Protocol Registration Receipt
06/19/2014

Ofatumumab Dose-finding in Relapsing Remitting Multiple Sclerosis (RRMS) Patients (OMS115102)

This study has been completed.

Sponsor:	GlaxoSmithKline
Collaborators:	
Information provided by (Responsible Party):	GlaxoSmithKline
ClinicalTrials.gov Identifier:	NCT00640328

Purpose

The trial consists of a dose escalation, to establish the safety of ofatumumab in RRMS patients. A 48-week treatment period followed by an individualized follow-up period until normalization of peripheral B-cell counts or Immunoglobulin G (IgG) levels.

Condition	Intervention	Phase
Multiple Sclerosis	Drug: Ofatumumab 100 Drug: Ofatumumab 300 Drug: Ofatumumab 700	Phase 2

Condition	Intervention	Phase
	Drug: Placebo	

Study Type: Interventional
Study Design: Treatment, Crossover Assignment, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Randomized, Safety Study
Official Title: A Double-blind, Randomized, Placebo Controlled, Multicenter, Dose-finding Trial of Ofatumumab in Relapsing Remitting Multiple Sclerosis (RRMS) Patients

Further study details as provided by GlaxoSmithKline:

Primary Outcome Measure:

- Number of Participants With Any Adverse Event [Time Frame: First Treatment Period (FTP): From Visit 3 (Week 0) up to Visit 10 (Week 24); Second Treatment Period (STP): From Visit 10 (Week 24) up to Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)] [Designated as safety issue: No]

  An Adverse Event (AE) is defined as any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. A list of all adverse events is reported in the "Other (Non-Serious) Adverse Events" section. Non-serious AEs were not collected during the Individualized Follow-up Period.
- Number of Participants With the Indicated Critical Adverse Events (CAEs) [Time Frame: FTP: From Visit 3 (Week 0) up to Visit 10 (Week 24); STP: From Visit 10 (Week 24) up to Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)] [Designated as safety issue: No]

  A CAE=treatment-related (TR) grade (G) >=3 AE on day of infusion (inf.) preventing inf. to be resumed, a TR G 3 bronchospasm during 1 inf., an AE whose severity becomes G 3 for the third time during 1 inf., infections reported as serious, a TR neurological event consistent with progressive multifocal leukoencephalopathy (PML), any malignancy, and any fatal adverse drug reaction. AE severity (assessed as G 1-5) was classified using the Common Terminology Criteria for Adverse Events v3.0: G 1=mild AE; G 2=moderate AE; G 3=severe AE; G 4=life-threatening or disabling AE; G 5=death related to AE.
- Number of Participants With Negative or Unconfirmed Human Anti-human Antibodies (HAHA) in Which Concentrations of Ofa Were Below 500 Nanograms Per Milliliter (ng/ml) [Time Frame: Visit 3 (Week 0), Visit 10 (Week 24), Visit 17 (Week 48) or early withdrawal (EW), and Visit 26 (Week 104)] [Designated as safety issue: No]

  Participants are checked for negative (or a lack of) HAHA at Baseline, and then throughout the study, to ensure that the investigational product is not causing HAHA development. Participants with concentrations of Ofa that are missing or are above 500 nanograms per milliliter (ng/mL) are considered to have unconfirmed HAHA results.
- Number of Participants With Abnormal Physical Examination Findings [Time Frame: FTP: From Visit 3 (Week 0) up to Visit 10 (Week 24); STP: From Visit 10 (Week 24) up to Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)] [Designated as safety issue: No]

  The investigator performed the physical examination, which included but was not limited to: general appearance and the following body systems: lymph nodes, mouth and throat, lungs, cardiovascular, abdomen, extremities, muscular-skeletal, neurological (apart from multiple sclerosis [a brain and spinal cord disease]), and skin. All abnormal clinically relevant findings such as vein problems (venous varices), disorder of the vertebral column (vertebropathy), increased hearing loss, post operative mark (scar), and chronic skin disorder with no sweat and itching (anhidrotic eczema) were

reported.

- Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Basophils, Eosinophils, Leukocytes, Monocytes, Lymphocytes, Neutrophils, and Platelet Count at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [Time Frame: FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: Visit 26 (Week 104)] [Designated as safety issue: No]

  Blood samples of participants were collected for hematology assessment. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in basophils, eosinophils, leukocytes, monocytes, lymphocytes, neutrophils, and platelets count was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Week 104 for the IFUP minus the value at Baseline.
- Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Erythrocyte Count at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [Time Frame: FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: Visit 26 (Week 104)] [Designated as safety issue: No]

  Blood samples of participants were collected for assessment of erythrocyte count. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in erythrocyte count was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline.
- Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Hematocrit at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [Time Frame: FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: Visit 26 (Week 104)] [Designated as safety issue: No]

  Blood samples of participants were collected for hematocrit assessment. Hematocrit is the percentage of blood volume (BV) that is occupied by red blood cells (RBCs). Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in hematocrit was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline. Hematocrit is measured as a percentage, i.e., volume (V) of red blood cells per volume of blood.
- Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Hemoglobin Count at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [Time Frame: FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: Visit 26 (Week 104)] [Designated as safety issue: No]

  Blood samples of participants were collected for assessment of hemoglobin count. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in hemoglobin was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline.
- Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Albumin at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [Time Frame: FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: VIsit 26 (Week 104)] [Designated as safety issue: No]

  Blood samples of participants were collected for assessment of albumin count. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 104 for the IFUP) in albumin was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline.
- Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Alkaline Phosphatase, Aspartate Aminotransferase (AST), and Alanine Transaminase (ALT) at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [Time Frame: FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)] [Designated as safety issue: No]

Blood samples of participants were collected for the assessment of alkaline phosphatase, AST, and ALT. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline.

- Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Bicarbonate, Glucose, Potassium, Sodium, and Urea at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [Time Frame: FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)] [Designated as safety issue: No]

  Blood samples of participants were collected for the assessment of bicarbonate, glucose, potassium, and urea. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline.
- Change From Baseline (Week 0 for the FTP,Week 24 for the STP, and Week 0 for the IFUP) in Bilirubin and Creatinine at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [Time Frame: FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)] [Designated as safety issue: No]

  Blood samples of participants were collected for the assessment of bilirubin and creatinine. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline.
- Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Immunoglobins at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [Time Frame: FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)] [Designated as safety issue: No]

  Blood samples of participants were collected for the assessment of antibodies produced by B-cells (immunoglobins): immunoglobulin A, immunoglobin G, and immunoglobin M. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline.
- Change From Baseline (Week 0 for the FTP and Week 24 for the STP) in Blood Pressure (BP) at Week 24 (FTP) and Week 48 (STP) [Time Frame: FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48)] [Designated as safety issue: No]

  Maximum (systolic) and minimum (diastolic) BP were assessed prior to infusion. Change from Baseline (Week 0 for the FTP and Week 24 for the STP) was calculated as the value at Visit 10 (Week 24) for the FTP and the value at Visit 17 (Week 48) for the STP minus the value at Baseline.
- Change From Baseline (Week 0 for the FTP and Week 24 for the STP) in Pulse Rate at Week 24 (FTP) and Week 48 (STP) [Time Frame: FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48)] [Designated as safety issue: No]

  The pulse rate of each participant was assessed prior to infusion. Change from Baseline (Week 0 for the FTP and Week 24 for the STP) was calculated as the value at Visit 10 (Week 24) for the FTP and the value at Visit 17 (Week 48) for the STP minus the value at Baseline.
- Change From Baseline (Week 0 for the FTP and Week 24 for the STP) in Temperature at Week 24 (FTP) and Week 48 (STP) [Time Frame: FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48)] [Designated as safety issue: No]

  The temperature of each participant was assessed prior to infusion. Change from Baseline (Week 0 for the FTP and Week 24 for the STP) was calculated as the value at Visit 10 (Week 24) for the FTP and the value at Visit 17 (Week 48) for the STP minus the value at Baseline.
- Change From Baseline (Week 0 for the FTP and Week 24 for the STP) in Complement Activation (CH50) at Week 24 (FTP) and Week 48 (STP) [Time

Frame: FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48)] [Designated as safety issue: No]

Blood samples of participants were collected for CH50 prior to and 2 hours after dosing, and the samples were sent to a Central Laboratory for analysis: Bio Analytical Research Corporation (BARC). Change from Baseline (Week 0 for the FTP; Week 24 for the STP) was calculated as the value at Weeks 24 (FTP) and 48 (STP) minus the value at Baseline. Ofa depletes (induces the cell death of) B cells. When Ofa binds to a B cell, it induces complement CH50, which in turn causes cell death via cytotoxicity. Therefore, the CH50 levels were measured to ensure that CH50 was being appropriately activated.

Secondary Outcome Measures:

- Number of the Indicated Types of Lesions (Ls) Assessed Per Magnetic Resonance Imaging (MRI) [Time Frame: FTP: From Visit 3 (Week 0) up to Visit 10 (Week 24); STP: From Visit 10 (Week 24) up to Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)] [Designated as safety issue: No]

  The MRI scan was performed prior to dosing and could be performed up to 4 days prior to Visits 3 and 10. An IDMC reviewed the data. T1 enhancing Ls are enhanced by gadolinium, are considered representative of disease activity/inflammation, and may signify a relapse. Measurement of these Ls is comparative from visit to visit. "Total T1 enhancing Ls" represent the total of the new T1 enhancing Ls over the entire study period. T2 L measurements measure all Ls on the brain in terms of volume and size, measuring for new or enlarging Ls. T1 hypointensive Ls are areas of permanent damage.
- Total Volume of T2 Lesions at Week 24 and Week 48 [Time Frame: Visit 10 (Week 24) and Visit 17 (Week 48)] [Designated as safety issue: No]

  The MRI scan should be performed prior to dosing and can be performed up to 4 days prior to Visits 3 and 10. An IDMC reviewed the data. The volume of T2 lesions was not a cumulative volume, but the volume measured at Visit 10 and Visit 17. T2 lesion measurements measure all lesions on the brain in terms of volume and size, measuring for new lesions or enlarging lesions.
- Ofa Drug Concentration After the First (Visit 3), Second (Visit 4), Third (Visit 10), and Fourth (Visit 11) Intravenous (i.v.) Infusions [Time Frame: Visit 3 (Week 0), Visit 4 (Week 2), Visit 10 (Week 24), and Visit 11 (Week 26). Samples were drawn predose, immediately following the end of infusion, 10 minutes after infusion, 1 hour after infusion, and 2 hours after infusion.] [Designated as safety issue: No]

  The peripheral blood for each participant was collected and analyzed for the concentration of the drug in serum. There were four infusions in the study; the third infusion at Visit 10 represents the first infusion of the second treatment period (Weeks 24-48). Data are presented for the predose concentrations.
- The Maximum Observed Plasma Concentration (Cmax) After the First (Visit 3), Second (Visit 4), Third (Visit 10), and Fourth (Visit 11) i.v. Infusions [Time Frame: Visit 3 (Week 0), Visit 4, (Week 2), Visit 10 (Week 24), and Visit 11 (Week 26). Samples were drawn predose, immediately following the end of infusion, 10 minutes after infusion, 1 hour after infusion, and 2 hours after infusion.] [Designated as safety issue: No]

  The peripheral blood for each participant was collected and analyzed for Cmax after the first, second, third, and fourth i.v. infusions. Assessment was performed using the noncompartmental method (this analysis is highly dependent on the estimation of total drug exposure).
- The Area Under the Plasma Concentration-time Curve From Time Zero to the Last Quantifiable Time Point (AUC(0-t)) After the First (Visit 3), Second (Visit 4), Third (Visit 10), and Fourth (Visit 11) i.v. Infusions [Time Frame: Visit 3 (Week 0), Visit 4 (Week 2), Visit 10 (Week 24), and Visit 11 (Week 26). Samples were drawn predose, immediately following the end of infusion, 10 minutes after infusion, 1 hour (hr) after infusion, and 2 hours after infusion.] [Designated as safety issue: No]

  The peripheral blood for each participant was collected and analyzed to estimate the area under the plasma concetration-time curve, AUC(0-t), and was assessed using the non-compartmental method.

