ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 05/08/2014

ClinicalTrials.gov ID: NCT00611455

Study Identification

Unique Protocol ID:	110635
Brief Title:	Investigating Clinical Efficacy of Ofatumumab in Adult Rheumatoid Arthritis (RA) Patients Who Had an Inadequate Response to MTX Therapy
Official Title:	A Double-blind, Randomized, Placebo Controlled, Parallel Group, Multi-center, Phase III Trial of Ofatumumab Investigating Clinical Efficacy in Adult Patients With Active Rheumatoid Arthritis Who Have Had an Inadequate Response to Methotrexate Therapy
Secondary IDs:	GEN410 [GENMAB]

Study Status

Record Verification:	December 2013
Overall Status:	Terminated
Study Start:	January 2008
Primary Completion:	July 2009 [Actual]
Study Completion:	July 2013 [Actual]

Sponsor/Collaborators

Sponsor:	GlaxoSmithKline
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 08/MREOO/31 Board Name: Scotland A MREC Board Affiliation: NHS Scotland Phone: 0131-465-5678 Email: Dorothy.garrow@nhslothian.scot.nhs.uk
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	United Kingdom: Research Ethics Committee United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study Description

Brief Summary:	This is a phase III, double-blind, randomized, multicenter, and parallel group trial with a duration of 24 weeks, followed by a 120 week Open-label Period. the primary purpose of the study is to demonstrate the efficacy of ofatumumab in reducing clinical signs and symptoms in adult RA patients after a single course of ofatumumab.
Detailed Description:	This study consists of a Double-blind , placebo controlled, and parallel group part with eligible patients enrolled into a 24 week Double-Blind Period, and randomized in a 1:1 ratio to receive ofatumumab (700mg x 2 infusions) or placebo (saline x 2 infusions) in addition to their background methotrexate treatment. Patients who completed the 24 week Double-Blind period without receiving rescue DMARD treatment will be eligible to proceed into the 120 week Open-Label Period to receive repeat treatment courses with ofatumumab. In the Open-label Period ofatumumab treatment courses will be given at individualized time intervals only if a clinical response has been achieved following the previous treatment course, and followed by a subsequent worsening in disease activity . Patients who have completed the Open-Label Period or have withdrawn will enter a maximum 2 year Follow-up Period, or until their Bcells return to normal or to baseline levels, whichever occurs earlier.

Conditions

Conditions:	Arthritis, Rheumatoid
Keywords:	

Study Design

Study Type:	Interventional

Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Investigator)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	265 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: ofatumumab 1000 mL dilution of 35ml of ofatumumab in sterile, pyrogen free 0.9% NaCl. Each Treatment Cycle consisting of two 700mg IV infusions taken 14 days apart. A total of 8 infusions cycles given over a 144 week period	Drug: ofatumumab 1000 mL dilution of 35ml of ofatumumab in sterile, pyrogen free 0.9% NaCl. Each Treatment Cycle consisting of two 700mg IV infusions taken 14 days apart. A total of 8 infusions cycles given over a 144 week period
Placebo Comparator: 1000 ml Saline 1000 mL dilution of 35ml of ofatumumab in sterile, pyrogen free 0.9% NaCl. Each Treatment Cycle consisting of two IV infusions taken 14 days apart. Only one placebo treatment cycle provided over a 24 week period	Drug: Placebo 1000 mL dilution of 35ml of ofatumumab in sterile, pyrogen free 0.9% NaCl. Each Treatment Cycle consisting of two IV infusions taken 14 days apart. Only one placebo treatment cycle provided over a 24 week period

Outcome Measures

[See Results Section.]

Eligibility

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

- Age ≥ 18 years;
- Active disease at the time of screening as defined by:

  ≥ 8 swollen joints (of 66 joints assessed) and ≥ 8 tender joints (of 68 joints assessed), C-Reactive Protein (CRP) ≥ 1.0 mg/dL or Erythrocyte Sedimentation Rate (ESR) ≥ 22 mm/hour, DAS28≥3.2 (based on ESR);

- Inadequate response to previous or current methotrexate treatment;
- Treatment with methotrexate (MTX), 7.5-25 mg/week, for at least 12 weeks and at a stable dose for at least 4 weeks.

Exclusion Criteria

- Patients with a history of a rheumatic autoimmune disease other than RA or with significant systemic involvement secondary to RA;
- Previous exposure to biologic anti-rheumatic therapies, including investigational compounds;
- Previous exposure to biologic DMARDs; Chronic or ongoing active infectious disease requiring systemic treatment;
- Clinically significant cardiac disease; History of significant cerebrovascular disease;
- Significant concurrent, uncontrolled medical condition including, but not limited to, renal, hepatic, hematological, gastrointestinal, endocrine, pulmonary, neurological, cerebral psychiatric disease, or evidence of demyelinating disease;
- Known HIV positive; Serologic evidence of Hepatitis B infection; Positive test for Hepatitis C; Positive plasma / white cell JC Virus PCR;
- Serum IgG < lower limit of normal;
- Breast feeding women or women with a positive pregnancy test at screening;
- Current participation in any other interventional clinical study;
- Patients known or suspected of not being able to comply with a study protocol.

Contacts/Locations

Study Officials: GSK Clinical Trials
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References

Citations: P. Taylor, E. Quattrocchi, S. Mallett, R. Kurrasch, Jorgen Petersen, David Chang. Ofatumumab, a fully human anti-CD20 monoclonal antibody, in biologic-naïve, rheumatoid arthritis patients with an inadequate response to methotrexate: a randomised, double-blind, placebo-controlled clinical trial. [Ann Rheum Dis]. 2011;

Links:

Study Data/Documents:

Participant Flow

Pre-Assignment Details	Study OFA110635 was comprised of a 24-week Double-blind (DB) Period, followed by a 120-week Open-label (OL) Period. Participants who completed the OL Period, or who were withdrawn, entered a Follow-up (FU) period (approximately 2 years).

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

DB Treatment Period (24 Weeks)

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Started	134	131	0
Completed	121	117	0
Not Completed	13	14	0
Adverse Event	2	8	0
Lack of Efficacy	2	0	0
Protocol Violation	4	1	0
Withdrawal by Subject	2	3	0
Randomized in Error; Not Treated	2	2	0

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Randomized, but Not Treated	1	0	0

OL Treatment Period (120 Weeks)

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Started	0	231 [1]	0
Completed	0	52	0
Not Completed	0	179	0
Adverse Event	0	17	0
Lack of Efficacy	0	9	0
Protocol Violation	0	3	0
Protocol-defined Stopping Criteria Met	0	12	0
Study Closed/Terminated	0	110	0
Lost to Follow-up	0	5	0
Physician Decision	0	5	0
Withdrawal by Subject	0	18	0

[1] 118 participants received OFA during the DB Period; 113 received placebo during the DB Period.

Follow-up Period (Approximately 2 Years)

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Started	0	0	260 [1]
Completed	0	0	49
Not Completed	0	0	211
Adverse Event	0	0	30
Lack of Efficacy	0	0	12
Protocol Violation	0	0	4
Protocol-defined Stopping Criteria Met	0	0	23

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Study Closed/Terminated	0	0	80
Lost to Follow-up	0	0	13
Withdrawal by Subject	0	0	49

[1] These participants received at least one infusion of placebo or ofatumumab.

Baseline Characteristics

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Baseline Measures

	Placebo	Ofatumumab 700 mg	Total
Number of Participants	131	129	260
Age, Continuous [1] [units: Years] Mean (Standard Deviation)	53.6 (11.50)	51.7 (11.24)	52.7 (11.39)
Gender, Male/Female [2] [units: Participants]			
Female	108	106	214
Male	23	23	46
Race/Ethnicity, Customized [2] [units: participants]			
Hispanic/Latino	52	51	103
Not Hispanic/Latino	79	78	157

[1] Baseline characteristics are reported for members of the Intent-to-Treat (ITT) Population, comprised of all randomized participants who were exposed to investigational product irrespective of their compliance to the planned course of treatment. Participants were analyzed according to their randomized treatment.

[2] Baseline characteristics are reported for members of the ITT Population, comprised of all randomized participants who were exposed to investigational product irrespective of their compliance to the planned course of treatment. Participants were analyzed according to their randomized treatment.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With a 20% Improvement From Baseline in Their American College of Rheumatology (ACR) Score (ACR20) at Week 24
Measure Description	The ACR score was based on improvement from baseline in tender (TJC) and swollen joint counts (SJC). A participant had achieved ACR20 if he experienced >=20% improvement from baseline in TJC and SJC and a >=20% improvement from baseline in 3 out of 5 of the following assessments: participant pain assessment on a 100 millimeter (mm) visual analog scale (VAS), participant global assessment on a 100 mm VAS scale, physician global assessment on a 100 mm VAS scale, participant self-assessed disability, and C-reactive protein.
Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population: all randomized participants who were exposed to investigational product irrespective of their compliance to the planned course of treatment. Participants were analyzed according to their randomized treatment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	131	129

	Placebo	Ofatumumab 700 mg
Number of Participants With a 20% Improvement From Baseline in Their American College of Rheumatology (ACR) Score (ACR20) at Week 24 [units: participants]	35	64

Statistical Analysis 1 for Number of Participants With a 20% Improvement From Baseline in Their American College of Rheumatology (ACR) Score (ACR20) at Week 24

Statistical Analysis Overview	Comparison Groups	Placebo, Ofatumumab 700 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	2.86
	Confidence Interval	(2-Sided) 95% 1.67 to 4.91
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Number of Participants With a 20% Improvement From Baseline in Their American College of Rheumatology (ACR) Score (ACR20) at Weeks 4, 8, 12, 16, and 20
Measure Description	The ACR score was based on improvement from baseline in tender (TJC) and swollen joint counts (SJC). A participant had achieved ACR20 if he experienced >=20% improvement from baseline in TJC and SJC and a >=20% improvement from baseline in 3 out of 5 of the following assessments: participant pain assessment on a 100 millimeter (mm) visual analog scale (VAS), participant global assessment on a 100 mm VAS scale, physician global assessment on a 100 mm VAS scale, participant self-assessed disability, and C-reactive protein.
Time Frame	Baseline and Weeks 4, 8, 12, 16, and 20

Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	131	129
Number of Participants With a 20% Improvement From Baseline in Their American College of Rheumatology (ACR) Score (ACR20) at Weeks 4, 8, 12, 16, and 20 [units: participants]		
Week 4	42	52
Week 8	43	66
Week 12	44	71
Week 16	38	67
Week 20	40	62

3. Secondary Outcome Measure:

Measure Title	Number of Participants With a 50% Improvement From Baseline in Their ACR Score (ACR50) at Weeks 4, 8, 12, 16, 20, and 24

Measure Description	The ACR score was based on improvement from baseline in tender (TJC) and swollen joint counts (SJC). A participant had achieved ACR50 if he experienced >=50% improvement from baseline in TJC and SJC and a >=50% improvement from baseline in 3 out of 5 of the following assessments: participant pain assessment on a 100 millimeter (mm) visual analog scale (VAS), participant global assessment on a 100 mm VAS scale, physician global assessment on a 100 mm VAS scale, participant self-assessed disability, and C-reactive protein.
Time Frame	Baseline and Weeks 4, 8, 12, 16, 20, and 24
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	131	129
Number of Participants With a 50% Improvement From Baseline in Their ACR Score (ACR50) at Weeks 4, 8, 12, 16, 20, and 24 [units: participants]		
Week 4	13	14
Week 8	12	23
Week 12	14	36
Week 16	13	37
Week 20	19	31
Week 24	14	35

4. Secondary Outcome Measure:

Measure Title	Number of Participants With a 70% Improvement From Baseline in Their ACR Score (ACR70) at Weeks 4, 8, 12, 16, 20, and 24
Measure Description	The ACR score was based on improvement from baseline in tender (TJC) and swollen joint counts (SJC). A participant had achieved ACR70 if he experienced >=70% improvement from baseline in TJC and SJC and a >=70% improvement from baseline in 3 out of 5 of the following assessments: participant pain assessment on a 100 millimeter (mm) visual analog scale (VAS), participant global assessment on a 100 mm VAS scale, physician global assessment on a 100 mm VAS scale, participant self-assessed disability, and C-reactive protein.
Time Frame	Baseline and Weeks 4, 8, 12, 16, 20, and 24
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	131	129
Number of Participants With a 70% Improvement From Baseline in Their ACR Score (ACR70) at Weeks 4, 8, 12, 16, 20, and 24 [units: participants]		
Week 4	6	4
Week 8	3	10
Week 12	6	19
Week 16	5	18
Week 20	6	18
Week 24	3	17

5. Secondary Outcome Measure:

Measure Title	Median ACRn at Weeks 4, 8, 12, 16, 20, and 24
Measure Description	ACRn = the largest integer n for which a participant (par.) met the criteria requiring an improvement of n%. ACRn is a measure characterizing percent (%) improvement from baseline (IFBL). A par. with an ACRn of X had an improvement of >=X% in tender/swollen joints (TJC/SJC), and an improvement of >=X% in 3 of the 5 parameters (patient [pt] pain assessment, pt global assessment [GA], physician GA, pt self-assessed disability, acute phase reactant). ACRn = minimum(TJC % IFBL, SJC % IFBL, composite measure % IFBL). Composite measure % IFBL is the 3rd highest value of % IFBL for the 5 parameters.
Time Frame	Weeks 4, 8, 12, 16, 20, and 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using last observation carried forward (LOCF). Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	130	126
Median ACRn at Weeks 4, 8, 12, 16, 20, and 24 [units: percent change] Median (Full Range)		
Week 4, n=129, 124	6.0 (-77 to 85)	13.0 (-98 to 92)
Week 8, n=130, 126	5.5 (-250 to 86)	22.0 (-264 to 84)
Week 12, n=130, 126	0.5 (-200 to 85)	25.0 (-73 to 100)
Week 16, n=130, 126	0.0 (-210 to 85)	26.0 (-138 to 93)

	Placebo	Ofatumumab 700 mg
Week 20, n=130, 126	4.0 (-185 to 90)	21.0 (-74 to 92)
Week 24, n=130, 126	-2.5 (-272 to 90)	21.0 (-87 to 95)

6. Secondary Outcome Measure:

Measure Title	Mean Disease Activity Score Based on 28 Joints (DAS28) at Weeks 4, 8, 12, 16, 20, and 24 Using C-reactive Protein (CRP) as the Acute Phase Reactant (APR)
Measure Description	The DAS28 is a clinical index of rheumatoid arthritis disease activity (DA) that combines information from swollen and tender joints (jts.), the APR, and general health (patient global assessment). The following jts. were assessed on both sides of the body: shoulder, elbow, wrist, metacarpophalangeal (5 per side), proximal interphalangeal (5 per side), and knee. The level of DA can be interpreted as low (DAS28<=3.2), moderate (3.2<DAS28<=5.1), or high (DAS28>5.1); total score, 0-9.4. A DAS28 <2.6 corresponds to remission. APRs are a class of proteins that are useful markers for inflammation.
Time Frame	Weeks 4, 8, 12, 16, 20, and 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	130	126

	Placebo	Ofatumumab 700 mg
Mean Disease Activity Score Based on 28 Joints (DAS28) at Weeks 4, 8, 12, 16, 20, and 24 Using C-reactive Protein (CRP) as the Acute Phase Reactant (APR) [units: scores on a scale] Mean (Standard Deviation)		
Week 4, n=129, 124	4.78 (1.241)	4.74 (1.099)
Week 8, n=130, 126	4.75 (1.205)	4.41 (1.285)
Week 12, n=130, 126	4.66 (1.333)	4.14 (1.367)
Week 16, n=130, 126	4.78 (1.327)	4.11 (1.296)
Week 20, n=130, 126	4.78 (1.387)	4.13 (1.395)
Week 24, n=130, 126	4.98 (1.437)	4.12 (1.270)

7. Secondary Outcome Measure:

Measure Title	Change From Baseline in DAS28 at Weeks 4, 8, 12, 16, 20, and 24 Using CRP as the Acute Phase Reactant
Measure Description	The DAS28 is a clinical index of RA disease activity that combines information from swollen joints, tender joints, the acute phase reactant, and general health (patient global assessment). Change from baseline in DAS28 is calculated as the Week 4, 8, 12, 16, 20, and 24 values minus the baseline value.
Time Frame	Baseline and Weeks 4, 8, 12, 16, 20, and 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	130	126
Change From Baseline in DAS28 at Weeks 4, 8, 12, 16, 20, and 24 Using CRP as the Acute Phase Reactant [units: scores on a scale] Mean (Standard Deviation)		
Week 4, n=129, 124	-0.84 (1.053)	-1.09 (0.886)
Week 8, n=130, 126	-0.88 (0.992)	-1.41 (1.112)
Week 12, n=130, 126	-0.97 (1.221)	-1.69 (1.255)
Week 16, n=130, 126	-0.85 (1.194)	-1.72 (1.166)
Week 20, n=130, 126	-0.85 (1.215)	-1.70 (1.262)
Week 24, n=130, 126	-0.65 (1.218)	-1.71 (1.201)

