ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 12/12/2013

ClinicalTrials.gov ID: NCT00394836

Study Identification

Unique Protocol ID:	111772
Brief Title:	HuMax-CD20 i(Ofatumumab) n Follicular Lymphoma (FL) Patients Refractory to Rituximab
Official Title:	A Single-arm, International, Multi-center Trial of HuMax-CD20, a Fully Human Monoclonal Anti-CD20 Antibody, in Patients With Follicular Lymphoma Who Are Refractory to Rituximab as Monotherapy or in Combination With Chemotherapy
Secondary IDs:	Hx-CD20-405 [Genmab] 111772 [GSK]

Study Status

Record Verification:	November 2013
Overall Status:	Completed
Study Start:	May 2007
Primary Completion:	April 2009 [Actual]
Study Completion:	September 2013 [Actual]

Sponsor/Collaborators

Sponsor:	GlaxoSmithKline
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes

Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 11465 Serial Number: 045 Has Expanded Access? No
Review Board:	Approval Status: Approved Board Name: CDER Board Affiliation: FDA Phone: Email:
Data Monitoring?:	Yes
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	A Single-Arm, International, Multi-Center Trial of HuMax-CD20 (Ofatumumab), a Fully Human Monoclonal Anti-CD20 Antibody, in Patients With Follicular Lymphoma Who Are Refractory to Rituximab as Monotherapy or in Combination With Chemotherapy
Detailed Description:	Patients in the study will be randomized into two dose groups. Patients in each dose group will receive one infusion of 300 mg of HuMax-CD20 followed by 7 weekly infusions of either 500 or 1000 mg of HuMax-CD20. Disease status will be assessed every 3 months until month 24.

Conditions

Conditions:	Lymphoma, Follicular
Keywords:	ofatumumab rituximab NHL CD20 refractory

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment

Study Phase:	Phase 2
Intervention Model:	Single Group Assignment
Number of Arms:	
Masking:	Single Blind (Outcomes Assessor)
Allocation:	N/A
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	116 [Actual]

Arms and Interventions

Intervention Details:

Drug: Ofatumumab

Eight weekly infusions of ofatumumab. The first infusion of 300mg ofatumunab

Drug: Ofatumumab

followed by 7 weekly infusions of 1000mg ofatumumab

Outcome Measures

[See Results Section.]

Eligibility

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

- Patient with follicular lymphoma grade 1 – 2
- Refractory to rituximab given as monotherapy or in combination with any chemotherapy or to rituximab given as maintenance treatment following R-chemo, defined as:
- failure to achieve at least PR to rituximab given as monotherapy or in combination with any chemotherapy; or,
- disease progression while on rituximab (either given as monotherapy or in combination with any chemotherapy or during rituximab maintenance treatment following R-chemo); or,
- disease progression in responders within 6 months of the last dose of rituximab (either given as monotherapy or in combination with any chemotherapy or after rituximab maintenance treatment schedule following R-chemo)
- Tumor verified to be CD20+ positive from excisional lymph node biopsy
- CT scan in screening phase (based on local evaluation) showing:

- 2 or more clearly demarcated lesions with a largest diameter ≥ 1.5 cm, or
- 1 clearly demarcated lesion with a largest diameter ≥ 2,0 cm
- ECOG Performance Status of 0, 1, or 2
- Age ≥ 18 years
- Following receipt of verbal and written information about the study, the patient must provide signed informed consent before any study related activity is carried out

Exclusion Criteria

- Previous autologous stem cell transplantation within 6 months
- Previous allogeneic stem cell transplantation
- More than 1 previous radio immunotherapy regimen
- Received radio immunotherapy within 3 months
- Received any Anti-cancer treatment within 4 weeks
- Received monoclonal antibodies, other than rituximab within 3 months
- Patients previously treated with anti-CD20 monoclonal antibodies, other than rituximab
- Life expectancy less than 6 months

Contacts/Locations

Study Officials: GSK Clinical Trials
Study Director
GlaxoSmithKline

Locations: United Kingdom
GSK Investigational Site
Southampton, United Kingdom, SO16 6YD

References

Citations: Czuczman MS, Fayad L, Delwail V, Cartron G, Jacobsen E, Kuliczkowski K, Link BK, Pinter-Brown L, Radford J, Hellmann A, Gallop-Evans E, DiRienzo CG, Goldstein N, Gupta I, Jewell RC, Lin TS, Lisby S, Schultz M, Russell CA, Hagenbeek A . Ofatumumab Monotherapy in Rituximab-Refractory Follicular Lymphoma: Results from a Multicenter Study . [Blood]. 2012;119(16):3698-3704.