- Time to Reach Cmax (Tmax) After the First (Visit 3), Second (Visit 4), Third (Visit 10), and Fourth (Visit 11) i.v. Infusions [Time Frame: Visit 3 (Week 0), Visit 4 (Week 2),Visit 10 (Week 24), and Visit 11 (Week 26). Samples were drawn predose, immediately following the end of infusion, 10 minutes after infusion, 1 hour after infusion, and 2 hours after infusion.] [Designated as safety issue: No]
  The peripheral blood for each participant was collected and analyzed for tmax.
- Clearance of Ofa Over the Course of Weeks 0-2 and 24-26 [Time Frame: Weeks 0-2 and 24-26] [Designated as safety issue: No]
  The peripheral blood for each participant was collected and analyzed for clearance. Clearance is the measure of efficiency with which a drug is irreversibly removed form the body. The average clearance over the course of Weeks 0-2 and 24-26 is reported.
- The Volume of Distribution at Steady State (Vss) of Ofatumumab Over the Course of Weeks 0-2 and 24-26 [Time Frame: Weeks 0-2 and 24-26] [Designated as safety issue: No]
  The peripheral blood for each participant was collected and analyzed for Vss. The average Vss over the course of Weeks 0-2 and 24-26 is reported.
- Half Life (t1/2) of Ofatumumab in the Terminal Elimination Phase Over the Course of Weeks 0-2 and 24-26 [Time Frame: Weeks 0-2 and 24-26] [Designated as safety issue: No]
  The peripheral blood for each participant was collected and analyzed for half life. Half life is defined as the period of time required for the amount of drug in the body to be reduced by half. The average t1/2 over the course of Weeks 0-2 and 24-26 is reported.

Enrollment: 38
Study Start Date: May 2008
Study Completion Date: October 2011
Primary Completion Date: May 2010

Arms	Assigned Interventions
Experimental: Cohort 1.1 100mg ofatumumab then placebo	Drug: Ofatumumab 100 100mg Drug: Placebo matching placebo
Experimental: Cohort 1.2 placebo then 100mg ofatumumab	Drug: Ofatumumab 100 100mg Drug: Placebo matching placebo
Experimental: Cohort 2.1 300mg ofatumumab then placebo	Drug: Ofatumumab 300 300mg

Arms	Assigned Interventions
	Drug: Placebo matching placebo
Experimental: Cohort 2.2 placebo then 300mg ofatumumab	Drug: Ofatumumab 300 300mg Drug: Placebo matching placebo
Experimental: Cohort 3.1 700mg ofatumumab then placebo	Drug: Ofatumumab 700 700mg Drug: Placebo matching placebo
Experimental: Cohort 3.2 placebo then 700mg ofatumumab	Drug: Ofatumumab 700 700mg Drug: Placebo matching placebo

The trial consists of two phases, a 48 week treatment period, followed by an individualized treatment period of up to two years.

Patients are treated in cohorts of increasing doses (100 mg, 300 mg and 700 mg) with 12 patients in each dose cohort. Within each cohort patients are randomized asymmetrically in a 2:1 ratio such that eight patients will receive ofatumumab and four patients will receive placebo. After 24 weeks the patients randomized to placebo will be treated with the active dose for the cohort. For blinding purposes, patients randomized to the active dose will be treated with placebo after 24 weeks. Thus, each patient will receive two administrations of trial product with 24 weeks follow-up resulting in a total treatment period of 48 weeks duration. An Independent Data Monitoring Committee (IDMC) will review and evaluate the safety data of each cohort, a minimum of 4 weeks data including the week 4 Magnetic Resonance Imaging (MRI) from at least 10 patients, to consider if progression to the next higher dose cohort is acceptable.

The trial product is administered as two infusions separated by two weeks. Clinical assessment and Gadolinium enhanced (Gd-enhanced) MRI scan will be performed at weeks -4, 0, 2, 4, and every 4 weeks until week 48. The MRI scan at week 2 is carried out for safety assessment prior to administering the second infusion in the first treatment course. When patients in all dose cohorts have been dosed and have had week 4 MRI scans performed, an IDMC will review all available safety data.

After completion of week 48 patients will be followed to monitor B-cell and IgG normalization. B-cell levels will be monitored every 12 weeks until CD19+ cells have returned to baseline level (Visit 3) or normalized level. If the B-cell levels are not normalized after two years the patient should be followed until either the IgG or the B-cell levels are normalized (see Section 9.2.4 for details). During this period Gd-enhanced MRI follow up scans will be performed every 12 weeks to evaluate potential rebound, safety and for Progressive Multifocal Leukoencephalopathy (PML) monitoring.

Eligibility

Ages Eligible for Study: 18 Years to 55 Years
Genders Eligible for Study: Both

Inclusion Criteria:

- Patients with definite diagnosis of relapsing-remitting MS according to McDonald criteria
- Patients with:
- At least two confirmed relapses within the last 24 months or
- At least one confirmed relapse within the last 12 months or
- One confirmed relapse between 12 and 24 months prior to screening, and at least one documented T1 Gd-enhancing lesion on an MRI performed within 12 months prior to screening.
- Patients with disability equivalent to Expanded Disability Status Scale (EDSS) score of 0-5.0 (both included) at screening
- Neurologically stable patients with no evidence of relapse for at least 30 days prior to start of Screening and during the Screening Phase
- Female patients must be either post-menopausal, surgically incapable of bearing children or practicing an acceptable method of birth control e.g. hormonal contraceptives, intrauterine device, spermicide and barrier as long as they are on trial medication and for a period of 1 year following the last infusion of trial drug. Females of childbearing potential must have a negative pregnancy test at screening visit prior to entry into the treatment period
- Following receipt of verbal and written information about the trial, the patient must provide signed informed consent before any trial related activity is carried out.

Exclusion Criteria:

- Diagnosis of Secondary Progressive Multiple Sclerosis (SPMS), Primary Progressive Multiple Sclerosis (PPMS) or Progressive Relapsing Multiple Sclerosis (PRMS) or Neuromyelitis optica
- Neurological findings consistent with Progressive Multifocal Leukoencephalopathy (PML) or confirmed PML
- Findings on brain MRI scan indicating any other clinically significant brain abnormality other than MS
- Patients unable to undergo MRI scans (e.g. due to pacemaker, severe claustrophobia, hypersensitivity to contrast media) or who lack adequate peripheral venous access
- Patients who have had the following treatments:
- Lymphocyte-depleting therapies (e.g. alemtuzumab (Campath®), anti-Cluster of Differentiation (CD4), cladribine, total body irradiation, bone marrow transplantation), mitoxantrone or cyclophosphamide at any time

- Anti-CD20 treatments or any monoclonal antibodies at any time
- Immunoglobulin, azathioprine, cyclosporine, tacrolimus or other immunosuppressive agents, immunomodulatory agents or plasma exchange within six months prior to randomization in the trial apart from Glatiramer Acetate and Interferon Beta (IFN-b).
- Glatiramer Acetate or IFN-b within three months prior to the randomization in the trial.
- Glucocorticoids or Adrenocorticotropic Hormone (ACTH) within one month prior to the screening in the trial.
- Receipt of a live vaccine within one month prior to screening in the trial.
- Plasmapheresis for treatment of relapses within 2 months prior to randomization in the trial.
- Initiation of therapy with Statins or hormone replacement treatment within one month or less prior to screening in the trial.
- Patients who have received other disease modifying therapies for MS may be allowed on a case to case basis after discussion with the sponsors medical monitor
- Past or current history of medically significant adverse effects (including allergic reactions) from:
- Cetirizine
- Prednisolone
- Paracetamol/acetaminophen
- Plasma proteins or a known hypersensitivity to components of the investigational product.
- Past or current malignancy, except for
- Cervical carcinoma Stage 1B or less
- Non-invasive basal cell and squamous cell skin carcinoma
- Cancer diagnoses with a complete response of a duration of > 5 years. Patients with a prior history of hematological malignancies are excluded regardless of response
- Clinically significant cardiac disease, including acute myocardial infarction within six months from screening, unstable angina, congestive heart failure, previous venous or arterial thrombosis or arrhythmia requiring therapy.
- Electrocardiogram (ECG) showing significant abnormality that the treating investigator determines may jeopardize the subject’s health (i.e. acute ischemia, left bundle branch or bifascicular block)
- Significant concurrent, uncontrolled medical condition including, but not limited to, renal, hepatic, hematological, gastrointestinal, endocrine, immunodeficiency syndrome, pulmonary, cerebral, psychiatric or neurological disease which may impair their reliable participation in the trial or necessitate the use of medication not allowed by this protocol.
- History of severe, clinically significant Central Nervous System (CNS) trauma (e.g. cerebral contusion, spinal cord compression) or a history or presence of myelopathy due to spinal cord compression by disk or vertebral disease
- Chronic or ongoing active infectious disease requiring systemic treatment such as, but not limited to, chronic renal infection, chronic chest infection with bronchiectasis, tuberculosis and active Hepatitis C. Any previous serious infections should be discussed with the sponsors medical monitor (e.g. opportunistic or atypical infections)
- Female patients who are pregnant or nursing.
- Use of an investigational drug or other experimental therapy for a condition other than MS within 4 weeks prior to screening. Any prior use of an investigational drug or other experimental therapy for MS at any time should be discussed with the medical monitor.

- Current participation in any other interventional clinical trial. Participation in non-interventional trial requires approval of the protocol by the sponsor
- Serum vitamin B12 below lower limit of normal
- Positive polymerase chain reaction (PCR) screening for John Cunningham Virus (JC Virus) as measured by qualitative plasma and/or white blood cell JCV DNA
- Serologic evidence of Hepatitis B (HB) infection based on the results of testing for Hepatitis B Surface Antigen (HBsAg), anti- Hepatitis B Core (HBc) and anti- Hepatitis B Surface (HBs) antibodies with eligibility based on the results as follows:
- Patients positive for HBsAg are excluded
- Patients negative for HBsAg but positive for both anti-HBc and anti-HBs antibodies (indicating past infection) are eligible
- Patients negative for HBsAg and anti-HBc antibody but positive for anti-HBs antibody (indicating past vaccination) are eligible
- Patients negative for HBsAg and anti-HBs antibody but positive for anti-HBc antibody will require clarification of their status by testing for HB DNA, which if positive will exclude the patient from participation
- Patient with documented vaccination against Hepatitis B (primary and secondary immunization and booster) will be considered eligible for the trial.
- Positive serology for HIV
- Screening laboratory values:
- White Blood Cell (WBC) < 3.0 x 109/L
- Neutrophils < 2 x 109/L
- Platelets < 100 x 109/L
- Circulating IgG level < lower limit of normal (according to central laboratory range)
- Serum Alanine Aminotransferase (S-ALAT) > 2.5 times the upper limit of normal (according to central laboratory range)
- Serum Alpha Fetoprotein (S-AP) > 2.0 times the upper limit of normal (according to central laboratory range)
- Serum Aspartate Aminotransferase (ASAT) >3.0 times the upper limit of normal (according to central laboratory range)
- Bilirubin > 1.5 times the upper limit of normal (according to central laboratory range)
- S-creatinine > the upper limit of normal (according to central laboratory range)
- CD4 count <500 cells/mm3, CD4:CD8 <0.9
- Patients known or suspected of not being able to comply with a trial protocol (e.g. due to alcoholism, drug dependency or psychological disorder).
- Positive test for Hepatitis C antibody confirmed with a Hepatitis C real time (RT) PCR assay.

Patients who are positive for Hepatitis C antibody and negative when the Hepatitis C RT PCR assay is performed will be eligible for the study. Patients who are positive for Hepatitis C antibody and have a positive or indeterminate result when the Hepatitis C RT PCR assay is performed will not be eligible for the study.

