0%)
Hepatobiliary disorders		
Cholecystitis [A] †	1/92 (1.09%)	0/79 (0%)
Cholelithiasis [A] †	1/92 (1.09%)	0/79 (0%)
Infections and infestations		
Pneumonia [A] †	1/92 (1.09%)	0/79 (0%)
Injury, poisoning and procedural complications		
Fall [A] †	1/92 (1.09%)	0/79 (0%)

	Ofatumumab 700 mg IV Infusion: Treatment Period	Ofatumumab 700 mg IV Infusion: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)
Joint dislocation [A] †	1/92 (1.09%)	0/79 (0%)
Investigations		
Blood creatinine increased [A] †	0/92 (0%)	1/79 (1.27%)
Musculoskeletal and connective tissue disorders		
Osteitis [A] †	1/92 (1.09%)	0/79 (0%)
Rheumatoid arthritis [A] †	1/92 (1.09%)	1/79 (1.27%)
Nervous system disorders		
Amnesia [A] †	1/92 (1.09%)	0/79 (0%)
Disturbance in attention [A] †	1/92 (1.09%)	0/79 (0%)
Memory impairment [A] †	2/92 (2.17%)	0/79 (0%)
Speech disorder [A] †	1/92 (1.09%)	0/79 (0%)
Skin and subcutaneous tissue disorders		
Rash [A] †	1/92 (1.09%)	0/79 (0%)
Vascular disorders		
Hypertension [A] †	1/92 (1.09%)	0/79 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Ofatumumab 700 mg IV Infusion: Treatment Period	Ofatumumab 700 mg IV Infusion: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)
Total	70/92 (76.09%)	2/79 (2.53%)
Blood and lymphatic system disorders		
Anemia [A] †	3/92 (3.26%)	0/79 (0%)

	Ofatumumab 700 mg IV Infusion: Treatment Period	Ofatumumab 700 mg IV Infusion: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)
Leukopenia [A] †	4/92 (4.35%)	0/79 (0%)
Lymphadenitis [A] †	1/92 (1.09%)	0/79 (0%)
Lymphadenopathy [A] †	1/92 (1.09%)	0/79 (0%)
Lymphopenia [A] †	2/92 (2.17%)	0/79 (0%)
Neutropenia [A] †	5/92 (5.43%)	0/79 (0%)
Cardiac disorders		
Atrial fibrillation [A] †	1/92 (1.09%)	0/79 (0%)
Myocardial infarction [A] †	1/92 (1.09%)	0/79 (0%)
Tachycardia [A] †	1/92 (1.09%)	0/79 (0%)
Congenital, familial and genetic disorders		
Demoid cyst [A] †	1/92 (1.09%)	0/79 (0%)
Ear and labyrinth disorders		
Ear pruritus [A] †	1/92 (1.09%)	0/79 (0%)
Tinnitus [A] †	1/92 (1.09%)	0/79 (0%)
Vertigo [A] †	3/92 (3.26%)	0/79 (0%)
Eye disorders		
Conjunctival irritation [A] †	1/92 (1.09%)	0/79 (0%)
Conjunctivitis [A] †	3/92 (3.26%)	0/79 (0%)
Dry eye [A] †	3/92 (3.26%)	0/79 (0%)
Eye swelling [A] †	1/92 (1.09%)	0/79 (0%)
Eyelid edema [A] †	1/92 (1.09%)	0/79 (0%)
Lacrimation increased [A] †	1/92 (1.09%)	0/79 (0%)
Photopsia [A] †	1/92 (1.09%)	0/79 (0%)