Links:

Study Data/Documents:

Participant Flow

Pre-Assignment Details	Participants were randomized to one of two ofatumumab dose arms. Disease progression and treatment refusal resulted in some participants entering early follow up after early withdrawal from study treatment. They are being followed for overall survival.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions. In the extended follow-up phase of the study, participants were followed only for survival status for up to 5 years and new follicular lymphoma (FL) treatment. Time to the next FL treatment analysis included participants which received new FL treatment during extended follow-up.
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions. In the extended follow-up phase of the study, participants were followed only for survival status for up to 5 years and new Follicular lymphoma (FL) treatment. Time to the next FL treatment analysis included participants which received new FL treatment during extended follow-up.

Teatment or Follow-up Phase

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Started	30	86
Early Follow-up Entry	4 [1]	8 [1]
Completed	2	8
Not Completed	28	78
Adverse Event	0	2
Protocol Violation	0	2
Disease Progression	27	60
Patient Refusal	1	2
Death	0	1
Patient refuses to continue with CT scan	0	1
Started alternative treatment	0	6
Suspicion of cholangiocarcinoma	0	1

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Physician Decision	0	1
Patient progressed, return to Pakistan	0	1
Non compliance	0	1

[1] Did not complete treatment.

Extended Follow-up Phase (2-5 Years)

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Started	20 [1]	58 [1]
Completed	0	5
Not Completed	20	53
Lost to Follow-up	0	1
Death	0	1
Alternative treatment	13	41
Medical Reasons	7	10

[1] Not all participants went into extended follow up per protocol.

Baseline Characteristics

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Baseline Measures

	Ofatumumab 500 mg	Ofatumumab 1000 mg	Total
Number of Participants	30	86	116

	Ofatumumab 500 mg	Ofatumumab 1000 mg	Total
Age, Continuous [units: Years] Mean (Standard Deviation)	60.4 (10.1)	59.7 (11.1)	59.9 (10.8)
Gender, Male/Female [units: Participants]			
Female	11	43	54
Male	19	43	62
Race/Ethnicity, Customized [units: participants]			
Asian	1	4	5
Black or African American	0	1	1
Hispanic or Latino	0	3	3
White	28	78	106
Reunion Island Native	1	0	1

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With Objective Response (OR)
Measure Description	OR was assessed by an Independent endpoints Review Committee (IRC) according to the standardized response criteria for Non-Hodgkin's lymphoma. Participants with Complete Response (CR; complete disappearance of all detectable disease), Complete Response unconfirmed (CRu; any residual lymph node/nodal mass >1.5 centimeters [cm] in its longest transverse diameter that regressed >75% compared to baseline), or Partial Response (PR; >=50% decrease in the sum of the product of diameters of indicator lesions) were defined as responders for OR.
Time Frame	Start of treatment (Day 1 of Week 0) until 3 months after start of last infusion (up to Week 32)
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions

	Description
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	30	86
Number of Participants With Objective Response (OR) [units: participants]		
CR	0	1
CRu	2	0
PR	2	8

Statistical Analysis 1 for Number of Participants With Objective Response (OR)

Statistical Analysis Overview	Comparison Groups	Ofatumumab 500 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [percentage of responders]
	Estimated Value	13
	Confidence Interval	(2-Sided) 95% 4 to 31
	Estimation Comments	Response rate is calculated as the number of responses divided by the number of participants treated * 100.

Statistical Analysis 2 for Number of Participants With Objective Response (OR)

Statistical Analysis Overview	Comparison Groups	Ofatumumab 1000 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [percentage of responders]
	Estimated Value	10
	Confidence Interval	(2-Sided) 95% 5 to 19
	Estimation Comments	[Not specified]

2. Primary Outcome Measure:

Measure Title	Number of Participants Classified as Responders and Non-responders for Objective Response (OR)
Measure Description	Based on OR over a 6-month period from start of treatment, participants were classified as responders/non-responders as follows: participants with CR, CRu, or PR were classified as responders, whereas participants with Stable Disease (SD; achieving less than PR but not consistent with PD), Progressive Disease (PD; 50% increase from nadir in the products of the greatest perpendicular diameters of any previously identified node or appearance of any new node >1 cm), or Not Evaluable (NE) participants were classified as non-responders.
Time Frame	6-month period from the start of treatment. There was a median time of response at Month 5.5 (participants were followed for up to 24 months).
Safety Issue?	No

Analysis Population Description
FAS

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	30	86
Number of Participants Classified as Responders and Non-responders for Objective Response (OR) [units: participants]		
Responders with CR	0	1

