ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 05/22/2014

ClinicalTrials.gov ID: NCT00603525

Study Identification

Unique Protocol ID:	110634
Brief Title:	Investigating Clinical Efficacy of Ofatumumab in Adult Rheumatoid Arthritis (RA) Patients Who Had an Inadequate Response to TNF-α Antagonist Therapy
Official Title:	A Double-blind, Randomized, Placebo Controlled, Parallel Group, Multi-center, Phase III Trial of Ofatumumab Investigating Clinical Efficacy in Patients With Active Rheumatoid Arthritis Who Have Previously Had an Inadequate Response to One or More TNF Antagonist Therapies
Secondary IDs:	GEN411 [GENMAB]

Study Status

Record Verification:	April 2014
Overall Status:	Terminated
Study Start:	January 2008
Primary Completion:	March 2011 [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 and safety of ofatumumab in reducing clinical signs and symptoms in adult RA patients who had an inadequate response to TNF-α antagonist therapy.
Detailed Description:	This study consist 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 either ofatumumab or placebo in addition to their background methotrexate treatment. Patients who complete the 24 week Double-blind Period without receiving rescue DMARD treatment will then 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 been withdrawn will then enter a maximum 2 year Follow-up Period, or until there B-cells 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:	169 [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 IV infusion taken 14 days apart. A total of 8 infusion 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 IV infusion taken 14 days apart. A total of 8 infusion cycles given over a 144 week period
Placebo Comparator: 1000 ml Saline 1000 mL sterile, pyrogen free 0.9% NaCl. A treatment cycle consisting of two IV infusion taken 14 days apart. Only one placebo treatment cycle provided over a 24 week period	Drug: Placebo 1000 mL sterile, pyrogen free 0.9% NaCl. A treatment cycle consisting of two IV infusion 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 TNF-alpha antagonist 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;
- Exposure to TNF-alpha antagonist treatment < 12 weeks prior to visit 2;
- 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
Study Director
GlaxoSmithKline

Locations: Italy
GSK Investigational Site
Napoli, Campania, Italy, 80131

Argentina
GSK Investigational Site
Cordoba, Argentina, 5000

Korea, Republic of
GSK Investigational Site
Seoul, Korea, Republic of, 120-752

Italy
GSK Investigational Site
Telese Terme (BN), Campania, Italy, 82100

GSK Investigational Site
Milano, Lombardia, Italy, 20157

France
GSK Investigational Site
Echirolles, France, 38434

Germany
GSK Investigational Site
Hamburg, Hamburg, Germany, 22081

Italy
GSK Investigational Site
Roma, Lazio, Italy, 00161

Norway
GSK Investigational Site
Haugesund, Norway, N-5528

GSK Investigational Site
Trondheim, Norway, 7006

Netherlands
GSK Investigational Site
Amsterdam, Netherlands, 1056 AB

GSK Investigational Site
Zwolle, Netherlands, 8011 JW

United Kingdom
GSK Investigational Site
Leytonstone, London, United Kingdom, E11 1NR

France
GSK Investigational Site
Cahors cedex 9, France, 46005

Germany
GSK Investigational Site
Berlin, Berlin, Germany, 14129

Argentina
GSK Investigational Site
Ciudad Autónoma de Buenos Aires, Buenos Aires, Argentina, AAL1426

Norway
GSK Investigational Site
Lillehammer, Norway, 2609

Sweden
GSK Investigational Site
Oskarström, Sweden, SE-313 92

Argentina
GSK Investigational Site
Tucuman, Argentina, 4000

France
GSK Investigational Site
Amiens, Picardie, France, 80054

Spain
GSK Investigational Site
Getafe/Madrid, Spain, 28905

Netherlands
GSK Investigational Site
Enschede, Netherlands, 7511JX

Germany
GSK Investigational Site
Leipzg, Sachsen, Germany, 04109

Spain
GSK Investigational Site
Madrid, Spain, 28007

United Kingdom
GSK Investigational Site
Newcastle, Northumberland, United Kingdom, NE1 4LP

Spain
GSK Investigational Site
Sevilla, Spain, 41071

Italy
GSK Investigational Site
Padova, Veneto, Italy, 35121

Germany
GSK Investigational Site
Magdeburg, Sachsen-Anhalt, Germany, 39112

United Kingdom
GSK Investigational Site

Wishaw, Lanarkshire, United Kingdom, ML2 0DP

Korea, Republic of
GSK Investigational Site
Seoul, Korea, Republic of, 110-744

Germany
GSK Investigational Site
Erlangen, Bayern, Germany, 91054

France
GSK Investigational Site
Corbeil Essonnes Cedex, France, 91106

Spain
GSK Investigational Site
Mérida (Badajoz), Spain, 06800

Italy
GSK Investigational Site
Milano, Lombardia, Italy, 20162

United Kingdom
GSK Investigational Site
Dundee, United Kingdom, DD1 9SY

Norway
GSK Investigational Site
Levanger, Norway, 7600

Spain
GSK Investigational Site
Santander, Spain, 39008

Korea, Republic of
GSK Investigational Site
Seoul, Korea, Republic of, 137-701

Germany
GSK Investigational Site
Berlin, Berlin, Germany, 10559

France
GSK Investigational Site
Strasbourg, France, 67098

Argentina
GSK Investigational Site
Rosario, Santa Fe, Argentina, 2000

Denmark
GSK Investigational Site
Silkeborg, Denmark, 8600

Sweden
GSK Investigational Site
Stockholm, Sweden, SE-171 76

Italy
GSK Investigational Site
Milano, Lombardia, Italy, 20132

GSK Investigational Site
Varese, Lombardia, Italy, 21100

Germany
GSK Investigational Site
Potsdam, Brandenburg, Germany, 14467

Denmark
GSK Investigational Site
Herlev, Denmark, 2730

Spain
GSK Investigational Site
Valencia, Spain, 46017

Italy
GSK Investigational Site
Prato, Toscana, Italy, 59100

Germany
GSK Investigational Site
Hannover, Niedersachsen, Germany, 30625

France
GSK Investigational Site
Toulouse, France, 31059

Italy
GSK Investigational Site
Genova, Liguria, Italy, 16132

Korea, Republic of
GSK Investigational Site
Seoul, Korea, Republic of, 133-792

Germany
GSK Investigational Site
Heidelberg, Baden-Wuerttemberg, Germany, 69120

GSK Investigational Site
Osnabrueck, Niedersachsen, Germany, 49074

United Kingdom
GSK Investigational Site
Cannock, United Kingdom, WS11 5XY

Korea, Republic of
GSK Investigational Site
Incheon, Korea, Republic of, 400-711

Germany
GSK Investigational Site
Hamburg, Hamburg, Germany, 22415

Spain
GSK Investigational Site
Madrid, Spain, 28046

Peru
GSK Investigational Site
Lima, Lima, Peru, Lima 27

References

Citations:

Links:

Study Data/Documents:

Participant Flow

Pre-Assignment Details	Study OFA110634 is comprised of a 24-week Double-blind (DB) Period, followed by a 120-week Open-label (OL) Period. Participants who complete the OL Period, or who are withdrawn, enter a Follow-up (FU) period (anticipated to be 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	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	Placebo or OFA 700 mg: FU Period
Started	84	85	0
Completed	67	63	0
Not Completed	17	22	0
Adverse Event	3	9	0
Lack of Efficacy	7	0	0
Protocol Violation	1	2	0
Lost to Follow-up	1	3	0
Withdrawal by Subject	5	6	0

	Placebo	Ofatumumab	Placebo or OFA 700 mg: FU Period
Physician Decision	0	1	0
Participant Met Stopping Criteria	0	1	0

OL Treatment Period (120 Weeks)

	Placebo	Ofatumumab	Placebo or OFA 700 mg: FU Period
Started	0	125 [1]	0
Completed	0	13	0
Not Completed	0	112	0
Adverse Event	0	12	0
Lack of Efficacy	0	13	0
Protocol Violation	0	1	0
Protocol-defined Stopping Criteria Met	0	5	0
Study Closed/Terminated	0	71	0
Physician Decision	0	2	0
Withdrawal by Subject	0	8	0

[1] 61 participants received OFA during the DB Period; 64 received placebo during the DB Period.

Follow-up Period (Approximately 2 Years)

	Placebo	Ofatumumab	Placebo or OFA 700 mg: FU Period
Started	0	0	124 [1]
Unknown Reason for Withdrawal	0	0	111 [2]
Completed	0	0	13
Not Completed	0	0	111
Unknown Reason for Withdrawal	0	0	111

[1] 124 participants (par) completing/withdrawing from the DB or OL Periods attended >=1 follow-up visit

[2] As par. were not on active drug during the Follow-up Period, withdrawal reasons were not collected.

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	84	85	169
Age, Continuous [units: Years] Mean (Standard Deviation)	53.3 (11.69)	53.7 (13.64)	53.5 (12.67)
Gender, Male/Female [units: Participants]			
Female	67	73	140
Male	17	12	29
Race/Ethnicity, Customized [units: participants]			
Hispanic/Latino	35	35	70
Not Hispanic/Latino	49	50	99

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	84	85
Number of Participants With a 20% Improvement From Baseline in Their American College of Rheumatology (ACR) Score (ACR20) at Week 24 [units: participants]	16	36

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	84	85
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	22	25
Week 8	23	29
Week 12	30	36
Week 16	23	36
Week 20	21	40

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	84	85
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	9	4
Week 8	8	9
Week 12	11	17
Week 16	10	17
Week 20	8	18
Week 24	5	19

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	84	85
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	3	0
Week 8	2	3
Week 12	3	5
Week 16	3	5
Week 20	3	5
Week 24	3	6

5. 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. Only those participants contributing values at the relevant visit 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 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	80	73
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=80, 73	5.00 (1.492)	5.02 (1.361)
Week 8, n=74, 73	4.96 (1.352)	4.60 (1.300)
Week 12, n=73, 71	4.86 (1.537)	4.16 (1.194)
Week 16, n=69, 71	4.88 (1.526)	4.17 (1.273)

	Placebo	Ofatumumab 700 mg
Week 20, n=67, 68	4.91 (1.505)	4.04 (1.262)
Week 24, n=68, 67	5.21 (1.324)	4.22 (1.432)

6. 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 rheumatoid arthritis disease activity (DA) that combines information from swollen and tender joints, the APR, and general health (patient global assessment). 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. 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. Only those participants contributing values at baseline and the relevant visit 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 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	80	73
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=80, 73	-0.83 (1.237)	-0.89 (1.094)

	Placebo	Ofatumumab 700 mg
Week 8, n=74, 73	-0.81 (1.127)	-1.22 (1.142)
Week 12, n=73, 71	-0.92 (1.382)	-1.64 (1.242)
Week 16, n=69, 71	-0.86 (1.362)	-1.64 (1.318)
Week 20, n=67, 68	-0.79 (1.270)	-1.75 (1.311)
Week 24, n=68, 67	-0.51 (1.142)	-1.56 (1.370)