	Ofatumumab 700 mg IV Infusion: Treatment Period	Ofatumumab 700 mg IV Infusion: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)
Vision blurred [A] †	1/92 (1.09%)	0/79 (0%)
Visual acuity reduced [A] †	1/92 (1.09%)	0/79 (0%)
Visual impairment [A] †	2/92 (2.17%)	0/79 (0%)
Vitreous floaters [A] †	1/92 (1.09%)	0/79 (0%)
Gastrointestinal disorders		
Abdominal distension [A] †	1/92 (1.09%)	0/79 (0%)
Dental caries [A] †	1/92 (1.09%)	0/79 (0%)
Diarrhea [A] †	2/92 (2.17%)	0/79 (0%)
Dry mouth [A] †	2/92 (2.17%)	0/79 (0%)
Duodenal ulcer [A] †	1/92 (1.09%)	0/79 (0%)
Dysphagia [A] †	2/92 (2.17%)	0/79 (0%)
Mouth ulceration [A] †	1/92 (1.09%)	0/79 (0%)
Nausea [A] †	3/92 (3.26%)	1/79 (1.27%)
Pancreatitis [A] †	1/92 (1.09%)	0/79 (0%)
Vomiting [A] †	1/92 (1.09%)	0/79 (0%)
General disorders		
Chest discomfort [A] †	1/92 (1.09%)	0/79 (0%)
Edema peripheral [A] †	2/92 (2.17%)	0/79 (0%)
Fatigue [A] †	4/92 (4.35%)	0/79 (0%)
Influenza like illness [A] †	1/92 (1.09%)	0/79 (0%)
Thirst [A] †	1/92 (1.09%)	0/79 (0%)
Hepatobiliary disorders		

	Ofatumumab 700 mg IV Infusion: Treatment Period	Ofatumumab 700 mg IV Infusion: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)
Cholecystitis [A] †	1/92 (1.09%)	0/79 (0%)
Cholelithiasis [A] †	1/92 (1.09%)	0/79 (0%)
Immune system disorders		
Allergy to vaccine [A] †	1/92 (1.09%)	0/79 (0%)
Oral allergy syndrome [A] †	2/92 (2.17%)	0/79 (0%)
Infections and infestations		
Abscess [A] †	2/92 (2.17%)	0/79 (0%)
Bronchitis [A] †	4/92 (4.35%)	0/79 (0%)
Cystitis [A] †	2/92 (2.17%)	0/79 (0%)
Enterobiasis [A] †	1/92 (1.09%)	0/79 (0%)
Eye infection [A] †	1/92 (1.09%)	0/79 (0%)
Furuncle [A] †	1/92 (1.09%)	0/79 (0%)
Gastroenteritis viral [A] †	1/92 (1.09%)	0/79 (0%)
Influenza [A] †	3/92 (3.26%)	0/79 (0%)
Laryngitis [A] †	1/92 (1.09%)	0/79 (0%)
Lobar pneumonia [A] †	1/92 (1.09%)	0/79 (0%)
Lower respiratory tract infection [A] †	2/92 (2.17%)	0/79 (0%)
Nasopharyngitis [A] †	4/92 (4.35%)	0/79 (0%)
Oral herpes [A] †	4/92 (4.35%)	0/79 (0%)
Periodontitis [A] †	1/92 (1.09%)	0/79 (0%)
Pharyngitis [A] †	3/92 (3.26%)	0/79 (0%)
Pneumonia [A] †	1/92 (1.09%)	0/79 (0%)

	Ofatumumab 700 mg IV Infusion: Treatment Period	Ofatumumab 700 mg IV Infusion: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)
Rash pustular [A] †	1/92 (1.09%)	0/79 (0%)
Respiratory tract infection [A] †	3/92 (3.26%)	0/79 (0%)
Rhinitis [A] †	5/92 (5.43%)	0/79 (0%)
Sinusitis [A] †	3/92 (3.26%)	0/79 (0%)
Skin infection [A] †	1/92 (1.09%)	0/79 (0%)
Tonsillitis [A] †	1/92 (1.09%)	0/79 (0%)
Tracheitis [A] †	1/92 (1.09%)	0/79 (0%)
Upper respiratory tract infection [A] †	14/92 (15.22%)	0/79 (0%)
Urinary tract infection [A] †	5/92 (5.43%)	0/79 (0%)
Injury, poisoning and procedural complications		
Fall [A] †	1/92 (1.09%)	0/79 (0%)
Fibula fracture [A] †	1/92 (1.09%)	0/79 (0%)
Joint dislocation [A] †	1/92 (1.09%)	0/79 (0%)
Limb crushing injury [A] †	1/92 (1.09%)	0/79 (0%)
Patella fracture [A] †	1/92 (1.09%)	0/79 (0%)
Tendon rupture [A] †	1/92 (1.09%)	0/79 (0%)
Upper limb fracture [A] †	1/92 (1.09%)	0/79 (0%)
Investigations		
Alanine aminotransferase increased [A] †	2/92 (2.17%)	0/79 (0%)
Aspartate aminotransferase increased [A] †	2/92 (2.17%)	0/79 (0%)
Blood alkaline phosphatase increased [A] †	1/92 (1.09%)	0/79 (0%)
Blood creatinine increased [A] †	2/92 (2.17%)	0/79 (0%)