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Responders with CRu	2	0
Responders with PR	2	8
Non-responders with SD	9	43
Non-responders with PD	14	26
Non-responders with NE	3	8

3. Secondary Outcome Measure:

Measure Title	Duration of Response
Measure Description	The duration of response is defined as the time from the initial response (the first visit at which response was observed) to progression or death. For participants who were lost to follow-up, duration of response was censored at the date of the last attended visit at which the endpoint was assessed. The Kaplan-Meier method was used to estimate duration of response.
Time Frame	From start of treatment (Week 0) until Month 24
Safety Issue?	No

Analysis Population Description

FAS. Only those participants classified as responders were analyzed.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	4	9
Duration of Response [units: months] Median (95% Confidence Interval)	6.0 (2.9 to 6.2)	6.0 (2.8 to 12.3)

4. Secondary Outcome Measure:

Measure Title	Progression-Free Survival
Measure Description	Progression-free survival (PFS) is defined as the time from randomization until the first radiologically or clinically documented evidence of progression or death due to any cause, if sooner. For participants who were lost to follow-up, PFS was censored at the date of the last attended visit at which the endpoint was assessed. The Kaplan-Meier method was used to estimate PFS.
Time Frame	From start of treatment (Week 0) until Month 24
Safety Issue?	No

Analysis Population Description
FAS

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	30	86
Progression-Free Survival [units: Months] Median (95% Confidence Interval)	3.2 (2.9 to 9.2)	6.0 (4.4 to 9.0)

5. Secondary Outcome Measure:

Measure Title	Time to Next Follicular Lymphoma (FL) Therapy
Measure Description	Time to next FL (anti-lymphoma) therapy is defined as the time from randomization until the time of first administration of the next anti-lymphoma therapy other than ofatumumab. For participants who were lost to follow-up, the time was censored at the date of the last attended visit at which the endpoint was assessed.
Time Frame	From start of treatment (Week 0) until Month 24

Safety Issue?	No

Analysis Population Description
FAS

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	30	86
Time to Next Follicular Lymphoma (FL) Therapy [units: Months] Median (95% Confidence Interval)	4.2 (3.8 to 8.6)	7.0 (5.5 to 9.9)

6. Secondary Outcome Measure:

Measure Title	Overall Survival
Measure Description	Overall survival is defined as the time from randomization until death. For participants who are lost to follow-up, overall survival will be censored at the date of the last attended visit at which the endpoint was assessed.
Time Frame	First dose (Week 0) until 5 years
Safety Issue?	No

Analysis Population Description
FAS. As of the time of data cut-off, data for Overall Survival was not estimable because too few deaths have occurred at the time of study completion.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	30	86
Overall Survival [units: Months] Median (95% Confidence Interval)	NA (NA to NA) [1]	NA (NA to NA) [1]

[1] Overall survival was not estimable due to too few deaths.; therefore the median and CI cannot be calculated.

7. Secondary Outcome Measure:

Measure Title	Percent Change From Screening (Visit 1) in Tumor Size as Assessed by Radiologist 1 (R1) and Radiologist 2 (R2) at Months 3, 6, 9, 12, 18, and 24
Measure Description	Tumor size was measured by computed tomography (CT) scan and was computed as the sum of product of diameters (SPD) for the indicator lesions. CT scans with contrast of the neck, thorax, abdomen, and pelvis were performed at Screening and during the follow-up period (Month 3, 6, 9, 12, 18, and 24). The change in tumor size from Screening (Visit 1) was presented per Radiologist 1 (R1) and Radiologist 2 (R2). Percent change from Screening (Visit 1, Week -2) = (value at Visits 11, 12, 13, 14, 16, and 18 minus the value at Visit 1 divided by the value at Visit 1) * 100.
Time Frame	Visits 1 (Week -2), 11 (Month 3), 12 (Month 6), 13 (Month 9), 14 (Month 12), 16 (Month 18), and 18 (Month 24)
Safety Issue?	No

Analysis Population Description

FAS. Data were provided for the number of participants attending each visit. Participants withdrawn during the study were not analyzed.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	15	47
Percent Change From Screening (Visit 1) in Tumor Size as Assessed by Radiologist 1 (R1) and Radiologist 2 (R2) at Months 3, 6, 9, 12, 18, and 24		