7. 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 (ARP)
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. Only those participants contributing values at the relevant visit 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 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	80	74

	Placebo	Ofatumumab 700 mg
Mean DAS28 at Weeks 4, 8, 12, 16, 20, and 24 Using Erythrocyte Sedimentation Rate (ESR) as the Acute Phase Reactant (ARP) [units: scores on a scale] Mean (Standard Deviation)		
Week 4, n=80, 74	5.84 (1.455)	5.80 (1.390)
Week 8, n=74, 72	5.76 (1.327)	5.41 (1.335)
Week 12, n=73, 71	5.60 (1.498)	4.99 (1.269)
Week 16, n=69, 71	5.66 (1.481)	4.95 (1.356)
Week 20, n=67, 68	5.74 (1.539)	4.79 (1.312)
Week 24, n=68, 67	5.96 (1.358)	5.03 (1.537)

8. 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 rheumatoid arthritis disease activity (DA) that combines information from swollen and tender joints, the APR, and general health (patient global assessment). 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. 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. Only those participants contributing values at baseline and the relevant visit 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 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	80	74
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=80, 74	-0.85 (1.210)	-0.98 (1.105)
Week 8, n=74, 72	-0.88 (1.117)	-1.28 (1.165)
Week 12, n=73, 71	-1.05 (1.332)	-1.70 (1.304)
Week 16, n=69, 71	-0.95 (1.353)	-1.75 (1.350)
Week 20, n=67, 68	-0.85 (1.299)	-1.89 (1.299)
Week 24, n=68, 67	-0.63 (1.211)	-1.64 (1.473)

9. 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	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	84	85
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	15	8
Week 4, Moderate	18	25
Week 4, None	47	40
Week 8, Good	11	11
Week 8, Moderate	23	31
Week 8, None	40	31
Week 12, Good	13	14
Week 12, Moderate	22	39
Week 12, None	38	18
Week 16, Good	9	17
Week 16, Moderate	23	33
Week 16, None	37	21
Week 20, Good	10	18
Week 20, Moderate	21	32
Week 20, None	36	18

	Placebo	Ofatumumab 700 mg
Week 24, Good	6	15
Week 24, Moderate	19	29
Week 24, None	43	23

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 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	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	84	85
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		

	Placebo	Ofatumumab 700 mg
[units: participants]		
Week 4, Good	3	4
Week 4, Moderate	29	21
Week 4, None	48	49
Week 8, Good	2	5
Week 8, Moderate	28	33
Week 8, None	44	34
Week 12, Good	2	7
Week 12, Moderate	36	41
Week 12, None	35	23
Week 16, Good	3	6
Week 16, Moderate	29	43
Week 16, None	37	22
Week 20, Good	1	5
Week 20, Moderate	27	46
Week 20, None	39	17
Week 24, Good	2	6
Week 24, Moderate	20	37
Week 24, None	46	24

11. Secondary Outcome Measure:

Measure Title	Median of the Largest Integer n, for Which a Participant Met the ACR Criteria Requiring an Improvement of n% (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 percentage (%) 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 = min(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. This trial was terminated prematurely due to the Sponsor's decision to not pursue clinical development of the IV formulation of ofatumumab in an autoimmune indication; thus, no participants were analyzed for this endpoint.

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	0	0

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

12. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Health Assessment Questionnaire Disability Index (HAQ-DI) Score at Weeks 4, 8, 12, 16, 20, and 24
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	Weeks 4, 8, 12, 16, 20, and 24
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants contributing values at baseline and the relevant visit 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 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	75	72
Change From Baseline in the Health Assessment Questionnaire Disability Index (HAQ-DI) Score at Weeks 4, 8, 12, 16, 20, and 24 [units: scores on a scale] Median (Full Range)		
Week 4, n=75, 72	-0.13 (-1.9 to 0.8)	-0.13 (-1.9 to 1.4)
Week 8, n=69, 68	-0.25 (-2.1 to 1.1)	-0.38 (-1.6 to 0.9)
Week 12, n=68, 65	-0.13 (-2.3 to 1.0)	-0.38 (-1.9 to 1.0)
Week 16, n=65, 64	-0.13 (-2.1 to 1.0)	-0.38 (-2.0 to 0.5)
Week 20, n=64, 64	-0.13 (-2.3 to 1.1)	-0.38 (-2.1 to 1.3)
Week 24, n=63, 61	0.00 (-2.3 to 1.0)	-0.38 (-2.1 to 1.5)

13. 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. Only those participants contributing values at baseline and the relevant visit 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 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	68	66
Change From Baseline in Tender Joint Count at Week 24 [units: tender joints] Median (Full Range)	-5 (-46 to 23)	-11 (-56 to 14)

14. 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. Only those participants contributing values at baseline and the relevant visit 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 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	68	66
Change From Baseline in Swollen Joint Count at Week 24 [units: swollen joints] Median (Full Range)	-3.50 (-27 to 37)	-7.50 (-27 to 33)

15. 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. Only those participants contributing values at baseline and the relevant visit 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 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	66	66
Change From Baseline in CRP at Week 24 [units: milligrams per liter (mg/L)] Median (Full Range)	1.05 (-51.5 to 94.0)	-2.85 (-150.6 to 41.4)

16. 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. Only those participants contributing values at baseline and the relevant visit 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 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	67	67
Change From Baseline in ESR at Week 24 [units: millimeters per hour (mm/hr)] Median (Full Range)	0.00 (-73 to 52)	-12.00 (-100 to 45)

17. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Participant-assessed Pain Score Using Visual Analogue Scale (VAS) 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. This trial was terminated prematurely due to the Sponsor's decision to not pursue clinical development of the IV formulation of ofatumumab in an autoimmune indication; thus, no participants were analyzed for this endpoint.

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	0	0

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

18. Secondary Outcome Measure:

Measure Title	Change From Baseline in Participant-assessed Global Disease Score Using VAS 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. This trial was terminated prematurely due to the Sponsor's decision to not pursue clinical development of the IV formulation of ofatumumab in an autoimmune indication; thus, no participants were analyzed for this endpoint.

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	0	0

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

19. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Physician-assessed Global Disease Score Using VAS 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. This trial was terminated prematurely due to the Sponsor's decision to not pursue clinical development of the IV formulation of ofatumumab in an autoimmune indication; thus, no participants were analyzed for this endpoint.

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	0	0

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

20. 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. This trial was terminated prematurely due to the Sponsor's decision to not pursue clinical development of the IV formulation of ofatumumab in an autoimmune indication; thus, no participants were analyzed for this endpoint.

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	0	0

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

21. 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. This trial was terminated prematurely due to the Sponsor's decision to not pursue clinical development of the IV formulation of ofatumumab in an autoimmune indication; thus, no participants were analyzed for this endpoint.

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	0	0

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

22. 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. This trial was terminated prematurely due to the Sponsor's decision to not pursue clinical development of the IV formulation of ofatumumab in an autoimmune indication; thus, no participants were analyzed for this endpoint.

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	0	0

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

23. Secondary Outcome Measure:

Measure Title	Biomarker Levels for Anti-CCP, RF-IgA, RF-IgG, and RF-IgM at Baseline and Week 4
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 4
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants contributing values at the relevant visit 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 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	81	82
Biomarker Levels for Anti-CCP, RF-IgA, RF-IgG, and RF-IgM at Baseline and Week 4 [units: Units/Liter] Median (Full Range)		
Anti-CCP, Baseline, n=81, 82	466 (8 to 10828)	449.5 (8 to 8261)
RF-IgA, Baseline, n=81, 81	9 (2.5 to 100)	11 (2.5 to 100)
RF-IgA, Week 4, n=0, 1	NA (NA to NA) [1]	100 (100 to 100)
IgG, Baseline, n=81, 81	5 (2.5 to 100)	2.5 (2.5 to 100)
IgG, Week4, n=0, 1	NA (NA to NA) [1]	5 (5 to 5)
RF-IgM, Baseline, n=81, 81	92 (2.5 to 100)	68 (2.5 to 100)
RF-IgM, Week 4, n=0, 1	NA (NA to NA) [1]	43 (43 to 43)

[1] No participants were analyzed at this time point.

24. Secondary Outcome Measure:

Measure Title	Number of Participants With Positive Human Anti-human Antibodies (HAHA) at Week 24
Measure Description	Detection of human anti-human antibodies (HAHAs) against ofatumumab was to be performed by Electrochemiluminescent (ECL) Meso-Scale Discovery (MSD) immunoassay. Positive samples from the binding antibody test were also tested in a neutralizing antibody assay.
Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description

ITT Population. This trial was terminated prematurely due to the Sponsor's decision to not pursue clinical development of the IV formulation of ofatumumab in an autoimmune indication; thus, no participants were analyzed for this endpoint.

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	0	0

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

25. Secondary Outcome Measure:

Measure Title	Change From Baseline in Levels of IgA, IgG and IgM at Week 12 and Week 24
Measure Description	The following immunoglobulins were assessed: IgA, IgG and IgM. Immunoglobulins, or antibodies, are large proteins used by the immune system to identify and neutralize foreign particles such as bacteria and viruses. Their normal blood levels indicate proper immune status. Low levels indicate immuno-suppression.
Time Frame	Baseline, Week 12, and Week 24
Safety Issue?	No

Analysis Population Description

Safety Population: identical to the ITT population except that participants were analyzed according to their actual treatment when this differed from their randomized treatment. Only those participants contributing values at baseline and the relevant visit were analzyed.