8. Secondary Outcome Measure:

Measure Title	Mean DAS28 at Weeks 4, 8, 12, 16, 20, and 24 Using Erythrocyte Sedimentation Rate (ESR) as the Acute Phase Reactant
Measure Description	The DAS28 is a clinical index of rheumatoid arthritis disease activity (DA) that combines information from swollen and tender joints (jts.), the APR, and general health (patient global assessment). The following jts. were assessed on both sides of the body: shoulder, elbow, wrist, metacarpophalangeal (5 per side), proximal interphalangeal (5 per side), and knee. The level of DA can be interpreted as low (DAS28<=3.2), moderate (3.2<DAS28<=5.1), or high (DAS28>5.1); total score, 0-9.4. A DAS28 <2.6 corresponds to remission. APRs are a class of proteins that are useful markers for inflammation.
Time Frame	Weeks 4, 8, 12, 16, 20, and 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	130	126
Mean DAS28 at Weeks 4, 8, 12, 16, 20, and 24 Using Erythrocyte Sedimentation Rate (ESR) as the Acute Phase Reactant [units: scores on a scale] Mean (Standard Deviation)		
Week 4, n=129, 124	5.48 (1.332)	5.51 (1.127)
Week 8, n=130, 126	5.43 (1.289)	5.14 (1.276)
Week 12, n=130, 126	5.31 (1.349)	4.83 (1.358)
Week 16, n=130, 126	5.43 (1.329)	4.81 (1.310)
Week 20, n=130, 126	5.41 (1.414)	4.77 (1.427)
Week 24, n=130, 126	5.67 (1.439)	4.84 (1.360)

9. Secondary Outcome Measure:

Measure Title	Change From Baseline in DAS28 at Weeks 4, 8, 12, 16, 20, and 24 Using ESR as the Acute Phase Reactant
Measure Description	The DAS28 is a clinical index of RA disease activity that combines information from swollen joints, tender joints, the acute phase reactant, and general health (patient global assessment). Change from baseline in DAS28 is calculated as the Week 4, 8, 12, 16, 20, and 24 values minus the baseline value.
Time Frame	Baseline and Weeks 4, 8, 12, 16, 20, and 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	130	126
Change From Baseline in DAS28 at Weeks 4, 8, 12, 16, 20, and 24 Using ESR as the Acute Phase Reactant [units: scores on a scale] Mean (Standard Deviation)		
Week 4, n=129, 124	-0.92 (1.106)	-1.08 (0.891)
Week 8, n=130, 126	-0.97 (1.048)	-1.46 (1.092)
Week 12, n=130, 126	-1.10 (1.211)	-1.77 (1.257)
Week 16, n=130, 126	-0.97 (1.183)	-1.79 (1.189)
Week 20, n=130, 126	-0.99 (1.175)	-1.83 (1.304)
Week 24, n=130, 126	-0.73 (1.203)	-1.76 (1.264)

10. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated European League Against Rheumatism (EULAR) Response at Weeks 4, 8, 12, 16, 20, and 24 Using CRP as the Acute Phase Reactant

Measure Description	The DAS28-based EULAR response criteria were used to measure individual response as none, good, and moderate, depending on the extent of change from baseline and the level of disease activity reached. Good responders: change from baseline >1.2 with DAS28 <=3.2; moderate responders: change from baseline >1.2 with DAS28 <=3.2 to >5.1 or change from baseline >0.6 to <=1.2 with DAS28 <=3.2 to <=5.1); non-responders: change from baseline <=0.6 or change from baseline >0.6 and <=1.2 with DAS28 >5.1.
Time Frame	Weeks 4, 8, 12, 16, 20, and 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	130	126
Number of Participants With the Indicated European League Against Rheumatism (EULAR) Response at Weeks 4, 8, 12, 16, 20, and 24 Using CRP as the Acute Phase Reactant [units: participants]		
Week 4, Good; n=129, 124	15	12
Week 4, Moderate; n=129, 124	41	63
Week 4, None; n=129, 124	73	49
Week 8, Good; n=130, 126	16	22
Week 8, Moderate; n=130, 126	49	62
Week 8, None; n=130, 126	65	42
Week 12, Good; n=130, 126	17	32

	Placebo	Ofatumumab 700 mg
Week 12, Moderate; n=130, 126	51	56
Week 12, None; n=130, 126	62	38
Week 16, Good; n=130, 126	16	32
Week 16, Moderate; n=130, 126	51	58
Week 16, None; n=130, 126	63	36
Week 20, Good; n=130, 126	17	34
Week 20, Moderate; n=130, 126	41	52
Week 20, None; n=130, 126	72	40
Week 24, Good; n=130, 126	18	32
Week 24, Moderate; n=130, 126	37	60
Week 24, None; n=130, 126	75	34

11. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated European League Against Rheumatism (EULAR) Response at Weeks 4, 8, 12, 16, 20, and 24 Using ESR as the Acute Phase Reactant
Measure Description	The DAS28-based EULAR response criteria were used to measure individual response as none, good, and moderate, depending on the extent of change from baseline and the level of disease activity reached. Good responders: change from baseline >1.2 with DAS28 <=3.2; moderate responders: change from baseline >1.2 with DAS28 <=3.2 to >5.1 or change from baseline >0.6 to <=1.2 with DAS28 <=3.2 to <=5.1); non-responders: change from baseline <=0.6 or change from baseline >0.6 and <=1.2 with DAS28 >5.1.
Time Frame	Weeks 4, 8, 12, 16, 20, and 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	130	126
Number of Participants With the Indicated European League Against Rheumatism (EULAR) Response at Weeks 4, 8, 12, 16, 20, and 24 Using ESR as the Acute Phase Reactant [units: participants]		
Week 4, Good; n=129, 124	6	5
Week 4, Moderate; n=129, 124	49	50
Week 4, None; n=129, 124	74	69
Week 8, Good; n=130, 126	7	8
Week 8, Moderate; n=130, 126	53	67
Week 8, None; n=130, 126	70	51
Week 12, Good; n=130, 126	7	17
Week 12, Moderate; n=130, 126	57	63
Week 12, None; n=130, 126	66	46
Week 16, Good; n=130, 126	4	15
Week 16, Moderate; n=130, 126	58	70
Week 16, None; n=130, 126	68	41
Week 20, Good; n=130, 126	8	22
Week 20, Moderate; n=130, 126	45	63
Week 20, None; n=130, 126	77	41

	Placebo	Ofatumumab 700 mg
Week 24, Good; n=130, 126	4	14
Week 24, Moderate; n=130, 126	44	67
Week 24, None; n=130, 126	82	45

12. Secondary Outcome Measure:

Measure Title	Number of Participants Classified as Responders at Week 24 According to the Self-Assessed Health Assessment Questionnaire Disability Index (HAQ-DI)
Measure Description	The HAQ-DI is a 20-question instrument used to assess the degree of difficulty a participant had in accomplishing tasks in 8 functional areas (FAs): dressing, arising, eating, walking, hygiene, reaching, gripping, and errands/chores. Responses for each FA were scored from 0 (no difficulty) to 3 (inability to perform a task). The total score (range of 0-3) was calculated by adding the 8 individual FA scores, then dividing this sum by the total number of components answered. Responders were defined as participants achieving an improvement from baseline in the HAQ-DI score at Week 24 of >=0.22.
Time Frame	Week 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	117	112

	Placebo	Ofatumumab 700 mg
Number of Participants Classified as Responders at Week 24 According to the Self-Assessed Health Assessment Questionnaire Disability Index (HAQ-DI) [units: participants]	59	74

13. Secondary Outcome Measure:

Measure Title	Number of Participants With Clinical Remission at Week 24
Measure Description	Participants achieving clinical remission were defined as those with a low disease activity, i.e., DAS28 score (using CRP) <2.6 at Week 24.
Time Frame	Week 24
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	131	129
Number of Participants With Clinical Remission at Week 24 [units: participants]	7	13

14. Secondary Outcome Measure:

Measure Title	Change From Baseline in Tender Joint Count at Week 24
Measure Description	Change from baseline in tender joint count was calculated as the Week 24 count minus the baseline count. A total of 68 joints were assessed. Joints were classified as either tender or not tender by an independent assessor, who had documented experience in performing joint assessments.
Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	130	126
Change From Baseline in Tender Joint Count at Week 24 [units: number of tender joints] Median (Full Range)	-5 (-38 to 36)	-12 (-52 to 20)

15. Secondary Outcome Measure:

Measure Title	Change From Baseline in Swollen Joint Count at Week 24
Measure Description	Change from baseline in swollen joint count was calculated as the Week 24 count minus the baseline count. A total of 66 joints were assessed. Joints were classified as either swollen or not swollen by an independent assessor, who had documented experience in performing joint assessments.
Time Frame	Baseline and Week 24

Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	130	126
Change From Baseline in Swollen Joint Count at Week 24 [units: number of swollen joints] Median (Full Range)	-4.50 (-24 to 16)	-8.00 (-43 to 12)

16. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Participant-assessed Pain Score at Week 24
Measure Description	A horizontal VAS of 100 mm was used to report the participant’s level of joint pain. The scale ranged from 0 (no pain) to 100 (unbearable pain). Participants were instructed to draw a vertical line through the horizontal line to indicate how much joint pain they had. The distance from the "no pain" end to the vertical line drawn by the participant was the joint pain score. Change from baseline was calculated as the Week 24 value minus the baseline value.
Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	128	119
Change From Baseline in the Participant-assessed Pain Score at Week 24 [units: scores on a scale] Median (Full Range)	-5 (-93 to 54)	-22 (-95 to 35)

17. Secondary Outcome Measure:

Measure Title	Change From Baseline in Participant-assessed Global Disease Score at Week 24
Measure Description	The participant used a horizontal VAS of 100 mm for overall assessment of disease. The scale ranged from 0 (very well) to 100 (very poor). Participants were instructed to draw a vertical line through the horizontal line to indicate the state of the arthritis. The distance from the "very well" end to the vertical line drawn by the participant was the global disease assessment score. Change from baseline in participant-assessed global disease was calculated as the Week 24 value minus the baseline value.
Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).

	Description
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	130	126
Change From Baseline in Participant-assessed Global Disease Score at Week 24 [units: scores on a scale] Median (Full Range)	-6.0 (-76 to 57)	-16.5 (-83 to 28)

18. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Physician-assessed Global Disease Score at Week 24
Measure Description	The physician used a horizontal VAS of 100 mm for overall assessment of disease. The scale ranged from 0 (very well) to 100 (very poor). Physicians were instructed to draw a vertical line through the horizontal line to indicate the state of the arthritis. The distance from the "very well" end to the vertical line drawn by the participant was the global disease assessment score. Change from baseline in the physician-assessed global disease was calculated as the Week 24 value minus the baseline value.
Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	130	124
Change From Baseline in the Physician-assessed Global Disease Score at Week 24 [units: scores on a scale] Median (Full Range)	-9.50 (-70 to 37)	-20.50 (-77 to 17)

19. Secondary Outcome Measure:

Measure Title	Change From Baseline in HAQ-DI Score at Week 24
Measure Description	The self-assessed HAQ-DI is a 20-question instrument used to assess the degree of difficulty a participant had in accomplishing tasks in 8 functional areas (FAs): dressing, arising, eating, walking, hygiene, reaching, gripping, and errands/chores. Responses for each FA were scored from 0 (no difficulty) to 3 (inability to perform a task). The total score (range of 0-3) was calculated by adding the 8 individual FA scores, then dividing this sum by the total number of components answered. Change from baseline was calculated as the value at Week 24 minus the baseline value.
Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	123	122
Change From Baseline in HAQ-DI Score at Week 24 [units: scores on a scale]	-0.25 (-2.4 to 1.3)	-0.38 (-2.4 to 1.0)

	Placebo	Ofatumumab 700 mg
Median (Full Range)		

20. Secondary Outcome Measure:

Measure Title	Change From Baseline in CRP at Week 24
Measure Description	Blood samples for the determination of CRP were taken at pre-specified visits and were sent to the central laboratory for analysis. Change from Baseline in CRP was calculated as the Week 24 value minus the baseline value. CRP is an acute-phase protein whose plasma concentration increases in response to inflammation. CRP is a useful marker of inflammation.
Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	130	126
Change From Baseline in CRP at Week 24 [units: milligrams per liter (mg/L)] Median (Full Range)	-0.10 (-55.1 to 96.2)	-4.85 (-96.2 to 30.2)

21. Secondary Outcome Measure:

Measure Title	Change From Baseline in ESR at Week 24
Measure Description	ESR is measured by a blood test that shows the rate at which red blood cells sediment in a period of 1 hour. Blood samples for the determination of ESR were taken at pre-specified visits and were measured immediately at the trial site. Change from baseline in ESR was calculated as the Week 24 value minus the baseline value.
Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	130	126
Change From Baseline in ESR at Week 24 [units: millimeters per hour (mm/hr)] Median (Full Range)	-5 (-57 to 89)	-15 (-85 to 34)

22. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Short-Form 36 (SF-36v2) Norm-based Scores for Physical Component Summary and Physical Items at Week 24
Measure Description	The SF-36v2 is a standardized questionnaire used to measure overall subjective health status by measuring 8 health-related parameters (each scored from 0 [poorer health] to 100 [better health]): body pain, general mental health (MH), perception of general health, physical functioning, role limitations (RL) caused by mental condition, RL caused by a physical condition, social functioning, and vitality. It yields an 8-scale profile of functional health and well-being scores, as well as psychometrically based physical and MH summary measures and a preference-based health utility index.

Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	117	116
Change From Baseline in the Short-Form 36 (SF-36v2) Norm-based Scores for Physical Component Summary and Physical Items at Week 24 [units: scores on a scale] Least Squares Mean (Standard Error)		
Physical Component Summary	4.21 (1.048)	6.69 (1.031)
Physical Functioning	3.14 (1.125)	5.70 (1.100)
Role Physical	5.43 (1.259)	6.64 (1.231)
Bodily Pain	3.63 (1.197)	8.28 (1.170)
General Health	2.28 (1.033)	4.08 (1.011)

23. Secondary Outcome Measure:

Measure Title	Change From Baseline in the SF-36v2 Norm-based Scores for Mental Component Summary and Mental Items at Week 24

Measure Description	The SF-36v2 is a standardized questionnaire used to measure overall subjective health status by measuring 8 health-related parameters (each scored from 0 [poorer health] to 100 [better health]): body pain, general mental health (MH), perception of general health, physical functioning, role limitations (RL) caused by mental condition, RL caused by a physical condition, social functioning, and vitality. It yields an 8-scale profile of functional health and well-being scores, as well as psychometrically based physical and MH summary measures and a preference-based health utility index.
Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	117	116
Change From Baseline in the SF-36v2 Norm-based Scores for Mental Component Summary and Mental Items at Week 24 [units: scores on a scale] Least Squares Mean (Standard Error)		
Mental Component Summary	1.57 (1.308)	4.60 (1.272)
Vitality	2.46 (1.169)	7.26 (1.154)
Social Functioning	3.56 (1.361)	4.98 (1.331)
Role Emotional	2.23 (1.612)	4.93 (1.563)
Mental Health	2.92 (1.278)	5.40 (1.249)

24. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Functional Assessment of Chronic Illness Therapy (FACIT) Questionnaire Score at Week 24
Measure Description	The FACIT-F score has a valid range of values from 0 to 52, with a higher score indicating a lower burden of fatigue. The subset determining fatigue contains 13 questions. Responses to each question were scored from 0, indicating "Not at all fatigued," to 4, indicating "Very much fatigued."
Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	111	114
Change From Baseline in the Functional Assessment of Chronic Illness Therapy (FACIT) Questionnaire Score at Week 24 [units: scores on a scale] Median (Full Range)	2 (-37 to 27)	6 (-19 to 42)

25. Secondary Outcome Measure:

Measure Title	Change From Baseline in Levels of Anti-CCP, RF-IgA, RF-IgG, and RF-IgM at Week 24

Measure Description	The following biomarkers were assessed: Anti-Cyclic Citrullinated Peptide 3 antibody (Anti-CCP), Rheumatoid factor IgA (RF-IgA), RF IgG (RF-IgG), and RF IgM (RF-IgM). Measurements of RF were used to characterize participants' disease activity and immune status. Anti-CCP was used to characterize the disease type and the immune status of the participants. Assessments for which results were below the lower limit of quantification (LLQ) were reported using a value of LLQ/2. Assessments for which results were above the upper limit of quantification (ULQ) were reported using a value of ULQ.
Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	120	115
Change From Baseline in Levels of Anti-CCP, RF-IgA, RF-IgG, and RF-IgM at Week 24 [units: Units/Liter] Median (Full Range)		
Anti-CCP, n=120, 115	0.0 (-1613 to 4042)	-138.0 (-13000 to 762)
RF-IgA, n=119, 110	0.0 (-79 to 72)	-3 (-93 to 3)
RF-IgG, n=119, 110	0.0 (-71 to 58)	-4.8 (-87 to 9)
RF-IgM, n=119, 110	0.0 (-68 to 98)	-6.3 (-93 to 98)

26. Secondary Outcome Measure:

Measure Title	Change From Baseline in Levels of IL-6 and Serum Amyloid A at Week 24
Measure Description	The following biomarkers were assessed: Interleukin 6 (IL-6) and Serum Amyloid A. These biomarkers were used to further characterize disease activity.
Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description

ITT Population. Missing data were imputed using LOCF. Analysis included those participants in the ITT Population with at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks).
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks).