	Ofatumumab 500 mg	Ofatumumab 1000 mg
[units: percent change in tumor size] Median (Full Range)		
Visit 11 (Month 3), R1, n=14, 47	5.50 (-85.00 to 52.00)	-7.20 (-66.00 to 69.00)
Visit 11 (Month 3), R2, n=15, 47	-2.10 (-84.00 to 27.00)	-8.10 (-82.00 to 56.00)
Visit 12 (Month 6), R1, n=7, 34	-20.30 (-90.00 to 13.00)	-16.10 (-91.00 to 123.00)
Visit 12 (Month 6), R2, n=7, 33	-39.90 (-86.00 to 29.00)	-29.80 (-83.00 to 61.00)
Visit 13 (Month 9), R1, n=6, 25	-28.90 (-85.00 to 30.00)	-22.60 (-88.00 to 138.00)
Visit 13 (Month 9), R2, n=6, 26	-48.30 (-84.00 to 34.00)	-39.80 (-85.00 to 91.00)
Visit 14 (Month 12), R1, n=4, 17	5.50 (-69.00 to 74.00)	-16.00 (-73.00 to 42.00)
Visit 14 (Month 12), R2, n=4, 18	-14.70 (-83.00 to 63.00)	-44.60 (-91.00 to 62.00)
Visit 16 (Month 18), R1, n=3, 12	31.10 (-81.00 to 202.00)	-18.30 (-49.00 to 45.00)
Visit 16 (Month 18), R2, n=3, 12	22.90 (-87.00 to 52.00)	-28.70 (-91.00 to 50.00)
Visit 18 (Month 24), R1, n=2, 8	-4.80 (-85.00 to 75.00)	-20.10 (-64.00 to 4.00)
Visit 18 (Month 24), R2, n=2, 8	-14.40 (-88.00 to 59.00)	-36.50 (-92.00 to 35.00)

8. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline (Visit 2) in CD19+ and CD20+ Cells in Peripheral Blood at Visits 11 and 12
Measure Description	CD19 and CD20 are proteins found on the cell surface of B cells, and they can be detected in peripheral blood by flow cytometry. Flow cytometry of peripheral blood was performed for immediate analysis of cells with cluster of differentiation 19 (CD19+) and CD20+. The analysis will be done until a value is reached that is in the normal range. Percent change from Baseline (Visit 2) = (value at Visits 11 and 12 minus the value at Visit 2 divided by the value at Visit 2) * 100.
Time Frame	Visits 2 (Baseline), 11 (Month 3), and 12 (Month 6)
Safety Issue?	No

Analysis Population Description

FAS. Data were provided for the number of participants attending each visit. Participants withdrawn during the study were not analyzed.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	15	45
Percent Change From Baseline (Visit 2) in CD19+ and CD20+ Cells in Peripheral Blood at Visits 11 and 12 [units: percent change in cells] Median (95% Confidence Interval)		
Visit 11 (Month 3), CD19+, n=15, 42	-100.00 (-100.00 to 0.00)	-80.1 (-100.00 to 566.00)
Visit 11 (Month 3), CD20+, n=15, 45	-100.00 (-100.00 to 0.00)	-100.00 (-100.00 to 43.00)
Visit 12 (Month 6), CD19+, n=8, 32	-48.80 (-100.00 to 129.00)	-19.00 (-100.00 to 838.00)
Visit 12 (Month 6), CD20+, n=8, 34	-48.20 (-100.00 to 129.00)	-19.00 (-100.00 to 18.00)

9. Secondary Outcome Measure:

Measure Title	Number of Participants With Conversion and no Conversion of BCL2 Positive to BCL2 Negative in Peripheral Blood
Measure Description	B-cell lymphoma 2 (BCL2) is the second member of a range of proteins initially described in chromosomal translocations involving chromosomes 14 and 18 in follicular lymphomas. BCL2 mitochondrial ribonucleic acid (mRNA) was measured by polymerase chain reaction (PCR) from peripheral blood. Participants who had no post-screening data were categorized as "Missing."
Time Frame	Screening (Visit 1) until Month 24 (Visit 18)
Safety Issue?	No

Analysis Population Description

FAS. Only those participants who were BCL2 positive at Screening were analyzed.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	11	31
Number of Participants With Conversion and no Conversion of BCL2 Positive to BCL2 Negative in Peripheral Blood [units: participants]		
Participants converted from positive to negative	2	6
Participants not converted	6	15
Missing	3	10

10. Secondary Outcome Measure:

Measure Title	Number of Participants Who Experienced Any Adverse Event From First Treatment (Visit 2) to Visit 18 (Month 24)
Measure Description	An adverse event (AE) is defined as any untoward medical occurrence in a participant administered a pharmaceutical product and which did not necessarily have a causal relationship with this treatment. A list of AEs experienced in the study at a frequency threshold of 5% can be found in the AE section.
Time Frame	From first treatment (Visit 2) until Visit 18 (Month 24)
Safety Issue?	Yes