Reporting Groups

	Description
Placebo	Placebo 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).
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	79	75
Change From Baseline in Levels of IgA, IgG and IgM at Week 12 and Week 24 [units: grams per Liter (g/L)] Median (Full Range)		
IgA, Week 12; n=79, 75	-0.020 (-1.72 to 1.47)	-0.250 (-2.32 to 0.65)
IgA, Week 24; n=69, 68	0.050 (-1.51 to 1.47)	-0.350 (-2.58 to 0.81)
IgG, Week 12; n=79, 75	-0.400 (-7.30 to 7.20)	-1.300 (-7.60 to 2.10)
IgG, Week 24; n=69, 68	-0.700 (-8.30 to 8.30)	-1.615 (-9.70 to 4.80)
IgM, Week 12; n=79, 75	-0.040 (-1.58 to 0.75)	-0.260 (-2.92 to 0.17)
IgM, Week 24; n=69, 68	-0.050 (-1.30 to 1.47)	-0.355 (-4.12 to 0.40)

26. Secondary Outcome Measure:

Measure Title	Minimum DAS28-ESR 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 (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

Reporting Groups

	Description
Placebo	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	148	0
Minimum DAS28-ESR Score During the DB and OL Periods, by Ofatumumab Treatment Course [units: Scores on a scale] Mean (Standard Deviation)			
TC 1, n=0, 148, 0		4.64 (1.511)	
TC 2, n=0, 92, 0		4.08 (1.129)	
TC 3, n=0, 62, 0		4.09 (1.346)	
TC 4, n=0, 29, 0		3.84 (1.437)	
TC 5, n=0, 13, 0		3.95 (1.327)	
TC 6, n=0, 6, 0		3.33 (1.245)	

27. 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

Reporting Groups

	Description
Placebo	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	147	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, 147, 0		3.86 (1.443)	
TC 2, n=0, 92, 0		3.37 (1.120)	
TC 3, n=0, 62, 0		3.35 (1.181)	
TC 4, n=0, 29, 0		3.15 (1.214)	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 5, n=0, 13, 0		3.23 (1.129)	
TC 6, n=0, 6, 0		2.84 (1.193)	

28. Secondary Outcome Measure:

Measure Title	Minimum Change From Baseline 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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	134	0

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Minimum Change From Baseline DAS28-ESR Score, During the DB and OL Periods, by Ofatumumab Treatment Course [units: scores on a scale] Mean (Standard Deviation)			
TC 1, n=0, 134, 0		-2.04 (1.348)	
TC 2, n=0, 90, 0		-1.70 (1.090)	
TC 3, n=0, 59, 0		-1.52 (1.052)	
TC 4, n=0, 28, 0		-1.76 (1.499)	
TC 5, n=0, 12, 0		-1.50 (1.052)	
TC 6, n=0, 6, 0		-2.39 (0.581)	

29. Secondary Outcome Measure:

Measure Title	Minimum Change From Baseline 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	

	Description
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	134	0
Minimum Change From Baseline 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, 134, 0		-1.93 (1.297)	
TC 2, n=0, 92, 0		-1.65 (1.086)	
TC 3, n=0, 61, 0		-1.44 (1.006)	
TC 4, n=0, 28, 0		-1.65 (1.378)	
TC 5, n=0, 12, 0		-1.46 (1.006)	
TC 6, n=0, 6, 0		-2.20 (0.610)	

30. 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 contributing values at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	93	0
Time to Retreatment, by Ofatumumab Treatment Course [units: Days] Mean (Standard Deviation)			
TC 1, n=0, 93, 0		32.79 (12.031)	
TC 2, n=0, 63, 0		28.62 (11.108)	
TC 3, n=0, 30, 0		24.56 (8.127)	
TC 4, n=0, 13, 0		23.93 (6.143)	
TC 5, n=0, 6, 0		19.07 (2.795)	
TC 6, n=0, 0, 0		NA (NA) [1]	

[1] No participants were analyzed in this treatment group for Treatment Course 6.

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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	148	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]			
TC 1, Remission, n=0, 148, 0		15	
TC 1, Low Disease Activity, n=0, 148		7	
TC 2, Remission, n=0, 93, 0		5	
TC 2, Low Disease Activity, n=0, 93, 0		20	
TC 3, Remission, n=0, 63, 0		8	
TC 3, Low Disease Activity, n=0, 63, 0		8	
TC 4, Remission, n=0, 30, 0		6	
TC 4, Low Disease Activity, n=0, 30, 0		5	
TC 5, Remission, n=0, 13, 0		2	
TC 5, Low Disease Activity, n=0, 13, 0		2	
TC 6, Remission, n=0, 6, 0		2	
TC 6, Low Disease Activity, n=0, 6, 0		2	

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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	148	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, 148, 0		27	
TC 1, Low Disease Activity, n=0, 148, 0		26	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 2, Remission, n=0, 93, 0		24	
TC 2, Low Disease Activity, n=0, 93, 0		17	
TC 3, Remission, n=0, 63, 0		19	
TC 3, Low Disease Activity, n=0, 63, 0		10	
TC 4, Remission, n=0, 30, 0		10	
TC 4, Low Disease Activity, n=0, 30, 0		5	
TC 5, Remission,n=0, 13, 0		5	
TC 5, Low Disease Activity,n=0, 13, 0		1	
TC 6, Remission,n=0, 6, 0		3	
TC 6, Low Disease Activity,n=0, 6, 0		2	

33. 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	
Ofatumumab 700 mg	

	Description
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	148	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, 148, 0		126	
Any AE, TC 2, n=0, 93, 0		60	
Any AE, TC 3, n=0, 63, 0		36	
Any AE, TC 4, n=0, 30, 0		17	
Any AE, TC 5, n=0, 13, 0		8	
Any AE, TC 6, n=0, 6, 0		5	
Any SAE, TC 1, n=0, 148, 0		20	
Any SAE, TC 2, n=0, 93, 0		10	
Any SAE, TC 3, n=0, 63, 0		2	
Any SAE, TC 4, n=0, 30, 0		0	
Any SAE, TC 5, n=0, 13, 0		0	
Any SAE, TC 6, n=0, 6, 0		0	

34. 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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	117	0
Number of Participants With the Indicated Electrocardiogram (ECG) Findings, During the OL Period [units: Participants]			
Week 48, normal, n=0, 117, 0		81	
Week 48, abnormal CS, n=0, 117, 0		0	
Week 48, abnormal NCS, n=0, 117, 0		34	
Week 48, NR, n=0, 117, 0		2	
Week 72, normal, n=0, 87, 0		59	
Week 72, abnormal CS, n=0, 87, 0		0	
Week 72, abnormal NCS, n=0, 87, 0		25	
Week 72, NR, n=0, 87, 0		3	
Week 96, normal, n=0, 57, 0		40	
Week 96, abnormal CS, n=0, 57, 0		0	
Week 96, abnormal NCS, n=0, 57, 0		16	
Week 96, NR, n=0, 57, 0		1	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Week 120, normal, n=0, 33, 0		16	
Week 120, abnormal CS, n=0, 33, 0		0	
Week 120, abnormal NCS, n=0, 33, 0		17	
Week 120, NR, n=0, 33, 0		0	
Week 144, normal, n=0, 17, 0		10	
Week 144, abnormal CS, n=0, 17, 0		0	
Week 144, abnormal NCS, n=0, 17, 0		7	
Week 144, NR, n=0, 17, 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 Indicated the 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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	136	0
Number of Participants With a CD19+ Cell Count Greater Than or Equal to the Lower Limit of Normal or the Baseline Value at Indicated the Time Point, During the DB and OL Periods, by Ofatumumab Treatment Course [units: Participants]			
TC 1, Week 8, n=0, 136, 0		0	
TC 1, Week 16, n=0, 100, 0		0	
TC 1, Week 24, n=0, 99, 0		2	
TC 1, Week 32, n=0, 50, 0		1	
TC 1, Week 40, n=0, 30, 0		3	
TC 1, Week 48, n=0, 23, 0		1	
TC 1, Week 56, n=0, 14, 0		3	
TC 1, Week 64, n=0, 7, 0		1	
TC 1, Week 72, n=0, 4, 0		0	
TC 1, Week 80, n=0, 1, 0		0	
TC 1, Week 88, n=0, 1, 0		0	
TC 1, Week 96, n=0, 1, 0		0	
TC 1, Week 104, n=0, 2, 0		1	
TC 1, Week 112, n=0, 1, 0		0	
TC 1, Week 120, n=0, 1, 0		0	
TC 1, Week 128, n=0, 1, 0		0	
TC 1, Week 144, n=0, 1, 0		0	
TC 2, Week 8, n=0, 93, 0		0	
TC 2, Week 16, n=0, 80, 0		1	
TC 2, Week 24, n=0, 70, 0		0	
TC 2, Week 32, n=0, 31, 0		2	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 2, Week 40, n=0, 20, 0		2	
TC 2, Week 48, n=0, 11, 0		1	
TC 2, Week 56, n=0, 8, 0		0	
TC 2, Week 64, n=0, 6, 0		1	
TC 2, Week 72, n=0, 2, 0		0	
TC 2, Week 80, n=0, 2, 0		0	
TC 2, Week 96, n=0, 1, 0		0	
TC 3, Week 8, n=0, 60, 0		0	
TC 3, Week 16, n=0, 45, 0		0	
TC 3, Week 24, n=0, 29, 0		0	
TC 3, Week 32, n=0, 12, 0		1	
TC 3, Week 40, n=0, 4, 0		0	
TC 3, Week 48, n=0, 2, 0		1	
TC 3, Week 56, n=0, 1, 0		1	
TC 4, Week 8, n=0, 29, 0		0	
TC 4, Week 16, n=0, 24, 0		0	
TC 4, Week 24, n=0, 13, 0		0	
TC 4, Week 32, n=0, 4, 0		0	
TC 4, Week 40, n=0, 1, 0		0	
TC 4, Week 48, n=0, 1, 0		0	
TC 5, Week 8, n=0, 13, 0		0	
TC 5, Week 16, n=0, 8, 0		0	
TC 5, Week 24, n=0, 5, 0		0	
TC 5, Week 32, n=0, 5, 0		0	
TC 5, Week 40, n=0, 1, 0		0	
TC 6, Week 8, n=0, 6, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 6, Week 16, n=0, 6, 0		0	
TC 6, Week 24, n=0, 5, 0		0	
TC 6, Week 32, n=0, 3, 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 gill 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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	136	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]			

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 1, Week 8, n=0, 136, 0		115	
TC 1, Week 16, n=0, 100, 0		79	
TC 1, Week 24, n=0, 99, 0		75	
TC 1, Week 32, n=0, 50, 0		44	
TC 1, Week 40, n=0, 30, 0		27	
TC 1, Week 48, n=0, 23, 0		21	
TC 1, Week 56, n=0, 14, 0		11	
TC 1, Week 64, n=0, 7, 0		7	
TC 1, Week 72, n=0, 4, 0		4	
TC 1, Week 80, n=0, 1, 0		1	
TC 1, Week 88, n=0, 1, 0		1	
TC 1, Week 96, n=0, 1, 0		1	
TC 1, Week 104, n=0, 2, 0		2	
TC 1, Week 112, n=0, 1, 0		1	
TC 1, Week 120, n=0, 1, 0		1	
TC 1, Week 128, n=0, 1, 0		1	
TC 1, Week 144, n=0, 1, 0		1	
TC 2, Week 8, n=0, 93, 0		78	
TC 2, Week 16, n=0, 80, 0		70	
TC 2, Week 24, n=0, 70, 0		58	
TC 2, Week 32, n=0, 31, 0		29	
TC 2, Week 40, n=0, 20, 0		16	
TC 2, Week 48, n=0, 11, 0		9	
TC 2, Week 56, n=0, 8, 0		7	
TC 2, Week 64, n=0, 6, 0		4	
TC 2, Week 72, n=0, 2, 0		2	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 2, Week 80, n=0, 2, 0		2	
TC 2, Week 96, n=0, 1, 0		1	
TC 3, Week 8, n=0, 60, 0		49	
TC 3, Week 16, n=0, 45, 0		36	
TC 3, Week 24, n=0, 29, 0		22	
TC 3, Week 32, n=0, 12, 0		10	
TC 3, Week 40, n=0, 4, 0		2	
TC 3, Week 48, n=0, 2, 0		1	
TC 3, Week 56, n=0, 1, 0		1	
TC 4, Week 8, n=0, 29, 0		24	
TC 4, Week 16, n=0, 24, 0		20	
TC 4, Week 24, n=0, 13, 0		11	
TC 4, Week 32, n=0, 4, 0		3	
TC 4, Week 40, n=0, 1, 0		1	
TC 4, Week 48, n=0, 1, 0		1	
TC 5, Week 8, n=0, 13, 0		10	
TC 5, Week 16, n=0, 8, 0		7	
TC 5, Week 24, n=0, 5, 0		4	
TC 5, Week 32, n=0, 5, 0		4	
TC 5, Week 40, n=0, 1, 0		1	
TC 6, Week 8, n=0, 6, 0		5	
TC 6, Week 16, n=0, 6, 0		5	
TC 6, Week 24, n=0, 5, 0		5	
TC 6, Week 32, n=0, 3, 0		3	