	Ofatumumab 700 mg IV Infusion: Treatment Period	Ofatumumab 700 mg IV Infusion: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)
Blood immunoglobulin G decreased [A] †	1/92 (1.09%)	0/79 (0%)
Blood pressure increased [A] †	1/92 (1.09%)	1/79 (1.27%)
Blood urea increased [A] †	1/92 (1.09%)	0/79 (0%)
Blood uric acid increased [A] †	1/92 (1.09%)	1/79 (1.27%)
Cardiac murmur [A] †	1/92 (1.09%)	0/79 (0%)
Heart rate abnormal [A] †	1/92 (1.09%)	0/79 (0%)
Hepatic enzyme Increased [A] †	3/92 (3.26%)	0/79 (0%)
John Cunningham virus test positive [A] †	1/92 (1.09%)	0/79 (0%)
Neutrophil count decreased [A] †	1/92 (1.09%)	0/79 (0%)
Transaminases increased [A] †	1/92 (1.09%)	0/79 (0%)
Metabolism and nutrition disorders		
Fluid retention [A] †	1/92 (1.09%)	0/79 (0%)
Gout [A] †	1/92 (1.09%)	1/79 (1.27%)
Hyperuricemia [A] †	1/92 (1.09%)	0/79 (0%)
Increased appetite [A] †	1/92 (1.09%)	0/79 (0%)
Musculoskeletal and connective tissue disorders		
Arthralgia [A] †	1/92 (1.09%)	0/79 (0%)
Back pain [A] †	2/92 (2.17%)	0/79 (0%)
Bursitis [A] †	2/92 (2.17%)	0/79 (0%)
Flank pain [A] †	1/92 (1.09%)	0/79 (0%)
Joint range of motion decreased [A] †	1/92 (1.09%)	0/79 (0%)
Limb discomfort [A] †	1/92 (1.09%)	0/79 (0%)

	Ofatumumab 700 mg IV Infusion: Treatment Period	Ofatumumab 700 mg IV Infusion: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)
Muscle spasms [A] †	1/92 (1.09%)	0/79 (0%)
Neck pain [A] †	1/92 (1.09%)	0/79 (0%)
Osteitis [A] †	1/92 (1.09%)	0/79 (0%)
Osteoarthritis [A] †	1/92 (1.09%)	0/79 (0%)
Pain in extremity [A] †	1/92 (1.09%)	0/79 (0%)
Rheumatoid arthritis [A] †	2/92 (2.17%)	0/79 (0%)
Sensation of heaviness [A] †	1/92 (1.09%)	0/79 (0%)
Spondylolisthesis [A] †	1/92 (1.09%)	0/79 (0%)
Synovial cyst [A] †	1/92 (1.09%)	0/79 (0%)
Tendon disorder [A] †	1/92 (1.09%)	0/79 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Seborrhoeic keratosis [A] †	1/92 (1.09%)	1/79 (1.27%)
Nervous system disorders		
Amnesia [A] †	1/92 (1.09%)	0/79 (0%)
Aphasia [A] †	2/92 (2.17%)	0/79 (0%)
Disturbance in attention [A] †	2/92 (2.17%)	0/79 (0%)
Dysgeusia [A] †	1/92 (1.09%)	0/79 (0%)
Headache [A] †	9/92 (9.78%)	0/79 (0%)
Hypoaesthesia [A] †	2/92 (2.17%)	0/79 (0%)
Memory impairment [A] †	3/92 (3.26%)	0/79 (0%)
Meralgia paraesthetica [A] †	1/92 (1.09%)	0/79 (0%)
Neuralgia [A] †	1/92 (1.09%)	0/79 (0%)