Measured Values

	Placebo	Ofatumumab 700 mg
Number of Participants Analyzed	120	115
Change From Baseline in Levels of IL-6 and Serum Amyloid A at Week 24 [units: nanogram per liter (ng/l)] Median (Full Range)		
IL-6, n=119, 115	-0.410 (-131.26 to 2632.66)	-4.040 (-106.98 to 63.44)
Serum Amyloid A, n=120, 114	-10850.5 (-1680680 to 3374580)	-53513.5 (-3724434 to 931790)

27. Secondary Outcome Measure:

Measure Title	Minimum DAS28-ESR Score During the Double-blind (DB) and Open-label (OL) Periods, by Ofatumumab Treatment Course

Measure Description	The DAS28 is a clinical index of rheumatoid arthritis disease activity that combines information from swollen and tender joints (jts.), the APR, and general health (patient global assessment). The following jts. were assessed on both sides of the body: shoulder, elbow, wrist, metacarpophalangeal (5 per side), proximal interphalangeal (5 per side), and knee. The level of disease activity can be interpreted as low (DAS28<=3.2), moderate (3.2<DAS28<=5.1), or high (DAS28>5.1); total score, 0-9.4. A DAS28 <2.6 corresponds to remission. The values summarized are the minimum DAS28 score (i.e. lowest level of disease activity) achieved by each participant within the first 24 weeks of each treatment course (TC), assessed using erythrocyte sedimentation rate (ESR; rate at which red blood cells sediment in 1 hour).
Time Frame	First 24 weeks of each treatment course (assessed up to Week 144)
Safety Issue?	No

Analysis Population Description

As Treated (AT) Population: all participants who received at least one infusion of ofatumumab in the DB and/or OL Period. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	243	0
Minimum DAS28-ESR Score During the Double-blind (DB) and Open-label (OL) Periods, by Ofatumumab Treatment Course [units: Scores on a scale]			

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Mean (Standard Deviation)			
TC 1, n=0, 243, 0		4.01 (1.396)	
TC 2, n=0, 198, 0		3.59 (1.227)	
TC 3, n=0, 136, 0		3.36 (1.225)	
TC 4, n=0, 72, 0		3.50 (1.175)	
TC 5, n=0, 31, 0		3.34 (1.326)	
TC 6, n=0, 11, 0		3.82 (1.588)	
TC 7, n=0, 2, 0		5.34 (1.038)	

28. Secondary Outcome Measure:

Measure Title	Minimum DAS28-CRP Score During the DB and OL Periods, by Ofatumumab Treatment Course
Measure Description	The DAS28 is a clinical index of rheumatoid arthritis disease activity that combines information from swollen and tender joints (jts.), the APR, and general health (patient global assessment). The following jts. were assessed on both sides of the body: shoulder, elbow, wrist, metacarpophalangeal (5 per side), proximal interphalangeal (5 per side), and knee. The level of disease activity can be interpreted as low (DAS28<=3.2), moderate (3.2<DAS28<=5.1), or high (DAS28>5.1); total score, 0-9.4. A DAS28 <2.6 corresponds to remission. The values summarized are the minimum DAS28 score (i.e. lowest level of disease activity) achieved by each participant within the first 24 weeks of each treatment course, assessed using C-reactive Protein (CRP: used to monitor acute inflammatory phases of rheumatoid arthritis).
Time Frame	First 24 weeks of each treatment course (assessed up to Week 144)
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.

	Description
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	243	0
Minimum DAS28-CRP Score During the DB and OL Periods, by Ofatumumab Treatment Course [units: scores on a scale] Mean (Standard Deviation)			
TC 1, n=0, 243, 0		3.43 (1.321)	
TC 2, n=0, 198, 0		3.09 (1.142)	
TC 3, n=0, 136, 0		2.86 (1.156)	
TC 4, n=0, 72, 0		2.94 (1.161)	
TC 5, n=0, 31, 0		2.90 (1.362)	
TC 6, n=0, 11, 0		3.39 (1.401)	
TC 7, n=0, 2, 0		4.55 (1.003)	

29. Secondary Outcome Measure:

Measure Title	Minimum Change From Baseline in the DAS28-ESR Score, During the DB and OL Periods, by Ofatumumab Treatment Course

Measure Description	The level of rheumatoid arthritis disease activity based on the DAS28 score is defined as low if DAS28 <=3.2, moderate if 3.2< DAS28 <=5.1, or high if DAS28 > 5.1. A DAS28 <2.6 corresponds to clinical remission. The values summarized are the minimum change from baseline DAS28 score (i.e. greatest change in disease activity during the treatment course) achieved by each participant within the first 24 weeks of each treatment course, assessed by using ESR. Baseline score was determined at the start of each treatment course. For change from baseline, participants had to have both a baseline DAS28 value for the treatment course (i.e., the latest value on or before the date of infusion A of the treatment course, providing it was done within a 14 day window prior to the date of infusion A) and a DAS28 value during the treatment course (i.e., during first 24 weeks of each treatment course). Change from baseline was calculated as the value during the treatment course minus the baseline value.
Time Frame	First 24 weeks of each treatment course (assessed up to Week 144)
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	238	0
Minimum Change From Baseline in the DAS28-ESR Score, During the DB and OL Periods, by Ofatumumab Treatment Course [units: scores on a scale]			

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Mean (Standard Deviation)			
TC 1, n=0, 238, 0		-2.32 (1.192)	
TC 2, n=0, 194, 0		-1.77 (1.072)	
TC 3, n=0, 129, 0		-1.77 (1.203)	
TC 4, n=0, 69, 0		-1.47 (1.065)	
TC 5, n=0, 31, 0		-1.77 (1.015)	
TC 6, n=0, 11, 0		-1.45 (0.845)	
TC 7, n=0, 2, 0		-0.07 (0.696)	

30. Secondary Outcome Measure:

Measure Title	Minimum Change From Baseline in the DAS28-CRP Score, During the DB and OL Periods, by Ofatumumab Treatment Course
Measure Description	The level of rheumatoid arthritis disease activity based on the DAS28 score is defined as low if DAS28 <=3.2, moderate if 3.2< DAS28 <=5.1, or high if DAS28 > 5.1. A DAS28 <2.6 corresponds to clinical remission. The values summarized are the minimum change from baseline DAS28 score (i.e. greatest change in disease activity during the treatment course) achieved by each participant within the first 24 weeks of each treatment course, assessed by using CRP. Baseline score was determined at the start of each treatment course. For change from baseline, participants had to have both a baseline DAS28 value for the treatment course (i.e., the latest value on or before the date of infusion A of the treatment course, providing it was done within a 14 day window prior to the date of infusion A) and a DAS28 value during the treatment course (i.e., during first 24 weeks of each treatment course). Change from baseline was calculated as the value during the treatment course minus the baseline value.
Time Frame	First 24 weeks of each treatment course (assessed up to Week 144)
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.

	Description
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	237	0
Minimum Change From Baseline in the DAS28-CRP Score, During the DB and OL Periods, by Ofatumumab Treatment Course [units: scores on a scale] Mean (Standard Deviation)			
TC 1, n=0, 237, 0		-2.15 (1.166)	
TC 2, n=0, 193, 0		-1.55 (1.020)	
TC 3, n=0, 125, 0		-1.67 (1.144)	
TC 4, n=0, 69, 0		-1.40 (1.081)	
TC 5, n=0, 31, 0		-1.61 (1.036)	
TC 6, n=0, 11, 0		-1.33 (0.710)	
TC 7, n=0, 2, 0		-0.05 (0.200)	

31. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved Remission or Low Disease Activity Based on DAS28 (Using ESR), During the DB and OL Periods, by Ofatumumab Treatment Course

Measure Description	The DAS28 is a clinical index of rheumatoid arthritis disease activity that combines information from swollen and tender joints (jts.), the APR, and general health (patient global assessment). The following jts. were assessed on both sides of the body: shoulder, elbow, wrist, metacarpophalangeal (5 per side), proximal interphalangeal (5 per side), and knee. The level of disease activity can be interpreted as low (DAS28<=3.2), moderate (3.2<DAS28<=5.1), or high (DAS28>5.1); total score, 0-9.4. A DAS28 <2.6 corresponds to remission. Remission is defined as a DAS28 score <2.6 at any time during the first 24 weeks of each treatment course. Low disease activity is defined as a DAS28 score >=2.6 and <3.2 at any time during the first 24 weeks of each treatment course.
Time Frame	First 24 weeks of each treatment course (assessed up to Week 144)
Safety Issue?	No

Analysis Population Description
AT Population

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	243	0
Number of Participants Who Achieved Remission or Low Disease Activity Based on DAS28 (Using ESR), During the DB and OL Periods, by Ofatumumab Treatment Course [units: participants]			

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 1, Remission, n=0, 243, 0		38	
TC 1, Low Disease Activity, n=0, 243, 0		33	
TC 2, Remission, n=0, 198, 0		47	
TC 2, Low Disease Activity, n=0, 198, 0		33	
TC 3, Remission, n=0, 136, 0		40	
TC 3, Low Disease Activity, n=0, 136, 0		31	
TC 4, Remission, n=0, 72, 0		15	
TC 4, Low Disease Activity, n=0, 72, 0		20	
TC 5, Remission, n=0, 31, 0		13	
TC 5, Low Disease Activity, n=0, 31, 0		4	
TC 6, Remission, n=0, 11, 0		3	
TC 6, Low Disease Activity, n=0, 11, 0		1	
TC 7, Remission, n=0, 2, 0		0	
TC 7, Low Disease Activity, n=0, 2, 0		0	

32. Secondary Outcome Measure:

Measure Title	Number of Participants Who Achieved Remission or Low Disease Activity Based on DAS28 (Using CRP), During the DB and OL Periods, by Ofatumumab Treatment Course
Measure Description	The DAS28 is a clinical index of rheumatoid arthritis disease activity that combines information from swollen and tender joints (jts.), the APR, and general health (patient global assessment). The following jts. were assessed on both sides of the body: shoulder, elbow, wrist, metacarpophalangeal (5 per side), proximal interphalangeal (5 per side), and knee. The level of disease activity can be interpreted as low (DAS28<=3.2), moderate (3.2<DAS28<=5.1), or high (DAS28>5.1); total score, 0-9.4. A DAS28 <2.6 corresponds to remission. Remission is defined as a DAS28 score <2.6 at any time during the first 24 weeks of each treatment course. Low disease activity is defined as a DAS28 score >=2.6 and <3.2 at any time during the first 24 weeks of each treatment course.
Time Frame	First 24 weeks of each treatment course (assessed up to Week 144)
Safety Issue?	No

Analysis Population Description
AT Population

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	243	0
Number of Participants Who Achieved Remission or Low Disease Activity Based on DAS28 (Using CRP), During the DB and OL Periods, by Ofatumumab Treatment Course [units: participants]			
TC 1, Remission, n=0, 243, 0		71	
TC 1, Low Disease Activity, n=0, 243, 0		44	
TC 2, Remission, n=0, 198, 0		71	
TC 2, Low Disease Activity, n=0, 198, 0		36	
TC 3, Remission, n=0, 136, 0		63	
TC 3, Low Disease Activity, n=0, 136, 0		21	
TC 4, Remission, n=0, 72, 0		30	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 4, Low Disease Activity, n=0, 72, 0		11	
TC 5, Remission,n=0, 31, 0		14	
TC 5, Low Disease Activity,n=0, 31, 0		4	
TC 6, Remission,n=0, 11, 0		4	
TC 6, Low Disease Activity,n=0, 11, 0		2	
TC 7, Remission, n=0, 2, 0		0	
TC 7, Low Disease Activity, n=0, 2, 0		0	

33. Secondary Outcome Measure:

Measure Title	Time to Retreatment, by Ofatumumab Treatment Course
Measure Description	Time to retreatment is defined as the time in days between infusion A of each treatment course and infusion A of the following treatment course. For participants randomized to ofatumumab in the Double-blind Period, Treatment Course 1 refers to the course of ofatumumab received in the Double-blind Period. The minimum period allowed per protocol before retreatment was 24 weeks (end of Double-blind Period). For participants randomized to placebo in the Double-blind Period, Treatment Course 1 refers to the first course of ofatumumab received in the Open-label Period. The minimum period allowed per protocol before retreatment during the Open-label Period was 16 weeks.
Time Frame	From Baseline up to Week 144
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants who were retreated from Week 24 were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.

	Description
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	198	0
Time to Retreatment, by Ofatumumab Treatment Course [units: Weeks] Mean (Standard Deviation)			
TC 1, n=0, 198, 0		34.26 (15.828)	
TC 2, n=0, 136, 0		34.50 (15.151)	
TC 3, n=0, 72, 0		28.83 (10.713)	
TC 4, n=0, 31, 0		20.82 (6.952)	
TC 5, n=0, 11, 0		19.94 (5.411)	
TC 6, n=0, 2, 0		17.86 (0.404)	
TC 7, n=0, 0, 0		NA (NA) [1]	

[1] Data are not available because there was no subsequent treatment course after Treatment Course 7.

34. Secondary Outcome Measure:

Measure Title	Number of Participants With Any On-treatment Adverse Event or Serious Adverse Event, During the DB and OL Periods, by Ofatumumab Treatment Course

Measure Description	An adverse event (AE) is defined as any untoward medical occurrence in a participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. A serious adverse event (SAE) is defined as any untoward medical occurrence that, at any dose: results in death; is life-threatening; requires hospitalization or prolongation of existing hospitalization; results in disability/incapacity; or is a congenital anomaly/ birth defect. Medical or scientific judgment should have been exercised in other situations. Refer to the general AE/SAE module for a list of AEs (occurring at a frequency threshold >=2%) and SAEs.
Time Frame	First treatment (Day 0) until the participant terminated the trial, assessed up to Week 144
Safety Issue?	No

Analysis Population Description

AT Population

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	243	0
Number of Participants With Any On-treatment Adverse Event or Serious Adverse Event, During the DB and OL Periods, by Ofatumumab Treatment Course [units: Participants]			
Any AE, TC 1, n=0, 243, 0		212	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Any AE, TC 2, n=0, 198, 0		151	
Any AE, TC 3, n=0, 136, 0		91	
Any AE, TC 4, n=0, 72, 0		43	
Any AE, TC 5, n=0, 31, 0		14	
Any AE, TC 6, n=0, 11, 0		5	
Any AE, TC 7, n=0, 2, 0		0	
Any SAE, TC 1, n=0, 243, 0		14	
Any SAE, TC 2, n=0, 198, 0		19	
Any SAE, TC 3, n=0, 136, 0		12	
Any SAE, TC 4, n=0, 72, 0		4	
Any SAE, TC 5, n=0, 31, 0		1	
Any SAE, TC 6, n=0, 11, 0		0	
Any AE, TC 7, n=0, 2, 0		0	

35. Secondary Outcome Measure:

Measure Title	Number of Participants With a CD19+ Cell Count Greater Than or Equal to the Lower Limit of Normal or the Baseline Value at the Indicated Time Point, During the DB and OL Periods, by Ofatumumab Treatment Course
Measure Description	The number of participants with a CD19+ cell count greater than or equal to the lower limit of normal (LLN; reference range 0.11 to 0.66 giga [10^9] per liter) or the baseline value (whichever was lower) is presented. The baseline assessment is defined as the start of the Double-blind Period.
Time Frame	From baseline up to Week 144
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	237	0
Number of Participants With a CD19+ Cell Count Greater Than or Equal to the Lower Limit of Normal or the Baseline Value at the Indicated Time Point, During the DB and OL Periods, by Ofatumumab Treatment Course [units: Participants]			
TC 1, Week 8, n=0, 237, 0		1	
TC 1, Week 16, n=0, 182, 0		1	
TC 1, Week 24, n=0, 177, 0		2	
TC 1, Week 32, n=0, 96, 0		9	
TC 1, Week 40, n=0, 59, 0		3	
TC 1, Week 48, n=0, 46, 0		9	
TC 1, Week 56, n=0, 31, 0		5	
TC 1, Week 64, n=0, 23, 0		7	
TC 1, Week 72, n=0, 19, 0		4	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 1, Week 80, n=0, 15, 0		5	
TC 1, Week 88, n=0, 13, 0		1	
TC 1, Week 96, n=0, 12, 0		4	
TC 1, Week 104, n=0, 10, 0		1	
TC 1, Week 112, n=0, 8, 0		0	
TC 1, Week 120, n=0, 7, 0		1	
TC 1, Week 128, n=0, 4, 0		2	
TC 1, Week 136, n=0, 4, 0		1	
TC 1, Week 144, n=0, 4, 0		1	
TC 2, Week 8, n=0, 194, 0		1	
TC 2, Week 16, n=0, 177, 0		1	
TC 2, Week 24, n=0, 150, 0		1	
TC 2, Week 32, n=0, 97, 0		7	
TC 2, Week 40, n=0, 69, 0		12	
TC 2, Week 48, n=0, 58, 0		8	
TC 2, Week 56, n=0, 43, 0		13	
TC 2, Week 64, n=0, 31, 0		13	
TC 2, Week 72, n=0, 24, 0		11	
TC 2, Week 80, n=0, 21, 0		12	
TC 2, Week 88, n=0, 16, 0		7	
TC 2, Week 96, n=0, 10, 0		6	
TC 2, Week 104, n=0, 8, 0		5	
TC 2, Week 112, n=0, 4, 0		2	
TC 2, Week 120, n=0, 3, 0		2	
TC 2, Week 128, n=0, 1, 0		0	
TC 3, Week 8, n=0, 132, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 3, Week 16, n=0, 119, 0		0	
TC 3, Week 24, n=0, 92, 0		0	
TC 3, Week 32, n=0, 63, 0		5	
TC 3, Week 40, n=0, 35, 0		4	
TC 3, Week 48, n=0, 24, 0		7	
TC 3, Week 56, n=0, 14, 0		2	
TC 3, Week 64, n=0, 10, 0		2	
TC 3, Week 72, n=0, 8, 0		5	
TC 3, Week 80, n=0, 8, 0		5	
TC 3, Week 88, n=0, 4, 0		3	
TC 3, Week 96, n=0, 2, 0		1	
TC 3, Week 104, n=0, 1, 0		1	
TC 4, Week 8, n=0, 70, 0		0	
TC 4, Week 16, n=0, 53, 0		0	
TC 4, Week 24, n=0, 37, 0		0	
TC 4, Week 32, n=0, 25, 0		4	
TC 4, Week 40, n=0, 8, 0		0	
TC 4, Week 48, n=0, 2, 0		1	
TC 5, Week 8, n=0, 30, 0		0	
TC 5, Week 16, n=0, 20, 0		0	
TC 5, Week 24, n=0, 20, 0		1	
TC 5, Week 32, n=0, 9, 0		2	
TC 5, Week 40, n=0, 3, 0		2	
TC 6, Week 8, n=0, 11, 0		0	
TC 6, Week 16, n=0, 10, 0		0	
TC 6, Week 24, n=0, 7, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 6, Week 32, n=0, 2, 0		0	
TC 7, Week 8, n=0, 2, 0		0	
TC 7, Week 16, n=0, 1, 0		0	