Analysis Population Description

FAS

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions

	Description
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	30	86
Number of Participants Who Experienced Any Adverse Event From First Treatment (Visit 2) to Visit 18 (Month 24) [units: participants]	30	79

11. Secondary Outcome Measure:

Measure Title	Number of Participants With Positive Human Anti-human Antibodies (HAHA) at Visits 1, 12, 13, and 14
Measure Description	HAHA are indicators of immunogenicity to ofatumumab. Blood samples were withdrawn from participants at Visits 1, 12, 13, and 18 for analysis of HAHA. Analysis of HAHA was done in batches.
Time Frame	Visits 1 (Screening), 12 (Month 6), 13 (Month 9), and 18 (Month 24)
Safety Issue?	No

Analysis Population Description

FAS. Data were provided for the number of participants attending each visit. Participants withdrawn during the study were not analyzed.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	30	85
Number of Participants With Positive Human Anti-human Antibodies (HAHA) at Visits 1, 12, 13, and 14		

	Ofatumumab 500 mg	Ofatumumab 1000 mg
[units: participants]		
Visit 1 (Week -2), n=30, 85	0	0
Visit 12 (Month 6), n=8, 33	0	0
Visit 13 (Month 9), n=7, 24	0	0
Visit 14 (Month 12), n=3, 11	0	0

12. Secondary Outcome Measure:

Measure Title	Complement (CH50) Levels at Visit 1 and at the End of Infusion at Visit 2
Measure Description	Blood samples were drawn from participants at Visits 1 and 2 for analysis of complement (CH50) levels. Analysis of CH50 was done in batches, and CH50 levels were measured two hours after the end of study medication infusion. Percent change from Screening (Visit 1, Week -2) = (value at Visit 2 minus the value at Visit 1 divided by the value at Visit 1) * 100.
Time Frame	Visits 1 (Week -2) and 2 (Week 0)
Safety Issue?	No

Analysis Population Description

FAS. Data were provided for the number of participants attending each visit. Participants withdrawn during the study were not analyzed.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	30	85
Complement (CH50) Levels at Visit 1 and at the End of Infusion at Visit 2 [units: Units per milliliter (U/mL)] Median (Full Range)		

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Visit 1 (Week -2), n=30, 85	57.00 (10.00 to 79.00)	54.00 (10.00 to 99.00)
Visit 2 (Week 0), n=30, 84	49.00 (10.00 to 76.00)	49.50 (10.00 to 92.00)

13. Secondary Outcome Measure:

Measure Title	Number of Participants Classified as Responders for Fragment C Receptor (FcR) Polymorphism (Poly.)
Measure Description	FcR poly. affect the affinity with which FcRs interact with immunoglobulin molecules and are prognostic factors that are indicative of altered responsiveness to treatment and/or survival. A blood sample was drawn at Visit 1 for analysis (done in batches of several samples) of FcR poly. (Fcgamma RIIIa Valine/Phenylalanine genotypes [TT=thymidine/thymidine, TG=thymidine/guanine, GG=guanine/guanine] and Fcgamma RIIa Arginine/Histidine genotypes [AA=adenine/adenine, AG=adenine/guanine, GG=guanine/guanine]). Responders must have met the criteria for CR, CRu, or PR at either Month 3 or Month 6. Fc receptor polymorphisms and C1qA-276 results are not included in this results summary.
Time Frame	From first treatment (Visit 2) until Visit 12 (Month 6)
Safety Issue?	No

Analysis Population Description

FAS. Data were provided for the number of participants attending each visit. Participants withdrawn during the study were not analyzed.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	11	37
Number of Participants Classified as Responders for Fragment C Receptor (FcR) Polymorphism (Poly.) [units: participants]		
Fc Gamma IIa Genotype = AA, n=4, 9	NA [1]	NA [1]

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Fc Gamma IIa Genotype = AG, n=11, 37	NA [1]	NA [1]
Fc Gamma IIa Genotype = GG, n=3, 12	NA [1]	NA [1]
Fc Gamma IIIa Genotype = TT, n=5, 31	NA [1]	NA [1]
Fc Gamma IIIa Genotype = TG, n=11, 23	NA [1]	NA [1]
Fc Gamma IIIa Genotype = GG, n=2, 4	NA [1]	NA [1]

[1] Proper informed consent was not obtained; therefore, we cannot use these data.