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 gill 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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	136	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, 136, 0		118	
TC 1, Week 16, n=0, 100, 0		83	
TC 1, Week 24, n=0, 99, 0		80	
TC 1, Week 32, n=0, 50, 0		45	
TC 1, Week 40, n=0, 30, 0		27	
TC 1, Week 48, n=0, 23, 0		21	
TC 1, Week 56, n=0, 14, 0		13	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 1, Week 64, n=0, 7, 0		7	
TC 1, Week 72, n=0, 4, 0		4	
TC 1, Week 80, n=0, 1, 0		1	
TC 1, Week 88, n=0, 1, 0		1	
TC 1, Week 96, n=0, 1, 0		1	
TC 1, Week 104, n=0, 2, 0		2	
TC 1, Week 112, n=0, 1, 0		1	
TC 1, Week 120, n=0, 1, 0		1	
TC 1, Week 128, n=0, 1, 0		1	
TC 1, Week 144, n=0, 1, 0		1	
TC 2, Week 8, n=0, 93, 0		81	
TC 2, Week 16, n=0, 80, 0		67	
TC 2, Week 24, n=0, 70, 0		62	
TC 2, Week 32, n=0, 31, 0		29	
TC 2, Week 40, n=0, 20, 0		16	
TC 2, Week 48, n=0, 11, 0		9	
TC 2, Week 56, n=0, 8, 0		7	
TC 2, Week 64, n=0, 6, 0		4	
TC 2, Week 72, n=0, 2, 0		2	
TC 2, Week 80, n=0, 2, 0		2	
TC 2, Week 96, n=0, 1, 0		1	
TC 3, Week 8, n=0, 60, 0		49	
TC 3, Week 16, n=0, 45, 0		36	
TC 3, Week 24, n=0, 29, 0		23	
TC 3, Week 32, n=0, 12, 0		11	
TC 3, Week 40, n=0, 4, 0		3	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 3, Week 48, n=0, 2, 0		2	
TC 3, Week 56, n=0, 1, 0		1	
TC 4, Week 8, n=0, 29, 0		26	
TC 4, Week 16, n=0, 24, 0		20	
TC 4, Week 24, n=0, 13, 0		11	
TC 4, Week 32, n=0, 4, 0		3	
TC 4, Week 40, n=0, 1, 0		1	
TC 4, Week 48, n=0, 1		1	
TC 5, Week 8, n=0, 13, 0		12	
TC 5, Week 16, n=0, 8, 0		8	
TC 5, Week 24, n=0, 5, 0		5	
TC 5, Week 32, n=0, 5, 0		5	
TC 5, Week 40, n=0, 1, 0		1	
TC 6, Week 8, n=0, 6, 0		5	
TC 6, Week 16, n=0, 6, 0		6	
TC 6, Week 24, n=0, 5, 0		5	
TC 6, Week 32, n=0, 3, 0		3	

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 gill 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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	136	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, 136, 0		121	
TC 1, Week 16, n=0, 100, 0		86	
TC 1, Week 24, n=0, 99, 0		87	
TC 1, Week 32, n=0, 50, 0		47	
TC 1, Week 40, n=0, 30, 0		27	
TC 1, Week 48, n=0, 23, 0		20	
TC 1, Week 56, n=0, 14, 0		13	
TC 1, Week 64, n=0, 7, 0		7	
TC 1, Week 72, n=0, 4, 0		4	
TC 1, Week 80, n=0, 1, 0		1	
TC 1, Week 88, n=0, 1, 0		1	
TC 1, Week 96, n=0, 1, 0		1	
TC 1, Week 104, n=0, 2, 0		2	
TC 1, Week 112, n=0, 1, 0		1	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 1, Week 120, n=0, 1, 0		1	
TC 1, Week 128, n=0, 1, 0		1	
TC 1, Week 144, n=0, 1, 0		1	
TC 2, Week 8, n=0, 93, 0		82	
TC 2, Week 16, n=0, 80, 0		74	
TC 2, Week 24, n=0, 70, 0		63	
TC 2, Week 32, n=0, 31, 0		29	
TC 2, Week 40, n=0, 20, 0		19	
TC 2, Week 48, n=0, 11, 0		11	
TC 2, Week 56, n=0, 8, 0		7	
TC 2, Week 64, n=0, 6, 0		5	
TC 2, Week 72, n=0, 2, 0		2	
TC 2, Week 80, n=0, 2, 0		2	
TC 2, Week 96, n=0, 1, 0		1	
TC 3, Week 8, n=0, 60, 0		54	
TC 3, Week 16, n=0, 45, 0		43	
TC 3, Week 24, n=0, 29, 0		24	
TC 3, Week 32, n=0, 12, 0		12	
TC 3, Week 40, n=0, 4, 0		3	
TC 3, Week 48, n=0, 2, 0		1	
TC 3, Week 56, n=0, 1, 0		1	
TC 4, Week 8, n=0, 29, 0		26	
TC 4, Week 16, n=0, 24, 0		23	
TC 4, Week 24, n=0, 13, 0		13	
TC 4, Week 32, n=0, 4, 0		4	
TC 4, Week 40, n=0, 1, 0		1	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 4, Week 48, n=0, 1, 0		1	
TC 5, Week 8, n=0, 13, 0		13	
TC 5, Week 16, n=0, 8, 0		8	
TC 5, Week 24, n=0, 5, 0		5	
TC 5, Week 32, n=0, 5, 0		5	
TC 5, Week 40, n=0, 1, 0		1	
TC 6, Week 8, n=0, 6, 0		5	
TC 6, Week 16, n=0, 6, 0		5	
TC 6, Week 24, n=0, 5, 0		5	
TC 6, Week 32, n=0, 3, 0		2	