36. Secondary Outcome Measure:

Measure Title	Number of Participants With a CD3+ Cell Count Greater Than or Equal to the Lower Limit of Normal or the Baseline Value at the Indicated Time Point, During the DB and OL Periods, by Ofatumumab Treatment Course
Measure Description	The number of participants with a CD3+ cell count greater than or equal to the lower limit of normal (LLN; reference range 0.11 to 0.66 giga [10^9] per liter) or the baseline value (whichever was lower) is presented. The baseline assessment is defined as the start of the Double-blind Period.
Time Frame	From baseline up to Week 144
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	237	0
Number of Participants With a CD3+ Cell Count Greater Than or Equal to the Lower Limit of Normal or the Baseline Value at the Indicated Time Point, During the DB and OL Periods, by Ofatumumab Treatment Course [units: Participants]			
TC 1, Week 8, n=0, 237, 0		197	
TC 1, Week 16, n=0, 182, 0		156	
TC 1, Week 24, n=0, 177, 0		152	
TC 1, Week 32, n=0, 96, 0		88	
TC 1, Week 40, n=0, 59, 0		51	
TC 1, Week 48, n=0, 46, 0		40	
TC 1, Week 56, n=0, 31, 0		26	
TC 1, Week 64, n=0, 23, 0		18	
TC 1, Week 72, n=0, 19, 0		16	
TC 1, Week 80, n=0, 15, 0		13	
TC 1, Week 88, n=0, 13, 0		11	
TC 1, Week 96, n=0, 12, 0		9	
TC 1, Week 104, n=0, 10, 0		9	
TC 1, Week 112, n=0, 8, 0		7	
TC 1, Week 120, n=0, 7, 0		6	
TC 1, Week 128, n=0, 4, 0		4	
TC 1, Week 136, n=0, 4, 0		4	
TC 1, Week 144, n=0, 4, 0		4	
TC 2, Week 8, n=0, 194, 0		170	
TC 2, Week 16, n=0, 177, 0		155	
TC 2, Week 24, n=0, 150, 0		128	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 2, Week 32, n=0, 97, 0		82	
TC 2, Week 40, n=0, 69, 0		60	
TC 2, Week 48, n=0, 58, 0		48	
TC 2, Week 56, n=0, 43, 0		35	
TC 2, Week 64, n=0, 31, 0		28	
TC 2, Week 72, n=0, 24, 0		20	
TC 2, Week 80, n=0, 21, 0		17	
TC 2, Week 88, n=0, 16, 0		14	
TC 2, Week 96, n=0, 10, 0		10	
TC 2, Week 104, n=0, 8, 0		8	
TC 2, Week 112, n=0, 4, 0		4	
TC 2, Week 120, n=0, 3, 0		3	
TC 2, Week 128, n=0, 1, 0		1	
TC 3, Week 8, n=0, 132, 0		118	
TC 3, Week 16, n=0, 119, 0		105	
TC 3, Week 24, n=0, 92, 0		81	
TC 3, Week 32, n=0, 63, 0		57	
TC 3, Week 40, n=0, 35, 0		32	
TC 3, Week 48, n=0, 24, 0		21	
TC 3, Week 56, n=0, 14, 0		12	
TC 3, Week 64, n=0, 10, 0		9	
TC 3, Week 72, n=0, 8, 0		8	
TC 3, Week 80, n=0, 8, 0		7	
TC 3, Week 88, n=0, 4, 0		4	
TC 3, Week 96, n=0, 2, 0		2	
TC 3, Week 104, n=0, 1, 0		1	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 4, Week 8, n=0, 70, 0		66	
TC 4, Week 16, n=0, 53, 0		49	
TC 4, Week 24, n=0, 37, 0		34	
TC 4, Week 32, n=0, 25, 0		23	
TC 4, Week 40, n=0, 8, 0		7	
TC 4, Week 48, n=0, 2, 0		2	
TC 5, Week 8, n=0, 30, 0		26	
TC 5, Week 16, n=0, 27, 0		24	
TC 5, Week 24, n=0, 20, 0		19	
TC 5, Week 32, n=0, 9, 0		9	
TC 5, Week 40, n=0, 3, 0		3	
TC 6, Week 8, n=0, 11, 0		9	
TC 6, Week 16, n=0, 10, 0		9	
TC 6, Week 24, n=0, 7, 0		6	
TC 6, Week 32, n=0, 2, 0		2	
TC 7, Week 8, n=0, 2, 0		2	
TC 7, Week 16, n=0, 1, 0		1	

37. Secondary Outcome Measure:

Measure Title	Number of Participants With a CD4+ Cell Count Greater Than or Equal to the Lower Limit of Normal or the Baseline Value at the Indicated Time Point, During the DB and OL Periods, by Ofatumumab Treatment Course
Measure Description	The number of participants with a CD4+ cell count greater than or equal to the lower limit of normal (LLN; reference range 0.11 to 0.66 giga [10^9] per liter) or the baseline value (whichever was lower) is presented. The baseline assessment is defined as the start of the Double-blind Period.
Time Frame	From baseline up to Week 144
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	237	0
Number of Participants With a CD4+ Cell Count Greater Than or Equal to the Lower Limit of Normal or the Baseline Value at the Indicated Time Point, During the DB and OL Periods, by Ofatumumab Treatment Course [units: Participants]			
TC 1, Week 8, n=0, 237, 0		209	
TC 1, Week 16, n=0, 182, 0		163	
TC 1, Week 24, n=0, 177, 0		150	
TC 1, Week 32, n=0, 96, 0		89	
TC 1, Week 40, n=0, 59, 0		50	
TC 1, Week 48, n=0, 46, 0		40	
TC 1, Week 56, n=0, 31, 0		26	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 1, Week 64, n=0, 23, 0		18	
TC 1, Week 72, n=0, 19, 0		16	
TC 1, Week 80, n=0, 15, 0		14	
TC 1, Week 88, n=0, 13, 0		10	
TC 1, Week 96, n=0, 12, 0		10	
TC 1, Week 104, n=0, 10, 0		9	
TC 1, Week 112, n=0, 8, 0		7	
TC 1, Week 120, n=0, 7, 0		6	
TC 1, Week 128, n=0, 4, 0		4	
TC 1, Week 136, n=0, 4, 0		4	
TC 1, Week 144, n=0, 4, 0		4	
TC 2, Week 8, n=0, 194, 0		174	
TC 2, Week 16, n=0, 177, 0		162	
TC 2, Week 24, n=0, 150, 0		136	
TC 2, Week 32, n=0, 97, 0		85	
TC 2, Week 40, n=0, 69, 0		63	
TC 2, Week 48, n=0, 58, 0		51	
TC 2, Week 56, n=0, 43, 0		37	
TC 2, Week 64, n=0, 31, 0		29	
TC 2, Week 72, n=0, 24, 0		22	
TC 2, Week 80, n=0, 21, 0		19	
TC 2, Week 88, n=0, 16, 0		15	
TC 2, Week 96, n=0, 10, 0		10	
TC 2, Week 104, n=0, 8, 0		8	
TC 2, Week 112, n=0, 4, 0		4	
TC 2, Week 120, n=0, 3, 0		3	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 2, Week 128, n=0, 1, 0		1	
TC 3, Week 8, n=0, 132, 0		120	
TC 3, Week 16, n=0, 119, 0		108	
TC 3, Week 24, n=0, 92, 0		81	
TC 3, Week 32, n=0, 63, 0		58	
TC 3, Week 40, n=0, 35, 0		33	
TC 3, Week 48, n=0, 24, 0		20	
TC 3, Week 56, n=0, 14, 0		13	
TC 3, Week 64, n=0, 10, 0		8	
TC 3, Week 72, n=0, 8, 0		8	
TC 3, Week 80, n=0, 8, 0		7	
TC 3, Week 88, n=0, 4, 0		4	
TC 3, Week 96, n=0, 2, 0		2	
TC 3, Week 104, n=0, 1, 0		1	
TC 4, Week 8, n=0, 70, 0		68	
TC 4, Week 16, n=0, 53, 0		51	
TC 4, Week 24, n=0, 37, 0		35	
TC 4, Week 32, n=0, 25, 0		24	
TC 4, Week 40, n=0, 8, 0		8	
TC 4, Week 48, n=0, 2, 0		2	
TC 5, Week 8, n=0, 30, 0		27	
TC 5, Week 16, n=0, 27, 0		26	
TC 5, Week 24, n=0, 20, 0		18	
TC 5, Week 32, n=0, 9, 0		9	
TC 5, Week 40, n=0, 3, 0		3	
TC 6, Week 8, n=0, 11, 0		10	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 6, Week 16, n=0, 10, 0		9	
TC 6, Week 24, n=0, 7, 0		7	
TC 6, Week 32, n=0, 2, 0		2	
TC 7, Week 8, n=0, 2, 0		2	
TC 7, Week 16, n=0, 1, 0		1	

38. Secondary Outcome Measure:

Measure Title	Number of Participants With a CD8+ Cell Count Greater Than or Equal to the Lower Limit of Normal or the Baseline Value at the Indicated Time Point, During the DB and OL Periods, by Ofatumumab Treatment Course
Measure Description	The number of participants with a CD8+ cell count greater than or equal to the lower limit of normal (LLN; reference range 0.11 to 0.66 giga [10^9] per liter) or the baseline value (whichever was lower) is presented. The baseline assessment is defined as the start of the Double-blind Period.
Time Frame	From baseline up to Week 144
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).

	Description
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	237	0
Number of Participants With a CD8+ Cell Count Greater Than or Equal to the Lower Limit of Normal or the Baseline Value at the Indicated Time Point, During the DB and OL Periods, by Ofatumumab Treatment Course [units: Participants]			
TC 1, Week 8, n=0, 237, 0		216	
TC 1, Week 16, n=0, 182, 0		166	
TC 1, Week 24, n=0, 177, 0		160	
TC 1, Week 32, n=0, 96, 0		90	
TC 1, Week 40, n=0, 59, 0		51	
TC 1, Week 48, n=0, 46, 0		42	
TC 1, Week 56, n=0, 31, 0		29	
TC 1, Week 64, n=0, 23, 0		19	
TC 1, Week 72, n=0, 19, 0		15	
TC 1, Week 80, n=0, 15, 0		14	
TC 1, Week 88, n=0, 13, 0		12	
TC 1, Week 96, n=0, 12, 0		11	
TC 1, Week 104, n=0, 10, 0		10	
TC 1, Week 112, n=0, 8, 0		8	
TC 1, Week 120, n=0, 7, 0		6	
TC 1, Week 128, n=0, 4, 0		4	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 1, Week 136, n=0, 4, 0		4	
TC 1, Week 144, n=0, 4, 0		3	
TC 2, Week 8, n=0, 194, 0		181	
TC 2, Week 16, n=0, 177, 0		164	
TC 2, Week 24, n=0, 150, 0		140	
TC 2, Week 32, n=0, 97, 0		91	
TC 2, Week 40, n=0, 69, 0		65	
TC 2, Week 48, n=0, 58, 0		54	
TC 2, Week 56, n=0, 43, 0		40	
TC 2, Week 64, n=0, 31, 0		29	
TC 2, Week 72, n=0, 24, 0		23	
TC 2, Week 80, n=0, 21, 0		19	
TC 2, Week 88, n=0, 16, 0		15	
TC 2, Week 96, n=0, 10, 0		10	
TC 2, Week 104, n=0, 8, 0		8	
TC 2, Week 112, n=0, 4, 0		4	
TC 2, Week 120, n=0, 3, 0		3	
TC 2, Week 128, n=0, 1, 0		1	
TC 3, Week 8, n=0, 132, 0		128	
TC 3, Week 16, n=0, 119, 0		113	
TC 3, Week 24, n=0, 92, 0		88	
TC 3, Week 32, n=0, 63, 0		61	
TC 3, Week 40, n=0, 35, 0		34	
TC 3, Week 48, n=0, 24, 0		24	
TC 3, Week 56, n=0, 14, 0		13	
TC 3, Week 64, n=0, 10, 0		8	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 3, Week 72, n=0, 8, 0		8	
TC 3, Week 80, n=0, 8, 0		8	
TC 3, Week 88, n=0, 4, 0		4	
TC 3, Week 96, n=0, 2, 0		2	
TC 3, Week 104, n=0, 1, 0		1	
TC 4, Week 8, n=0, 70, 0		68	
TC 4, Week 16, n=0, 53, 0		52	
TC 4, Week 24, n=0, 37, 0		37	
TC 4, Week 32, n=0, 25, 0		24	
TC 4, Week 40, n=0, 8, 0		8	
TC 4, Week 48, n=0, 2, 0		2	
TC 5, Week 8, n=0, 30, 0		28	
TC 5, Week 16, n=0, 27, 0		26	
TC 5, Week 24, n=0, 20, 0		20	
TC 5, Week 32, n=0, 9, 0		9	
TC 5, Week 40, n=0, 3, 0		3	
TC 6, Week 8, n=0, 11, 0		10	
TC 6, Week 16, n=0, 10, 0		10	
TC 6, Week 24, n=0, 7, 0		6	
TC 6, Week 32, n=0, 2, 0		2	
TC 7, Week 8, n=0, 2, 0		2	
TC 7, Week 16, n=0, 1, 0		1	

39. Secondary Outcome Measure:

Measure Title	Number of Participants With Vital Sign Data Outside the Clinical Concern Range at Baseline or Any Visit Post-baseline, During the DB and OL Periods, by Ofatumumab Treatment Course