	Ofatumumab 700 mg IV Infusion: Treatment Period	Ofatumumab 700 mg IV Infusion: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)
Paraesthesia [A] †	1/92 (1.09%)	0/79 (0%)
Sciatica [A] †	2/92 (2.17%)	0/79 (0%)
Speech disorder [A] †	1/92 (1.09%)	0/79 (0%)
Psychiatric disorders		
Anxiety [A] †	1/92 (1.09%)	0/79 (0%)
Depression [A] †	1/92 (1.09%)	0/79 (0%)
Insomnia [A] †	1/92 (1.09%)	0/79 (0%)
Stress [A] †	1/92 (1.09%)	0/79 (0%)
Renal and urinary disorders		
Leukocyturia [A] †	1/92 (1.09%)	0/79 (0%)
Nephrolithiasis [A] †	1/92 (1.09%)	0/79 (0%)
Nocturia [A] †	1/92 (1.09%)	0/79 (0%)
Proteinuria [A] †	1/92 (1.09%)	0/79 (0%)
Renal impairment [A] †	1/92 (1.09%)	0/79 (0%)
Reproductive system and breast disorders		
Breast pain [A] †	1/92 (1.09%)	0/79 (0%)
Respiratory, thoracic and mediastinal disorders		
Bronchospasm [A] †	1/92 (1.09%)	0/79 (0%)
Cough [A] †	10/92 (10.87%)	0/79 (0%)
Dry throat [A] †	2/92 (2.17%)	0/79 (0%)
Dysphonia [A] †	1/92 (1.09%)	0/79 (0%)
Dyspnea [A] †	5/92 (5.43%)	2/79 (2.53%)
Nasal congestion [A] †	1/92 (1.09%)	0/79 (0%)

	Ofatumumab 700 mg IV Infusion: Treatment Period	Ofatumumab 700 mg IV Infusion: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)
Nasal dryness [A] †	1/92 (1.09%)	0/79 (0%)
Oropharyngeal pain [A] †	3/92 (3.26%)	0/79 (0%)
Pharyngeal edema [A] †	1/92 (1.09%)	0/79 (0%)
Rhinorrhea [A] †	1/92 (1.09%)	0/79 (0%)
Sneezing [A] †	6/92 (6.52%)	0/79 (0%)
Throat irritation [A] †	9/92 (9.78%)	0/79 (0%)
Throat tightness [A] †	2/92 (2.17%)	0/79 (0%)
Upper-airway cough syndrome [A] †	1/92 (1.09%)	0/79 (0%)
Skin and subcutaneous tissue disorders		
Alopecia [A] †	2/92 (2.17%)	0/79 (0%)
Dry skin [A] †	1/92 (1.09%)	0/79 (0%)
Erythema [A] †	1/92 (1.09%)	0/79 (0%)
Pruritus [A] †	3/92 (3.26%)	0/79 (0%)
Psoriasis [A] †	1/92 (1.09%)	0/79 (0%)
Rash [A] †	20/92 (21.74%)	1/79 (1.27%)
Rash erythematous [A] †	1/92 (1.09%)	0/79 (0%)
Rash generalized [A] †	2/92 (2.17%)	0/79 (0%)
Rash maculo-papular [A] †	1/92 (1.09%)	0/79 (0%)
Urticaria [A] †	5/92 (5.43%)	0/79 (0%)
Vascular disorders		
Flushing [A] †	3/92 (3.26%)	0/79 (0%)
Hypertension [A] †	4/92 (4.35%)	0/79 (0%)

	Ofatumumab 700 mg IV Infusion: Treatment Period	Ofatumumab 700 mg IV Infusion: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)
Varicophlebitis [A] †	1/92 (1.09%)	0/79 (0%)
Varicose vein [A] †	1/92 (1.09%)	0/79 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA

Limitations and Caveats

Development of the IV route of ofatumumab (OFA) administration in RA will no longer be pursued. This study was prematurely terminated; OFA treatment was discontinued. Participants could complete only <=7 treatment courses and a follow-up evaluation.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

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