- Positive test results for tuberculosis using the QuantiFERON test and/or Chest X-ray findings suggestive of tuberculosis (TB). For patients who have had a Chest X-ray performed within the past 6 months without any findings indicative of TB, QuantiFERON test alone may be performed.

Contacts and Locations

Locations

Belgium

Algemeen Ziekenhuis Sint-Jan Neurologie
Brugge, Brugge, Belgium, 8000

Czech Republic

MS Centre of Neurology Department, Hospital Teplice
Teplice, Czech Republic, 415 29

MS centre of neurology clinic, Faculty policlinic
Praha 2, Praha, Czech Republic, 128 08

Denmark

Danish Multiple Sclerosis Research Centre, Copenhagen University Hospital
Copenhagen, Denmark, 2100

Poland

Department of Neurology, Medical University of Lodz
Lodz, Poland, 91-153

Institute of Psychiatry and Neurology
Warszawa, Poland, 04-749

Serbia

Clinical Centre Nis, Clinic for Neurology
Nis, Serbia, 18000

Military Medical Academy, Clinic for Neurology
Belgrade, Belgrade, Serbia, 11 000

Clinical Centre of Serbia, Institute of Neurology
Belgrade, Belgrade, Serbia, 11 000

Sweden

Neuroimmunology Unit, Karolinska Hospital
Stockholm, Sweden, S-171 76

United Kingdom

Royal Hallamshire Hospital, Department of Neurology
Sheffield, United Kingdom, S10 2JF

The Waltn Centre for Neurology & Neurosurgery NHS Trust. Clinical Trials Unit
Fazakerley, Liverpool, United Kingdom, L97LJ

Investigators

Study Director:	GSK Clinical Trials	GlaxoSmithKline

More Information

Responsible Party:	GlaxoSmithKline
Study ID Numbers:	115102 GEN414 [Genmab]
Health Authority:	Poland: Ethics Committees United Kingdom: Research Ethics Committee Denmark: The Danish National Committee on Biomedical Research Ethics Denmark: Danish Dataprotection Agency Sweden: Regional Ethical Review Board Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Czech Republic: Ethics Committee Serbia: ALIMS - Medicines and Medical Devices Agency of Serbia Poland: Ministry of Health United Kingdom: Medicines and Healthcare Products Regulatory Agency Denmark: Danish Medicines Agency Serbia: Ethics Committees Sweden: Medical Products Agency Czech Republic: State Institute for Drug Control

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Study Results

Participant Flow

Pre-Assignment Details

In all 3 dose cohorts, participants in the active/placebo group received treatment with ofatumumab during the First Treatment

Period and placebo during the Second Treatment Period. Participants in the placebo/active group received treatment with placebo during the First Treatment Period and ofatumumab during the second treatment period.

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP)

	Description
	in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

First Treatment Period (Weeks 0-24)

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Started	8	11	7	4	4	4
Completed	8	10	7	4	4	4
Not Completed	0	1	0	0	0	0
Adverse Event	0	1	0	0	0	0

Second Treatment Period (Weeks 24-48)

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Started	8	10	7	4	4	4
Completed	8	10	7	4	3	4
Not Completed	0	0	0	0	1	0
Adverse Event	0	0	0	0	1	0

IFUP (Week 48 to Individual Termination)

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Started	8	11	7	4	4	4
Completed	8	10	6	3	4	4
Not Completed	0	1	1	1	0	0
Withdrawal by Subject	0	0	1	0	0	0
Not Recommended - Informed Consent Form	0	1	0	1	0	0

Baseline Characteristics

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose

	Description
	before considering progression to the 700 mg dose.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period.

Baseline Measures

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa	Total
Number of Participants	8	11	7	4	4	4	38
Age, Continuous [units: Years] Mean (Standard Deviation)	38.0 (9.0)	36.6 (7.0)	33.7 (8.4)	37.0 (6.5)	27.0 (2.2)	44.0 (8.1)	36.3 (7.9)
Gender, Male/Female [units: Participants]							
Female	6	6	4	3	3	0	22
Male	2	5	3	1	1	4	16
Race/Ethnicity, Customized White/Caucasian [units: participants]	8	11	7	4	4	4	38

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With Any Adverse Event
Measure Description	An Adverse Event (AE) is defined as any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. A list of all adverse events is reported in the "Other (Non-Serious) Adverse Events" section. Non-serious AEs were not collected during the Individualized Follow-up Period.
Time Frame	First Treatment Period (FTP): From Visit 3 (Week 0) up to Visit 10 (Week 24); Second Treatment Period (STP): From Visit 10 (Week 24)

	up to Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)
Safety Issue?	No

Analysis Population Description

Full Analysis Set (FAS): all participants who had been exposed to the investigational product (IP) irrespective of their compliance to the planned course of treatment.

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions

	Description
	separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the

	Description
	second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	11	7	4	4	4
Number of Participants With Any Adverse Event [units: participants]						
Weeks 0-24	8	10	7	3	2	2
Weeks 24-48	4	5	4	3	4	4
Individualized Follow-up Period	0	0	0	0	0	0

2. Primary Outcome Measure:

Measure Title	Number of Participants With the Indicated Critical Adverse Events (CAEs)
Measure Description	A CAE=treatment-related (TR) grade (G) >=3 AE on day of infusion (inf.) preventing inf. to be resumed, a TR G 3 bronchospasm during 1 inf., an AE whose severity becomes G 3 for the third time during 1 inf.,

	infections reported as serious, a TR neurological event consistent with progressive multifocal leukoencephalopathy (PML), any malignancy, and any fatal adverse drug reaction. AE severity (assessed as G 1-5) was classified using the Common Terminology Criteria for Adverse Events v3.0: G 1=mild AE; G 2=moderate AE; G 3=severe AE; G 4=life-threatening or disabling AE; G 5=death related to AE.
Time Frame	FTP: From Visit 3 (Week 0) up to Visit 10 (Week 24); STP: From Visit 10 (Week 24) up to Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)
Safety Issue?	No

Analysis Population Description

FAS

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the

	Description
	safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the

	Description
	second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	11	7	4	4	4
Number of Participants With the Indicated Critical Adverse Events (CAEs) [units: participants]						
Week 0-24; Influenza	0	0	0	1	0	0
Week 0-24; Bronchospasm	0	1	0	0	0	0
Week 0-24; Cough	0	1	0	0	0	0
Week 0-24; Rash pruritic	0	1	0	0	0	0

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Week 24-48; any CAE	0	0	0	0	0	0
Individualized Follow-up Period; any CAE	0	0	0	0	0	0

3. Primary Outcome Measure:

Measure Title	Number of Participants With Negative or Unconfirmed Human Anti-human Antibodies (HAHA) in Which Concentrations of Ofa Were Below 500 Nanograms Per Milliliter (ng/ml)
Measure Description	Participants are checked for negative (or a lack of) HAHA at Baseline, and then throughout the study, to ensure that the investigational product is not causing HAHA development. Participants with concentrations of Ofa that are missing or are above 500 nanograms per milliliter (ng/mL) are considered to have unconfirmed HAHA results.
Time Frame	Visit 3 (Week 0), Visit 10 (Week 24), Visit 17 (Week 48) or early withdrawal (EW), and Visit 26 (Week 104)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2

	Description
	wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	11	7	4	4	4
Number of Participants With Negative or Unconfirmed Human Anti-human Antibodies (HAHA) in Which Concentrations of Ofa Were Below 500 Nanograms Per Milliliter (ng/ml) [units: participants]						
Week 0; n=8, 8, 2, 4, 3, 4	8	8	2	4	3	4
Week 24; n=8, 9, 1, 4, 4, 4	8	9	1	4	4	4
Week 48 or EW, negative; n=8, 11, 7, 4, 3, 4	8	11	7	4	3	1
Week 48 or EW, unconfirmed, n=8, 11, 7, 4, 3, 4	0	0	0	0	0	3
IFUP, n=8, 11, 7, 4, 4, 4	0	0	0	0	0	0

4. Primary Outcome Measure:

Measure Title	Number of Participants With Abnormal Physical Examination Findings
Measure Description	The investigator performed the physical examination, which included but was not limited to: general appearance and the following body systems: lymph nodes, mouth and throat, lungs, cardiovascular, abdomen, extremities, muscular-skeletal, neurological (apart from

	multiple sclerosis [a brain and spinal cord disease]), and skin. All abnormal clinically relevant findings such as vein problems (venous varices), disorder of the vertebral column (vertebropathy), increased hearing loss, post operative mark (scar), and chronic skin disorder with no sweat and itching (anhidrotic eczema) were reported.
Time Frame	FTP: From Visit 3 (Week 0) up to Visit 10 (Week 24); STP: From Visit 10 (Week 24) up to Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)
Safety Issue?	No

Analysis Population Description

FAS

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose

	Description
	before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason,

	Description
	participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	11	7	4	4	4
Number of Participants With Abnormal Physical Examination Findings [units: participants]						
Week 0-24; Venous varices on legs	1	0	0	0	0	0
Week 0-24; Vertebropathy	1	0	0	0	0	0
Week 0-24; Obesitas	1	0	0	0	0	0
Week 0-24; Increased hearing loss	0	0	1	0	0	0

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Week 0-24; Post operative scar	0	0	1	0	0	0
Week 0-24; Anhidrotic eczema	0	0	0	0	0	1
Week 24-48; Venous varices on legs	1	0	0	0	0	0
Week 24-48; Vertebropathy	1	0	0	0	0	0
Week 24-48; Obesitas	1	0	0	0	0	0
Week 24-48; Acne vulgaris	0	1	0	0	0	0
Week 24-48; Post operative scar	0	0	1	0	0	0
IFUP; Any physical examination finding	0	0	0	0	0	0

5. Primary Outcome Measure:

Measure Title	Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Basophils, Eosinophils, Leukocytes, Monocytes, Lymphocytes, Neutrophils, and Platelet Count at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP)
Measure Description	Blood samples of participants were collected for hematology assessment. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in basophils, eosinophils, leukocytes, monocytes, lymphocytes, neutrophils, and platelets count was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Week 104 for

	the IFUP minus the value at Baseline.
Time Frame	FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: Visit 26 (Week 104)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

	Description
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as

	Description
	two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	10	7	3	4	4
Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Basophils, Eosinophils, Leukocytes, Monocytes, Lymphocytes, Neutrophils, and Platelet Count at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [units: Giga (10^9) per liter] Mean (Standard Deviation)						
Week 0-24, Basophils; n=7, 10, 7, 3, 3, 4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Week 0-24, Eosinophils; n=8, 10, 6, 2, 3, 4	0 (0.05)	-0.05 (0.13)	0.02 (0.15)	0 (0)	-0.23 (0.21)	0.03 (0.05)
Week 0-24, Leukocytes; n=8, 10, 7, 3, 4, 4	0.7 (1.6)	0.6 (2.4)	-0.1 (3.3)	-0.3 (1.6)	0.7 (5.9)	0.4 (0.7)