39. 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. The baseline (BL) value for a treatment course is defined as the latest value on or before the date of infusion A of the treatment course. The post-baseline (PBL) visit is defined as any visit after the date of infusion A during the specified treatment course. 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: 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, 1.2; Creatine kinase (CK): NA, 2; Creatinine: NA, 1.2; Gamma glutamyl transferase (GGT): NA, 2; Potassium: 0.9, 1.1; 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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	144	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, 144, 0		1	
Albumin, TC 1, PBL, CC low, n=0, 136, 0		1	
ALT, TC 1, BL, CC high, n=0, 144, 0		1	
ALT, TC 1, PBL, CC high, n=0, 136, 0		6	
ALP, TC 1, BL, CC high, n=0, 144, 0		0	
ALP, TC 1, PBL, CC high, n=0, 136, 0		4	
AST, TC 1, BL, CC high, n=0, 142, 0		0	
AST, TC 1, PBL, CC high, n=0, 136, 0		2	
TBIL, TC 1, BL, CC high, n=0, 144, 0		0	
TBIL, TC 1, PBL, CC high, n=0, 136, 0		0	
Calcium, TC 1, BL, CC low, n=0, 142, 0		0	
Calcium, TC 1, PBL, CC low, n=0, 136, 0		2	
Calcium, TC 1, BL, CC high, n=0, 142, 0		0	
Calcium, TC 1, PBL, CC high, n=0, 136, 0		0	
CO2/BCO, TC 1, BL, CC low, n=0, 142, 0		5	
CO2/BCO, TC 1, PBL, CC low, n=0, 136, 0		9	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
CK, TC 1, BL, CC high, n=0, 144, 0		0	
CK, TC 1, PBL, CC high, n=0, 136, 0		1	
Creatinine, TC 1, BL, CC high, n=0, 144, 0		0	
Creatinine, TC 1,PBL, CC high, n=0, 136, 0		1	
GGT, TC 1, BL, CC high, n=0, 144, 0		7	
GGT, TC 1, PBL, CC high, n=0, 136, 0		8	
Potassium, TC 1, BL, CC high, n=0, 142, 0		2	
Potassium, TC 1, PBL, CC high, n=0, 136, 0		0	
Potassium, TC 1, BL, CC low, n=0, 142, 0		1	
Potassium, TC 1, PBL, CC low, n=0, 136, 0		1	
Urea/BUN, TC 1, BL, CC high, n=0, 144, 0		2	
Urea/BUN, TC 1, PBL, CC high, n=0, 136, 0		3	
Uric acid, TC 1, BL, CC high, n=0, 144, 0		0	
Uric acid, TC 1, PBL, CC high, n=0, 136, 0		0	
Albumin, TC 2, BL, CC low, n=0, 85, 0		0	
Albumin, TC 2, PBL, CC low, n=0, 92, 0		0	
ALT, TC 2, BL, CC high, n=0, 85, 0		1	
ALT, TC 2, PBL, CC high, n=0, 92, 0		5	
ALP, TC 2, BL, CC high, n=0, 85, 0		0	
ALP, TC 2, PBL, CC high, n=0, 92, 0		1	
AST, TC 2, BL, CC high, n=0, 85, 0		1	
AST, TC 2, PBL, CC high, n=0, 92, 0		2	
TBIL, TC 2, BL, CC high, n=0, 85, 0		0	
TBIL, TC 2, PBL, CC high, n=0, 92, 0		0	
Calcium, TC 2, BL, CC low, n=0, 85, 0		0	
Calcium, TC 2, PBL, CC low, n=0, 92, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Calcium, TC 2, BL, CC high, n=0, 85, 0		0	
Calcium, TC 2, PBL, CC high, n=0, 92, 0		1	
CO2/BCO, TC 2, BL, CC low, n=0, 85, 0		1	
CO2/BCO, TC 2, PBL, CC low, n=0, 92		7	
CK, TC 2, BL, CC high, n=0, 85, 0		0	
CK, TC 2, PBL, CC high, n=0, 92, 0		0	
Creatinine, TC 2, BL, CC high, n=0, 85, 0		0	
Creatinine, TC 2,PBL, CC high, n=0, 92, 0		0	
GGT, TC 2, BL, CC high, n=0, 85, 0		3	
GGT, TC 2, PBL, CC high, n=0, 92, 0		3	
Potassium, TC 2, BL, CC high, n=0, 85, 0		1	
Potassium, TC 2, PBL, CC high, n=0, 92, 0		0	
Potassium, TC 2, BL, CC low, n=0, 85, 0		0	
Potassium, TC 2, PBL, CC low, n=0, 92, 0		0	
Urea/BUN, TC 2, BL, CC high, n=0, 85, 0		1	
Urea/BUN, TC 2, PBL, CC high, n=0, 92, 0		3	
Uric acid, TC 2, BL, CC high, n=0, 85, 0		0	
Uric acid, TC 2, PBL, CC high, n=0, 92, 0		1	
Albumin, TC 3, BL, CC low, n=0, 57, 0		0	
Albumin, TC 3, PBL, CC low, n=0, 62, 0		1	
ALT, TC 3, BL, CC high, n=0, 57, 0		1	
ALT, TC 3, PBL, CC high, n=0, 62, 0		1	
ALP, TC 3, BL, CC high, n=0, 57, 0		0	
ALP, TC 3, PBL, CC high, n=0, 62, 0		1	
AST, TC 3, BL, CC high, n=0, 57, 0		1	
AST, TC 3, PBL, CC high, n=0, 62, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TBIL, TC 3, BL, CC high, n=0, 57, 0		0	
TBIL, TC 3, PBL, CC high, n=0, 62, 0		0	
Calcium, TC 3, BL, CC low, n=0, 57, 0		0	
Calcium, TC 3, PBL, CC low, n=0, 62, 0		0	
Calcium, TC 3, BL, CC high, n=0, 57, 0		1	
Calcium, TC 3, PBL, CC high, n=0, 62, 0		1	
CO2/BCO, TC 3, BL, CC low, n=0, 57, 0		0	
CO2/BCO, TC 3, PBL, CC low, n=0, 62, 0		2	
CK, TC 3, BL, CC high, n=0, 57, 0		0	
CK, TC 3, PBL, CC high, n=0, 62, 0		0	
Creatinine, TC 3, BL, CC high, n=0, 57, 0		0	
Creatinine, TC 3,PBL, CC high, n=0, 62, 0		0	
GGT, TC 3, BL, CC high, n=0, 57, 0		0	
GGT, TC 3, PBL, CC high, n=0, 62, 0		3	
Potassium, TC 3, BL, CC high, n=0, 57, 0		0	
Potassium, TC 3, PBL, CC high, n=0, 62, 0		0	
Potassium, TC 3, BL, CC low, n=0, 57, 0		0	
Potassium, TC 3, PBL, CC low, n=0, 62, 0		0	
Urea/BUN, TC 3, BL, CC high, n=0, 57, 0		0	
Urea/BUN, TC 3, PBL, CC high, n=0, 62, 0		0	
Uric acid, TC 3, BL, CC high, n=0, 57, 0		0	
Uric acid, TC 3, PBL, CC high, n=0, 62, 0		0	
Albumin, TC 4, BL, CC low, n=0, 28, 0		0	
Albumin, TC 4, PBL, CC low, n=0, 29, 0		0	
ALT, TC 4, BL, CC high, n=0, 28, 0		0	
ALT, TC 4, PBL, CC high, n=0, 29, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
ALP, TC 4, BL, CC high, n=0, 28, 0		1	
ALP, TC 4, PBL, CC high, n=0, 29, 0		1	
AST, TC 4, BL, CC high, n=0, 28, 0		0	
AST, TC 4, PBL, CC high, n=0, 29, 0		0	
TBIL, TC 4, BL, CC high, n=0, 28, 0		0	
TBIL, TC 4, PBL, CC high, n=0, 29, 0		1	
Calcium, TC 4, BL, CC low, n=0, 28, 0		0	
Calcium, TC 4, PBL, CC low, n=0, 29, 0		0	
Calcium, TC 4, BL, CC high, n=0, 28, 0		0	
Calcium, TC 4, PBL, CC high, n=0, 29, 0		0	
CO2/BCO, TC 4, BL, CC low, n=0, 28, 0		1	
CO2/BCO, TC 4, PBL, CC low, n=0, 29, 0		1	
CK, TC 4, BL, CC high, n=0, 28, 0		0	
CK, TC 4, PBL, CC high, n=0, 29, 0		0	
Creatinine, TC 4, BL, CC high, n=0, 28, 0		0	
Creatinine, TC 4,PBL, CC high, n=0, 29, 0		0	
GGT, TC 4, BL, CC high, n=0, 28, 0		2	
GGT, TC 4, PBL, CC high, n=0, 29, 0		1	
Potassium, TC 4, BL, CC high, n=0, 28, 0		0	
Potassium, TC 4, PBL, CC high, n=0, 29, 0		0	
Potassium, TC 4, BL, CC low, n=0, 28, 0		0	
Potassium, TC 4, PBL, CC low, n=0, 29, 0		0	
Urea/BUN, TC 4, BL, CC high, n=0, 28, 0		0	
Urea/BUN, TC 4, PBL, CC high, n=0, 29, 0		0	
Uric acid, TC 4, BL, CC high, n=0, 28, 0		0	
Uric acid, TC 4, PBL, CC high, n=0, 29, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Albumin, TC 5, BL, CC low, n=0, 12, 0		0	
Albumin, TC 5, PBL, CC low, n=0, 13, 0		0	
ALT, TC 5, BL, CC high, n=0, 12		0	
ALT, TC 5, PBL, CC high, n=0, 13, 0		0	
ALP, TC 5, BL, CC high, n=0, 12, 0		0	
ALP, TC 5, PBL, CC high, n=0, 13, 0		0	
AST, TC 5, BL, CC high, n=0, 12, 0		0	
AST, TC 5, PBL, CC high, n=0, 13, 0		0	
TBIL, TC 5, BL, CC high, n=0, 12, 0		0	
TBIL, TC 5, PBL, CC high, n=0, 13, 0		1	
Calcium, TC 5, BL, CC low, n=0, 12, 0		0	
Calcium, TC 5, PBL, CC low, n=0, 13, 0		0	
Calcium, TC 5, BL, CC high, n=0, 12, 0		0	
Calcium, TC 5, PBL, CC high, n=0, 13, 0		0	
CO2/BCO, TC 5, BL, CC low, n=0, 12, 0		0	
CO2/BCO, TC 5, PBL, CC low, n=0, 13, 0		1	
CK, TC 5, BL, CC high, n=0, 12, 0		0	
CK, TC 5, PBL, CC high, n=0, 13, 0		0	
Creatinine, TC 5, BL, CC high, n=0, 12, 0		0	
Creatinine, TC 5,PBL, CC high, n=0, 13, 0		0	
GGT, TC 5, BL, CC high, n=0, 12, 0		1	
GGT, TC 5, PBL, CC high, n=0, 13, 0		1	
Potassium, TC 5, BL, CC high, n=0, 12, 0		0	
Potassium, TC 5, PBL, CC high, n=0, 13, 0		0	
Potassium, TC 5, BL, CC low, n=0, 12, 0		0	
Potassium, TC 5, PBL, CC low, n=0, 13, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Urea/BUN, TC 5, BL, CC high, n=0, 12, 0		0	
Urea/BUN, TC 5, PBL, CC high, n=0, 13, 0		0	
Uric acid, TC 5, BL, CC high, n=0, 12, 0		0	
Uric acid, TC 5, PBL, CC high, n=0, 13, 0		0	
Albumin, TC 6, BL, CC low, n=0, 6, 0		0	
Albumin, TC 6, PBL, CC low, n=0, 6, 0		0	
ALT, TC 6, BL, CC high, n=0, 6, 0		0	
ALT, TC 6, PBL, CC high, n=0, 6, 0		0	
ALP, TC 6, BL, CC high, n=0, 6, 0		0	
ALP, TC 6, PBL, CC high, n=0, 6, 0		1	
AST, TC 6, BL, CC high, n=0, 6, 0		0	
AST, TC 6, PBL, CC high, n=0, 6, 0		0	
TBIL, TC 6, BL, CC high, n=0, 6, 0		1	
TBIL, TC 6, PBL, CC high, n=0, 6, 0		0	
Calcium, TC 6, BL, CC low, n=0, 6, 0		0	
Calcium, TC 6, PBL, CC low, n=0, 6, 0		0	
Calcium, TC 6, BL, CC high, n=0, 6, 0		0	
Calcium, TC 6, PBL, CC high, n=0, 6, 0		0	
CO2/BCO, TC 6, BL, CC low, n=0, 6, 0		0	
CO2/BCO, TC 6, PBL, CC low, n=0, 6, 0		0	
CK, TC 6, BL, CC high, n=0, 6, 0		0	
CK, TC 6, PBL, CC high, n=0, 6, 0		0	
Creatinine, TC , BL, CC high, n=0, 6, 0		0	
Creatinine, TC 6,PBL, CC high, n=0, 6, 0		0	
GGT, TC 6, BL, CC high, n=0, 6, 0		0	
GGT, TC 6, PBL, CC high, n=0, 6, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Potassium, TC 6, BL, CC high, n=0, 6, 0		0	
Potassium, TC 6, PBL, CC high, n=0, 6, 0		0	
Potassium, TC 6, BL, CC low, n=0, 6, 0		0	
Potassium, TC 6, PBL, CC low, n=0, 6, 0		0	
Urea/BUN, TC 6, BL, CC high, n=0, 6, 0		0	
Urea/BUN, TC 6, PBL, CC high, n=0, 6, 0		0	
Uric acid, TC 6, BL, CC high, n=0, 6, 0		0	
Uric acid, TC 6, PBL, CC high, n=0, 6, 0		0	