Measure Description	The baseline value for a treatment course is defined as the value before infusion A of each treatment course. The post-baseline visit is defined as any assessment during or after the start of infusion A during the specified treatment course. Pre-defined limits of potential clinical concern for vital signs (Low, High) are: Diastolic blood pressure (DBP) (millimeters of mercury [mmHg]): 40, 110; Systolic blood pressure (SBP) (mmHg): 90, 170; Heart rate (beats per minute): 35, 120. LLN=lower limit of normal; ULN=upper limit of normal.
Time Frame	From baseline up to Week 144
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	243	0
Number of Participants With Vital Sign Data Outside the Clinical Concern Range at Baseline or Any Visit Post-baseline, During the DB and OL Periods, by Ofatumumab Treatment Course [units: Participants]			
DBP, TC 1, BL, <LLN, n=0, 242, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
DBP, TC 1, PBL, <LLN, n=0, 243, 0		2	
DBP, TC 1, BL, >ULN, n=0, 242, 0		1	
DBP, TC 1, PBL, >ULN, n=0, 243, 0		3	
SBP, TC 1, BL, <LLN, n=0, 242, 0		1	
SBP, TC 1, PBL, <LLN, n=0, 243, 0		15	
SBP, TC 1, BL, >ULN, n=0, 242, 0		1	
SBP, TC 1, PBL, >ULN, n=0, 243, 0		15	
HR, TC 1, BL, <LLN, n=0, 243, 0		0	
HR, TC 1, PBL, <LLN, n=0, 243, 0		0	
HR, TC 1, BL, >ULN, n=0, 243, 0		0	
HR, TC 1, PBL, >ULN, n=0, 243, 0		0	
DBP, TC 2, BL, <LLN, n=0, 196, 0		0	
DBP, TC 2, PBL, <LLN, n=0, 198, 0		0	
DBP, TC 2, BL, >ULN, n=0, 196, 0		0	
DBP, TC 2, PBL, >ULN, n=0, 198, 0		2	
SBP, TC 2, BL, <LLN, n=0, 196, 0		1	
SBP, TC 2, PBL, <LLN, n=0, 198, 0		9	
SBP, TC 2, BL, >ULN, n=0, 196, 0		0	
SBP, TC 2, PBL, >ULN, n=0, 198, 0		12	
HR, TC 2, BL, <LLN, n=0, 196, 0		0	
HR, TC 2, PBL, <LLN, n=0, 198, 0		0	
HR, TC 2, BL, >ULN, n=0, 196, 0		0	
HR, TC 2, PBL, >ULN, n=0, 198, 0		2	
DBP, TC 3, BL, <LLN, n=0, 136, 0		0	
DBP, TC 3, PBL, <LLN, n=0, 136, 0		1	
DBP, TC 3, BL, >ULN, n=0, 136, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
DBP, TC 3, PBL, >ULN, n=0, 136, 0		1	
SBP, TC 3, BL, <LLN, n=0, 136, 0		0	
SBP, TC 3, PBL, <LLN, n=0, 136, 0		6	
SBP, TC 3, BL, >ULN, n=0, 136, 0		1	
SBP, TC 3, PBL, >ULN, n=0, 136, 0		3	
HR, TC 3, BL, <LLN, n=0, 136, 0		0	
HR, TC 3, PBL, <LLN, n=0, 136, 0		0	
HR, TC 3, BL, >ULN, n=0, 136, 0		0	
HR, TC 3, PBL, >ULN, n=0, 136, 0		1	
DBP, TC 4, BL, <LLN, n=0, 72, 0		0	
DBP, TC 4, PBL, <LLN, n=0, 72, 0		0	
DBP, TC 4, BL, >ULN, n=0, 72, 0		0	
DBP, TC 4, PBL, >ULN, n=0, 72, 0		1	
SBP, TC 4, BL, <LLN, n=0, 72, 0		0	
SBP, TC 4, PBL, <LLN, n=0, 72, 0		4	
SBP, TC 4, BL, >ULN, n=0, 72, 0		0	
SBP, TC 4, PBL, >ULN, n=0, 72, 0		2	
HR, TC 4, BL, <LLN, n=0, 72, 0		0	
HR, TC 4, PBL, <LLN, n=0, 72, 0		0	
HR, TC 4, BL, >ULN, n=0, 72, 0		0	
HR, TC 4, PBL, >ULN, n=0, 72, 0		0	
DBP, TC 5, BL, <LLN, n=0, 31, 0		0	
DBP, TC 5, PBL, <LLN, n=0, 31, 0		0	
DBP, TC 5, BL, >ULN, n=0, 31, 0		0	
DBP, TC 5, PBL, >ULN, n=0, 31, 0		0	
SBP, TC 5, BL, <LLN, n=0, 31, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
SBP, TC 5, PBL, <LLN, n=0, 31, 0		1	
SBP, TC 5, BL, >ULN, n=0, 31, 0		0	
SBP, TC 5, PBL, >ULN, n=0, 31, 0		0	
HR, TC 5, BL, <LLN, n=0, 31, 0		0	
HR, TC 5, PBL, <LLN, n=0, 31, 0		0	
HR, TC 5, BL, >ULN, n=0, 31, 0		0	
HR, TC 5, PBL, >ULN, n=0, 31, 0		0	
DBP, TC 6, BL, <LLN, n=0, 11, 0		0	
DBP, TC 6, PBL, <LLN, n=0, 11, 0		0	
DBP, TC 6, BL, >ULN, n=0, 11, 0		0	
DBP, TC 6, PBL, >ULN, n=0, 11, 0		0	
SBP, TC 6, BL, <LLN, n=0, 11, 0		0	
SBP, TC 6, PBL, <LLN, n=0, 11, 0		0	
SBP, TC 6, BL, >ULN, n=0, 11, 0		0	
SBP, TC 6, PBL, >ULN, n=0, 11, 0		1	
HR, TC 6, BL, <LLN, n=0, 11, 0		0	
HR, TC 6, PBL, <LLN, n=0, 11, 0		0	
HR, TC 6, BL, >ULN, n=0, 11, 0		0	
HR, TC 6, PBL, >ULN, n=0, 11, 0		0	
DBP, TC 7, BL, <LLN, n=0, 2, 0		0	
DBP, TC 7, PBL, <LLN, n=0, 2, 0		0	
DBP, TC 7, BL, >ULN, n=0, 2, 0		0	
DBP, TC 7, PBL, >ULN, n=0, 2, 0		0	
SBP, TC 7, BL, <LLN, n=0, 2, 0		0	
SBP, TC 7, PBL, <LLN, n=0, 2, 0		0	
SBP, TC 7, BL, >ULN, n=0, 2, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
SBP, TC 7, PBL, >ULN, n=0, 2, 0		0	
HR, TC 7, BL, <LLN, n=0, 2, 0		0	
HR, TC 7, PBL, <LLN, n=0, 2, 0		0	
HR, TC 7, BL, >ULN, n=0, 2, 0		0	
HR, TC 7, PBL, >ULN, n=0, 2, 0		0	

40. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Electrocardiogram (ECG) Findings, During the OL Period
Measure Description	The number of participants with normal, abnormal clinically significant (CS), and abnormal not clinically significant (NCS) ECG findings, as well as the number of participants with no results (NR), during the OL Period are presented. An overall interpretation of the ECG was made by the investigator, or the investigator could delegate this task to a cardiologist, if applicable.
Time Frame	From DB Period completion (Week 24) until the completion of the OL Period, assessed up to Week 144
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).

	Description
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	225	0
Number of Participants With the Indicated Electrocardiogram (ECG) Findings, During the OL Period [units: Participants]			
Week 48, normal, n=0, 225, 0		150	
Week 48, abnormal CS, n=0, 225, 0		2	
Week 48, abnormal NCS, n=0, 225, 0		71	
Week 48, NR, n=0, 225, 0		2	
Week 72, normal, n=0, 202, 0		133	
Week 72, abnormal CS, n=0, 202, 0		1	
Week 72, abnormal NCS, n=0, 202, 0		67	
Week 72, NR, n=0, 202, 0		1	
Week 96, normal, n=0, 180, 0		119	
Week 96, abnormal CS, n=0, 180, 0		0	
Week 96, abnormal NCS, n=0, 180, 0		60	
Week 96, NR, n=0, 180, 0		1	
Week 120, normal, n=0, 167, 0		120	
Week 120, abnormal CS, n=0, 167, 0		1	
Week 120, abnormal NCS, n=0, 167, 0		46	
Week 120, NR, n=0, 167, 0		0	
Week 144, normal, n=0, 95, 0		68	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Week 144, abnormal CS, n=0, 95, 0		1	
Week 144, abnormal NCS, n=0, 95, 0		26	
Week 144, NR, n=0, 95, 0		0	

41. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Clinical Chemistry Values of Potential Clinical Concern at Baseline or Any Visit Post-baseline, During the DB and OL Periods, by Ofatumumab Treatment Course
Measure Description	Only those parameters for which at least one value of clinical concern (CC) was reported are summarized. Baseline (BL) value for a treatment course (TC) is defined as the latest value on or before the date of infusion A of the TC. The post-baseline (PBL) visit is defined as any visit after the date of infusion A during the specified TC. Pre-defined limits of potential CC (CC Low [relative to the lower limit of normal], CC High [relative to the upper limit of normal]) are: Albumin: 0.9, 1.5; Alanine amino transferase (ALT): NA, 2; Alkaline phosphatase (ALP): NA, 1.5; Aspartate amino transferase (AST): NA, 2; Bilirubin total (TBIL): NA, 1.5; Calcium: 0.85, 1.08; CO2 content/bicarbonate (BCO): 0.85/0.75, 1.2/1.3, ; Chloride: 0.9, 1.1; Creatine kinase (CK): NA, 2; Creatinine: NA, 1.2; Gamma glutamyl transferase (GGT): NA, 2; Lactate dehydrogenase (LDH): NA, 2; Potassium: 0.9, 1.1; Sodium: 0.93, 1.07; Total protein: 0.8, 1.15; Urea/blood urea nitrogen (BUN): NA, 1.5; Uric acid: NA, 1.5.
Time Frame	From baseline up to Week 144
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).