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Week 0-24, Lymphocytes; n=8, 10, 7, 3, 3, 4	0.15 (1.03)	-0.36 (0.67)	-0.19 (0.78)	-0.37 (0.31)	-0.60 (0.79)	0.12 (0.21)
Week 0-24, Monocytes; n=8, 10, 7, 3, 3, 4	0.20 (0.31)	-0.07 (0.23)	0.00 (0.20)	0.07 (0.06)	-0.40 (0.17)	0.05 (0.10)
Week 0-24, Neutrophils; n=8, 10, 7, 3, 3, 4	0.4 (0.9)	1 (2.2)	0 (3.8)	-0.1 (1.5)	-0.8 (1.7)	0.2 (0.7)
Week 0-24, Platelets; n=8, 10, 7, 3, 4, 4	0.8 (33.3)	10.8 (44.0)	7.6 (39.7)	0.3 (29.5)	5.8 (36.2)	-4.8 (34.8)
Week 24-48, Basophils; n=8, 8, 5, 3, 2, 3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Week 24-48, Eosinophils; n=8, 8, 5, 3, 2, 4	0 (0.05)	-0.04 (0.16)	0.04 (0.09)	-0.07 (0.06)	-0.20 (0.28)	0.03 (0.13)
Week 24-48, Leukocytes; n=8, 10, 7, 3, 3, 4	0.5 (1.1)	-0.1 (1.7)	-0.3 (1.1)	-0.9 (0.6)	-3.7 (1.7)	0.9 (0.9)
Week 24-48, Lymphocytes; n=8, 8, 6, 3, 2, 4	-0.11 (0.36)	-0.28 (0.47)	0.15 (0.36)	-0.50 (0.20)	-0.65 (0.78)	-0.25 (0.45)
Week 24-48, Monocytes; n=8, 8, 6, 3, 2, 4	-0.20 (0.07)	-0.01 (0.12)	0.02 (0.17)	0.03 (0.06)	-0.04 (0.28)	0.13 (0.25)
Week 24-48, Neutrophils; n=8, 8, 6, 3, 2, 4	0.7 (1.2)	0.2 (1.8)	-0.4 (1.0)	-0.4 (0.4)	-2.9 (1.3)	1.0 (0.7)
Week 24-48, Platelets; n=8, 10, 7, 3, 3, 4	-6.5 (17.3)	-16.3 (74.2)	-10.1 (14.7)	-13.7 (20.6)	-34.3 (47.3)	-11.0 (38.4)
Week 0-104, Basophils; n=1, 0, 0, 0, 0,	0 (NA) [1]	NA (NA) [2]	NA (NA) [3]	NA (NA) [4]	NA (NA) [5]	NA (NA) [6]

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
0						
Week 0-104, Eosinophils; n=1, 0, 0, 0, 0, 0	0 (NA) [7]	NA (NA) [8]	NA (NA) [9]	NA (NA) [10]	NA (NA) [11]	NA (NA) [12]
Week 0-104, Leukocytes; n=1, 0, 0, 0, 0, 0	1.30 (NA) [13]	NA (NA) [14]	NA (NA) [15]	NA (NA) [16]	NA (NA) [17]	NA (NA) [18]
Week 0-104, Lymphocytes; n=1, 0, 0, 0, 0, 0	-0.60 (NA) [19]	NA (NA) [20]	NA (NA) [21]	NA (NA) [22]	NA (NA) [23]	NA (NA) [24]
Week 0-104, Monocytes; n=1, 0, 0, 0, 0, 0	0 (NA) [25]	NA (NA) [26]	NA (NA) [27]	NA (NA) [28]	NA (NA) [29]	NA (NA) [30]
Week 0-104, Neutrophils; n=1, 0, 0, 0, 0, 0	1.90 (NA) [31]	NA (NA) [32]	NA (NA) [33]	NA (NA) [34]	NA (NA) [35]	NA (NA) [36]
Week 0-104, Platelets; n=1, 0, 0, 0, 0, 0	-20.0 (NA) [37]	NA (NA) [38]	NA (NA) [39]	NA (NA) [40]	NA (NA) [41]	NA (NA) [42]

[1] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[2] No participants were analyzed in this treatment arm at this time point.

[3] No participants were analyzed in this treatment arm at this time point.

[4] No participants were analyzed in this treatment arm at this time point.

[5] No participants were analyzed in this treatment arm at this time point.

[6] No participants were analyzed in this treatment arm at this time point.

[7] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[8] No participants were analyzed in this treatment arm at this time point.

[9] No participants were analyzed in this treatment arm at this time point.
[10] No participants were analyzed in this treatment arm at this time point.
[11] No participants were analyzed in this treatment arm at this time point.
[12] No participants were analyzed in this treatment arm at this time point.
[13] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.
[14] No participants were analyzed in this treatment arm at this time point.
[15] No participants were analyzed in this treatment arm at this time point.
[16] No participants were analyzed in this treatment arm at this time point.
[17] No participants were analyzed in this treatment arm at this time point.
[18] No participants were analyzed in this treatment arm at this time point.
[19] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.
[20] No participants were analyzed in this treatment arm at this time point.
[21] No participants were analyzed in this treatment arm at this time point.
[22] No participants were analyzed in this treatment arm at this time point.
[23] No participants were analyzed in this treatment arm at this time point.
[24] No participants were analyzed in this treatment arm at this time point.
[25] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.
[26] No participants were analyzed in this treatment arm at this time point.
[27] No participants were analyzed in this treatment arm at this time point.
[28] No participants were analyzed in this treatment arm at this time point.
[29] No participants were analyzed in this treatment arm at this time point.
[30] No participants were analyzed in this treatment arm at this time point.
[31] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.
[32] No participants were analyzed in this treatment arm at this time point.
[33] No participants were analyzed in this treatment arm at this time point.

[34] No participants were analyzed in this treatment arm at this time point.

[35] No participants were analyzed in this treatment arm at this time point.

[36] No participants were analyzed in this treatment arm at this time point.

[37] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[38] No participants were analyzed in this treatment arm at this time point.

[39] No participants were analyzed in this treatment arm at this time point.

[40] No participants were analyzed in this treatment arm at this time point.

[41] No participants were analyzed in this treatment arm at this time point.

[42] No participants were analyzed in this treatment arm at this time point.

6. Primary Outcome Measure:

Measure Title	Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Erythrocyte Count at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP)
Measure Description	Blood samples of participants were collected for assessment of erythrocyte count. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in erythrocyte count was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline.
Time Frame	FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: Visit 26 (Week 104)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2

	Description
	wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	10	7	3	4	4
Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Erythrocyte Count at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [units: Pico (10^12) per liter] Mean (Standard Deviation)						
Week 24; n=8, 10, 7, 3, 4, 4	0.06 (0.25)	-0.11 (0.33)	-0.02 (0.23)	-0.09 (0.20)	-0.06 (0.42)	0.07 (0.12)
Week 48; n=8, 10, 7, 3, 3, 4	0.05 (0.26)	0.12 (0.34)	0.12 (0.25)	0.01 (0.43)	0.06 (0.18)	0.09 (0.04)
Week 104; n=1, 0, 0, 0, 0, 0	-0.08 (NA) [1]	NA (NA) [2]	NA (NA) [3]	NA (NA) [4]	NA (NA) [5]	NA (NA) [6]

[1] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[2] No participants were analyzed in this treatment arm at this time point.

[3] No participants were analyzed in this treatment arm at this time point.

[4] No participants were analyzed in this treatment arm at this time point.

[5] No participants were analyzed in this treatment arm at this time point.

[6] No participants were analyzed in this treatment arm at this time point.

7. Primary Outcome Measure:

Measure Title	Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Hematocrit at Week

	24 (FTP), Week 48 (STP), and Week 104 (IFUP)
Measure Description	Blood samples of participants were collected for hematocrit assessment. Hematocrit is the percentage of blood volume (BV) that is occupied by red blood cells (RBCs). Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in hematocrit was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline. Hematocrit is measured as a percentage, i.e., volume (V) of red blood cells per volume of blood.
Time Frame	FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: Visit 26 (Week 104)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions

	Description
	separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the

	Description
	second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	10	7	3	4	4
Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Hematocrit at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [units: Percentage of BV occupied by RBCs]						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Mean (Standard Deviation)						
Week 24; n=8, 10, 7, 3, 4, 4	-0.00 (0.03)	0.01 (0.03)	-0.01 (0.02)	-0.02 (0.02)	0.02 (0.04)	0.01 (0.01)
Week 48; n=8, 10, 7, 3, 3, 4	0.01 (0.02)	0.02 (0.03)	0.00 (0.03)	0.01 (0.05)	0.01 (0.01)	0.02 (0.01)
Week 104; n=1, 0, 0, 0, 0, 0	0.01 (NA) [1]	NA (NA) [2]	NA (NA) [3]	NA (NA) [4]	NA (NA) [5]	NA (NA) [6]

[1] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[2] No participants were analyzed in this treatment arm at this time point.

[3] No participants were analyzed in this treatment arm at this time point.

[4] No participants were analyzed in this treatment arm at this time point.

[5] No participants were analyzed in this treatment arm at this time point.

[6] No participants were analyzed in this treatment arm at this time point.

8. Primary Outcome Measure:

Measure Title	Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Hemoglobin Count at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP)
Measure Description	Blood samples of participants were collected for assessment of hemoglobin count. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in hemoglobin was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline.

Time Frame	FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: Visit 26 (Week 104)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions

	Description
	separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the

	Description
	second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	10	7	3	4	4
Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Hemoglobin Count at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [units: Millimoles/liter] Mean (Standard Deviation)						
Week 24; n=8, 10, 7, 3, 4, 4	0.1 (0.5)	-0.3 (0.7)	-0.0 (0.5)	-0.4 (0.4)	-0.1 (0.8)	0.2 (0.2)
Week 48; n=8, 10, 7, 3, 3, 4	0.1 (0.5)	0.1 (0.7)	0.2 (0.5)	-0.3 (1.1)	0.0 (0.3)	0.5 (0.3)
Week 104; n=1, 0, 0, 0, 0, 0	0.10 (NA) [1]	NA (NA) [2]	NA (NA) [3]	NA (NA) [4]	NA (NA) [5]	NA (NA) [6]

[1] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[2] No participants were analyzed in this treatment arm at this time point.

[3] No participants were analyzed in this treatment arm at this time point.

[4] No participants were analyzed in this treatment arm at this time point.

[5] No participants were analyzed in this treatment arm at this time point.

[6] No participants were analyzed in this treatment arm at this time point.

9. Primary Outcome Measure:

Measure Title	Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Albumin at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP)
Measure Description	Blood samples of participants were collected for assessment of albumin count. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 104 for the IFUP) in albumin was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline.
Time Frame	FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: VIsit 26 (Week 104)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before

	Description
	considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason,

	Description
	participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	11	7	4	4	4

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Albumin at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [units: grams per liter] Mean (Standard Deviation)						
Week 24; n=8, 10, 6, 4, 4, 4	-0.6 (2.5)	-0.5 (2.5)	1.3 (1.2)	-1.6 (3.4)	-1.2 (6.1)	2.0 (2.4)
Week 48; n=8, 11, 7, 4, 3, 4	0.1 (2.5)	-0.2 (3.1)	1.4 (3.0)	-1.1 (5.7)	0.4 (4.0)	1.1 (1.5)
Week 104; n=1, 0, 0, 0, 0, 0	-2.00 (NA) [1]	NA (NA) [2]	NA (NA) [3]	NA (NA) [4]	NA (NA) [5]	NA (NA) [6]

[1] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[2] No participants were analyzed in this treatment arm at this time point.

[3] No participants were analyzed in this treatment arm at this time point.

[4] No participants were analyzed in this treatment arm at this time point.

[5] No participants were analyzed in this treatment arm at this time point.

[6] No participants were analyzed in this treatment arm at this time point.