14. Secondary Outcome Measure:

Measure Title	Ctrough and Cmax at the Eighth Infusion (Visit 9, Week 7)
Measure Description	Cmax is defined as the maximum concentration of drug in plasma samples. Ctrough is defined as the trough plasma concentration (measured concentration at the end of a dosing interval [taken directly before the start of the next infusion]).
Time Frame	Visit 9 (Week 7; up to 10 months after dose)
Safety Issue?	No

Analysis Population Description

FAS. Data were provided for the number of participants who had a value. Cmax was not reported for one participant due to missing data. Participants withdrawn during the study were not analyzed. Interim results; data as of 28 April 2009.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	24	78
Ctrough and Cmax at the Eighth Infusion (Visit 9, Week 7)		

	Ofatumumab 500 mg	Ofatumumab 1000 mg
[units: Milligrams per liter (mg/L)] Geometric Mean (Geometric Coefficient of Variation)		
Ctrough, n=24, 78	183 (3.40%)	447 (1.31%)
Cmax, n=23, 78	479 (0.40%)	879 (0.45%)

15. Secondary Outcome Measure:

Measure Title	AUC(0-inf) and AUC(0-168) After the Eighth Infusion (Visit 9, Week 7)
Measure Description	AUC is defined as the area under the ofatumumab concentration-time curve as a measure of drug exposure. AUC(0-168) is AUC from the start of infusion to 168 hours after the start of the infusion; AUC(0-inf) is AUC from the start of infusion extrapolated to infinity.
Time Frame	Visit 9 (Week 7; up to 10 months after dose)
Safety Issue?	No

Analysis Population Description

FAS. Data were provided for the number of participants for whom the parameter could be calculated. Participants withdrawn during the study were not analyzed. Interim results; data as of 28 April 2009.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	19	75
AUC(0-inf) and AUC(0-168) After the Eighth Infusion (Visit 9, Week 7) [units: Milligrams * hour per liter (mg.h/L)] Geometric Mean (Geometric Coefficient of Variation)		
AUC(0-inf), n=12, 55	327715 (1.03%)	566717 (1.07%)
AUC(0-168), n=19, 75	71513 (0.40%)	113622 (0.65%)

16. Secondary Outcome Measure:

Measure Title	t1/2 After the Eighth Infusion (Visit 9, Week 7)
Measure Description	t1/2 is defined as terminal half-life, which is the time required for the amount of the drug in the body to decrease by half.
Time Frame	Visit 9 (Week 7; up to 10 months after dose)
Safety Issue?	No

Analysis Population Description

FAS. Data were provided for the number of participants for whom the parameter could be calculated. Participants withdrawn during the study were not analyzed. Interim results; data as of 28 April 2009.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	12	55
t1/2 After the Eighth Infusion (Visit 9, Week 7) [units: hours] Geometric Mean (Geometric Coefficient of Variation)	444 (0.76%)	443 (0.64%)

17. Secondary Outcome Measure:

Measure Title	CL After the Eighth Infusion (Visit 9, Week 7)
Measure Description	CL is the clearance of drug from plasma, which is defined as the volume of plasma from which drug is removed per unit time.
Time Frame	Visit 9 (Week 7; up to 10 months after dose)
Safety Issue?	No

Analysis Population Description

FAS. Data were provided for the number of participants for whom the parameter could be calculated. Participants withdrawn during the study were not analyzed. Interim results; data as of 28 April 2009.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	18	75
CL After the Eighth Infusion (Visit 9, Week 7) [units: Milliliters per hour (mL/h)] Geometric Mean (Geometric Coefficient of Variation)	7.0 (0.41%)	8.8 (0.65%)

18. Secondary Outcome Measure:

Measure Title	Vss After the Eighth Infusion (Visit 9, Week 7)
Measure Description	Vss is the volume of distribution at steady state of ofatumumab.
Time Frame	Visit 9 (Week 7; to up 10 months after dose)
Safety Issue?	No

Analysis Population Description

FAS. Data were provided for the number of participants for whom the parameter could be calculated. Participants withdrawn during the study were not analyzed. Interim results; data of 28 April 2009.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions

Measured Values

	Ofatumumab 500 mg	Ofatumumab 1000 mg
Number of Participants Analyzed	11	55
Vss After the Eighth Infusion (Visit 9, Week 7) [units: mL] Geometric Mean (Geometric Coefficient of Variation)	4414 (0.48%)	5408 (0.34%)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	During the Extended Follow-up Phase, from 2 years to 5 years after first treatment, only serious adverse events (SAEs) were collected; no non-serious AEs were collected during this period.