	Description
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	239	0
Number of Participants With the Indicated Clinical Chemistry Values of Potential Clinical Concern at Baseline or Any Visit Post-baseline, During the DB and OL Periods, by Ofatumumab Treatment Course [units: Participants]			
Albumin, TC 1, BL, CC low, n=0, 234, 0		0	
Albumin, TC 1, PBL, CC low, n=0, 239, 0		0	
ALT, TC 1, BL, CC high, n=0, 234, 0		0	
ALT, TC 1, PBL, CC high, n=0, 239, 0		3	
ALP, TC 1, BL, CC high, n=0, 234, 0		0	
ALP, TC 1, PBL, CC high, n=0, 239, 0		0	
AST, TC 1, BL, CC high, n=0, 234, 0		0	
AST, TC 1, PBL, CC high, n=0, 239, 0		1	
TBIL, TC 1, BL, CC high, n=0, 234, 0		0	
TBIL, TC 1, PBL, CC high, n=0, 239, 0		1	
Calcium, TC 1, BL, CC low, n=0, 234, 0		0	
Calcium, TC 1, PBL, CC low, n=0, 239, 0		1	
CO2/BCO, TC 1, BL, CC low, n=0, 234, 0		9	
CO2/BCO, TC 1, PBL, CC low, n=0, 239, 0		15	
Chloride, TC 1, BL, CC low, n=0, 234, 0		0	
Chloride, TC 1, PBL, CC low, n=0, 239, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
CK, TC 1, BL, CC high, n=0, 234, 0		1	
CK, TC 1, PBL, CC high, n=0, 239, 0		4	
Creatinine, TC 1, BL, CC high, n=0, 234, 0		0	
Creatinine, TC 1,PBL, CC high, n=0, 239, 0		0	
GGT, TC 1, BL, CC high, n=0, 234, 0		11	
GGT, TC 1, PBL, CC high, n=0, 239, 0		9	
LDH, TC 1, BL, CC high, n=0, 234, 0		1	
LDH, TC 1, PBL, CC high, n=0, 239, 0		1	
Potassium, TC 1, BL, CC high, n=0, 234, 0		2	
Potassium, TC 1, PBL, CC high, n=0, 239, 0		2	
Potassium, TC 1, BL, CC low, n=0, 234, 0		0	
Potassium, TC 1, PBL, CC low, n=0, 239, 0		0	
Sodium, TC 1, BL, CC low, n=0, 234, 0		0	
Sodium, TC 1, PBL, CC low, n=0, 239, 0		1	
Total Protein, TC 1, BL, CC low, n=0, 234, 0		0	
Total Protein, TC 1, PBL, CC low, n=0, 239, 0		0	
Urea/BUN, TC 1, BL, CC high, n=0, 234, 0		0	
Urea/BUN, TC 1, PBL, CC high, n=0, 239, 0		1	
Uric acid, TC 1, BL, CC high, n=0, 234, 0		0	
Uric acid, TC 1, PBL, CC high, n=0, 239, 0		0	
Albumin, TC 2, BL, CC low, n=0, 177, 0		1	
Albumin, TC 2, PBL, CC low, n=0, 196, 0		0	
ALT, TC 2, BL, CC high, n=0, 177, 0		0	
ALT, TC 2, PBL, CC high, n=0, 196, 0		2	
ALP, TC 2, BL, CC high, n=0, 177, 0		1	
ALP, TC 2, PBL, CC high, n=0, 196, 0		1	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
AST, TC 2, BL, CC high, n=0, 176, 0		0	
AST, TC 2, PBL, CC high, n=0, 196, 0		1	
TBIL, TC 2, BL, CC high, n=0, 177, 0		0	
TBIL, TC 2, PBL, CC high, n=0, 196, 0		1	
Calcium, TC 2, BL, CC low, n=0, 176, 0		1	
Calcium, TC 2, PBL, CC low, n=0, 196, 0		0	
CO2/BCO, TC 2, BL, CC low, n=0, 176, 0		5	
CO2/BCO, TC 2, PBL, CC low, n=0, 196, 0		10	
Chloride, TC 2, BL, CC low, n=0, 177, 0		0	
Chloride, TC 2, PBL, CC low, n=0, 196, 0		1	
CK, TC 2, BL, CC high, n=0, 177, 0		0	
CK, TC 2, PBL, CC high, n=0, 196, 0		4	
Creatinine, TC 2, BL, CC high, n=0, 177, 0		1	
Creatinine, TC 2,PBL, CC high, n=0, 196, 0		0	
GGT, TC 2, BL, CC high, n=0, 117, 0		3	
GGT, TC 2, PBL, CC high, n=0, 196, 0		9	
LDH, TC 2, BL, CC high, n=0, 176, 0		0	
LDH, TC 2, PBL, CC high, n=0, 196, 0		0	
Potassium, TC 2, BL, CC high, n=0, 176, 0		1	
Potassium, TC 2, PBL, CC high, n=0, 196, 0		1	
Potassium, TC 2, BL, CC low, n=0, 176, 0		1	
Potassium, TC 2, PBL, CC low, n=0, 196, 0		1	
Sodium, TC 2, BL, CC low, n=0, 177, 0		0	
Sodium, TC 2, PBL, CC low, n=0, 196, 0		1	
Total Protein, TC 2, BL, CC low, n=0, 177, 0		1	
Total Protein, TC 2, PBL, CC low, n=0, 196, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Urea/BUN, TC 2, BL, CC high, n=0, 177, 0		1	
Urea/BUN, TC 2, PBL, CC high, n=0, 196, 0		1	
Uric acid, TC 2, BL, CC high, n=0, 177, 0		0	
Uric acid, TC 2, PBL, CC high, n=0, 196, 0		0	
Albumin, TC 3, BL, CC low, n=0, 116, 0		0	
Albumin, TC 3, PBL, CC low, n=0, 134, 0		0	
ALT, TC 3, BL, CC high, n=0, 116, 0		1	
ALT, TC 3, PBL, CC high, n=0, 135, 0		2	
ALP, TC 3, BL, CC high, n=0, 116, 0		1	
ALP, TC 3, PBL, CC high, n=0, 135, 0		3	
AST, TC 3, BL, CC high, n=0, 116, 0		0	
AST, TC 3, PBL, CC high, n=0, 135, 0		2	
TBIL, TC 3, BL, CC high, n=0, 116, 0		0	
TBIL, TC 3, PBL, CC high, n=0, 135, 0		1	
Calcium, TC 3, BL, CC low, n=0, 116, 0		0	
Calcium, TC 3, PBL, CC low, n=0, 134, 0		1	
CO2/BCO, TC 3, BL, CC low, n=0, 116, 0		2	
CO2/BCO, TC 3, PBL, CC low, n=0, 134, 0		6	
Chloride, TC 3, BL, CC low, n=0, 116, 0		0	
Chloride, TC 3, PBL, CC low, n=0, 134, 0		0	
CK, TC 3, BL, CC high, n=0, 116, 0		2	
CK, TC 3, PBL, CC high, n=0, 135, 0		2	
Creatinine, TC 3, BL, CC high, n=0, 116, 0		0	
Creatinine, TC 3, PBL, CC high, n=0, 134, 0		1	
GGT, TC 3, BL, CC high, n=0, 116, 0		5	
GGT, TC 3, PBL, CC high, n=0, 134, 0		7	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
LDH, TC 3, BL, CC high, n=0, 116, 0		0	
LDH, TC 3, PBL, CC high, n=0, 135, 0		1	
Potassium, TC 3, BL, CC high, n=0, 116, 0		0	
Potassium, TC 3, PBL, CC high, n=0, 134, 0		0	
Potassium, TC 3, BL, CC low, n=0, 116, 0		0	
Potassium, TC 3, PBL, CC low, n=0, 134, 0		2	
Sodium, TC 3, BL, CC low, n=0, 116, 0		0	
Sodium, TC 3, PBL, CC low, n=0, 134, 0		0	
Total Protein, TC 3, BL, CC low, n=0, 116, 0		0	
Total Protein, TC 3, PBL, CC low, n=0, 134, 0		0	
Urea/BUN, TC 3, BL, CC high, n=0, 116, 0		1	
Urea/BUN, TC 3, PBL, CC high, n=0, 134, 0		1	
Uric acid, TC 3, BL, CC high, n=0, 116, 0		0	
Uric acid, TC 3, PBL, CC high, n=0, 134, 0		1	
Albumin, TC 4, BL, CC low, n=0, 67, 0		0	
Albumin, TC 4, PBL, CC low, n=0, 72, 0		0	
ALT, TC 4, BL, CC high, n=0, 67, 0		1	
ALT, TC 4, PBL, CC high, n=0, 72, 0		2	
ALP, TC 4, BL, CC high, n=0, 67, 0		0	
ALP, TC 4, PBL, CC high, n=0, 72, 0		1	
AST, TC 4, BL, CC high, n=0, 67, 0		1	
AST, TC 4, PBL, CC high, n=0, 72, 0		2	
TBIL, TC 4, BL, CC high, n=0, 67, 0		0	
TBIL, TC 4, PBL, CC high, n=0, 72, 0		0	
Calcium, TC 4, BL, CC low, n=0, 67, 0		0	
Calcium, TC 4, PBL, CC low, n=0, 72, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
CO2/BCO, TC 4, BL, CC low, n=0, 67, 0		1	
CO2/BCO, TC 4, PBL, CC low, n=0, 72, 0		2	
Chloride, TC 4, BL, CC low, n=0, 67, 0		0	
Chloride, TC 4, PBL, CC low, n=0, 72, 0		0	
CK, TC 4, BL, CC high, n=0, 67, 0		0	
CK, TC 4, PBL, CC high, n=0, 72, 0		1	
Creatinine, TC 4, BL, CC high, n=0, 67, 0		1	
Creatinine, TC 4, PBL, CC high, n=0, 72, 0		1	
GGT, TC 4, BL, CC high, n=0, 67, 0		2	
GGT, TC 4, PBL, CC high, n=0, 72, 0		3	
LDH, TC 4, BL, CC high, n=0, 67, 0		0	
LDH, TC 4, PBL, CC high, n=0, 72, 0		0	
Potassium, TC 4, BL, CC high, n=0, 67, 0		0	
Potassium, TC 4, PBL, CC high, n=0, 72, 0		0	
Potassium, TC 4, BL, CC low, n=0, 67, 0		0	
Potassium, TC 4, PBL, CC low, n=0, 72, 0		0	
Sodium, TC 4, BL, CC low, n=0, 67, 0		0	
Sodium, TC 4, PBL, CC low, n=0, 72, 0		0	
Total Protein, TC 4, BL, CC low, n=0, 67, 0		0	
Total Protein, TC 4, PBL, CC low, n=0, 72, 0		0	
Urea/BUN, TC 4, BL, CC high, n=0, 67, 0		0	
Urea/BUN, TC 4, PBL, CC high, n=0, 72, 0		1	
Uric acid, TC 4, BL, CC high, n=0, 67, 0		0	
Uric acid, TC 4, PBL, CC high, n=0, 72, 0		0	
Albumin, TC 5, BL, CC low, n=0, 29, 0		0	
Albumin, TC 5, PBL, CC low, n=0, 31, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
ALT, TC 5, BL, CC high, n=0, 29, 0		0	
ALT, TC 5, PBL, CC high, n=0, 31, 0		1	
ALP, TC 5, BL, CC high, n=0, 29, 0		0	
ALP, TC 5, PBL, CC high, n=0, 31, 0		1	
AST, TC 5, BL, CC high, n=0, 29, 0		0	
AST, TC 5, PBL, CC high, n=0, 31, 0		0	
TBIL, TC 5, BL, CC high, n=0, 29, 0		0	
TBIL, TC 3, PBL, CC high, n=0, 31, 0		0	
Calcium, TC 5, BL, CC low, n=0, 29, 0		0	
Calcium, TC 5, PBL, CC low, n=0, 31, 0		0	
CO2/BCO, TC 5, BL, CC low, n=0, 29, 0		0	
CO2/BCO, TC 5, PBL, CC low, n=0, 31, 0		0	
Chloride, TC 5, BL, CC low, n=0, 29, 0		0	
Chloride, TC 5, PBL, CC low, n=0, 31, 0		0	
CK, TC 5, BL, CC high, n=0, 29, 0		0	
CK, TC 5, PBL, CC high, n=0, 31, 0		1	
Creatinine, TC 5, BL, CC high, n=0, 29, 0		0	
Creatinine, TC 5, PBL, CC high, n=0, 31, 0		0	
GGT, TC 5, BL, CC high, n=0, 29, 0		0	
GGT, TC 5, PBL, CC high, n=0, 31, 0		1	
LDH, TC 5, BL, CC high, n=0, 29, 0		0	
LDH, TC 5, PBL, CC high, n=0, 31, 0		0	
Potassium, TC 5, BL, CC high, n=0, 29, 0		0	
Potassium, TC 5, PBL, CC high, n=0, 31, 0		0	
Potassium, TC 5, BL, CC low, n=0, 29, 0		0	
Potassium, TC 5, PBL, CC low, n=0, 31, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Sodium, TC 5, BL, CC low, n=0, 29, 0		0	
Sodium, TC 5, PBL, CC low, n=0, 31, 0		0	
Total Protein, TC 5, BL, CC low, n=0, 29, 0		0	
Total Protein, TC 5, PBL, CC low, n=0, 31, 0		0	
Urea/BUN, TC 5, BL, CC high, n=0, 29, 0		0	
Urea/BUN, TC 5, PBL, CC high, n=0, 31, 0		0	
Uric acid, TC 5, BL, CC high, n=0, 29, 0		0	
Uric acid, TC 5, PBL, CC high, n=0, 31, 0		0	
Albumin, TC 6, BL, CC low, n=0, 11, 0		0	
Albumin, TC 6, PBL, CC low, n=0, 11, 0		0	
ALT, TC 6, BL, CC high, n=0, 11, 0		0	
ALT, TC 6, PBL, CC high, n=0, 11, 0		0	
ALP, TC 6, BL, CC high, n=0, 11, 0		0	
ALP, TC 6, PBL, CC high, n=0, 11, 0		0	
AST, TC 6, BL, CC high, n=0, 10, 0		0	
AST, TC 6, PBL, CC high, n=0, 11, 0		0	
TBIL, TC 6, BL, CC high, n=0, 11, 0		0	
TBIL, TC 6, PBL, CC high, n=0, 11, 0		0	
Calcium, TC 6, BL, CC low, n=0, 10, 0		0	
Calcium, TC 6, PBL, CC low, n=0, 11, 0		0	
CO2/BCO, TC 6, BL, CC low, n=0, 10, 0		0	
CO2/BCO, TC 6, PBL, CC low, n=0, 11, 0		1	
Chloride, TC 6, BL, CC low, n=0, 11, 0		0	
Chloride, TC 6, PBL, CC low, n=0, 11, 0		0	
CK, TC 6, BL, CC high, n=0, 11, 0		0	
CK, TC 6, PBL, CC high, n=0, 11, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Creatinine, TC 6, BL, CC high, n=0, 11, 0		0	
Creatinine, TC 6, PBL, CC high, n=0, 11, 0		0	
GGT, TC 6, BL, CC high, n=0, 11, 0		0	
GGT, TC 6, PBL, CC high, n=0, 11, 0		0	
LDH, TC 6, BL, CC high, n=0, 10, 0		0	
LDH, TC 6, PBL, CC high, n=0, 11, 0		0	
Potassium, TC 6, BL, CC high, n=0, 10, 0		0	
Potassium, TC 6, PBL, CC high, n=0, 11, 0		0	
Potassium, TC 6, BL, CC low, n=0, 10, 0		0	
Potassium, TC 6, PBL, CC low, n=0, 11, 0		0	
Sodium, TC 6, BL, CC low, n=0, 11, 0		0	
Sodium, TC 6, PBL, CC low, n=0, 11, 0		0	
Total Protein, TC 6, BL, CC low, n=0, 11, 0		0	
Total Protein, TC 6, PBL, CC low, n=0, 11, 0		0	
Urea/BUN, TC 6, BL, CC high, n=0, 11, 0		0	
Urea/BUN, TC 6, PBL, CC high, n=0, 11, 0		0	
Uric acid, TC 6, BL, CC high, n=0, 11, 0		0	
Uric acid, TC 6, PBL, CC high, n=0, 11, 0		0	
Albumin, TC 7, BL, CC low, n=0, 2, 0		0	
Albumin, TC 7, PBL, CC low, n=0, 2, 0		0	
ALT, TC 7, BL, CC high, n=0, 2, 0		0	
ALT, TC 7, PBL, CC high, n=0, 2, 0		0	
ALP, TC 7, BL, CC high, n=0, 2, 0		0	
ALP, TC 7, PBL, CC high, n=0, 2, 0		0	
AST, TC 7, BL, CC high, n=0, 2, 0		0	
AST, TC 7, PBL, CC high, n=0, 2, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TBIL, TC 7, BL, CC high, n=0, 2, 0		0	
TBIL, TC 7, PBL, CC high, n=0, 2, 0		0	
Calcium, TC 7, BL, CC low, n=0, 2, 0		0	
Calcium, TC 7, PBL, CC low, n=0, 2, 0		0	
CO2/BCO, TC 7, BL, CC low, n=0, 2, 0		0	
CO2/BCO, TC 7, PBL, CC low, n=0, 2, 0		0	
Chloride, TC 7, BL, CC low, n=0, 2, 0		0	
Chloride, TC 7, PBL, CC low, n=0, 2, 0		0	
CK, TC 7, BL, CC high, n=0, 2, 0		0	
CK, TC 7, PBL, CC high, n=0, 2, 0		0	
Creatinine, TC 7, BL, CC high, n=0, 2, 0		0	
Creatinine, TC 7, PBL, CC high, n=0, 2, 0		0	
GGT, TC 7, BL, CC high, n=0, 2, 0		0	
GGT, TC 7, PBL, CC high, n=0, 2, 0		0	
LDH, TC 7, BL, CC high, n=0, 2, 0		0	
LDH, TC 7, PBL, CC high, n=0, 2, 0		0	
Potassium, TC 7, BL, CC high, n=0, 2, 0		0	
Potassium, TC 7, PBL, CC high, n=0, 2, 0		0	
Potassium, TC 7, BL, CC low, n=0, 2, 0		0	
Potassium, TC 7, PBL, CC low, n=0, 2, 0		0	
Sodium, TC 7, BL, CC low, n=0, 2, 0		0	
Sodium, TC 7, PBL, CC low, n=0, 2, 0		0	
Total Protein, TC 7, BL, CC low, n=0, 2, 0		0	
Total Protein, TC 7, PBL, CC low, n=0, 2, 0		0	
Urea/BUN, TC 7, BL, CC high, n=0, 2, 0		0	
Urea/BUN, TC 7, PBL, CC high, n=0, 2, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Uric acid, TC 7, BL, CC high, n=0, 2, 0		0	
Uric acid, TC 7, PBL, CC high, n=0, 2, 0		0	

42. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Hematology Values of Potential Clinical Concern at Baseline or Any Visit Post-baseline, During the DB and OL Periods, by Ofatumumab Treatment Course
Measure Description	Only those parameters for which at least one value of clinical concern (CC) was reported are summarized. The baseline (BL) value for a treatment course (TC) is defined as the latest value on or before the date of infusion A of the TC. The post-baseline (PBL) visit is defined as any visit after the date of infusion A during the specified TC. Pre-defined limits of potential clinical concern (CC Low [relative to lower limit of normal], CC High [relative to upper limit of normal]) are: Eosinophils: NA, 2; Hematocrit (HCT): 0.75, 1.2; Hemoglobin (Hb): 0.75, 1.2; Lymphocytes: 0.4, 2; Neutrophils total (TNUE): 0.8, 1.6; Platelet count (PC): 0.65, 1.5; Red blood cell count (RBC): 0.75, 2; White blood cell count (WBC): 0.7, 1.6.
Time Frame	From baseline up to Week 144
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).

	Description
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	239	0
Number of Participants With the Indicated Hematology Values of Potential Clinical Concern at Baseline or Any Visit Post-baseline, During the DB and OL Periods, by Ofatumumab Treatment Course [units: Participants]			
Eosinophils, TC 1, BL, CC high, n=0, 224, 0		2	
Eosinophils, TC 1, PBL, CC high, n=0, 239, 0		4	
HCT, TC 1, BL, CC low, n=0, 224, 0		0	
HCT, TC 1, PBL, CC low, n=0, 239, 0		2	
Hb, TC 1, BL, CC low, n=0, 224, 0		3	
Hb, TC 1, PBL, CC low, n=0, 239, 0		6	
Lymphocytes, TC 1, BL, CC low, n=0, 232, 0		1	
Lymphocytes, TC 1, PBL, CC low, n=0, 239, 0		1	
PC, TC 1, BL, CC high, n=0, 221, 0		1	
PC, TC 1, PBL, CC high, n=0, 239, 0		3	
RBC count, TC 1, BL, CC low, n=0, 224, 0		1	
RBC count, TC 1, PBL, CC low, n=0, 239, 0		1	
TNUE, TC 1, BL, CC low, n=0, 224, 0		0	
TNUE, TC 1, PBL, CC low, n=0, 239, 0		8	
TNUE, TC 1, BL, CC high, n=0, 224, 0		5	
TNUE, TC 1,PBL, CC high, n=0, 239, 0		6	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
WBC count, TC 1, BL, CC low, n=0, 224, 0		0	
WBC count, TC 1, PBL, CC low, n=0, 239, 0		1	
WBC count, TC 1, BL, CC high, n=0, 224, 0		1	
WBC count, TC 1, PBL, CC high, n=0, 239, 0		1	
Eosinophils, TC 2, BL, CC high, n=0, 171, 0		2	
Eosinophils, TC 2, PBL, CC high, n=0, 195, 0		6	
HCT, TC 2, BL, CC low, n=0, 173, 0		0	
HCT, TC 2, PBL, CC low, n=0, 195, 0		0	
Hb, TC 2, BL, CC low, n=0, 172, 0		0	
Hb, TC 2, PBL, CC low, n=0, 195, 0		1	
Lymphocytes, TC 2, BL, CC low, n=0, 177, 0		0	
Lymphocytes, TC 2, PBL, CC low, n=0, 196, 0		1	
PC, TC 2, BL, CC high, n=0, 170, 0		0	
PC, TC 2, PBL, CC high, n=0, 195, 0		0	
RBC count, TC 2, BL, CC low, n=0, 172, 0		0	
RBC count, TC 2, PBL, CC low, n=0, 195, 0		0	
TNUE, TC 2, BL, CC low, n=0, 171, 0		1	
TNUE, TC 2, PBL, CC low, n=0, 195, 0		3	
TNUE, TC 2, BL, CC high, n=0, 171, 0		0	
TNUE, TC 2,PBL, CC high, n=0, 195, 0		1	
WBC count, TC 2, BL, CC low, n=0, 171, 0		1	
WBC count, TC 2, PBL, CC low, n=0, 195, 0		1	
WBC count, TC 2, BL, CC high, n=0, 171, 0		0	
WBC count, TC 2, PBL, CC high, n=0, 195, 0		1	
Eosinophils, TC 3, BL, CC high, n=0, 114, 0		2	
Eosinophils, TC 3, PBL, CC high, n=0, 134, 0		2	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
HCT, TC 3, BL, CC low, n=0, 115, 0		0	
HCT, TC 3, PBL, CC low, n=0, 134, 0		0	
Hb, TC 3, BL, CC low, n=0, 115, 0		0	
Hb, TC 3, PBL, CC low, n=0, 134, 0		0	
Lymphocytes, TC 3, BL, CC low, n=0, 117, 0		0	
Lymphocytes, TC 3, PBL, CC low, n=0, 134, 0		0	
PC, TC 3, BL, CC high, n=0, 115, 0		0	
PC, TC 3, PBL, CC high, n=0, 134, 0		0	
RBC count, TC 3, BL, CC low, n=0, 115, 0		0	
RBC count, TC 3, PBL, CC low, n=0, 134, 0		0	
TNUE, TC 3, BL, CC low, n=0, 114, 0		0	
TNUE, TC 3, PBL, CC low, n=0, 134, 0		2	
TNUE, TC 3, BL, CC high, n=0, 114, 0		0	
TNUE, TC 3,PBL, CC high, n=0, 134, 0		0	
WBC count, TC 3, BL, CC low, n=0, 114, 0		0	
WBC count, TC 3, PBL, CC low, n=0, 134, 0		0	
WBC count, TC 3, BL, CC high, n=0, 114, 0		0	
WBC count, TC 3, PBL, CC high, n=0, 134, 0		0	
Eosinophils, TC 4, BL, CC high, n=0, 66, 0		1	
Eosinophils, TC 4, PBL, CC high, n=0, 72, 0		1	
HCT, TC 4, BL, CC low, n=0, 66, 0		0	
HCT, TC 4, PBL, CC low, n=0, 72, 0		0	
Hb, TC 4, BL, CC low, n=0, 66, 0		0	
Hb, TC 4, PBL, CC low, n=0, 72, 0		0	
Lymphocytes, TC 4, BL, CC low, n=0, 67, 0		0	
Lymphocytes, TC 4, PBL, CC low, n=0, 72, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
PC, TC 4, BL, CC high, n=0, 65, 0		0	
PC, TC 4, PBL, CC high, n=0, 72, 0		0	
RBC count, TC 4, BL, CC low, n=0, 66, 0		0	
RBC count, TC 4, PBL, CC low, n=0, 72, 0		0	
TNUE, TC 4, BL, CC low, n=0, 66, 0		0	
TNUE, TC 4, PBL, CC low, n=0, 72, 0		5	
TNUE, TC 4, BL, CC high, n=0, 66, 0		0	
TNUE, TC 4,PBL, CC high, n=0, 72, 0		0	
WBC count, TC 4, BL, CC low, n=0, 66, 0		0	
WBC count, TC 4, PBL, CC low, n=0, 72, 0		0	
WBC count, TC 4, BL, CC high, n=0, 66, 0		0	
WBC count, TC 4, PBL, CC high, n=0, 72, 0		0	
Eosinophils, TC 5, BL, CC high, n=0, 29, 0		0	
Eosinophils, TC 5, PBL, CC high, n=0, 31, 0		1	
HCT, TC 5, BL, CC low, n=0, 29, 0		0	
HCT, TC 5, PBL, CC low, n=0, 31, 0		0	
Hb, TC 5, BL, CC low, n=0, 29, 0		0	
Hb, TC 5, PBL, CC low, n=0, 31, 0		0	
Lymphocytes, TC 5, BL, CC low, n=0, 29, 0		0	
Lymphocytes, TC 5, PBL, CC low, n=0, 31, 0		0	
PC, TC 5, BL, CC high, n=0, 29, 0		0	
PC, TC 5, PBL, CC high, n=0, 31, 0		0	
RBC count, TC 5, BL, CC low, n=0, 29, 0		0	
RBC count, TC 5, PBL, CC low, n=0, 31, 0		0	
TNUE, TC 5, BL, CC low, n=0, 29, 0		2	
TNUE, TC 5, PBL, CC low, n=0, 31, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TNUE, TC 5, BL, CC high, n=0, 29, 0		0	
TNUE, TC 5,PBL, CC high, n=0, 31, 0		0	
WBC count, TC 5, BL, CC low, n=0, 29, 0		0	
WBC count, TC 5, PBL, CC low, n=0, 31, 0		0	
WBC count, TC 5, BL, CC high, n=0, 29, 0		0	
WBC count, TC 5, PBL, CC high, n=0, 31, 0		0	
Eosinophils, TC 6, BL, CC high, n=0, 11, 0		0	
Eosinophils, TC 6, PBL, CC high, n=0, 11, 0		0	
HCT, TC 6, BL, CC low, n=0, 11, 0		0	
HCT, TC 6, PBL, CC low, n=0, 11, 0		0	
Hb, TC 6, BL, CC low, n=0, 11, 0		1	
Hb, TC 6, PBL, CC low, n=0, 11, 0		0	
Lymphocytes, TC 6, BL, CC low, n=0, 11, 0		0	
Lymphocytes, TC 6, PBL, CC low, n=0, 11, 0		0	
PC, TC 6, BL, CC high, n=0, 11, 0		0	
PC, TC 6, PBL, CC high, n=0, 11, 0		0	
RBC count, TC 6, BL, CC low, n=0, 11, 0		0	
RBC count, TC 6, PBL, CC low, n=0, 11, 0		0	
TNUE, TC 6, BL, CC low, n=0, 11, 0		0	
TNUE, TC 6, PBL, CC low, n=0, 11, 0		0	
TNUE, TC 6, BL, CC high, n=0, 11, 0		0	
TNUE, TC 6,PBL, CC high, n=0, 11, 0		0	
WBC count, TC 6, BL, CC low, n=0, 11, 0		0	
WBC count, TC 6, PBL, CC low, n=0, 11, 0		0	
WBC count, TC 6, BL, CC high, n=0, 11, 0		0	
WBC count, TC 6, PBL, CC high, n=0, 11, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Eosinophils, TC 7, BL, CC high, n=0, 2, 0		0	
Eosinophils, TC 7, PBL, CC high, n=0, 2, 0		0	
HCT, TC 7, BL, CC low, n=0, 2, 0		0	
HCT, TC 7, PBL, CC low, n=0, 2, 0		0	
Hb, TC 7, BL, CC low, n=0, 2, 0		0	
Hb, TC 7, PBL, CC low, n=0, 2, 0		0	
Lymphocytes, TC 7, BL, CC low, n=0, 2, 0		0	
Lymphocytes, TC 7, PBL, CC low, n=0, 2, 0		0	
PC, TC 7, BL, CC high, n=0, 2, 0		0	
PC, TC 7, PBL, CC high, n=0, 2, 0		0	
RBC count, TC 7, BL, CC low, n=0, 2, 0		0	
RBC count, TC 7, PBL, CC low, n=0, 2, 0		0	
TNUE, TC 7, BL, CC low, n=0, 2, 0		0	
TNUE, TC 7, PBL, CC low, n=0, 2, 0		0	
TNUE, TC 7, BL, CC high, n=0, 2, 0		0	
TNUE, TC 7,PBL, CC high, n=0, 2, 0		0	
WBC count, TC 7, BL, CC low, n=0, 2, 0		0	
WBC count, TC 7, PBL, CC low, n=0, 2, 0		0	
WBC count, TC 7, BL, CC high, n=0, 2, 0		0	
WBC count, TC 7, PBL, CC high, n=0, 2, 0		0	

43. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Biomarker Data Outside the Reference Range at Baseline or Any Post-Baseline Visit During the DB and OL Periods by Ofatumumab Treatment Course (TC)

Measure Description	Only those parameters for a particular flag (<LLN or >ULN) are summarized if at least one value was outside the specified reference range. The Baseline (BL) value for a TC was defined as the latest value on or before the date of infusion A of the TC. However to be evaluable as a baseline value, assessments must have been conducted within a 14 day window prior to the date of infusion A. The post-baseline (PBL) was any visit after the date of infusion A during the specified TC. The pre-defined LLN for biomarkers are: B-lymphocyte stimulator (B-ls):<486.5 nanograms per Liter (ng/L); Interleukin-6 (IL-6):<0.31ng/L and Serum amyloid A: <1951 ng/mL. LLN was not defined for Rheumatoid factor (RF)-IgA, RF-IgG, RF-IgM or anti- cyclic citrullinated peptide (CCP) antibody and RF. The pre- defined ULN range for biomarkers (RF)-IgA: >6 units; RF-IgG:>6 units; RF-IgM:>6 units; Anti-CCP:>19.9999 units; B-ls:>1343.3 ng/L; IL-6: >5 ng/L; RF:>11.9999 kilounits (KU)/L; Serum amyloid A:>82432 ng/mL.
Time Frame	From baseline up to Week 144
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	205	0
Number of Participants With the Indicated Biomarker Data Outside the Reference Range at Baseline or Any Post-Baseline Visit During the DB and OL Periods by Ofatumumab Treatment Course (TC)			

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
[units: Participants]			
RF IgA, TC 1, BL, >ULN, n=0, 205, 0		137	
RF IgA, TC 1, PBL, >ULN, n=0, 169, 0		93	
RF IgG, TC 1, BL, >ULN, n=0, 205, 0		114	
RF IgG, TC 1, PBL, >ULN, n=0, 169, 0		67	
RF IgM, TC 1, BL, >ULN, n=0, 205, 0		173	
RF IgM, TC 1, PBL, >ULN, n=0, 169, 0		129	
Anti-CCP, TC 1, BL, >ULN, n=0, 207, 0		185	
Anti-CCP, TC 1, PBL, >ULN, n=0, 168, 0		140	
B-ls, TC 1, BL, <LLN, n=0, 203, 0		21	
B-ls, TC 1, PBL, <LLN, n=0, 206, 0		4	
B-ls, TC 1, BL, >ULN, n=0, 203, 0		12	
B-ls, TC 1, PBL, >ULN, n=0, 206, 0		167	
Il-6, TC 1, BL, >ULN, n=0, 205, 0		144	
IL-6, TC 1, PBL, >ULN, n=0, 138, 0		79	
Serum amyloid A, TC 1, BL, >ULN, n=0, 204, 0		129	
Serum amyloid A, TC 1, PBL, >ULN, n=0, 138, 0		68	
RF IgA, TC 2, BL, >ULN, n=0, 59, 0		32	
RF IgA, TC 2, PBL, >ULN, n=0, 111, 0		51	
RF IgG, TC 2, BL, >ULN, n=0, 59, 0		20	
RF IgG, TC 2, PBL, >ULN, n=0, 111, 0		38	
RF IgM, TC 2, BL, >ULN, n=0, 59, 0		45	
RF IgM, TC 2, PBL, >ULN, n=0, 111, 0		80	
Anti-CCP, TC 2, BL, >ULN, n=0, 60, 0		51	
Anti-CCP, TC 2, PBL, >ULN, n=0, 111, 0		93	
B-ls, TC 2, BL, <LLN, n=0, 81, 0		1	
B-ls, TC 2, PBL, <LLN, n=0, 88, 0		1	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
B-ls, TC 2, BL, >ULN, n=0, 81, 0		60	
B-ls, TC 2, PBL, >ULN, n=0, 88, 0		72	
Il-6, TC 2, BL, >ULN, n=0, 52, 0		23	
IL-6, TC 2, PBL, >ULN, n=0, 23, 0		8	
Serum amyloid A, TC 2, BL, >ULN, n=0, 52, 0		18	
Serum amyloid A, TC 2, PBL, >ULN, n=0, 24, 0		4	
RF IgA, TC 3, BL, >ULN, n=0, 20, 0		9	
RF IgA, TC 3, PBL, >ULN, n=0, 95, 0		42	
RF IgG, TC 3, BL, >ULN, n=0, 20, 0		7	
RF IgG, TC 3, PBL, >ULN, n=0, 95, 0		21	
RF IgM, TC 3, BL, >ULN, n=0, 20, 0		14	
RF IgM, TC 3, PBL, >ULN, n=0, 95, 0		61	
Anti-CCP, TC 3, BL, >ULN, n=0, 20, 0		16	
Anti-CCP, TC 3, PBL, >ULN, n=0, 94, 0		78	
B-ls, TC 3, BL, <LLN, n=0, 16, 0		0	
B-ls, TC 3, PBL, <LLN, n=0, 4, 0		0	
B-ls, TC 3, BL, >ULN, n=0, 16, 0		14	
B-ls, TC 3, PBL, >ULN, n=0, 4, 0		4	
Il-6, TC 3, BL, >ULN, n=0, 0, 0		0	
IL-6, TC 3, PBL, >ULN, n=0, 21, 0		9	
Serum amyloid A, TC 3, BL, >ULN, n=0, 0, 0		0	
Serum amyloid A, TC 3, PBL, >ULN, n=0, 21, 0		4	
RF IgA, TC 4, BL, >ULN, n=0, 14, 0		6	
RF IgA, TC 4, PBL, >ULN, n=0, 43, 0		19	
RF IgG, TC 4, BL, >ULN, n=0, 14, 0		2	
RF IgG, TC 4, PBL, >ULN, n=0, 43, 0		13	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
RF IgM, TC 4, BL, >ULN, n=0, 14, 0		8	
RF IgM, TC 4, PBL, >ULN, n=0, 43, 0		27	
Anti-CCP, TC 4, BL, >ULN, n=0, 14, 0		10	
Anti-CCP, TC 4, PBL, >ULN, n=0, 45, 0		35	
B-ls, TC 4, BL, <LLN, n=0, 0, 0		0	
B-ls, TC 4, PBL, <LLN, n=0, 0, 0		0	
B-ls, TC 4, BL, >ULN, n=0, 0, 0		0	
B-ls, TC 4, PBL, >ULN, n=0, 0, 0		0	
Il-6, TC 4, BL, >ULN, n=0, 0, 0		0	
IL-6, TC 4, PBL, >ULN, n=0, 18, 0		5	
Serum amyloid A, TC 4, BL, >ULN, n=0, 0, 0		0	
Serum amyloid A, TC 4, PBL, >ULN, n=0, 17, 0		4	
RF IgA, TC 5, BL, >ULN, n=0, 5, 0		1	
RF IgA, TC 5, PBL, >ULN, n=0, 24, 0		10	
RF IgG, TC 5, BL, >ULN, n=0, 5, 0		1	
RF IgG, TC 5, PBL, >ULN, n=0, 24, 0		5	
RF IgM, TC 5, BL, >ULN, n=0, 5, 0		4	
RF IgM, TC 5, PBL, >ULN, n=0, 24, 0		17	
Anti-CCP, TC 5, BL, >ULN, n=0, 5, 0		4	
Anti-CCP, TC 5, PBL, >ULN, n=0, 24, 0		20	
B-ls, TC 5, BL, <LLN, n=0, 0, 0		0	
B-ls, TC 5, PBL, <LLN, n=0, 0, 0		0	
B-ls, TC 5, BL, >ULN, n=0, 0, 0		0	
B-ls, TC 5, PBL, >ULN, n=0, 0, 0		0	
Il-6, TC 5, BL, >ULN, n=0, 0, 0		0	
IL-6, TC 5, PBL, >ULN, n=0, 5, 0		1	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Serum amyloid A, TC 5, BL, >ULN, n=0, 0, 0		0	
Serum amyloid A, TC 5, PBL, >ULN, n=0, 5, 0		1	
RF IgA, TC 6, BL, >ULN, n=0, 6, 0		0	
RF IgA, TC 6, PBL, >ULN, n=0, 9, 0		3	
RF IgG, TC 6, BL, >ULN, n=0, 6, 0		0	
RF IgG, TC 6, PBL, >ULN, n=0, 9, 0		1	
RF IgM, TC 6, BL, >ULN, n=0, 6, 0		3	
RF IgM, TC 6, PBL, >ULN, n=0, 9, 0		6	
Anti-CCP, TC 6, BL, >ULN, n=0, 6, 0		4	
Anti-CCP, TC 6, PBL, >ULN, n=0, 9, 0		8	
B-ls, TC 6, BL, <LLN, n=0, 0, 0		0	
B-ls, TC 6, PBL, <LLN, n=0, 0, 0		0	
B-ls, TC 6, BL, >ULN, n=0, 0, 0		0	
B-ls, TC 6, PBL, >ULN, n=0, 0, 0		0	
Il-6, TC 6, BL, >ULN, n=0, 0, 0		0	
IL-6, TC 6, PBL, >ULN, n=0, 2, 0		0	
Serum amyloid A, TC 6, BL, >ULN, n=0, 0, 0		0	
Serum amyloid A, TC 6, PBL, >ULN, n=0, 2, 0		0	
RF IgA, TC 7, BL, >ULN, n=0, 2, 0		2	
RF IgA, TC 7, PBL, >ULN, n=0, 0, 0		0	
RF IgG, TC 7, BL, >ULN, n=0, 2, 0		0	
RF IgG, TC 7, PBL, >ULN, n=0, 0, 0		0	
RF IgM, TC 7, BL, >ULN, n=0, 2, 0		1	
RF IgM, TC 7, PBL, >ULN, n=0, 0, 0		0	
Anti-CCP, TC 7, BL, >ULN, n=0, 2, 0		2	
Anti-CCP, TC 7, PBL, >ULN, n=0, 0, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
B-ls, TC 7, BL, <LLN, n=0, 0, 0		0	
B-ls, TC 7, PBL, <LLN, n=0, 0, 0		0	
B-ls, TC 7, BL, >ULN, n=0, 0, 0		0	
B-ls, TC 7, PBL, >ULN, n=0, 0, 0		0	
Il-6, TC 7, BL, >ULN, n=0, 0, 0		0	
IL-6, TC 7, PBL, >ULN, n=0, 0, 0		0	
Serum amyloid A, TC 7, BL, >ULN, n=0, 0, 0		0	
Serum amyloid A, TC 7, PBL, >ULN, n=0, 0, 0		0	

44. Secondary Outcome Measure:

Measure Title	Number of Participants With Any Serious Adverse Event During the Follow-up Period
Measure Description	A serious adverse event is defined as any untoward medical occurrence that, at any dose: results in death; is life-threatening; requires hospitalization or prolongation of existing hospitalization; results in disability/incapacity; or is a congenital anomaly/birth defect. Medical or scientific judgment should have been exercised in other situations. Refer to the general SAE module for a list of SAEs.
Time Frame	From the last scheduled visit in the DB or OL Period until B-cells and circulating IgG had returned to normal or baseline levels (or maximum of 2 years from Last Subject Last Visit [LSLV])
Safety Issue?	No

Analysis Population Description

Safety Follow-up Population: all participants who withdrew from the Double-blind Period and had evidence of contact with the site after the end of the Double-blind Period and all participants who withdrew or completed the Open-label Period and had evidence of contact with the site after their end of Open-label date.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.