10. Primary Outcome Measure:

Measure Title	Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Alkaline Phosphatase, Aspartate Aminotransferase (AST), and

	Alanine Transaminase (ALT) at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP)
Measure Description	Blood samples of participants were collected for the assessment of alkaline phosphatase, AST, and ALT. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline.
Time Frame	FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching

	Description
	placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at

	Description
	Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	11	7	4	4	4
Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Alkaline Phosphatase, Aspartate Aminotransferase (AST), and Alanine Transaminase (ALT) at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP)						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
[units: Units per liter] Mean (Standard Deviation)						
Week 24, Alkaline phosphatase; n=8, 10, 6, 4, 4, 4	4.8 (9.0)	3.8 (11.9)	2.7 (8.3)	13.0 (20.2)	2.3 (10.6)	8.8 (8.3)
Week 24, AST; n=8, 10, 6, 4, 4, 4	3.6 (5.1)	1.6 (6.3)	-0.2 (3.1)	-9.5 (28.6)	4.3 (3.2)	-1.0 (6.1)
Week 24, ALT; n=8, 10, 6, 4, 4, 4	7.1 (10.2)	4.7 (10.0)	-1.7 (6.4)	7.3 (24.4)	5.3 (5.4)	0 (13.0)
Week 48, Alkaline phosphatase; n=8, 11, 7, 4, 3, 4	7.6 (10.7)	3.1 (8.8)	9.1 (12.6)	5.3 (17.7)	5.7 (7.6)	12.5 (12.9)
Week 48, AST; n=8, 11, 7, 4, 3, 4	0.6 (2.6)	1.5 (3.0)	0.3 (2.5)	-13.3 (28.5)	0.7 (4.7)	3.3 (10.7)
Week 48, ALT; n=8, 11, 7, 4, 3, 4	2.8 (5.3)	0.6 (4.7)	0.6 (7.4)	-4.3 (9.3)	0.7 (8.1)	8.0 (20.4)
Week 104, Alkaline phosphatase; n=1,0,0,0,0,0	16.0 (NA) [1]	NA (NA) [2]	NA (NA) [3]	NA (NA) [4]	NA (NA) [5]	NA (NA) [6]
Week 104, AST; n=1, 0, 0, 0, 0, 0	2.0 (NA) [7]	NA (NA) [8]	NA (NA) [9]	NA (NA) [10]	NA (NA) [11]	NA (NA) [12]
Week 104, ALT; n=1, 0, 0, 0, 0, 0	2.0 (NA) [13]	NA (NA) [14]	NA (NA) [15]	NA (NA) [16]	NA (NA) [17]	NA (NA) [18]

[1] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[2] No participants were analyzed in this treatment arm at this time point.

[3] No participants were analyzed in this treatment arm at this time point.

[4] No participants were analyzed in this treatment arm at this time point.

[5] No participants were analyzed in this treatment arm at this time point.

[6] No participants were analyzed in this treatment arm at this time point.

[7] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.
[8] No participants were analyzed in this treatment arm at this time point.
[9] No participants were analyzed in this treatment arm at this time point.
[10] No participants were analyzed in this treatment arm at this time point.
[11] No participants were analyzed in this treatment arm at this time point.
[12] No participants were analyzed in this treatment arm at this time point.
[13] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.
[14] No participants were analyzed in this treatment arm at this time point.
[15] No participants were analyzed in this treatment arm at this time point.
[16] No participants were analyzed in this treatment arm at this time point.
[17] No participants were analyzed in this treatment arm at this time point.
[18] No participants were analyzed in this treatment arm at this time point.

11. Primary Outcome Measure:

Measure Title	Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Bicarbonate, Glucose, Potassium, Sodium, and Urea at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP)
Measure Description	Blood samples of participants were collected for the assessment of bicarbonate, glucose, potassium, and urea. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline.
Time Frame	FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)

Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48

	Description
	of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before consideAfter completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.ring progression to the 700 mg dose.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which

	Description
	they were monitored for B cell and IgG normalization until individual study termination.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	11	7	4	4	4
Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Bicarbonate, Glucose, Potassium, Sodium, and Urea at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [units: millimoles per liter] Mean (Standard Deviation)						
Week 24, Bicarbonate; n=8, 10, 6, 4, 4, 4	0.6 (2.2)	-1.1 (2.6)	-0.6 (2.5)	1.5 (3.2)	-2.0 (1.3)	-0.6 (4.0)
Week 24, Glucose; n=8, 10, 7, 4, 4, 4	-0.12 (0.59)	0.39 (1.37)	0.64 (1.23)	0.21 (0.42)	0.08 (0.63)	-0.22 (0.50)
Week 24, Potassium; n=8, 10, 6, 4, 4, 4	-0.07 (0.35)	0.06 (0.52)	0.03 (0.27)	-0.63 (1.01)	-0.20 (0.63)	-0.00 (0.16)
Week 24, Sodium; n=8, 10, 6, 4, 4, 4	0.4 (2.7)	-0.5 (2.8)	-1.2 (1.3)	0.5 (1.7)	0.8 (2.1)	0.5 (2.1)
Week 24, Urea; n=8, 10, 6, 4, 4, 4	0.5 (1.6)	-0.8 (1.6)	0.4 (1.5)	-0.6 (0.8)	-0.7 (2.1)	-0.1 (0.4)
Week 48, Bicarbonate; n=8, 11, 7, 4, 4, 4	-0.0 (2.9)	-0.7 (2.8)	0.6 (1.3)	0.6 (0.2)	1.9 (3.1)	1.0 (2.3)

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Week 48, Glucose; n=8, 10, 7, 4, 2, 4	0.10 (0.50)	0.25 (0.95)	-0.05 (0.51)	0.09 (0.56)	-0.64 (0.44)	0.27 (0.79)
Week 48, Potassium; n=8, 10, 6, 4, 4, 4	4.21 (0.11)	4.43 (0.44)	4.18 (0.34)	4.23 (0.32)	3.98 (0.10)	4.20 (0.32)
Week 48, Sodium; n=8, 11, 7, 4, 3, 4	-2.3 (1.6)	-0.07 (3.1)	0.7 (1.0)	-0.5 (3.7)	-0.7 (1.2)	0.8 (1.0)
Week 48, Urea; n=8, 11, 7, 4, 3, 4	0.13 (1.40)	-0.05 (1.32)	-0.19 (0.68)	-0.30 (1.04)	1.00 (2.20)	-0.17 (0.46)
Week 104, Bicarbonate; n=1, 0, 0, 0, 0, 0	-1.00 (NA) [1]	NA (NA) [2]	NA (NA) [3]	NA (NA) [4]	NA (NA) [5]	NA (NA) [6]
Week 104, Glucose; n=1, 0, 0, 0, 0, 0	1.77 (NA) [7]	NA (NA) [8]	NA (NA) [9]	NA (NA) [10]	NA (NA) [11]	NA (NA) [12]
Week 104, Potassium; n=1, 0, 0, 0, 0, 0	0.00 (NA) [13]	NA (NA) [14]	NA (NA) [15]	NA (NA) [16]	NA (NA) [17]	NA (NA) [18]
Week 104, Sodium; n=1, 0, 0, 0, 0, 0	1.00 (NA) [19]	NA (NA) [20]	NA (NA) [21]	NA (NA) [22]	NA (NA) [23]	NA (NA) [24]
Week 104, Urea; n=1, 0, 0, 0, 0, 0	1.00 (NA) [25]	NA (NA) [26]	NA (NA) [27]	NA (NA) [28]	NA (NA) [29]	NA (NA) [30]

[1] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[2] No participants were analyzed in this treatment arm at this time point.

[3] No participants were analyzed in this treatment arm at this time point.

[4] No participants were analyzed in this treatment arm at this time point.

[5] No participants were analyzed in this treatment arm at this time point.

[6] No participants were analyzed in this treatment arm at this time point.

[7] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[8] No participants were analyzed in this treatment arm at this time point.

[9] No participants were analyzed in this treatment arm at this time point.
[10] No participants were analyzed in this treatment arm at this time point.
[11] No participants were analyzed in this treatment arm at this time point.
[12] No participants were analyzed in this treatment arm at this time point.
[13] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.
[14] No participants were analyzed in this treatment arm at this time point.
[15] No participants were analyzed in this treatment arm at this time point.
[16] No participants were analyzed in this treatment arm at this time point.
[17] No participants were analyzed in this treatment arm at this time point.
[18] No participants were analyzed in this treatment arm at this time point.
[19] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.
[20] No participants were analyzed in this treatment arm at this time point.
[21] No participants were analyzed in this treatment arm at this time point.
[22] No participants were analyzed in this treatment arm at this time point.
[23] No participants were analyzed in this treatment arm at this time point.
[24] No participants were analyzed in this treatment arm at this time point.
[25] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.
[26] No participants were analyzed in this treatment arm at this time point.
[27] No participants were analyzed in this treatment arm at this time point.
[28] No participants were analyzed in this treatment arm at this time point.
[29] No participants were analyzed in this treatment arm at this time point.
[30] No participants were analyzed in this treatment arm at this time point.

12. Primary Outcome Measure:

Measure Title	Change From Baseline (Week 0 for the FTP,Week 24 for

	the STP, and Week 0 for the IFUP) in Bilirubin and Creatinine at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP)
Measure Description	Blood samples of participants were collected for the assessment of bilirubin and creatinine. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline.
Time Frame	FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions

	Description
	separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the

	Description
	second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	11	7	4	4	4
Change From Baseline (Week 0 for the FTP,Week 24 for the STP, and Week 0 for the IFUP) in Bilirubin and Creatinine at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP) [units: Micromoles per liter (µmol/L)]						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Mean (Standard Deviation)						
Week 24, Bilirubin; n=8, 10, 5, 4, 4, 4	0.7 (5.2)	-0.0 (4.0)	1.2 (2.2)	0.5 (4.0)	-2.6 (3.5)	0.3 (5.3)
Week 24, Creatinine; n=8, 10, 6, 4, 4, 4	3.2 (11.8)	-0.1 (7.6)	2.5 (4.7)	2.5 (5.7)	-2.9 (7.8)	-1.2 (4.0)
Week 48, Bilirubin; n=8, 10, 6, 4, 2, 4	1.5 (4.9)	-0.1 (4.8)	1.5 (3.5)	0.7 (3.4)	-2.8 (1.0)	0.6 (2.8)
Week 48, Creatinine; n=8, 11, 7, 4, 3, 4	3.0 (8.7)	-1.9 (5.3)	-0.3 (4.1)	3.5 (6.7)	-5.0 (6.5)	2.0 (12.5)
Week 104, Bilirubin; n=1, 0, 0, 0, 0, 0	-4.70 (NA) [1]	NA (NA) [2]	NA (NA) [3]	NA (NA) [4]	NA (NA) [5]	NA (NA) [6]
Week 104, Creatinine; n=1, 0, 0, 0, 0, 0	11.5 (NA) [7]	NA (NA) [8]	NA (NA) [9]	NA (NA) [10]	NA (NA) [11]	NA (NA) [12]

[1] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[2] No participants were analyzed in this treatment arm at this time point.

[3] No participants were analyzed in this treatment arm at this time point.

[4] No participants were analyzed in this treatment arm at this time point.

[5] No participants were analyzed in this treatment arm at this time point.

[6] No participants were analyzed in this treatment arm at this time point.

[7] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[8] No participants were analyzed in this treatment arm at this time point.

[9] No participants were analyzed in this treatment arm at this time point.

[10] No participants were analyzed in this treatment arm at this time point.

[11] No participants were analyzed in this treatment arm at this time point.

[12] No participants were analyzed in this treatment arm at this time point.