40. 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 is defined as the latest value on or before the date of infusion A of the treatment course. The post-baseline (PBL) visit is defined as any visit after the date of infusion A during the specified treatment course. 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; Monocytes: 0.2, 5 2; Neutrophils total (TNUE): 0.8, 1.6; Platelet count (PC): 0.65, 1.5; Red blood cell count (RBC): 0.7, 5 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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	143	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, 143, 0		1	
Eosinophils, TC 1,PBL,CC high, n=0, 136, 0		1	
HCT, TC 1, BL, CC low, n=0, 143, 0		0	
HCT, TC 1, PBL, CC low, n=0, 136, 0		1	
Hb, TC 1, BL, CC low, n=0, 143, 0		1	
Hb, TC 1, PBL, CC low, n=0, 136, 0		5	
Monocytes, TC 1, BL, CC low, n=0, 143, 0		2	
Monocytes, TC 1, PBL, CC low, n=0, 136, 0		13	
Monocytes, TC 1, BL, CC high, n=0, 143, 0		0	
Monocytes, TC 1, PBL, CC high, n=0, 136, 0		0	
PC, TC 1, BL, CC low, n=0, 141, 0		0	
PC, TC 1, PBL, CC low, n=0, 136, 0		0	
PC, TC 1, BL, CC high, n=0, 141, 0		0	
PC, TC 1, PBL, CC high, n=0, 136, 0		1	
RBC count, TC 1, BL, CC low, n=0, 143, 0		1	
RBC count, TC 1, PBL, CC low, n=0, 136, 0		2	
TNUE, TC 1, BL, CC low, n=0, 142, 0		0	
TNUE, TC 1, PBL, CC low, n=0, 136, 0		0	
TNUE, TC 1, BL, CC high, n=0, 142, 0		0	
TNUE, TC 1,PBL, CC high, n=0, 136, 0		3	
WBC count, TC 1, BL, CC low, n=0, 143, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
WBC count, TC 1, PBL, CC low, n=0, 136, 0		0	
WBC count, TC 1, BL, CC high, n=0, 143, 0		0	
WBC count, TC 1, PBL, CC high, n=0, 136, 0		1	
Eosinophils, TC 2, BL,CC high, n=0, 85, 0		0	
Eosinophils, TC 2,PBL,CC high, n=0, 93, 0		0	
HCT, TC 2, BL, CC low, n=0, 85, 0		0	
HCT, TC 2, PBL, CC low, n=0, 93, 0		0	
Hb, TC 2, BL, CC low, n=0, 85, 0		1	
Hb, TC 2, PBL, CC low, n=0, 93, 0		1	
Monocytes, TC 2, BL, CC low, n=0, 85, 0		2	
Monocytes, TC 2, PBL, CC low, n=0, 93, 0		1	
Monocytes, TC 2, BL, CC high, n=0, 85, 0		0	
Monocytes, TC 2, PBL, CC high, n=0, 93, 0		1	
PC, TC 2, BL, CC low, n=0, 84, 0		0	
PC, TC 2, PBL, CC low, n=0, 93, 0		1	
PC, TC 2, BL, CC high, n=0, 84, 0		0	
PC, TC 2, PBL, CC high, n=0, 93, 0		0	
RBC count, TC 2, BL, CC low, n=0, 85, 0		1	
RBC count, TC 2, PBL, CC low, n=0, 93, 0		1	
TNUE, TC 2, BL, CC low, n=0, 85, 0		0	
TNUE, TC 2, PBL, CC low, n=0, 92, 0		1	
TNUE, TC 2, BL, CC high, n=0, 85, 0		1	
TNUE, TC 2,PBL, CC high, n=0, 92, 0		0	
WBC count, TC 2, BL, CC low, n=0, 85, 0		0	
WBC count, TC 2, PBL, CC low, n=0, 93, 0		1	
WBC count, TC 2, BL, CC high, n=0, 85, 0		1	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
WBC count, TC 2, PBL, CC high, n=0, 93, 0		0	
Eosinophils, TC 3, BL,CC high, n=0, 58, 0		0	
Eosinophils, TC 3,PBL,CC high, n=0, 62, 0		0	
HCT, TC 3, BL, CC low, n=0, 58, 0		0	
HCT, TC 3, PBL, CC low, n=0, 62, 0		0	
Hb, TC 3, BL, CC low, n=0, 58, 0		0	
Hb, TC 3, PBL, CC low, n=0, 62, 0		1	
Monocytes, TC 3, BL, CC low, n=0, 58, 0		1	
Monocytes, TC 3, PBL, CC low, n=0, 62, 0		3	
Monocytes, TC 3, BL, CC high, n=0, 58, 0		0	
Monocytes, TC 3, PBL, CC high, n=0, 62, 0		0	
PC, TC 3, BL, CC low, n=0, 57, 0		1	
PC, TC 3, PBL, CC low, n=0, 62, 0		1	
PC, TC 3, BL, CC high, n=0, 57, 0		0	
PC, TC 3, PBL, CC high, n=0, 62, 0		0	
RBC count, TC 3, BL, CC low, n=0, 58, 0		0	
RBC count, TC 3, PBL, CC low, n=0, 62, 0		0	
TNUE, TC 3, BL, CC low, n=0, 57, 0		0	
TNUE, TC 3, PBL, CC low, n=0, 60, 0		0	
TNUE, TC 3, BL, CC high, n=0, 57, 0		0	
TNUE, TC 3,PBL, CC high, n=0, 60, 0		0	
WBC count, TC 3, BL, CC low, n=0, 58, 0		0	
WBC count, TC 3, PBL, CC low, n=0, 62, 0		0	
WBC count, TC 3, BL, CC high, n=0, 58, 0		0	
WBC count, TC 4, PBL, CC high, n=0, 62, 0		0	
Eosinophils, TC 4, BL,CC high, n=0, 28, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Eosinophils, TC 4,PBL,CC high, n=0, 29, 0		0	
HCT, TC 4, BL, CC low, n=0, 28, 0		0	
HCT, TC 4, PBL, CC low, n=0, 29, 0		0	
Hb, TC 4, BL, CC low, n=0, 28, 0		1	
Hb, TC 1, PBL, CC low, n=0, 29, 0		0	
Monocytes, TC 4, BL, CC low, n=0, 28, 0		1	
Monocytes, TC 4, PBL, CC low, n=0, 29, 0		0	
Monocytes, TC 4, BL, CC high, n=0, 28, 0		0	
Monocytes, TC 4, PBL, CC high, n=0, 29, 0		0	
PC, TC 4, BL, CC low, n=0, 28, 0		0	
PC, TC 4, PBL, CC low, n=0, 29, 0		0	
PC, TC 4, BL, CC high, n=0, 28, 0		0	
PC, TC 4, PBL, CC high, n=0, 29, 0		0	
RBC count, TC 4, BL, CC low, n=0, 28, 0		1	
RBC count, TC 4, PBL, CC low, n=0, 29, 0		0	
TNUE, TC 4, BL, CC low, n=0, 26, 0		0	
TNUE, TC 4, PBL, CC low, n=0, 28, 0		0	
TNUE, TC 4, BL, CC high, n=0, 26, 0		0	
TNUE, TC 4,PBL, CC high, n=0, 28, 0		0	
WBC count, TC 4, BL, CC low, n=0, 28, 0		0	
WBC count, TC 4, PBL, CC low, n=0, 29, 0		0	
WBC count, TC 4, BL, CC high, n=0, 28, 0		0	
WBC count, TC 4, PBL, CC high, n=0, 29, 0		0	
Eosinophils, TC 5, BL,CC high, n=0, 12, 0		0	
Eosinophils, TC 5,PBL,CC high, n=0, 13, 0		0	
HCT, TC 5, BL, CC low, n=0, 12, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
HCT, TC 5, PBL, CC low, n=0, 13, 0		0	
Hb, TC 5, BL, CC low, n=0, 12		0	
Hb, TC 5, PBL, CC low, n=0, 13, 0		0	
Monocytes, TC 5, BL, CC low, n=0, 12, 0		0	
Monocytes, TC 5, PBL, CC low, n=0, 13, 0		0	
Monocytes, TC 5, BL, CC high, n=0, 12, 0		0	
Monocytes, TC 5, PBL, CC high, n=0, 13, 0		0	
PC, TC 5, BL, CC low, n=0, 12, 0		0	
PC, TC 5, PBL, CC low, n=0, 13, 0		0	
PC, TC 5, BL, CC high, n=0, 12, 0		0	
PC, TC 5, PBL, CC high, n=0, 13, 0		0	
RBC count, TC 5, BL, CC low, n=0, 12, 0		0	
RBC count, TC 5, PBL, CC low, n=0, 13, 0		0	
TNUE, TC 5, BL, CC low, n=0, 11, 0		0	
TNUE, TC 5, PBL, CC low, n=0, 13		0	
TNUE, TC 5, BL, CC high, n=0, 11		0	
TNUE, TC 5,PBL, CC high, n=0, 13, 0		0	
WBC count, TC 5, BL, CC low, n=0, 12, 0		0	
WBC count, TC 5, PBL, CC low, n=0, 13, 0		0	
WBC count, TC 5, BL, CC high, n=0, 12, 0		0	
WBC count, TC 5, PBL, CC high, n=0, 13, 0		0	
Eosinophils, TC 6, BL,CC high, n=0, 6, 0		0	
Eosinophils, TC 6,PBL,CC high, n=0, 6, 0		0	
HCT, TC 6, BL, CC low, n=0, 6, 0		0	
HCT, TC 6, PBL, CC low, n=0, 6, 0		0	
Hb, TC 6, BL, CC low, n=0, 6, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Hb, TC 6, PBL, CC low, n=0, 6, 0		0	
Monocytes, TC 6, BL, CC low, n=0, 6, 0		0	
Monocytes, TC 6, PBL, CC low, n=0, 6, 0		0	
Monocytes, TC 6, BL, CC high, n=0, 6, 0		0	
Monocytes, TC 6, PBL, CC high, n=0, 6, 0		0	
PC, TC 6, BL, CC low, n=0, 6, 0		0	
PC, TC 6, PBL, CC low, n=0, 6, 0		0	
PC, TC 6, BL, CC high, n=0, 6, 0		0	
PC, TC 6, PBL, CC high, n=0, 6, 0		0	
RBC count, TC 6, BL, CC low, n=0, 6, 0		0	
RBC count, TC 6, PBL, CC low, n=0, 6, 0		0	
TNUE, TC 6, BL, CC low, n=0, 6, 0		0	
TNUE, TC 6, PBL, CC low, n=0, 6, 0		0	
TNUE, TC 6, BL, CC high, n=0, 6, 0		0	
TNUE, TC 6,PBL, CC high, n=0, 6, 0		0	
WBC count, TC 6, BL, CC low, n=0, 6, 0		0	
WBC count, TC 6, PBL, CC low, n=0, 6, 0		0	
WBC count, TC 6, BL, CC high, n=0, 6, 0		0	
WBC count, TC 6, PBL, CC high, n=0, 6, 0		0	