	Description
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	0	224
Number of Participants With Any Serious Adverse Event During the Follow-up Period [units: Participants]			13

45. Secondary Outcome Measure:

Measure Title	Number of Participants With Immunoglobulin Values Outside the Reference Range During the Follow-up Period
Measure Description	The reference ranges for immunoglobulins (LLN, ULN) are defined as: IgA (grams/Liter): 0.81, 4.63; IgG (grams/Liter): 6.94, 16.18; IgM (grams/Liter): 0.48, 2.71.
Time Frame	From the last scheduled visit in the DB or OL Period until B-cells and circulating IgG had returned to normal or baseline levels (or maximum of 2 years from LSLV)
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	0	220
Number of Participants With Immunoglobulin Values Outside the Reference Range During the Follow-up Period [units: Participants]			
IgA <LLN			1
IgA >ULN			29
IgG <LLN			16
IgG >ULN			20
IgM <LLN			35
IgM >ULN			7

46. Secondary Outcome Measure:

Measure Title	Time to First CD19+ B-cell Repopulation Relative to the First Dose and Last Dose of Ofatumumab

Measure Description	Time to first CD19+ B-cell repopulation (return to normal or baseline level) relative to the first dose was assessed only for those participants whose B-cells repopulated after receiving ofatumumab. Time to first CD19+ B-cell repopulation relative to the last dose of ofatumumab was assessed only for those participants whose B-cells repopulated during their last ofatumumab treatment course or follow-up.
Time Frame	From the first dose of ofatumumab until the last Follow-up Period visit (up to Week 248)
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	0	133
Time to First CD19+ B-cell Repopulation Relative to the First Dose and Last Dose of Ofatumumab [units: Months] Median (Full Range)			
Relative to first dose, n=0, 0, 133			22.998 (0.43 to 56.64)
Relative to last dose, n=0, 0, 128			13.832 (3.06 to 54.77)

47. Secondary Outcome Measure:

Measure Title	Number of Participants With a Positive JC Virus Test Result During the Follow-up Period
Measure Description	Blood samples were collected for analysis of plasma/white blood cell JC Virus (JCV) using the polymerase chain reaction (PCR) assay. A positive JC Virus test result indicated the presence of JC Virus.
Time Frame	From the last scheduled visit in the DB or OL Period until B-cells and circulating IgG had returned to normal or baseline levels (or maximum of 2 years from LSLV)
Safety Issue?	No

Analysis Population Description

AT Population. Only those participants contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	0	243
Number of Participants With a Positive JC Virus Test Result During the Follow-up Period [units: Participants]			8

48. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Clinical Chemistry Values of Potential Clinical Concern During the Follow-up Period
Measure Description	Only those parameters for which at least one value of clinical concern (CC) was reported are summarized. Pre-defined limits of potential clinical concern (CC Low [relative to the lower limit of normal], CC High [relative to the upper limit of normal]) are: ALT: NA, 2; ALP: NA, 1.5; Creatinine: N/A, 1.2; CO2/BCO: 0.85/0.75, 1.2/1.3; CK: NA, 2; GGT: NA, 2; Urea/BUN: NA, 1.5.
Time Frame	From the last scheduled visit in the DB or OL Period until B-cells and circulating IgG had returned to normal or baseline levels (maximum of 2 years)
Safety Issue?	No

Analysis Population Description

AT Population. Only participants who withdrew from the DB Period and had evidence of contact with the site after the end of the DB Period and all participants who withdrew or completed the OL Period and had evidence of contact with the site after their end of OL date were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	0	224

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants With the Indicated Clinical Chemistry Values of Potential Clinical Concern During the Follow-up Period [units: Participants]			
ALT			1
ALP			1
CK			2
CO2/BCO			3
GGT			5
Creatinine			1
Urea/BUN			1

49. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Hematology Values of Potential Clinical Concern During the Follow-up Period
Measure Description	Only those parameters for which at least one value of clinical concern (CC) was reported are summarized. Pre-defined limits of potential clinical concern (CC Low [relative to lower limit of normal], CC High [relative to upper limit of normal]) are: Eosinophils: NA, 2; Total neutrophils: 0.8, 1.6; Platelet count: 0.65, 1.5.
Time Frame	From the last scheduled visit in the DB or OL Period until B-cells and circulating IgG had returned to normal or baseline levels (maximum of 2 years)
Safety Issue?	No

Analysis Population Description

AT Population. Only participants who withdrew from the DB Period and had evidence of contact with the site after the end of the DB Period and all participants who withdrew or completed the OL Period and had evidence of contact with the site after their end of OL date were analyzed.

Reporting Groups

	Description
Placebo	Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5-25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.

	Description
Ofatumumab 700 mg	Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or OFA 700 mg: FU Period	Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	0	224
Number of Participants With the Indicated Hematology Values of Potential Clinical Concern During the Follow-up Period [units: Participants]			
Eosinophils			1
Total neutrophils			2
Platelet count			1

Reported Adverse Events

Time Frame	Because no investigational product was administered during the Follow-up Period, per protocol, only serious adverse events (SAEs) were collected and reported for this period.
Additional Description	SAEs/AEs were collected in members of the Safety Population (SP), which is identical to the ITT Population, except that participants were analyzed according to the actual treatment received rather than to the treatment randomized to (one participant was randomized to placebo but received study drug).

Reporting Groups

	Description
Placebo: DB Period	Serious adverse events (SAEs) and non-serious AEs are reported for participants receiving placebo in the DB Period. Placebo was administered as two 1000 milliliter (ml) intravenous (IV) infusions, one at Day 0 and the other at Day 14, in addition to background methotrexate (MTX) treatment (7.5 to 25 milligrams [mg]/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period.
Ofatumumab 700 mg: DB and OL Periods	SAEs and non-serious AEs are reported for participants receiving ofatumumab 700 mg in either the DB or OL Period. Ofatumumab 700 mg (35 ml) was administered as two 1000 ml IV infusions, one at Day 0 and the other at Day 14, in addition to background MTX treatment (7.5 to 25 mg/week [oral, intramuscular, or subcutaneous] for 24 weeks) in the DB Period. Participants completing the 24-week DB Period without receiving rescue disease-modifying anti-rheumatic drug treatment were eligible to proceed into the 120-week OL Period to receive repeat ofatumumab treatment courses (at individualized time intervals if a clinical response had been achieved after the previous treatment course).
Placebo or Ofatumumab 700 mg: Follow-up Period	SAEs and non-serious AEs are reported for participants receiving either placebo or ofatumumab 700 mg in the Follow-up Period. Participants randomized to DB treatment who completed the OL Period, who did not enter the OL Period, who did not qualify for retreatment, or who were withdrawn were to be followed until the number of B-cells and circulating IgG had returned to normal (according to the central laboratory) or Baseline levels or for a maximum of 2 years from the last scheduled visit in the DB or OL Periods, whichever occurred earlier. No investigational product was administered in the Follow-up Period.

Serious Adverse Events

	Placebo: DB Period	Ofatumumab 700 mg: DB and OL Periods	Placebo or Ofatumumab 700 mg: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	4/130 (3.08%)	44/243 (18.11%)	13/224 (5.8%)
Cardiac disorders			
Acute coronary syndrome [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Acute myocardial infarction [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Angina unstable [A] †	0/130 (0%)	2/243 (0.82%)	0/224 (0%)
Arrhythmia supraventricular [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Cardiac aneurysm [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Myocardial infarction [A] †	1/130 (0.77%)	0/243 (0%)	0/224 (0%)
Pericardial effusion [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)

	Placebo: DB Period	Ofatumumab 700 mg: DB and OL Periods	Placebo or Ofatumumab 700 mg: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Supraventricular tachycardia [A] †	0/130 (0%)	0/243 (0%)	1/224 (0.45%)
Ear and labyrinth disorders			
Vertigo [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Eye disorders			
Blepharospasm [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Diplopia [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Gastrointestinal disorders			
Abdominal pain [A] †	0/130 (0%)	2/243 (0.82%)	0/224 (0%)
Colonic polyp [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Colonic stenosis [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Diarrhoea [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Inguinal hernia [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Pancreatic necrosis [A] †	0/130 (0%)	0/243 (0%)	1/224 (0.45%)
Umbilical hernia [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
General disorders			
Oedema peripheral [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Hepatobiliary disorders			
Bile duct stone [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Jaundice [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Post cholecystectomy syndrome [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Infections and infestations			
Diverticulitis [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)

	Placebo: DB Period	Ofatumumab 700 mg: DB and OL Periods	Placebo or Ofatumumab 700 mg: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Empyema [A] †	0/130 (0%)	0/243 (0%)	1/224 (0.45%)
Endometritis [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Gastroenteritis bacterial [A] †	1/130 (0.77%)	0/243 (0%)	0/224 (0%)
Hepatitis B [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Lower respiratory tract infection [A] †	0/130 (0%)	1/243 (0.41%)	1/224 (0.45%)
Pertusis [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Pneumonia [A] †	1/130 (0.77%)	1/243 (0.41%)	0/224 (0%)
Pyelonephritis acute [A] †	0/130 (0%)	1/243 (0.41%)	1/224 (0.45%)
Tooth infection [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Injury, poisoning and procedural complications			
Ankle fracture [A] †	0/130 (0%)	0/243 (0%)	1/224 (0.45%)
Incisional hernia [A] †	0/130 (0%)	1/243 (0.41%)	1/224 (0.45%)
Overdose [A] †	0/130 (0%)	0/243 (0%)	1/224 (0.45%)
Radius fracture [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Subcutaneous haematoma [A] †	0/130 (0%)	0/243 (0%)	1/224 (0.45%)
Thoracic vertebral fracture [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Toxicity to various agents [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Ulna fracture [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Investigations			
Electrocardiogram T wave inversion [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Troponin T increased [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Metabolism and nutrition disorders			

	Placebo: DB Period	Ofatumumab 700 mg: DB and OL Periods	Placebo or Ofatumumab 700 mg: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Diabetes mellitus [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Musculoskeletal and connective tissue disorders			
Arthralgia [A] †	0/130 (0%)	0/243 (0%)	1/224 (0.45%)
Arthritis [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Bunion [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Foot deformity [A] †	0/130 (0%)	2/243 (0.82%)	0/224 (0%)
Osteoarthritis [A] †	0/130 (0%)	1/243 (0.41%)	1/224 (0.45%)
Synovitis [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-cell lymphoma [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Gingival cancer [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Ovarian cancer [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Nervous system disorders			
Cerebrovascular accident [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Cerebrovascular disorder [A] †	0/130 (0%)	0/243 (0%)	1/224 (0.45%)
Headache [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Ischaemic stroke [A] †	1/130 (0.77%)	0/243 (0%)	0/224 (0%)
Myasthenia gravis [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Polyneuropathy [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Syncope [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Vertebrobasilar insufficiency [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Pregnancy, puerperium and perinatal conditions			

	Placebo: DB Period	Ofatumumab 700 mg: DB and OL Periods	Placebo or Ofatumumab 700 mg: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Abortion spontaneous [A] †	0/130 (0%)	0/243 (0%)	1/224 (0.45%)
Renal and urinary disorders			
Renal colic [A] †	0/130 (0%)	0/243 (0%)	1/224 (0.45%)
Reproductive system and breast disorders			
Metrorrhagia [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease [A] †	0/130 (0%)	0/243 (0%)	1/224 (0.45%)
Dyspnoea [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Interstitial lung disease [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Pulmonary embolism [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Skin and subcutaneous tissue disorders			
Angioedema [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Vascular disorders			
Axillary vein thrombosis [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (0%)
Varicose vein [A] †	0/130 (0%)	1/243 (0.41%)	0/224 (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: 2%

	Placebo: DB Period	Ofatumumab 700 mg: DB and OL Periods	Placebo or Ofatumumab 700 mg: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	46/130 (35.38%)	226/243 (93%)	0/224 (0%)
Blood and lymphatic system disorders			

	Placebo: DB Period	Ofatumumab 700 mg: DB and OL Periods	Placebo or Ofatumumab 700 mg: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Anaemia [A] †	5/130 (3.85%)	9/243 (3.7%)	0/224 (0%)
Leukopenia [A] †	0/130 (0%)	9/243 (3.7%)	0/224 (0%)
Neutropenia [A] †	0/130 (0%)	5/243 (2.06%)	0/224 (0%)
Cardiac disorders			
Tachycardia [A] †	0/130 (0%)	6/243 (2.47%)	0/224 (0%)
Ear and labyrinth disorders			
Vertigo [A] †	0/130 (0%)	8/243 (3.29%)	0/224 (0%)
Eye disorders			
Conjunctiviitis [A] †	0/130 (0%)	6/243 (2.47%)	0/224 (0%)
Gastrointestinal disorders			
Abdominal pain [A] †	0/130 (0%)	9/243 (3.7%)	0/224 (0%)
Abdominal pain upper [A] †	4/130 (3.08%)	9/243 (3.7%)	0/224 (0%)
Diarrhoea [A] †	3/130 (2.31%)	15/243 (6.17%)	0/224 (0%)
Dyspepsia [A] †	0/130 (0%)	6/243 (2.47%)	0/224 (0%)
Dysphagia [A] †	0/130 (0%)	5/243 (2.06%)	0/224 (0%)
Gastritis [A] †	0/130 (0%)	8/243 (3.29%)	0/224 (0%)
Mouth ulceration [A] †	0/130 (0%)	6/243 (2.47%)	0/224 (0%)
Nausea [A] †	4/130 (3.08%)	13/243 (5.35%)	0/224 (0%)
Odynophagia [A] †	0/130 (0%)	5/243 (2.06%)	0/224 (0%)
Vomiting [A] †	0/130 (0%)	6/243 (2.47%)	0/224 (0%)
General disorders			
Chest pain [A] †	0/130 (0%)	5/243 (2.06%)	0/224 (0%)

	Placebo: DB Period	Ofatumumab 700 mg: DB and OL Periods	Placebo or Ofatumumab 700 mg: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Drug intolerance [A] †	0/130 (0%)	5/243 (2.06%)	0/224 (0%)
Oedema peripheral [A] †	0/130 (0%)	6/243 (2.47%)	0/224 (0%)
Immune system disorders			
Hypersensitivity [A] †	0/130 (0%)	11/243 (4.53%)	0/224 (0%)
Infections and infestations			
Bacteriuria [A] †	2/130 (1.54%)	5/243 (2.06%)	0/224 (0%)
Bronchitis [A] †	4/130 (3.08%)	18/243 (7.41%)	0/224 (0%)
Cellulitis [A] †	0/130 (0%)	6/243 (2.47%)	0/224 (0%)
Gastroenteritis [A] †	0/130 (0%)	9/243 (3.7%)	0/224 (0%)
Influenza [A] †	4/130 (3.08%)	8/243 (3.29%)	0/224 (0%)
Nasopharyngitis [A] †	3/130 (2.31%)	34/243 (13.99%)	0/224 (0%)
Pharyngitis [A] †	1/130 (0.77%)	13/243 (5.35%)	0/224 (0%)
Sinusitis [A] †	0/130 (0%)	7/243 (2.88%)	0/224 (0%)
Upper respiratory tract infection [A] †	3/130 (2.31%)	20/243 (8.23%)	0/224 (0%)
Urinary tract infection [A] †	9/130 (6.92%)	27/243 (11.11%)	0/224 (0%)
Investigations			
Alanine aminotransferase increased [A] †	4/130 (3.08%)	0/243 (0%)	0/224 (0%)
Blood pressure increased [A] †	0/130 (0%)	6/243 (2.47%)	0/224 (0%)
Gamma-glutamyltransferase increased [A] †	3/130 (2.31%)	0/243 (0%)	0/224 (0%)
Lymphocyte count decreased [A] †	0/130 (0%)	6/243 (2.47%)	0/224 (0%)
Musculoskeletal and connective tissue disorders			
Arthralgia [A] †	0/130 (0%)	5/243 (2.06%)	0/224 (0%)

	Placebo: DB Period	Ofatumumab 700 mg: DB and OL Periods	Placebo or Ofatumumab 700 mg: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Back pain [A] †	1/130 (0.77%)	12/243 (4.94%)	0/224 (0%)
Bone pain [A] †	0/130 (0%)	6/243 (2.47%)	0/224 (0%)
Osteoarthritis [A] †	0/130 (0%)	5/243 (2.06%)	0/224 (0%)
Rheumatoid arthritis [A] †	3/130 (2.31%)	7/243 (2.88%)	0/224 (0%)
Nervous system disorders			
Dizziness [A] †	1/130 (0.77%)	7/243 (2.88%)	0/224 (0%)
Headache [A] †	8/130 (6.15%)	20/243 (8.23%)	0/224 (0%)
Sciatica [A] †	0/130 (0%)	5/243 (2.06%)	0/224 (0%)
Psychiatric disorders			
Depression [A] †	0/130 (0%)	8/243 (3.29%)	0/224 (0%)
Renal and urinary disorders			
Haematuria [A] †	1/130 (0.77%)	10/243 (4.12%)	0/224 (0%)
Leukocyturia [A] †	2/130 (1.54%)	9/243 (3.7%)	0/224 (0%)
Respiratory, thoracic and mediastinal disorders			
Cough [A] †	1/130 (0.77%)	24/243 (9.88%)	0/224 (0%)
Dyspnoea [A] †	0/130 (0%)	20/243 (8.23%)	0/224 (0%)
Oropharyngeal pain [A] †	0/130 (0%)	8/243 (3.29%)	0/224 (0%)
Respiratory disorder [A] †	0/130 (0%)	6/243 (2.47%)	0/224 (0%)
Rhinitis [A] †	0/130 (0%)	7/243 (2.88%)	0/224 (0%)
Throat irritation [A] †	1/130 (0.77%)	43/243 (17.7%)	0/224 (0%)
Skin and subcutaneous tissue disorders			
Dermatitis allergic [A] †	0/130 (0%)	5/243 (2.06%)	0/224 (0%)

	Placebo: DB Period	Ofatumumab 700 mg: DB and OL Periods	Placebo or Ofatumumab 700 mg: Follow-up Period
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Erythema [A] †	0/130 (0%)	13/243 (5.35%)	0/224 (0%)
Pruritus [A] †	2/130 (1.54%)	26/243 (10.7%)	0/224 (0%)
Rash [A] †	1/130 (0.77%)	89/243 (36.63%)	0/224 (0%)
Rash generalised [A] †	0/130 (0%)	5/243 (2.06%)	0/224 (0%)
Urticaria [A] †	1/130 (0.77%)	45/243 (18.52%)	0/224 (0%)
Vascular disorders			
Flushing [A] †	0/130 (0%)	6/243 (2.47%)	0/224 (0%)
Hypertension [A] †	5/130 (3.85%)	20/243 (8.23%)	0/224 (0%)

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

Limitations and Caveats

[Not specified]

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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