13. Primary Outcome Measure:

Measure Title	Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Immunoglobins at Week 24 (FTP), Week 48 (STP), and Week 104 (IFUP)
Measure Description	Blood samples of participants were collected for the assessment of antibodies produced by B-cells (immunoglobins): immunoglobulin A, immunoglobin G, and immunoglobin M. Change from Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) was calculated as the value at Visit 10 (Week 24) for the FTP, the value at Visit 17 (Week 48) for the STP, and the value at Visit 26 (Week 104) for the IFUP minus the value at Baseline.
Time Frame	FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP)

	Description
	in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

	Description
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	10	7	4	4	4
Change From Baseline (Week 0 for the FTP, Week 24 for the STP, and Week 0 for the IFUP) in Immunoglobins at Week						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
24 (FTP), Week 48 (STP), and Week 104 (IFUP) [units: grams per liter] Mean (Standard Deviation)						
Week 24, IGA; n=8, 10, 6, 4, 4, 4	0.05 (0.16)	0.08 (0.16)	0.40 (0.40)	-0.07 (0.18)	0 (0.44)	0.49 (0.35)
Week 24, IGG; n=8, 10, 6, 4, 4, 4	-0.6 (1.0)	-0.1 (0.8)	1.2 (1.0)	-0.5 (1.0)	-0.3 (0.9)	1.4 (0.9)
Week 24, IGM; n=8, 10, 6, 4, 4, 4	-0.09 (0.14)	-0.13 (0.39)	-0.19 (0.09)	0.25 (0.25)	-0.07 (0.19)	0.04 (0.08)
Week 48, IGA; n=8, 11, 7, 4, 3, 4	0.08 (0.24)	-0.03 (0.39)	0.13 (0.11)	-0.00 (0.24)	0.05 (0.21)	0.29 (0.26)
Week 48, IGG; n=8, 11, 7, 4, 3, 4	-0.8 (1.2)	0.5 (1.6)	1.0 (0.7)	-0.6 (1.2)	0.2 (1.6)	1.2 (0.6)
Week 48, IGM; n=8, 11, 7, 4, 3, 4	-0.17 (0.24)	-0.21 (0.22)	-0.18 (0.24)	-0.24 (0.24)	-0.40 (0.17)	-0.13 (0.04)
Week 104, IGA; n=1, 0, 0, 0, 0, 0	-0.23 (NA) [1]	NA (NA) [2]	NA (NA) [3]	NA (NA) [4]	NA (NA) [5]	NA (NA) [6]
Week 104, IGG; n=1, 0, 0, 0, 0, 0	-0.60 (NA) [7]	NA (NA) [8]	NA (NA) [9]	NA (NA) [10]	NA (NA) [11]	NA (NA) [12]
Week 104, IGM; n=1, 0, 0, 0, 0, 0	-0.07 (NA) [13]	NA (NA) [14]	NA (NA) [15]	NA (NA) [16]	NA (NA) [17]	NA (NA) [18]

[1] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[2] No participants were analyzed in this treatment arm at this time point.

[3] No participants were analyzed in this treatment arm at this time point.

[4] No participants were analyzed in this treatment arm at this time point.

[5] No participants were analyzed in this treatment arm at this time point.

[6] No participants were analyzed in this treatment arm at this time point.

[7] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot

be calculated.

[8] No participants were analyzed in this treatment arm at this time point.

[9] No participants were analyzed in this treatment arm at this time point.

[10] No participants were analyzed in this treatment arm at this time point.

[11] No participants were analyzed in this treatment arm at this time point.

[12] No participants were analyzed in this treatment arm at this time point.

[13] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[14] No participants were analyzed in this treatment arm at this time point.

[15] No participants were analyzed in this treatment arm at this time point.

[16] No participants were analyzed in this treatment arm at this time point.

[17] No participants were analyzed in this treatment arm at this time point.

[18] No participants were analyzed in this treatment arm at this time point.

14. Primary Outcome Measure:

Measure Title	Change From Baseline (Week 0 for the FTP and Week 24 for the STP) in Blood Pressure (BP) at Week 24 (FTP) and Week 48 (STP)
Measure Description	Maximum (systolic) and minimum (diastolic) BP were assessed prior to infusion. Change from Baseline (Week 0 for the FTP and Week 24 for the STP) was calculated as the value at Visit 10 (Week 24) for the FTP and the value at Visit 17 (Week 48) for the STP minus the value at Baseline.
Time Frame	FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the

	Description
	second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	11	7	4	4	4
Change From Baseline (Week 0 for the FTP and Week 24 for the STP) in Blood Pressure (BP) at Week 24 (FTP) and Week 48 (STP) [units: millimeters of mercury] Mean (Standard Deviation)						
Week 24, Diastolic BP; n=8, 10, 7, 4, 4, 4	5.3 (11.2)	-2.3 (11.1)	-5.4 (9.7)	-3.5 (7.2)	4.0 (4.9)	-1.8 (2.2)
Week 24, Systolic BP; n=8, 10, 7, 4, 4, 4	11.0 (19.7)	-2.5 (12.3)	-3.1 (14.2)	1.5 (11.3)	1.0 (9.0)	-6.5 (9.5)
Week 48, Diastolic BP; n=8, 11, 7, 4, 3, 4	6.6 (4.6)	2.1 (12.0)	0.1 (7.8)	3.0 (4.7)	3.3 (5.8)	6.0 (5.8)

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Week 48, Systolic BP; n=8, 11, 7, 4, 3, 4	2.0 (14.5)	-2.5 (13.9)	-4.9 (8.2)	-2.3 (7.4)	1.7 (10.4)	4.5 (1.0)

15. Primary Outcome Measure:

Measure Title	Change From Baseline (Week 0 for the FTP and Week 24 for the STP) in Pulse Rate at Week 24 (FTP) and Week 48 (STP)
Measure Description	The pulse rate of each participant was assessed prior to infusion. Change from Baseline (Week 0 for the FTP and Week 24 for the STP) was calculated as the value at Visit 10 (Week 24) for the FTP and the value at Visit 17 (Week 48) for the STP minus the value at Baseline.
Time Frame	FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions

	Description
	separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as

	Description
	two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	11	7	4	4	4
Change From Baseline (Week 0 for the FTP and Week 24 for the STP) in Pulse Rate at Week 24 (FTP) and Week 48 (STP) [units: beats per minute] Mean (Standard Deviation)						
Week 24; n=8, 10, 7, 4, 4, 4	-0.3 (11.5)	1.6 (8.4)	0.6 (10.7)	1.3 (13.8)	2.0 (8.0)	3.8 (8.1)
Week 48; n=8, 11, 7, 4, 3, 4	-0.1 (9.8)	0.4 (11.9)	-3.0 (10.7)	-5.5 (10.0)	-0.3 (9.5)	8.0 (5.0)

16. Primary Outcome Measure:

Measure Title	Change From Baseline (Week 0 for the FTP and Week 24 for the STP) in Temperature at Week 24 (FTP) and Week 48 (STP)
Measure Description	The temperature of each participant was assessed prior to infusion. Change from Baseline (Week 0 for the FTP and Week 24 for the STP) was calculated as the value at Visit 10 (Week 24) for the FTP and the

	value at Visit 17 (Week 48) for the STP minus the value at Baseline.
Time Frame	FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as

	Description
	two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	11	7	4	4	4
Change From Baseline (Week 0 for the FTP and Week 24 for the STP) in Temperature at Week 24 (FTP) and Week 48 (STP) [units: Degrees Celsius] Mean (Standard Deviation)						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Week 24; n=8, 10, 7, 4, 4, 4	-0.1 (0.5)	0.1 (0.2)	-0.2 (0.5)	-0.1 (0.4)	0.3 (0.5)	-0.3 (0.3)
Week 48; n=8, 11, 7, 4, 3, 4	-0.1 (0.4)	0.1 (0.2)	0.1 (0.5)	-0.1 (0.2)	0.2 (0.3)	0.1 (0.3)

17. Primary Outcome Measure:

Measure Title	Change From Baseline (Week 0 for the FTP and Week 24 for the STP) in Complement Activation (CH50) at Week 24 (FTP) and Week 48 (STP)
Measure Description	Blood samples of participants were collected for CH50 prior to and 2 hours after dosing, and the samples were sent to a Central Laboratory for analysis: Bio Analytical Research Corporation (BARC). Change from Baseline (Week 0 for the FTP; Week 24 for the STP) was calculated as the value at Weeks 24 (FTP) and 48 (STP) minus the value at Baseline. Ofa depletes (induces the cell death of) B cells. When Ofa binds to a B cell, it induces complement CH50, which in turn causes cell death via cytotoxicity. Therefore, the CH50 levels were measured to ensure that CH50 was being appropriately activated.
Time Frame	FTP: Visit 3 (Week 0) and Visit 10 (Week 24); STP: Visit 10 (Week 24) and Visit 17 (Week 48)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering

	Description
	progression to the 700 mg dose.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	7	0	4	2	0
Change From Baseline (Week 0 for the FTP and Week 24 for the STP) in Complement Activation (CH50) at Week 24 (FTP) and Week 48 (STP) [units: Units per milliliter] Mean (Standard Deviation)						
Week 24; n=8, 7, 0, 4, 2, 0	-0.6 (4.1)	-7.1 (12.9)		2.8 (9.1)	-19.5 (24.7)	
Week 48; n=4, 0, 0, 1, 0, 0	3.8 (7.8)	NA (NA) [1]		-31.0 (0)	NA (NA) [2]	

[1] Data were not collected for this cohort.

[2] Data were not collected for this cohort.

18. Secondary Outcome Measure:

Measure Title	Number of the Indicated Types of Lesions (Ls) Assessed Per Magnetic Resonance Imaging (MRI)
Measure Description	The MRI scan was performed prior to dosing and could be performed up to 4 days prior to Visits 3 and 10. An IDMC reviewed the data. T1 enhancing Ls are enhanced by gadolinium, are considered representative of disease activity/inflammation, and may signify a relapse. Measurement of these Ls is comparative from visit to visit. "Total T1 enhancing Ls" represent the total of the new T1 enhancing Ls over the entire study period. T2 L measurements measure all Ls on the brain in terms of volume and size, measuring for new or enlarging Ls. T1 hypointensive Ls are areas of permanent damage.
Time Frame	FTP: From Visit 3 (Week 0) up to Visit 10 (Week 24); STP: From Visit 10 (Week 24) up to Visit 17 (Week 48); IFUP: up to Visit 26 (Week 104)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

	Description
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as

	Description
	two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	11	7	4	4	4
Number of the Indicated Types of Lesions (Ls) Assessed Per Magnetic Resonance Imaging (MRI) [units: lesions] Mean (Standard Deviation)						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Week 24, New (N) T1 enhancing Ls; n=8,11,7,4,4, 4	0.13 (0.35)	0 (0)	0 (0)	3.06 (4.66)	23.50 (43.0)	2.50 (3.32)
Week 24, Total T1 enhancing Ls; n=8,11,7,4,4,4	0.13 (0.35)	0.09 (0.30)	0 (0)	3.63 (5.02)	25.75 (46.23)	4.50 (7.14)
Week 24, N and/or enlarging T2 Ls; n=8,11,7,4,4,4	0.25 (0.71)	0.09 (0.30)	0 (0)	4.00 (6.52)	25.00 (46.03)	3.00 (4.24)
Week 24, N T1 hypointense Ls; n=8,11,7,4, 4,4	0 (0)	0.27 (0.47)	0.29 (0.49)	1.50 (3.00)	5.00 (9.35)	0.25 (0.50)
Week 48, N T1 enhancing Ls; n=8,10,7,4,3,4	0.13 (0.35)	0 (0)	0.29 (0.76)	0 (0)	0.33 (0.58)	0 (0)
Week 48, Total T1 enhancing Ls; n=8,10,7,4,3,4	0.13 (0.35)	0 (0)	0.43 (1.13)	0 (0)	3.00 (5.20)	0 (0)
Week 48, N and/or enlarging T2 Ls; n=8,10,7,4, 3,4	0.13 (0.35)	0 (0)	0.29 (0.76)	0 (0)	0.33 (0.58)	0 (0)
Week 48, N T1 hypointense Ls; n=8,10,7,4,3,4	0 (0)	0 (0)	0 (0)	0 (0)	3.00 (4.36)	0 (0)
Week 104, N T1 enhancing Ls; n=1, 0, 0, 0, 0, 0	0.0 (NA) [1]	NA (NA) [2]	NA (NA) [3]	NA (NA) [4]	NA (NA) [5]	NA (NA) [6]
Week 104, Total T1 enhancing Ls; n=1, 0, 0, 0, 0,0	0.0 (NA) [7]	NA (NA) [8]	NA (NA) [9]	NA (NA) [10]	NA (NA) [11]	NA (NA) [12]
Week 104, N and /or enlarging T2 Ls; n=1,0,0,0,0,0	0.0 (NA) [13]	NA (NA) [14]	NA (NA) [15]	NA (NA) [16]	NA (NA) [17]	NA (NA) [18]

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Week 104, N T1 hypointense Ls; n=1, 0, 0, 0, 0, 0	0.0 (NA) [19]	NA (NA) [20]	NA (NA) [21]	NA (NA) [22]	NA (NA) [23]	NA (NA) [24]

[1] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[2] No participants were analyzed in this treatment arm at this time point.

[3] No participants were analyzed in this treatment arm at this time point.