Reporting Groups

	Description
Ofatumumab 500 mg	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions
Ofatumumab 1000 mg	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions
Ofatumumab 500 mg: Extended Follow-up Phase	Ofatumumab intravenous (iv) infusion initiated at 300 milligrams (mg), followed by an infusion of 500 mg administered once weekly for 7 infusions. In the extended follow-up phase of the study, participants were followed only for survival status for up to 5 years and new follicular lymphoma (FL) treatment. Time to the next FL treatment analysis included participants which received new FL treatment during extended follow-up.
Ofatumumab 1000 mg: Extended Follow-up Phase	Ofatumumab iv infusion initiated at 300 mg, followed by an infusion of 1000 mg administered once weekly for 7 infusions. In the extended follow-up phase of the study, participants were followed only for survival status for up to 5 years and new Follicular lymphoma (FL) treatment. Time to the next FL treatment analysis included participants which received new FL treatment during extended follow-up.

Serious Adverse Events

	Ofatumumab 500 mg	Ofatumumab 1000 mg	Ofatumumab 500 mg: Extended Follow-up Phase	Ofatumumab 1000 mg: Extended Follow-up Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	6/30 (20%)	25/86 (29.07%)	2/30 (6.67%)	6/86 (6.98%)
Blood and lymphatic system disorders				
Anemia [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Bone marrow failure [A] †	1/30 (3.33%)	0/86 (0%)	0/30 (0%)	0/86 (0%)
Febrile neutropenia [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Neutropenia [A] †	1/30 (3.33%)	5/86 (5.81%)	0/30 (0%)	0/86 (0%)
Cardiac disorders				
Bradycardia [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Eye disorders				
Blindness [A] †	0/30 (0%)	0/86 (0%)	0/30 (0%)	1/86 (1.16%)
Gastrointestinal disorders				
Constipation [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Tooth loss [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Vomiting [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
General disorders				
Death [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Disease progression [A] †	2/30 (6.67%)	4/86 (4.65%)	1/30 (3.33%)	3/86 (3.49%)
Generalised oedema [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Hypothermia [A] †	1/30 (3.33%)	0/86 (0%)	0/30 (0%)	0/86 (0%)
Pyrexia [A] †	1/30 (3.33%)	0/86 (0%)	0/30 (0%)	0/86 (0%)
Hepatobiliary disorders				

	Ofatumumab 500 mg	Ofatumumab 1000 mg	Ofatumumab 500 mg: Extended Follow-up Phase	Ofatumumab 1000 mg: Extended Follow-up Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Cholelithiasis [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Immune system disorders				
Drug hypersensitivity [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Infections and infestations				
Bronchitis [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Cystitis [A] †	1/30 (3.33%)	0/86 (0%)	0/30 (0%)	0/86 (0%)
Neutropenic infection [A] †	1/30 (3.33%)	0/86 (0%)	0/30 (0%)	0/86 (0%)
Pneumocystis jiroveci pneumonia [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Progressive Multifocal Leukoencephalopathy [A] †	0/30 (0%)	0/86 (0%)	0/30 (0%)	1/86 (1.16%)
Salmonellosis [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Sepsis [A] †	0/30 (0%)	1/86 (1.16%)	1/30 (3.33%)	1/86 (1.16%)
Injury, poisoning and procedural complications				
Drug toxicity [A] †	1/30 (3.33%)	0/86 (0%)	0/30 (0%)	0/86 (0%)
Investigations				
Neutrophil count decreased [A] †	1/30 (3.33%)	2/86 (2.33%)	0/30 (0%)	0/86 (0%)
Platelet count decreased [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Hodgkin's disease [A] †	0/30 (0%)	0/86 (0%)	0/30 (0%)	1/86 (1.16%)
Squamous cell carcinoma [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Nervous system disorders				
Headache [A] †	0/30 (0%)	0/86 (0%)	0/30 (0%)	1/86 (1.16%)

	Ofatumumab 500 mg	Ofatumumab 1000 mg	Ofatumumab 500 mg: Extended Follow-up Phase	Ofatumumab 1000 mg: Extended Follow-up Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Respiratory, thoracic and mediastinal disorders				
Pleural effusion [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Pulmonary embolism [A] †	0/30 (0%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)