41. 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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	148	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, 148, 0		0	
DBP, TC 1, PBL, <LLN, n=0, 148, 0		2	
DBP, TC 1, BL, >ULN, n=0, 148, 0		0	
DBP, TC 1, PBL, >ULN, n=0, 148, 0		1	
SBP, TC 1, BL, <LLN, n=0, 148, 0		0	
SBP, TC 1, PBL, <LLN, n=0, 148, 0		7	
SBP, TC 1, BL, >ULN, n=0, 148, 0		0	
SBP, TC 1, PBL, >ULN, n=0, 148, 0		7	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
HR, TC 1, BL, <LLN, n=0, 148, 0		0	
HR, TC 1, PBL, <LLN, n=0, 148, 0		0	
HR, TC 1, BL, >ULN, n=0, 148, 0		0	
HR, TC 1, PBL, >ULN, n=0, 148, 0		1	
DBP, TC 2, BL, <LLN, n=0, 93, 0		0	
DBP, TC 2, PBL, <LLN, n=0, 93, 0		0	
DBP, TC 2, BL, >ULN, n=0, 93, 0		0	
DBP, TC 2, PBL, >ULN, n=0, 93, 0		0	
SBP, TC 2, BL, <LLN, n=0, 93, 0		0	
SBP, TC 2, PBL, <LLN, n=0, 93, 0		3	
SBP, TC 2, BL, >ULN, n=0, 93, 0		0	
SBP, TC 2, PBL, >ULN, n=0, 93, 0		6	
HR, TC 2, BL, <LLN, n=0, 93, 0		0	
HR, TC 2, PBL, <LLN, n=0, 93, 0		0	
HR, TC 2, BL, >ULN, n=0, 93, 0		0	
HR, TC 2, PBL, >ULN, n=0, 93, 0		1	
DBP, TC 3, BL, <LLN, n=0, 62, 0		0	
DBP, TC 3, PBL, <LLN, n=0, 63, 0		0	
DBP, TC 3, BL, >ULN, n=0, 62, 0		0	
DBP, TC 3, PBL, >ULN, n=0, 63, 0		0	
SBP, TC 3, BL, <LLN, n=0, 62, 0		0	
SBP, TC 3, PBL, <LLN, n=0, 63, 0		0	
SBP, TC 3, BL, >ULN, n=0, 62, 0		0	
SBP, TC 3, PBL, >ULN, n=0, 63, 0		0	
HR, TC 3, BL, <LLN, n=0, 62, 0		0	
HR, TC 3, PBL, <LLN, n=0, 63, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
HR, TC 3, BL, >ULN, n=0, 62, 0		0	
HR, TC 3, PBL, >ULN, n=0, 63, 0		0	
DBP, TC 4, BL, <LLN, n=0, 29, 0		0	
DBP, TC 4, PBL, <LLN, n=0, 30, 0		0	
DBP, TC 4, BL, >ULN, n=0, 29, 0		0	
DBP, TC 4, PBL, >ULN, n=0, 30, 0		0	
SBP, TC 4, BL, <LLN, n=0, 29, 0		0	
SBP, TC 4, PBL, <LLN, n=0, 30, 0		2	
SBP, TC 4, BL, >ULN, n=0, 29, 0		0	
SBP, TC 4, PBL, >ULN, n=0, 30, 0		1	
HR, TC 4, BL, <LLN, n=0, 29, 0		0	
HR, TC 4, PBL, <LLN, n=0, 30, 0		0	
HR, TC 4, BL, >ULN, n=0, 29, 0		0	
HR, TC 4, PBL, >ULN, n=0, 30, 0		0	
DBP, TC 5, BL, <LLN, n=0, 13, 0		0	
DBP, TC 5, PBL, <LLN, n=0, 13, 0		0	
DBP, TC 5, BL, >ULN, n=0, 13, 0		0	
DBP, TC 5, PBL, >ULN, n=0, 13, 0		0	
SBP, TC 5, BL, <LLN, n=0, 13, 0		0	
SBP, TC 5, PBL, <LLN, n=0, 13, 0		2	
SBP, TC 5, BL, >ULN, n=0, 13, 0		0	
SBP, TC 5, PBL, >ULN, n=0, 13, 0		0	
HR, TC 5, BL, <LLN, n=0, 13, 0		0	
HR, TC 5, PBL, <LLN, n=0, 13, 0		0	
HR, TC 5, BL, >ULN, n=0, 13, 0		0	
HR, TC 5, PBL, >ULN, n=0, 13, 0		0	

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

42. Secondary Outcome Measure:

Measure Title	Number of Participants With Immunoglobulin Values Outside the Reference 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 latest value on or before the date of infusion A of the treatment course. The post-baseline visit is defined as any visit after the date of infusion A during the specified treatment course. Reference ranges (LLN, ULN) used for immunoglobulins are: immunoglobulin A (IgA) (grams/Liter): 0.81, 4.63; immunoglobulin G (IgG) (grams/Liter): 6.94, 16.18; immunoglobulin M (IgM) (grams/Liter): 0.48, 2.71.
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	

	Description
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	141	0
Number of Participants With Immunoglobulin Values Outside the Reference Range at Baseline or Any Visit Post-baseline, During the DB and OL Periods, by Ofatumumab Treatment Course [units: Participants]			
IgA, TC 1, BL, <LLN, n=0, 141, 0		1	
IgA, TC 1, PBL, <LLN, n=0, 133, 0		1	
IgA, TC 1, BL, >ULN, n=0, 141, 0		16	
IgA, TC 1, PBL, >ULN, n=0, 133, 0		14	
IgG, TC 1, BL, <LLN, n=0, 141, 0		0	
IgG, TC 1, PBL, <LLN, n=0, 133, 0		4	
IgG, TC 1, BL, >ULN, n=0, 141, 0		43	
IgG, TC 1, PBL, >ULN, n=0, 133, 0		25	
IgM, TC 1, BL, <LLN, n=0, 141, 0		7	
IgM, TC 1, PBL, <LLN, n=0, 133, 0		18	
IgM, TC 1, BL, >ULN, n=0, 141, 0		19	
IgM, TC 1, PBL, >ULN, n=0, 133, 0		12	
IgA, TC 2, BL, <LLN, n=0, 85, 0		0	
IgA, TC 2, PBL, <LLN, n=0, 93, 0		0	
IgA, TC 2, BL, >ULN, n=0, 85, 0		9	
IgA, TC 2, PBL, >ULN, n=0, 93, 0		1	
IgG, TC 2, BL, <LLN, n=0, 85, 0		1	
IgG, TC 2, PBL, <LLN, n=0, 93, 0		3	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
IgG, TC 2, BL, >ULN, n=0, 85, 0		11	
IgG, TC 2, PBL, >ULN, n=0, 93, 0		12	
IgM, TC 2, BL, <LLN, n=0, 85, 0		10	
IgM, TC 2, PBL, <LLN, n=0, 93, 0		18	
IgM, TC 2, BL, >ULN, n=0, 85, 0		6	
IgM, TC 2, PBL, >ULN, n=0, 93, 0		5	
IgA, TC 3, BL, <LLN, n=0, 59, 0		0	
IgA, TC 3, PBL, <LLN, n=0, 62, 0		0	
IgA, TC 3, BL, >ULN, n=0, 59, 0		5	
IgA, TC 3, PBL, >ULN, n=0, 62, 0		5	
IgG, TC 3, BL, <LLN, n=0, 59, 0		0	
IgG, TC 3, PBL, <LLN, n=0, 62, 0		2	
IgG, TC 3, BL, >ULN, n=0, 59, 0		6	
IgG, TC 3, PBL, >ULN, n=0, 62, 0		5	
IgM, TC 3, BL, <LLN, n=0, 59, 0		7	
IgM, TC 3, PBL, <LLN, n=0, 62, 0		11	
IgM, TC 3, BL, >ULN, n=0, 59, 0		3	
IgM, TC 3, PBL, >ULN, n=0, 62, 0		2	
IgA, TC 4, BL, <LLN, n=0, 28, 0		0	
IgA, TC 4, PBL, <LLN, n=0, 29, 0		0	
IgA, TC 4, BL, >ULN, n=0, 28, 0		4	
IgA, TC 4, PBL, >ULN, n=0, 29, 0		5	
IgG, TC 4, BL, <LLN, n=0, 28, 0		0	
IgG, TC 4, PBL, <LLN, n=0, 29, 0		1	
IgG, TC 4, BL, >ULN, n=0, 28, 0		1	
IgG, TC 4, PBL, >ULN, n=0, 29, 0		1	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
IgM, TC 4, BL, <LLN, n=0, 28, 0		1	
IgM, TC 4, PBL, <LLN, n=0, 29, 0		2	
IgM, TC 4, BL, >ULN, n=0, 28, 0		1	
IgM, TC 4, PBL, >ULN, n=0, 29, 0		1	
IgA, TC 5, BL, <LLN, n=0, 12, 0		0	
IgA, TC 5, PBL, <LLN, n=0, 13, 0		0	
IgA, TC 5, BL, >ULN, n=0, 12, 0		2	
IgA, TC 5, PBL, >ULN, n=0, 13, 0		2	
IgG, TC 5, BL, <LLN, n=0, 12, 0		1	
IgG, TC 5, PBL, <LLN, n=0, 13, 0		1	
IgG, TC 5, BL, >ULN, n=0, 12, 0		0	
IgG, TC 5, PBL, >ULN, n=0, 13, 0		1	
IgM, TC 5, BL, <LLN, n=0, 12, 0		0	
IgM, TC 5, PBL, <LLN, n=0, 13, 0		0	
IgM, TC 5, BL, >ULN, n=0, 12, 0		1	
IgM, TC 5, PBL, >ULN, n=0, 13, 0		1	
IgA, TC 6, BL, <LLN, n=0, 6, 0		0	
IgA, TC 6, PBL, <LLN, n=0, 6, 0		0	
IgA, TC 6, BL, >ULN, n=0, 6, 0		0	
IgA, TC 6, PBL, >ULN, n=0, 6, 0		0	
IgG, TC 6, BL, <LLN, n=0, 6, 0		0	
IgG, TC 6, PBL, <LLN, n=0, 6, 0		0	
IgG, TC 6, BL, >ULN, n=0, 6, 0		0	
IgG, TC 6, PBL, >ULN, n=0, 6, 0		0	
IgM, TC 6, BL, <LLN, n=0, 6, 0		0	
IgM, TC 6, PBL, <LLN, n=0, 6, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
IgM, TC 6, BL, >ULN, n=0, 6, 0		0	
IgM, TC 6, PBL, >ULN, n=0, 6, 0		0	

43. Secondary Outcome Measure:

Measure Title	Number of Participants With Positive John Cunningham (JC) Virus Test Results at Baseline or Any Visit Post-baseline During the DB and OL Periods
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 indicates the presence of JC Virus.
Time Frame	From basline 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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	118	0
Number of Participants With Positive John Cunningham (JC) Virus Test Results at Baseline or Any Visit Post-baseline During the DB and OL Periods [units: Participants]			
TC 1, BL, n=0, 76, 0		1	
TC 1, PBL, n=0, 118, 0		1	
TC 2, BL, n=0, 45, 0		0	

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
TC 2, PBL, n=0, 81, 0		1	
TC 3, BL, n=0, 30, 0		1	
TC 3, PBL, n=0, 48, 0		0	
TC 4, BL, n=0, 10, 0		0	
TC 4, PBL, n=0, 25, 0		0	
TC 5, BL, n=0, 4, 0		0	
TC 5, PBL, n=0, 8, 0		0	
TC 6, BL, n=0, 3, 0		0	
TC 6, PBL, n=0, 6, 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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	0	132
Number of Participants With Any Serious Adverse Event During the Follow-up Period [units: Participants]			17

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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	0	123
Number of Participants With Immunoglobulin Values Outside the Reference Range During the Follow-up Period [units: Participants]			

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
IgA <LLN			0
IgA >ULN			15
IgG <LLN			7
IgG >ULN			18
IgM <LLN			23
IgM >ULN			4

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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	0	63

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
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, 63			22.013 (0.46 to 49.25)
Relative to last dose, n=0, 0, 60			12.567 (0.03 to 29.47)

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. Positive JC Virus test result indicated 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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	0	132
Number of Participants With a Positive JC Virus Test Result During the Follow-up Period [units: Participants]			7

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; TBIL: NA, 1.5; CO2/BCO: 0.85, 1.2; 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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	0	132
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			2