[4] No participants were analyzed in this treatment arm at this time point.

[5] No participants were analyzed in this treatment arm at this time point.

[6] No participants were analyzed in this treatment arm at this time point.

[7] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[8] No participants were analyzed in this treatment arm at this time point.

[9] No participants were analyzed in this treatment arm at this time point.

[10] No participants were analyzed in this treatment arm at this time point.

[11] No participants were analyzed in this treatment arm at this time point.

[12] No participants were analyzed in this treatment arm at this time point.

[13] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[14] No participants were analyzed in this treatment arm at this time point.

[15] No participants were analyzed in this treatment arm at this time point.

[16] No participants were analyzed in this treatment arm at this time point.

[17] No participants were analyzed in this treatment arm at this time point.

[18] No participants were analyzed in this treatment arm at this time point.

[19] Only one participant in this treatment arm was assessed for this parameter at this time point; thus, the standard deviation cannot be calculated.

[20] No participants were analyzed in this treatment arm at this time point.

[21] No participants were analyzed in this treatment arm at this time point.

[22] No participants were analyzed in this treatment arm at this time point.

[23] No participants were analyzed in this treatment arm at this time point.

[24] No participants were analyzed in this treatment arm at this time point.

19. Secondary Outcome Measure:

Measure Title	Total Volume of T2 Lesions at Week 24 and Week 48
Measure Description	The MRI scan should be performed prior to dosing and can be performed up to 4 days prior to Visits 3 and 10. An IDMC reviewed the data. The volume of T2 lesions was not a cumulative volume, but the volume measured at Visit 10 and Visit 17. T2 lesion measurements measure all lesions on the brain in terms of volume and size, measuring for new lesions or enlarging lesions.
Time Frame	Visit 10 (Week 24) and Visit 17 (Week 48)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety

	Description
	data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	11	7	4	4	4
Total Volume of T2 Lesions at Week 24 and Week 48 [units: millimeters cubed] Mean (Standard Deviation)						
Week 24; n=8, 11, 7, 3, 4, 4	7898 (8802)	10323 (8281)	17399 (11641)	11290 (11746)	12194 (18008)	15039 (8984)
Week 48; n=8, 10, 7, 4, 3, 4	7791 (8878)	11304 (8269)	17566 (12413)	10684 (8903)	18164 (23696)	15166 (9060)

20. Secondary Outcome Measure:

Measure Title	Ofa Drug Concentration After the First (Visit 3), Second (Visit 4), Third (Visit 10), and Fourth (Visit 11) Intravenous (i.v.) Infusions
Measure Description	The peripheral blood for each participant was collected and analyzed for the concentration of the drug in serum. There were four infusions in the study; the third infusion at Visit 10 represents the first infusion of the second treatment period (Weeks 24-48). Data are presented for the predose concentrations.
Time Frame	Visit 3 (Week 0), Visit 4 (Week 2), Visit 10 (Week 24), and Visit 11 (Week 26). Samples were drawn predose, immediately following the end of infusion, 10 minutes after infusion, 1 hour after infusion, and 2

	hours after infusion.
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering

	Description
	progression to the 300 mg dose.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	10	6	4	4	4
Ofa Drug Concentration After the First (Visit 3), Second (Visit 4), Third (Visit 10), and Fourth (Visit 11) Intravenous (i.v.) Infusions [units: milligrams per liter] Mean (Standard Deviation)						
Week 0; n=8, 10, 6, 0, 0, 0	32.3 (9.65)	85.8 (53.7)	176 (24.2)	NA (NA) [1]	NA (NA) [2]	NA (NA) [3]
Week 2; n=8, 10, 6, 0, 0, 0	23.4 (19.9)	64.9 (67.1)	174 (187)	NA (NA) [4]	NA (NA) [5]	NA (NA) [6]

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Week 24; n=0, 0, 0, 4, 3, 4	NA (NA) [7]	NA (NA) [8]	NA (NA) [9]	28.9 (8.03)	43.4 (67.9)	72.7 (128)
Week 26; n=0, 0, 0, 4, 3, 4	NA (NA) [10]	NA (NA) [11]	NA (NA) [12]	21.6 (18.5)	47.7 (76.9)	82.4 (144)

[1] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[2] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[3] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[4] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[5] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[6] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[7] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[8] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[9] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[10] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[11] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.
[12] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

21. Secondary Outcome Measure:

Measure Title	The Maximum Observed Plasma Concentration (Cmax) After the First (Visit 3), Second (Visit 4), Third (Visit 10), and Fourth (Visit 11) i.v. Infusions
Measure Description	The peripheral blood for each participant was collected and analyzed for Cmax after the first, second, third, and fourth i.v. infusions. Assessment was performed using the noncompartmental method (this analysis is highly dependent on the estimation of total drug exposure).
Time Frame	Visit 3 (Week 0), Visit 4, (Week 2), Visit 10 (Week 24), and Visit 11 (Week 26). Samples were drawn predose, immediately following the end of infusion, 10 minutes after infusion, 1 hour after infusion, and 2 hours after infusion.
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety

	Description
	data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	10	6	4	3	4
The Maximum Observed Plasma Concentration (Cmax) After the First (Visit 3), Second (Visit 4), Third (Visit 10), and Fourth (Visit 11) i.v. Infusions [units: milligrams per liter] Geometric Mean (Geometric Coefficient of Variation)						
Week 0; n=8, 10, 6, 0, 0, 0	36.8 (13.1%)	124 (23.6%)	346 (24.0%)	NA (NA%) [1]	NA (NA%) [2]	NA (NA%) [3]
Week 2; n=8, 10, 6, 0, 0, 0	47.7 (14.7%)	157 (25.9%)	452 (28.5%)	NA (NA%) [4]	NA (NA%) [5]	NA (NA%) [6]
Week 24; n=0, 0, 0, 4, 3, 4	NA (NA%) [7]	NA (NA%) [8]	NA (NA%) [9]	33.2 (13.7%)	137 (40.7%)	312 (24.5%)
Week 26; n=0, 0, 0, 4, 3, 4	NA (NA%) [10]	NA (NA%) [11]	NA (NA%) [12]	43.5 (25.2%)	210 (54.1%)	416 (24.6%)

[1] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[2] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[3] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[4] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[5] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[6] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.
[7] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.
[8] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.
[9] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.
[10] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.
[11] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.
[12] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

22. Secondary Outcome Measure:

Measure Title	The Area Under the Plasma Concentration-time Curve From Time Zero to the Last Quantifiable Time Point (AUC(0-t)) After the First (Visit 3), Second (Visit 4), Third (Visit 10), and Fourth (Visit 11) i.v. Infusions
Measure Description	The peripheral blood for each participant was collected and analyzed to estimate the area under the plasma concetration-time curve, AUC(0-t), and was assessed using the non-compartmental method.
Time Frame	Visit 3 (Week 0), Visit 4 (Week 2), Visit 10 (Week 24), and Visit 11 (Week 26). Samples were drawn predose, immediately following the end of infusion, 10 minutes after infusion, 1 hour (hr) after infusion, and 2 hours after infusion.
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as

	Description
	two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	10	6	4	3	4
The Area Under the Plasma Concentration-time Curve From Time Zero to the Last Quantifiable Time Point (AUC(0-t)) After the First (Visit 3), Second (Visit 4), Third (Visit 10), and Fourth (Visit 11) i.v. Infusions [units: Millgram hour per liter] Geometric Mean (Geometric Coefficient of Variation)						
Week 0; n=8, 10, 6, 0, 0, 0	153 (19.4%)	498 (18.6%)	1528 (20.7%)	NA (NA%) [1]	NA (NA%) [2]	NA (NA%) [3]
Week 2; n=8, 10, 6, 0, 0, 0	15559 (34.4%)	63165 (40.6%)	225876 (30.4%)	NA (NA%) [4]	NA (NA%) [5]	NA (NA%) [6]
Week 24; n=0, 0, 0, 4, 3, 4	NA (NA%) [7]	NA (NA%) [8]	NA (NA%) [9]	123 (8.6%)	624 (32.7%)	1347 (29.1%)

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Week 26; n=0, 0, 0, 4, 3, 4	NA (NA%) [10]	NA (NA%) [11]	NA (NA%) [12]	12763 (29.3%)	71041 (54.9%)	217757 (44.5%)

[1] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[2] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[3] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[4] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[5] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[6] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[7] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[8] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[9] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[10] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[11] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo

during Treatment Period 2.

[12] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

23. Secondary Outcome Measure:

Measure Title	Time to Reach Cmax (Tmax) After the First (Visit 3), Second (Visit 4), Third (Visit 10), and Fourth (Visit 11) i.v. Infusions
Measure Description	The peripheral blood for each participant was collected and analyzed for tmax.
Time Frame	Visit 3 (Week 0), Visit 4 (Week 2),Visit 10 (Week 24), and Visit 11 (Week 26). Samples were drawn predose, immediately following the end of infusion, 10 minutes after infusion, 1 hour after infusion, and 2 hours after infusion.
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.

	Description
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	10	6	4	3	4
Time to Reach Cmax (Tmax) After the First (Visit 3), Second (Visit 4), Third (Visit 10), and Fourth (Visit 11) i.v. Infusions [units: hours] Median (Full Range)						
Week 0; n=8, 10, 6, 0, 0, 0	5.33 (4.00 to 8.60)	5.88 (4.17 to 7.67)	6.00 (5.17 to 9.42)	NA (NA to NA) [1]	NA (NA to NA) [2]	NA (NA to NA) [3]
Week 2; n=8, 10, 6, 0, 0, 0	4.25 (3.42 to 5.58)	4.33 (3.52 to 6.13)	3.83 (3.67 to 4.50)	NA (NA to NA) [4]	NA (NA to NA) [5]	NA (NA to NA) [6]
Week 24; n=0, 0, 0, 4, 3, 4	NA (NA to NA) [7]	NA (NA to NA) [8]	NA (NA to NA) [9]	4.42 (4.08 to 6.00)	6.00 (4.17 to 6.92)	6.54 (4.13 to 8.17)
Week 26; n=0, 0, 0, 4, 3, 4	NA (NA to NA) [10]	NA (NA to NA) [11]	NA (NA to NA) [12]	3.67 (3.58 to 6.00)	5.17 (4.08 to 5.50)	4.50 (3.75 to 5.50)

[1] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[2] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[3] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[4] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[5] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo

during Treatment Period 1.

[6] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[7] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[8] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[9] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[10] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[11] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[12] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

24. Secondary Outcome Measure:

Measure Title	Clearance of Ofa Over the Course of Weeks 0-2 and 24-26
Measure Description	The peripheral blood for each participant was collected and analyzed for clearance. Clearance is the measure of efficiency with which a drug is irreversibly removed form the body. The average clearance over the course of Weeks 0-2 and 24-26 is reported.
Time Frame	Weeks 0-2 and 24-26
Safety Issue?	No

Analysis Population Description

FAS. Only those participants contributing data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering

	Description
	progression to the 700 mg dose.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	10	6	4	3	4
Clearance of Ofa Over the Course of Weeks 0-2 and 24-26 [units: liters per hour] Geometric Mean (Geometric Coefficient of Variation)						
Weeks 0-2; n=8, 10, 6, 0, 0, 0	0.006 (34.2%)	0.005 (41.0%)	0.003 (30.8%)	NA (NA%) [1]	NA (NA%) [2]	NA (NA%) [3]
Weeks 24-26; n=0, 0, 0, 4, 3, 4	NA (NA%) [4]	NA (NA%) [5]	NA (NA%) [6]	0.008 (29.5%)	0.004 (54.4%)	0.03 (44.4%)

[1] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[2] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[3] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[4] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo

during Treatment Period 2.

[5] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[6] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

25. Secondary Outcome Measure:

Measure Title	The Volume of Distribution at Steady State (Vss) of Ofatumumab Over the Course of Weeks 0-2 and 24-26
Measure Description	The peripheral blood for each participant was collected and analyzed for Vss. The average Vss over the course of Weeks 0-2 and 24-26 is reported.
Time Frame	Weeks 0-2 and 24-26
Safety Issue?	No

Analysis Population Description

FAS. Only those participants who contributed data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions

	Description
	separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	10	6	4	3	4
The Volume of Distribution at Steady State (Vss) of Ofatumumab Over the Course of Weeks 0-2 and 24-26 [units: liters] Geometric Mean (Geometric Coefficient of Variation)						
Weeks 0-2; n=8, 10, 6, 0, 0, 0	2.48 (20.4%)	2.61 (42.0%)	2.19 (21.3%)	NA (NA%) [1]	NA (NA%) [2]	NA (NA%) [3]
Weeks 24-26; n=0, 0, 0, 4, 3, 4	NA (NA%) [4]	NA (NA%) [5]	NA (NA%) [6]	2.74 (6.54%)	2.20 (68.0%)	2.15 (20.8%)

[1] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[2] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[3] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[4] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[5] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[6] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

26. Secondary Outcome Measure:

Measure Title	Half Life (t1/2) of Ofatumumab in the Terminal Elimination Phase Over the Course of Weeks 0-2 and 24-26
Measure Description	The peripheral blood for each participant was collected and analyzed for half life. Half life is defined as the period of time required for the amount of drug in the body to be reduced by half. The average t1/2 over the course of Weeks 0-2 and 24-26 is reported.
Time Frame	Weeks 0-2 and 24-26
Safety Issue?	No

Analysis Population Description

FAS. Only those participants who contributed data at the indicated time points were analyzed (reflected by "n=" in the category titles).

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching

	Description
	placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period.

Measured Values

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Number of Participants Analyzed	8	10	6	4	3	4
Half Life (t1/2) of Ofatumumab in the						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Terminal Elimination Phase Over the Course of Weeks 0-2 and 24-26 [units: hours] Geometric Mean (Geometric Coefficient of Variation)						
Weeks 0-2; n=8, 10, 6, 0, 0, 0	246 (16.1%)	331 (35.2%)	452 (28.4%)	NA (NA%) [1]	NA (NA%) [2]	NA (NA%) [3]
Weeks 24-26; n=0, 0, 0, 4, 3, 4	NA (NA%) [4]	NA (NA%) [5]	NA (NA%) [6]	241 (23.6%)	342 (16.3%)	453 (49.9%)

[1] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[2] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[3] Ofa concentrations were only measured in Arms 1-3 during Treatment Period 1. Participants in Arms 4-6 received placebo during Treatment Period 1.

[4] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[5] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

[6] Ofa concentrations were only measured in Arms 4-6 during Treatment Period 2. Participants in Arms 1-3 received placebo during Treatment Period 2.

Reported Adverse Events

Reporting Groups

	Description
100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	Ofa was administered as two doses of 100 mg via intravenous (iv) infusions separated by 2 weeks (wks) during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An Independent Data Monitoring Committee (IDMC) evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
300 mg Ofa/Matching Placebo	Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
700 mg Ofa/Matching Placebo	Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the first 24-wk treatment period. Matching placebo was administered as two iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/100 mg Ofa	Matching placebo was administered as two iv infusions separated by 2

	Description
	wks during the first 24-wk treatment period. Ofa was administered as two doses of 100 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 100 mg dose before considering progression to the 300 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/300 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 300 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. An IDMC evaluated the safety data at Week 4 for participants receiving the 300 mg dose before considering progression to the 700 mg dose. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.
Matching Placebo/700 mg Ofa	Matching placebo was administered as two iv infusions separated by 2 wks during the first 24-wk treatment period. Ofa was administered as two doses of 700 mg via iv infusions separated by 2 wks during the second 24-wk treatment period. After completing Week 48 of the second treatment period or withdrawing from the study for any reason, participants entered an Individualized Follow-up Period (IFUP) in which they were monitored for B cell and IgG normalization until individual study termination.

Time Frame

Serious adverse events (SAEs) and non-serious AEs are reported for both the first period (FP; Weeks 0-24) and the second period

(SP; Weeks 24-48). SAEs were collected during the IFUP (collected/reported up to Week 104); however, non-serious AEs were not.

Additional Description

The duration of B-cell depletion observed following ofatumumab administration makes attribution of an SAE/AE in the SP to placebo versus ofatumumab difficult. Because it may not be appropriate to ascribe events reported in the SP to placebo, SAEs/AEs are reported by treatment sequence rather than by each individual treatment received.

Serious Adverse Events

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Total # participants affected/at risk	0/8 (0%)	2/11 (18.18%)	0/7 (0%)	1/4 (25%)	0/4 (0%)	0/4 (0%)
Blood and lymphatic system disorders						
Anaemia † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Infections and infestations						
Influenza † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	1/4 (25%)	0/4 (0%)	0/4 (0%)
# events						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Nervous system disorders						
Headache † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Total # participants affected/at risk	8/8 (100%)	10/11 (90.91%)	7/7 (100%)	3/4 (75%)	4/4 (100%)	4/4 (100%)
Blood and lymphatic system disorders						
Iron deficiency anaemia † [A]						
# participants affected/at	0/8 (0%)	0/11 (0%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	0/4 (0%)

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
risk						
# events						
Leukopenia † [A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	0/7 (0%)	1/4 (25%)	0/4 (0%)	1/4 (25%)
# events						
Lymphopenia † [A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	1/4 (25%)
# events						
Neutropenia † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	1/4 (25%)
# events						
Cardiac disorders						
Ventricular extrasystoles † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	1/4 (25%)	0/4 (0%)
# events						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Ear and labyrinth disorders						
Vertigo † [A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Eye disorders						
Abnormal sensation in eye † [A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Blepharospasm † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	1/4 (25%)	0/4 (0%)	0/4 (0%)
# events						
Vision blurred † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Visual impairment † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Gastrointestinal disorders						
Abdominal discomfort † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Abdominal pain upper † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Constipation † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Diarrhoea † [A]						
# participants affected/at	1/8 (12.5%)	1/11 (9.09%)	1/7 (14.29%)	1/4 (25%)	0/4 (0%)	0/4 (0%)

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
risk						
# events						
Flatulence † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Nausea † [A]						
# participants affected/at risk	1/8 (12.5%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Neck pain † [A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Vomiting † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	1/7 (14.29%)	1/4 (25%)	0/4 (0%)	0/4 (0%)
# events						
General disorders						
Fatigue † [A]						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
# participants affected/at risk	2/8 (25%)	2/11 (18.18%)	0/7 (0%)	1/4 (25%)	0/4 (0%)	0/4 (0%)
# events						
Pyrexia †[A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Immune system disorders						
Cytokine release syndrome †[A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	2/4 (50%)	0/4 (0%)
# events						
Infections and infestations						
Acute tonsillitis †[A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Influenza †[A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	1/4 (25%)	1/4 (25%)	0/4 (0%)
# events						
Laryngitis †[A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	1/4 (25%)	0/4 (0%)	0/4 (0%)
# events						
Nasopharyngitis †[A]						
# participants affected/at risk	4/8 (50%)	0/11 (0%)	1/7 (14.29%)	1/4 (25%)	0/4 (0%)	0/4 (0%)
# events						
Oral herpes †[A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	1/4 (25%)
# events						
Rhinitis †[A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	1/4 (25%)
# events						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Tonsilitis † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	1/4 (25%)
# events						
Tracheobronchitis † [A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Upper respiratory tract infection † [A]						
# participants affected/at risk	1/8 (12.5%)	2/11 (18.18%)	2/7 (28.57%)	3/4 (75%)	0/4 (0%)	0/4 (0%)
# events						
Urinary tract infection † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	1/4 (25%)	0/4 (0%)
# events						
Varicella † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	1/4 (25%)	0/4 (0%)

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
# events						
Viral infection † [A]						
# participants affected/at risk	1/8 (12.5%)	3/11 (27.27%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	1/4 (25%)
# events						
Injury, poisoning and procedural complications						
Concussion † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	1/4 (25%)	0/4 (0%)	1/4 (25%)
# events						
Contusion † [A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Wound † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Investigations						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Alanine aminotransferase increased † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	1/4 (25%)
# events						
Blood bicarbonate decreased † [A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Blood creatinine increased † [A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
False positive laboratory result † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Musculoskeletal and						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
connective tissue disorders						
Back pain †[A]						
# participants affected/at risk	1/8 (12.5%)	1/11 (9.09%)	0/7 (0%)	1/4 (25%)	0/4 (0%)	0/4 (0%)
# events						
Nervous system disorders						
Burning sensation †[A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Dizziness †[A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Headache †[A]						
# participants affected/at risk	1/8 (12.5%)	1/11 (9.09%)	0/7 (0%)	1/4 (25%)	1/4 (25%)	0/4 (0%)
# events						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Hypoaesthesia facial † [A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Neuralgia † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Oropharyngeal pain † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	1/4 (25%)	0/4 (0%)	0/4 (0%)
# events						
Tension headache † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Trigeminal neuralgia † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
Psychiatric disorders						
Anxiety †[A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	1/4 (25%)	0/4 (0%)	0/4 (0%)
# events						
Depressed mood †[A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Depression †[A]						
# participants affected/at risk	2/8 (25%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Insomnia †[A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	1/4 (25%)	0/4 (0%)	0/4 (0%)
# events						
Respiratory, thoracic and mediastinal disorders						
Asthma †[A]						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Bronchospasm † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Cough † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Dyspnoea † [A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Nasal congestion † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	1/4 (25%)	0/4 (0%)
# events						
Pharyngeal edema † [A]						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	1/4 (25%)	0/4 (0%)
# events						
Rhinorrhoea † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Sneezing † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Throat irritation † [A]						
# participants affected/at risk	3/8 (37.5%)	4/11 (36.36%)	2/7 (28.57%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Wheezing † [A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Skin and subcutaneous						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
tissue disorders						
Acne † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Anemia † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Erythema † [A]						
# participants affected/at risk	2/8 (25%)	1/11 (9.09%)	1/7 (14.29%)	0/4 (0%)	1/4 (25%)	0/4 (0%)
# events						
Hyperhidrosis † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	1/4 (25%)
# events						
Petechiae † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
# events						
Pruritus † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	1/4 (25%)	0/4 (0%)
# events						
Pruritus generalized † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Rash † [A]						
# participants affected/at risk	2/8 (25%)	3/11 (27.27%)	4/7 (57.14%)	2/4 (50%)	0/4 (0%)	2/4 (50%)
# events						
Rash erythematous † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Rash generalized † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	1/4 (25%)

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
# events						
Rash pruritic † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Urticaria † [A]						
# participants affected/at risk	0/8 (0%)	1/11 (9.09%)	1/7 (14.29%)	1/4 (25%)	0/4 (0%)	0/4 (0%)
# events						
Surgical and medical procedures						
Antibiotic prophylaxis † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	1/4 (25%)	0/4 (0%)
# events						
Bartholin's cyst removal † [A]						
# participants affected/at risk	0/8 (0%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	1/4 (25%)	0/4 (0%)
# events						
Tooth extraction † [A]						

	100 Milligrams (mg) Ofatumumab (Ofa)/Matching Placebo	300 mg Ofa/Matching Placebo	700 mg Ofa/Matching Placebo	Matching Placebo/100 mg Ofa	Matching Placebo/300 mg Ofa	Matching Placebo/700 mg Ofa
# participants affected/at risk	0/8 (0%)	0/11 (0%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						
Vascular disorders						
Flushing † [A]						
# participants affected/at risk	0/8 (0%)	2/11 (18.18%)	1/7 (14.29%)	0/4 (0%)	0/4 (0%)	1/4 (25%)
# events						
Hypotension † [A]						
# participants affected/at risk	1/8 (12.5%)	0/11 (0%)	0/7 (0%)	0/4 (0%)	0/4 (0%)	0/4 (0%)
# events						

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

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.

Limitations and Caveats:

Results Point of Contact:

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