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

Other Adverse Events

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

	Ofatumumab 500 mg	Ofatumumab 1000 mg	Ofatumumab 500 mg: Extended Follow-up Phase	Ofatumumab 1000 mg: Extended Follow-up Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	30/30 (100%)	79/86 (91.86%)	0/30 (0%)	0/86 (0%)
Blood and lymphatic system disorders				
Anemia [A] †	1/30 (3.33%)	6/86 (6.98%)	0/30 (0%)	0/86 (0%)
Leukopenia [A] †	0/30 (0%)	6/86 (6.98%)	0/30 (0%)	0/86 (0%)
Neutropenia [A] †	3/30 (10%)	7/86 (8.14%)	0/30 (0%)	0/86 (0%)
Gastrointestinal disorders				
Diarrhea [A] †	1/30 (3.33%)	5/86 (5.81%)	0/30 (0%)	0/86 (0%)
Nausea [A] †	6/30 (20%)	8/86 (9.3%)	0/30 (0%)	0/86 (0%)
General disorders				
Asthenia [A] †	2/30 (6.67%)	11/86 (12.79%)	0/30 (0%)	0/86 (0%)
Chest discomfort [A] †	2/30 (6.67%)	2/86 (2.33%)	0/30 (0%)	0/86 (0%)
Chest pain [A] †	2/30 (6.67%)	2/86 (2.33%)	0/30 (0%)	0/86 (0%)
Chills [A] †	1/30 (3.33%)	5/86 (5.81%)	0/30 (0%)	0/86 (0%)

	Ofatumumab 500 mg	Ofatumumab 1000 mg	Ofatumumab 500 mg: Extended Follow-up Phase	Ofatumumab 1000 mg: Extended Follow-up Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Disease progression [A] †	2/30 (6.67%)	4/86 (4.65%)	0/30 (0%)	0/86 (0%)
Fatigue [A] †	4/30 (13.33%)	13/86 (15.12%)	0/30 (0%)	0/86 (0%)
Oedema peripheral [A] †	6/30 (20%)	7/86 (8.14%)	0/30 (0%)	0/86 (0%)
Pyrexia [A] †	2/30 (6.67%)	11/86 (12.79%)	0/30 (0%)	0/86 (0%)
Immune system disorders				
Hypersensitivity [A] †	3/30 (10%)	6/86 (6.98%)	0/30 (0%)	0/86 (0%)
Infections and infestations				
Nasopharyngitis [A] †	5/30 (16.67%)	2/86 (2.33%)	0/30 (0%)	0/86 (0%)
Rhinitis [A] †	5/30 (16.67%)	4/86 (4.65%)	0/30 (0%)	0/86 (0%)
Upper respiratory tract infection [A] †	2/30 (6.67%)	6/86 (6.98%)	0/30 (0%)	0/86 (0%)
Musculoskeletal and connective tissue disorders				
Back pain [A] †	3/30 (10%)	8/86 (9.3%)	0/30 (0%)	0/86 (0%)
Muscle spasms [A] †	2/30 (6.67%)	0/86 (0%)	0/30 (0%)	0/86 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Paraesthesia [A] †	2/30 (6.67%)	6/86 (6.98%)	0/30 (0%)	0/86 (0%)
Nervous system disorders				
Dizziness [A] †	4/30 (13.33%)	1/86 (1.16%)	0/30 (0%)	0/86 (0%)
Headache [A] †	4/30 (13.33%)	7/86 (8.14%)	0/30 (0%)	0/86 (0%)
Psychiatric disorders				
Anxiety [A] †	3/30 (10%)	3/86 (3.49%)	0/30 (0%)	0/86 (0%)
Insomnia [A] †	2/30 (6.67%)	4/86 (4.65%)	0/30 (0%)	0/86 (0%)
Renal and urinary disorders				

	Ofatumumab 500 mg	Ofatumumab 1000 mg	Ofatumumab 500 mg: Extended Follow-up Phase	Ofatumumab 1000 mg: Extended Follow-up Phase
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Hematuria [A] †	2/30 (6.67%)	0/86 (0%)	0/30 (0%)	0/86 (0%)
Respiratory, thoracic and mediastinal disorders				
Cough [A] †	4/30 (13.33%)	10/86 (11.63%)	0/30 (0%)	0/86 (0%)
Dyspnea [A] †	3/30 (10%)	7/86 (8.14%)	0/30 (0%)	0/86 (0%)
Skin and subcutaneous tissue disorders				
Pruritus [A] †	5/30 (16.67%)	10/86 (11.63%)	0/30 (0%)	0/86 (0%)
Rash [A] †	4/30 (13.33%)	14/86 (16.28%)	0/30 (0%)	0/86 (0%)
Skin lesion [A] †	3/30 (10%)	0/86 (0%)	0/30 (0%)	0/86 (0%)
Urticaria [A] †	4/30 (13.33%)	12/86 (13.95%)	0/30 (0%)	0/86 (0%)
Vascular disorders				
Flushing [A] †	2/30 (6.67%)	3/86 (3.49%)	0/30 (0%)	0/86 (0%)
Hypotension [A] †	1/30 (3.33%)	5/86 (5.81%)	0/30 (0%)	0/86 (0%)

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

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

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

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

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