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
GGT			1
TBIL			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	
Ofatumumab 700 mg	
Placebo or OFA 700 mg: FU Period	

Measured Values

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
Number of Participants Analyzed	0	0	132
Number of Participants With the Indicated Hematology Values of Potential Clinical Concern During the Follow-up Period [units: Participants]			

	Placebo	Ofatumumab 700 mg	Placebo or OFA 700 mg: FU Period
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	6/83 (7.23%)	30/148 (20.27%)	17/132 (12.88%)
Blood and lymphatic system disorders			
Pancytopenia [A] †	0/83 (0%)	0/148 (0%)	1/132 (0.76%)
Cardiac disorders			
Myocardial infarction [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Eye disorders			
Cataract [A] †	0/83 (0%)	2/148 (1.35%)	0/132 (0%)
Retinal detachment [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Gastrointestinal disorders			
Gastritis [A] †	0/83 (0%)	0/148 (0%)	0/132 (0%)
General disorders			
Implant site reaction [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Hepatobiliary disorders			
Bile duct stone [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Immune system disorders			
Anaphylactic reaction [A] †	0/83 (0%)	4/148 (2.7%)	0/132 (0%)
Anaphylactic shock [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Hypersensitivity [A] †	0/83 (0%)	2/148 (1.35%)	0/132 (0%)
Infections and infestations			
Cellulitis [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Gastroenteritis [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Haemophilus infection [A] †	0/83 (0%)	0/148 (0%)	1/132 (0.76%)

	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 (%)
Herpes oesophagitis [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Meningitis viral [A] †	1/83 (1.2%)	0/148 (0%)	0/132 (0%)
Oesophageal candidiasis [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Oral candidiasis [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Pneumonia [A] †	0/83 (0%)	0/148 (0%)	2/132 (1.52%)
Pyelonephritis [A] †	0/83 (0%)	0/148 (0%)	1/132 (0.76%)
Respiratory tract infection [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Septic shock [A] †	0/83 (0%)	0/148 (0%)	1/132 (0.76%)
Urinary tract infection [A] †	0/83 (0%)	2/148 (1.35%)	0/132 (0%)
Urosepsis [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Injury, poisoning and procedural complications			
Hip fracture [A] †	0/83 (0%)	0/148 (0%)	1/132 (0.76%)
Infusion related reaction [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Intervertebral disc protrusion [A] †	0/83 (0%)	0/148 (0%)	1/132 (0.76%)
Post procedural complication [A] †	1/83 (1.2%)	0/148 (0%)	0/132 (0%)
Spinal compression fracture [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Ulna fracture [A] †	0/83 (0%)	0/148 (0%)	1/132 (0.76%)
Investigations			
Alanine aminotransferase increased [A] †	0/83 (0%)	2/148 (1.35%)	0/132 (0%)
John Cunningham (JC) virus test positive [A] †	1/83 (1.2%)	0/148 (0%)	2/132 (1.52%)
Transaminases increased [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (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 (%)
Metabolism and nutrition disorders			
Diabetes mellitus inadequate control [A] †	1/83 (1.2%)	0/148 (0%)	0/132 (0%)
Musculoskeletal and connective tissue disorders			
Arthralgia [A] †	1/83 (1.2%)	0/148 (0%)	1/132 (0.76%)
Arthritis [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Foot deformity [A] †	0/83 (0%)	1/148 (0.68%)	1/132 (0.76%)
Musculoskeletal pain [A] †	0/83 (0%)	0/148 (0%)	1/132 (0.76%)
Osteoarthritis [A] †	0/83 (0%)	0/148 (0%)	0/132 (0%)
Osteoporotic fracture [A] †	0/83 (0%)	0/148 (0%)	1/132 (0.76%)
Rheumatoid arthritis [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Nervous system disorders			
Cerebrovascular accident [A] †	1/83 (1.2%)	0/148 (0%)	0/132 (0%)
Cervical myelopathy [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Renal and urinary disorders			
Nephrolithiasis [A] †	0/83 (0%)	0/148 (0%)	1/132 (0.76%)
Reproductive system and breast disorders			
Ovarian cyst ruptured [A] †	0/83 (0%)	0/148 (0%)	1/132 (0.76%)
Vaginal prolapse [A] †	0/83 (0%)	0/148 (0%)	1/132 (0.76%)
Respiratory, thoracic and mediastinal disorders			
Pleurisy [A] †	1/83 (1.2%)	0/148 (0%)	0/132 (0%)
Skin and subcutaneous tissue 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 (%)
Rash [A] †	0/83 (0%)	1/148 (0.68%)	0/132 (0%)
Vascular disorders			
Deep vein thrombosis [A] †	0/83 (0%)	0/148 (0%)	1/132 (0.76%)
Peripheral ischaemia [A] †	0/83 (0%)	0/148 (0%)	1/132 (0.76%)

† 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	36/83 (43.37%)	133/148 (89.86%)	0/132 (0%)
Blood and lymphatic system disorders			
Anaemia [A] †	0/83 (0%)	4/148 (2.7%)	0/132 (0%)
Eye disorders			
Cataract [A] †	0/83 (0%)	5/148 (3.38%)	0/132 (0%)
Dry eye [A] †	2/83 (2.41%)	0/148 (0%)	0/132 (0%)
Gastrointestinal disorders			
Abdominal pain [A] †	2/83 (2.41%)	3/148 (2.03%)	0/132 (0%)
Abdominal pain upper [A] †	1/83 (1.2%)	5/148 (3.38%)	0/132 (0%)
Constipation [A] †	3/83 (3.61%)	0/148 (0%)	0/132 (0%)
Diarrhoea [A] †	0/83 (0%)	6/148 (4.05%)	0/132 (0%)
Nausea [A] †	2/83 (2.41%)	5/148 (3.38%)	0/132 (0%)
Sensation of foreign body [A] †	0/83 (0%)	3/148 (2.03%)	0/132 (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 (%)
Vomiting [A] †	0/83 (0%)	3/148 (2.03%)	0/132 (0%)
General disorders			
Chest discomfort [A] †	0/83 (0%)	4/148 (2.7%)	0/132 (0%)
Chest pain [A] †	0/83 (0%)	3/148 (2.03%)	0/132 (0%)
Pyrexia [A] †	2/83 (2.41%)	4/148 (2.7%)	0/132 (0%)
Immune system disorders			
Anaphylactic reaction [A] †	0/83 (0%)	4/148 (2.7%)	0/132 (0%)
Hypersensitivity [A] †	0/83 (0%)	3/148 (2.03%)	0/132 (0%)
Infections and infestations			
Bronchitis [A] †	1/83 (1.2%)	7/148 (4.73%)	0/132 (0%)
Cervicitis [A] †	2/83 (2.41%)	0/148 (0%)	0/132 (0%)
Erysipelas [A] †	0/83 (0%)	3/148 (2.03%)	0/132 (0%)
Gastroenteritis [A] †	4/83 (4.82%)	9/148 (6.08%)	0/132 (0%)
Herpes zoster [A] †	2/83 (2.41%)	5/148 (3.38%)	0/132 (0%)
Nasopharyngitis [A] †	5/83 (6.02%)	7/148 (4.73%)	0/132 (0%)
Onychomycosis [A] †	0/83 (0%)	3/148 (2.03%)	0/132 (0%)
Pharyngitis [A] †	2/83 (2.41%)	3/148 (2.03%)	0/132 (0%)
Rhinitis [A] †	2/83 (2.41%)	4/148 (2.7%)	0/132 (0%)
Upper respiratory tract infection [A] †	2/83 (2.41%)	6/148 (4.05%)	0/132 (0%)
Urinary tract infection [A] †	4/83 (4.82%)	9/148 (6.08%)	0/132 (0%)
Injury, poisoning and procedural complications			
Infusion related reaction [A] †	0/83 (0%)	8/148 (5.41%)	0/132 (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 (%)
Investigations			
Alanine aminotransferase increased [A] †	0/83 (0%)	5/148 (3.38%)	0/132 (0%)
Blood pressure increased [A] †	2/83 (2.41%)	0/148 (0%)	0/132 (0%)
Musculoskeletal and connective tissue disorders			
Arthralgia [A] †	4/83 (4.82%)	0/148 (0%)	0/132 (0%)
Arthritis [A] †	0/83 (0%)	4/148 (2.7%)	0/132 (0%)
Back pain [A] †	0/83 (0%)	10/148 (6.76%)	0/132 (0%)
Spinal osteoarthritis [A] †	0/83 (0%)	4/148 (2.7%)	0/132 (0%)
Nervous system disorders			
Dizziness [A] †	0/83 (0%)	8/148 (5.41%)	0/132 (0%)
Headache [A] †	3/83 (3.61%)	4/148 (2.7%)	0/132 (0%)
Post herpetic neuralgia [A] †	0/83 (0%)	3/148 (2.03%)	0/132 (0%)
Sciatica [A] †	0/83 (0%)	3/148 (2.03%)	0/132 (0%)
Psychiatric disorders			
Anxiety [A] †	0/83 (0%)	5/148 (3.38%)	0/132 (0%)
Depression [A] †	0/83 (0%)	6/148 (4.05%)	0/132 (0%)
Insomnia [A] †	0/83 (0%)	3/148 (2.03%)	0/132 (0%)
Respiratory, thoracic and mediastinal disorders			
Cough [A] †	1/83 (1.2%)	19/148 (12.84%)	0/132 (0%)
Dysphonia [A] †	0/83 (0%)	3/148 (2.03%)	0/132 (0%)
Dyspnoea [A] †	0/83 (0%)	13/148 (8.78%)	0/132 (0%)
Oropharyngeal discomfort [A] †	0/83 (0%)	3/148 (2.03%)	0/132 (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 (%)
Oropharyngeal pain [A] †	2/83 (2.41%)	3/148 (2.03%)	0/132 (0%)
Throat irritation [A] †	0/83 (0%)	20/148 (13.51%)	0/132 (0%)
Throat tightness [A] †	0/83 (0%)	6/148 (4.05%)	0/132 (0%)
Skin and subcutaneous tissue disorders			
Erythema [A] †	1/83 (1.2%)	9/148 (6.08%)	0/132 (0%)
Pruritus [A] †	2/83 (2.41%)	16/148 (10.81%)	0/132 (0%)
Rash [A] †	2/83 (2.41%)	53/148 (35.81%)	0/132 (0%)
Rash pruritic [A] †	0/83 (0%)	3/148 (2.03%)	0/132 (0%)
Urticaria [A] †	0/83 (0%)	24/148 (16.22%)	0/132 (0%)
Vascular disorders			
Flushing [A] †	0/83 (0%)	6/148 (4.05%)	0/132 (0%)
Hypertension [A] †	0/83 (0%)	8/148 (5.41%)	0/132 (0%)
Hypotension [A] †	2/83 (2.41%)	0/148 (0%)	0/132 (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.

Results Point of Contact:

Name/Official Title: GSK Response Center
Organization: GlaxoSmithKline
Phone: 866-435-7343
Email: