Clinical trial results:
Extension Study Evaluating Treatment with PF-05280586 Versus Rituximab in Subjects With Active Rheumatoid Arthritis Who Have Participated In Other PF-05280586 Clinical Trials

Summary

EudraCT number	2012-003223-38
Trial protocol	GB ES DE
Global end of trial date	14 March 2016

Results information

Result version number	v1
This version publication date	16 March 2017
First version publication date	16 March 2017

Trial information

Trial identification

Sponsor protocol code	B3281004

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01643928
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 March 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 March 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To provide continued treatment access to subjects with active rheumatoid arthritis (RA) who have participated for at least 16 weeks in other protocols in the rituximab-Pfizer program.
- To evaluate the overall safety, tolerability and immunogenicity of PF-05280586 occurring after transition from a licensed rituximab product to PF-05280586.
- To continue follow-up of biomarker and efficacy endpoints of interest in the previous B3281001 Study in the rituximab-Pfizer program contributing to this protocol.

Protection of trial subjects:

The final protocol, any amendments, and informed consent documentation were reviewed and approved by the Institutional Review Board(s) and/or Independent Ethics Committee(s) at each of the investigational sites participating in the study.

This study was conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonisation Good Clinical Practice Guidelines. In addition, all local regulatory requirements were followed, in particular, those affording greater protection to the safety of study participants.

Background therapy:

Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) during study participation.
The use of folate supplements during study treatment was required per Standard of Care.

Evidence for comparator:

Rituxan is the brand approved for use in the United States and will be referred to as rituximab-US, hereafter and MabThera is the brand approved for use in the European Union and will be referred to as rituximab-EU hereafter.

PF-05280586 has the same primary amino acid sequence as rituximab-EU (MabThera) and rituximab-US (Rituxan) and is being developed to be similar to the licensed products.

Actual start date of recruitment	16 August 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 1
Country: Number of subjects enrolled	Canada: 4
Country: Number of subjects enrolled	Colombia: 13
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	United Kingdom: 1

Country: Number of subjects enrolled	Israel: 1
Country: Number of subjects enrolled	Mexico: 10
Country: Number of subjects enrolled	Russian Federation: 18
Country: Number of subjects enrolled	South Africa: 6
Country: Number of subjects enrolled	United States: 128
Worldwide total number of subjects	183
EEA total number of subjects	2

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	140
From 65 to 84 years	43
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was an extension study for participants with active rheumatoid arthritis who had participated for at least 16 weeks in a prior rituximab-Pfizer protocol (B3281001) and had not received intervening treatment with investigational agents or other biologics (including Rituxan and MabThera).

Pre-assignment

Screening details:

Participants assigned to PF-05280586 in Study B3281001 continued to receive PF-05280586 in this study. Participants assigned to licensed product in Study B3281001 were assigned either the previously assigned licensed product or PF-05280586 for the first treatment course. In subsequent treatment courses, all participants were assigned PF-05280586.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

This study will be blinded to the participant, investigator/study staff and Sponsor’s study team conducting the trial. The study pharmacists preparing study treatment infusions will be unblinded. The E-DMC will review partially blinded study results
(ie, Arms A, B and C) and will receive fully unblinded information upon request. Sponsor management will be unblinded to summary results by treatment arm but blinded to individual participant treatment allocation.

Arms

Are arms mutually exclusive?	Yes
Arm title	PF-05280586/PF-05280586/PF-05280586

Arm description:

This group received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 3 24-week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received PF-05280586 in the B3281001 study.

Arm type	Active comparator
Investigational medicinal product name	PF-05280586
Investigational medicinal product code	
Other name	rituximab-Pfizer
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Blinded PF-05280586 was administered by IV infusion using an escalating infusion rate. All participants were to receive premedication with 100 mg IV methylprednisolone or its equivalent 30 mins before rituximab infusions to decrease the incidence rate and severity of acute infusion-related reactions. Further premedication consisting of an anti-pyretic and an antihistaminic, was administered before each infusion.
Rituximab was administered at 1000 mg/500 mL on study Days 1 and 15 of each course. When the drug product administration was complete, a 3.33 mL/minute flush with diluent for 10 minutes was performed.
Participants also continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) during study participation.
The use of folate supplements during study treatment was required per Standard of Care.

Arm title	Rituximab-EU/PF-05280586/PF-05280586

Arm description:

This group received IV rituximab (MabThera) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of a 24-week (±8 week) course followed by IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 2 24-week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received Rituximab-EU in the B3281001 study.

Arm type	Active comparator
Investigational medicinal product name	Rituximab-EU
Investigational medicinal product code	
Other name	MabThera
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Blinded rituximab-EU was administered by IV infusion using an escalating infusion rate. All participants were to receive premedication with 100 mg IV methylprednisolone or its equivalent 30 mins before rituximab infusions to decrease the incidence rate and severity of acute infusion-related reactions. Further premedication consisting of an anti-pyretic and an antihistaminic, was administered before each infusion. Rituximab was administered at 1000 mg/500 mL on study Days 1 and 15 of each course. When the drug product administration was complete, a 3.33 mL/minute flush with diluent for 10 minutes was performed. Participants also continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) during study participation. The use of folate supplements during study treatment was required per Standard of Care.

Investigational medicinal product name	PF-05280586
Investigational medicinal product code	
Other name	rituximab-Pfizer
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Blinded PF-05280586 was administered by IV infusion using an escalating infusion rate. All participants were to receive premedication with 100 mg IV methylprednisolone or its equivalent 30 mins before rituximab infusions to decrease the incidence rate and severity of acute infusion-related reactions. Further premedication consisting of an anti-pyretic and an antihistaminic, was administered before each infusion.
Rituximab was administered at 1000 mg/500 mL on study Days 1 and 15 of each course. When the drug product administration was complete, a 3.33 mL/minute flush with diluent for 10 minutes was performed.
Participants also continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) during study participation.
The use of folate supplements during study treatment was required per Standard of Care.

Arm title	PF-05280586/PF-05280586/PF-05280586 (EU)

Arm description:

This group received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 3 24--week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received Rituximab-EU in the B3281001 study.

Arm type	Active comparator
Investigational medicinal product name	PF-05280586
Investigational medicinal product code	
Other name	rituximab-Pfizer
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Blinded PF-05280586 was administered by IV infusion using an escalating infusion rate. All participants were to receive premedication with 100 mg IV methylprednisolone or its equivalent 30 mins before rituximab infusions to decrease the incidence rate and severity of acute infusion-related reactions.

Further premedication consisting of an anti-pyretic and an antihistaminic, was administered before each infusion.
Rituximab was administered at 1000 mg/500 mL on study Days 1 and 15 of each course. When the drug product administration was complete, a 3.33 mL/minute flush with diluent for 10 minutes was performed.
Participants also continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) during study participation.
The use of folate supplements during study treatment was required per Standard of Care.

Arm title	Rituximab-US/PF-05280586/PF-05280586

Arm description:

This group received IV rituximab (Rituxan) infusion 1000 mg/500 mL (preceded by 100 mg methylprednisolone, an antipyretic, and an antihistamine) on Study Days 1 and 15 of a 24--week (±8 week) course followed by IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 2 24-week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) for up to 25 weeks. Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received Rituximab-US in the B3281001 study.

Arm type	Active comparator
Investigational medicinal product name	Rituximab-US
Investigational medicinal product code	
Other name	Rituxan
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Blinded rituximab-US was administered by IV infusion using an escalating infusion rate. All participants were to receive premedication with 100 mg IV methylprednisolone or its equivalent 30 mins before rituximab infusions to decrease the incidence rate and severity of acute infusion-related reactions. Further premedication consisting of an anti-pyretic and an antihistaminic, was administered before each infusion. Rituximab was administered at 1000 mg/500 mL on study Days 1 and 15 of each course. When the drug product administration was complete, a 3.33 mL/minute flush with diluent for 10 minutes was performed. Participants also continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) during study participation. The use of folate supplements during study treatment was required per Standard of Care.

Investigational medicinal product name	PF-05280586
Investigational medicinal product code	
Other name	rituximab-Pfizer
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Blinded PF-05280586 was administered by IV infusion using an escalating infusion rate. All participants were to receive premedication with 100 mg IV methylprednisolone or its equivalent 30 mins before rituximab infusions to decrease the incidence rate and severity of acute infusion-related reactions. Further premedication consisting of an anti-pyretic and an antihistaminic, was administered before each infusion.
Rituximab was administered at 1000 mg/500 mL on study Days 1 and 15 of each course. When the drug product administration was complete, a 3.33 mL/minute flush with diluent for 10 minutes was performed.
Participants also continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) during study participation.
The use of folate supplements during study treatment was required per Standard of Care.

Arm title	PF-05280586/PF-05280586/PF-05280586 (US)

Arm description:

This group received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 3 24--week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received Rituximab-US in the B3281001 study.

Arm type	Active comparator

Investigational medicinal product name	PF-05280586
Investigational medicinal product code	
Other name	rituximab-Pfizer
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Blinded PF-05280586 was administered by IV infusion using an escalating infusion rate. All participants were to receive premedication with 100 mg IV methylprednisolone or its equivalent 30 mins before rituximab infusions to decrease the incidence rate and severity of acute infusion-related reactions. Further premedication consisting of an anti-pyretic and an antihistaminic, was administered before each infusion.
Rituximab was administered at 1000 mg/500 mL on study Days 1 and 15 of each course. When the drug product administration was complete, a 3.33 mL/minute flush with diluent for 10 minutes was performed.
Participants also continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) during study participation.
The use of folate supplements during study treatment was required per Standard of Care.

Number of subjects in period 1	PF-05280586/PF-05280586/PF-05280586	Rituximab-EU/PF-05280586/PF-05280586	PF-05280586/PF-05280586/PF-05280586 (EU)
Started	58	32	33
Completed	48	30	30
Not completed	10	2	3
Consent withdrawn by subject	2	-	-
Adverse event, non-fatal	2	1	-
Pregnancy	-	-	-
Unspecified	5	1	1
Lost to follow-up	1	-	2

Number of subjects in period 1	Rituximab-US/PF-05280586/PF-05280586	PF-05280586/PF-05280586/PF-05280586 (US)
Started	30	30
Completed	27	28
Not completed	3	2
Consent withdrawn by subject	1	-
Adverse event, non-fatal	1	2
Pregnancy	1	-
Unspecified	-	-
Lost to follow-up	-	-

Baseline characteristics

Reporting groups	
Reporting group title	PF-05280586/PF-05280586/PF-05280586

Reporting group description:

This group received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 3 24-week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received PF-05280586 in the B3281001 study.

Reporting group title	Rituximab-EU/PF-05280586/PF-05280586

Reporting group description:

This group received IV rituximab (MabThera) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of a 24-week (±8 week) course followed by IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 2 24-week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received Rituximab-EU in the B3281001 study.

Reporting group title	PF-05280586/PF-05280586/PF-05280586 (EU)

Reporting group description:

This group received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 3 24--week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received Rituximab-EU in the B3281001 study.

Reporting group title	Rituximab-US/PF-05280586/PF-05280586

Reporting group description:

This group received IV rituximab (Rituxan) infusion 1000 mg/500 mL (preceded by 100 mg methylprednisolone, an antipyretic, and an antihistamine) on Study Days 1 and 15 of a 24--week (±8 week) course followed by IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 2 24-week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) for up to 25 weeks. Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received Rituximab-US in the B3281001 study.

Reporting group title	PF-05280586/PF-05280586/PF-05280586 (US)

Reporting group description:

This group received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 3 24--week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received Rituximab-US in the B3281001 study.

Reporting group values	PF-05280586/PF-05280586/PF-05280586	Rituximab-EU/PF-05280586/PF-05280586	PF-05280586/PF-05280586/PF-05280586 (EU)
Number of subjects	58	32	33
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0

Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	42	25	26
From 65-84 years	16	7	7
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	55.3	56	56.7
standard deviation	± 12.01	± 11.88	± 9.35
Gender, Male/Female			
Units: Subjects			
Female	50	29	23
Male	8	3	10

Reporting group values	Rituximab-US/PF-05280586/PF-05280586	PF-05280586/PF-05280586/PF-05280586 (US)	Total
Number of subjects	30	30	183
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	24	23	140
From 65-84 years	6	7	43
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	52.6	55.8	
standard deviation	± 13.73	± 10.35	-
Gender, Male/Female			
Units: Subjects			
Female	20	25	147
Male	10	5	36

End points reporting groups

Reporting group title	PF-05280586/PF-05280586/PF-05280586

Reporting group description:

This group received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 3 24-week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received PF-05280586 in the B3281001 study.

Reporting group title	Rituximab-EU/PF-05280586/PF-05280586

Reporting group description:

This group received IV rituximab (MabThera) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of a 24-week (±8 week) course followed by IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 2 24-week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received Rituximab-EU in the B3281001 study.

Reporting group title	PF-05280586/PF-05280586/PF-05280586 (EU)

Reporting group description:

This group received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 3 24--week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received Rituximab-EU in the B3281001 study.

Reporting group title	Rituximab-US/PF-05280586/PF-05280586

Reporting group description:

This group received IV rituximab (Rituxan) infusion 1000 mg/500 mL (preceded by 100 mg methylprednisolone, an antipyretic, and an antihistamine) on Study Days 1 and 15 of a 24--week (±8 week) course followed by IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 2 24-week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) for up to 25 weeks. Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received Rituximab-US in the B3281001 study.

Reporting group title	PF-05280586/PF-05280586/PF-05280586 (US)

Reporting group description:

This group received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of up to 3 24--week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care. Participants in this treatment arm received Rituximab-US in the B3281001 study.

Subject analysis set title	Rituximab-EU Total
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Participants who received Rituximab-EU in the B3281001 study were either assigned Rituximab-EU in the first course of B3281004, or PF-05280586. This measures the total percentage of B3281001 Rituximab-EU participants.

Subject analysis set title	Rituximab-US Total
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Participants who received Rituximab-US in the B3281001 study were either assigned Rituximab-US in the first course of B3281004, or PF-05280586. This measures the total percentage of B3281001 Rituximab-US participants.

Subject analysis set title	Rituximab-EU Total

Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Participants who received Rituximab-EU in the B3281001 study were either assigned Rituximab-EU in the first course of B3281004, or PF-05280586. This measures the total percentage of B3281001 Rituximab-EU participants.

Subject analysis set title	Rituximab-US Total
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Participants who received Rituximab-US in the B3281001 study were either assigned Rituximab-US in the first course of B3281004, or PF-05280586. This measures the total percentage of B3281001 Rituximab-US participants.

Subject analysis set title	PF-05280586: by the end of Course 1
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received PF-05280586 during the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Subject analysis set title	Rituximab-EU: by the end of Course 1
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received Rituximab-EU in the B3281001 study, received IV rituximab (MabThera) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Subject analysis set title	PF-05280586 (EU): by the end of Course 1
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received Rituximab-EU in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Subject analysis set title	Rituximab-US: by the end of Course 1
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received Rituximab-US in the B3281001 study, received IV rituximab (Rituxan) infusion 1000 mg/500 mL (preceded by 100 mg methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) for up to 25 weeks. Folate supplementation was encouraged according to local standard of care.

Subject analysis set title	PF-05280586 (US): by the end of Course 1
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received Rituximab-US in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Subject analysis set title	PF-05280586: by the end of Course 2
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received PF-05280586 in the B3281001 study, received IV rituximab (PF-

05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first two 24-week (±8 week) courses in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Subject analysis set title	Rituximab-EU/PF-05280586: by the end of Course 2
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received Rituximab-EU in the B3281001 study, received IV rituximab (MabThera) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study, followed by IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the second 24-week (±8 week) course. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Subject analysis set title	PF-05280586 (EU): by the end of Course 2
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received Rituximab-EU in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first two 24-week (±8 week) courses in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Subject analysis set title	Rituximab-US/PF-05280586: by the end of Course 2
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received Rituximab-US in the B3281001 study, received IV rituximab (Rituxan) infusion 1000 mg/500 mL (preceded by 100 mg methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study, followed by IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the second 24-week (±8 week) course. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) for up to 25 weeks. Folate supplementation was encouraged according to local standard of care.

Subject analysis set title	PF-05280586 (US): by the end of Course 2
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received Rituximab-US in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first two 24-week (±8 week) courses in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Subject analysis set title	PF-05280586: by the end of Course 3
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received PF-05280586 in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of all three 24-week (±8 week) courses in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Subject analysis set title	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received Rituximab-EU in the B3281001 study, received IV rituximab (MabThera) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study, followed by IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by

100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the second and third 24-week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Subject analysis set title	PF-05280586 (EU): by the end of Course 3
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received Rituximab-EU in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of all three 24-week (±8 week) courses in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Subject analysis set title	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received Rituximab-US in the B3281001 study, received IV rituximab (Rituxan) infusion 1000 mg/500 mL (preceded by 100 mg methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study, followed by IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the second and third 24-week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) for up to 25 weeks. Folate supplementation was encouraged according to local standard of care.

Subject analysis set title	PF-05280586 (US): by the end of Course 3
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

This treatment group, which received Rituximab-US in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of all three 24-week (±8 week) courses in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Primary: Percentage of Participants by Anti-Drug Antibody (ADA) Status using Anti-PF-05280586 Antibody Assay

End point title	Percentage of Participants by Anti-Drug Antibody (ADA) Status using Anti-PF-05280586 Antibody Assay[1]

End point description:

Serum samples were collected to determine the presence of ADA using two validated assays, one specific for PF-05280586 and one specific for the licensed drug products. For participants assigned to PF-05280586 in Study B3281001, blood samples were screened for ADA using the assay specific to PF-05280586; if the blood samples were confirmed to be positive for ADA against PF-05280586, the samples were also analyzed using the assay specific for the licensed drug products to assess cross-reactivity of the ADA. For participants assigned to the licensed products in Study B3281001, blood samples were screened for ADA using both assays in order to assess any product-specific ADA and/or cross-reactivity for the transition from the licensed products to PF-05280586.

End point type	Primary

End point timeframe:

Course 1 Overall, Course 2 Overall, Course 3 Overall, and All Courses Overall.

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586/PF-05280586/PF-05280586	Rituximab-EU/PF-05280586/PF-05280586	PF-05280586/PF-05280586/PF-05280586 (EU)	Rituximab-US/PF-05280586/PF-05280586
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	32	33	30
Units: Percentage of Participants				
number (not applicable)				
Total (C1) n (N=58, 32, 33, 65, 30, 30, 60)	57	31	33	30
Total (C1) +ve (N=58, 32, 33, 65, 30, 30, 60)	3.5	0	15.2	13.3
Total (C2) n (N=54, 30, 31, 61, 29, 29, 58)	53	30	31	29
Total (C2) +ve (N=54, 30, 31, 61, 29, 29, 58)	5.7	3.3	0	0
Total (C3) n (N=48, 30, 30, 60, 27, 29, 56)	48	30	30	27
Total (C3) +ve (N=48, 30, 30, 60, 27, 29, 56)	2.1	0	0	0
C1 to C3 n (N=48, 30, 30, 60, 27, 29, 56)	58	32	33	30
C1 to C3 +ve (N=48, 30, 30, 60, 27, 29, 56)	8.6	3.1	15.2	13.3

End point values	PF-05280586/PF-05280586/PF-05280586 (US)	Rituximab-EU Total	Rituximab-US Total	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	30	65	60	
Units: Percentage of Participants				
number (not applicable)				
Total (C1) n (N=58, 32, 33, 65, 30, 30, 60)	30	64	60	
Total (C1) +ve (N=58, 32, 33, 65, 30, 30, 60)	6.7	7.8	10	
Total (C2) n (N=54, 30, 31, 61, 29, 29, 58)	29	61	58	
Total (C2) +ve (N=54, 30, 31, 61, 29, 29, 58)	6.9	1.6	3.4	
Total (C3) n (N=48, 30, 30, 60, 27, 29, 56)	29	60	56	
Total (C3) +ve (N=48, 30, 30, 60, 27, 29, 56)	0	0	0	
C1 to C3 n (N=48, 30, 30, 60, 27, 29, 56)	30	65	60	
C1 to C3 +ve (N=48, 30, 30, 60, 27, 29, 56)	6.7	9.2	10	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants by ADA Status using Anti-Rituximab Antibody Assay

End point title	Percentage of Participants by ADA Status using Anti-Rituximab Antibody Assay[2]

End point description:

Serum samples were collected to determine the presence of ADA using two validated assays, one specific for PF-05280586 and one specific for the licensed drug products. For participants assigned to PF-05280586 in Study B3281001, blood samples were screened for ADA using the assay specific to PF-05280586; if the blood samples were confirmed to be positive for ADA against PF-05280586, the samples were also analyzed using the assay specific for the licensed drug products to assess cross-reactivity of the ADA. For participants assigned to the licensed products in Study B3281001, blood samples were screened for ADA using both assays in order to assess any product-specific ADA and/or cross-reactivity for the transition from the licensed products to PF-05280586.

End point type	Primary

End point timeframe:

Course 1 Overall, Course 2 Overall, Course 3 Overall, and All Courses Overall.

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586/PF-05280586/PF-05280586	Rituximab-EU/PF-05280586/PF-05280586	PF-05280586/PF-05280586/PF-05280586 (EU)	Rituximab-US/PF-05280586/PF-05280586
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	32	33	30
Units: Percentage of Participants				
number (not applicable)				
Total (C1) n (N=58, 32, 33, 65, 30, 30, 60)	57	31	33	30
Total (C1) +ve (N=58, 32, 33, 65, 30, 30, 60)	3.5	3.2	15.2	10
Total (C2) n (N=54, 30, 31, 61, 29, 29, 58)	53	30	31	29
Total (C2) +ve (N=54, 30, 31, 61, 29, 29, 58)	5.7	6.7	3.2	3.4
Total (C3) n (N=48, 30, 30, 60, 27, 29, 56)	48	30	30	27
Total (C3) +ve (N=48, 30, 30, 60, 27, 29, 56)	2.1	0	3.3	0
C1 to C3 n (N=48, 30, 30, 60, 27, 29, 56)	58	32	33	30
C1 to C3 +ve (N=48, 30, 30, 60, 27, 29, 56)	8.6	6.3	18.2	13.3

End point values	PF-05280586/PF-05280586/PF-05280586 (US)	Rituximab-EU Total	Rituximab-US Total	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	30	65	60	
Units: Percentage of Participants				
number (not applicable)				
Total (C1) n (N=58, 32, 33, 65, 30, 30, 60)	30	64	60	

Total (C1) +ve (N=58, 32, 33, 65, 30, 30, 60)	10	9.4	10	
Total (C2) n (N=54, 30, 31, 61, 29, 29, 58)	29	61	58	
Total (C2) +ve (N=54, 30, 31, 61, 29, 29, 58)	13.8	4.9	8.6	
Total (C3) n (N=48, 30, 30, 60, 27, 29, 56)	29	60	56	
Total (C3) +ve (N=48, 30, 30, 60, 27, 29, 56)	3.4	1.7	1.8	
C1 to C3 n (N=48, 30, 30, 60, 27, 29, 56)	30	65	60	
C1 to C3 +ve (N=48, 30, 30, 60, 27, 29, 56)	13.3	12.3	13.3	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants by Neutralizing Antibody (Nab) Status in Participants with a Positive ADA using Anti-PF-05280586 NAb Assay

End point title	Percentage of Participants by Neutralizing Antibody (Nab) Status in Participants with a Positive ADA using Anti-PF-05280586 NAb Assay[3]

End point description:

Blood samples that were confirmed as positive for ADA were further evaluated for Nab using validated assays - None of the ADA samples tested positive for NAb.

End point type	Primary

End point timeframe:

Weeks 1, 3, 13, and 25 (Course 1, Course 2, and Course 3).

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586/PF-05280586/PF-05280586	Rituximab-EU/PF-05280586/PF-05280586	PF-05280586/PF-05280586/PF-05280586 (EU)	Rituximab-US/PF-05280586/PF-05280586
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[4]	0[5]	0[6]	0[7]
Units: Percentage of Participants				

Notes:

[4] - Zero participants analyzed tested positive for NAb.

[5] - Zero participants analyzed tested positive for NAb.

[6] - Zero participants analyzed tested positive for NAb.

[7] - Zero participants analyzed tested positive for NAb.

End point values	PF-05280586/PF-05280586/PF-05280586 (US)	Rituximab-EU Total	Rituximab-US Total	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[8]	0[9]	0[10]	
Units: Percentage of Participants				

Notes:

[8] - Zero participants analyzed tested positive for NAb.

[9] - Zero participants analyzed tested positive for NAb.

[10] - Zero participants analyzed tested positive for NAb.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants by Nab Status in Participants with a Positive ADA using Anti-PF-05280586 NAb Assay using Anti-Rituximab NAb Assay

End point title	Percentage of Participants by Nab Status in Participants with a Positive ADA using Anti-PF-05280586 NAb Assay using Anti-Rituximab NAb Assay[11]

End point description:

Blood samples that were confirmed as positive for ADA were further evaluated for Nab using validated assays. - None of the ADA samples tested positive for NAb.

End point type	Primary

End point timeframe:

Weeks 1, 3, 13, and 25 (Course 1, Course 2, and Course 3).

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586/PF-05280586/PF-05280586	Rituximab-EU/PF-05280586/PF-05280586	PF-05280586/PF-05280586/PF-05280586 (EU)	Rituximab-US/PF-05280586/PF-05280586
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[12]	0[13]	0[14]	0[15]
Units: Percentage of Participants				

Notes:

[12] - Zero participants analyzed tested positive for NAb.

[13] - Zero participants analyzed tested positive for NAb.

[14] - Zero participants analyzed tested positive for NAb.

[15] - Zero participants analyzed tested positive for NAb.

End point values	PF-05280586/PF-05280586/PF-05280586 (US)	Rituximab-EU Total	Rituximab-US Total	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	0[16]	0[17]	0[18]	
Units: Percentage of Participants				

Notes:

[16] - Zero participants analyzed tested positive for NAb.

[17] - Zero participants analyzed tested positive for NAb.

[18] - Zero participants analyzed tested positive for NAb.

Statistical analyses

No statistical analyses for this end point

Primary: Mean Rituximab Serum Trough Concentrations

End point title	Mean Rituximab Serum Trough Concentrations[19]

End point description:

Serum samples for determination of drug concentrations were collected pre-dose concurrent with ADA sample collection. Drug concentrations in the samples were determined using a validated assay.

End point type	Primary

End point timeframe:

Weeks 1, 3, 13, and 25 (Course 1, Course 2, and Course 3), Follow up Months 3, 6, 9, and 12.

Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586/PF-05280586/PF-05280586	Rituximab-EU/PF-05280586/PF-05280586	PF-05280586/PF-05280586/PF-05280586 (EU)	Rituximab-US/PF-05280586/PF-05280586
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	32	33	30
Units: nanograms per milliliter				
arithmetic mean (standard deviation)				
Course 1/Week 1 (n=51, 27, 31, 29, 28)	636.5 (± 816.33)	855.5 (± 1594.51)	416.6 (± 615.86)	1525.8 (± 3709.9)
Course 1/Week 3 (n=57, 31, 33, 30, 30)	103019.3 (± 29250.13)	114341.9 (± 39023.45)	89790.9 (± 23247.03)	96323.3 (± 33396.81)
Course 1/Week 13 (n=56, 30, 33, 30, 29)	22613.1 (± 16526.33)	27542.3 (± 18879.35)	16973.6 (± 10736.22)	26359.8 (± 27063.7)
Course 1/Week 25 (n=32, 10, 20, 12, 19)	2844.2 (± 4271.65)	3573.3 (± 3569.9)	1719.3 (± 3383.03)	8205.1 (± 9923.43)
Course 2/Week 1 (n=54, 30, 31, 29, 29)	1628.2 (± 2712.3)	2493.2 (± 3631.38)	924.1 (± 1546.2)	3463.6 (± 5311.01)
Course 2/Week 3 (n=53, 30, 30, 29, 27)	108064.2 (± 37043.94)	114266.7 (± 29897.86)	91006.7 (± 23725.24)	102937.9 (± 29824.58)
Course 2/Week 13 (n=52, 30, 30, 29, 29)	26527.9 (± 17903)	31829.7 (± 17954.12)	21467 (± 11390.72)	27730.7 (± 21932)
Course 2/Week 25 (n=29, 10, 18, 14, 15)	3431.9 (± 4155.8)	4074.2 (± 5043.55)	1375.8 (± 1507.1)	5103.3 (± 5344.88)
Course 3/Week 1 (n=48, 30, 30, 27, 29)	3347.7 (± 6919.26)	4276.1 (± 4959.22)	1569.5 (± 2592.13)	3239.2 (± 4330.47)
Course 3/Week 3 (n=48, 30, 30, 27, 29)	101043.8 (± 27832.21)	118256.7 (± 30549.75)	96213.3 (± 22232.76)	107677.8 (± 38759.97)
Course 3/Week 13 (n=46, 29, 29, 25, 29)	26795.2 (± 18635.09)	31180 (± 20926.62)	21268.6 (± 11639.25)	28801.2 (± 21593.73)
Course 3/Week 25 (EOT) (n=53, 30, 31, 28, 26)	5908.1 (± 22274.41)	6485.6 (± 12462.24)	6539.7 (± 23577.35)	8603.7 (± 13217.69)
Follow up-Month 3 (n=35, 22, 21, 15, 22)	2448.3 (± 13132.59)	9061.5 (± 30261.67)	208.3 (± 255.87)	2477.5 (± 5571.32)
Follow up-Month 6 (n=29, 19, 15, 9, 19)	44.2 (± 140.06)	99.3 (± 253.66)	17.4 (± 46.39)	140.8 (± 297.54)
Follow up-Month 9 (n=4, N/A, N/A, N/A, 2)	0 (± 0)	99999999.9 (± 99999999.9)	99999999.9 (± 99999999.9)	99999999.9 (± 99999999.9)
Follow up-Month 12 (n=N/A, N/A, N/A, N/A, 1)	99999999.9 (± 99999999.9)	99999999.9 (± 99999999.9)	99999999.9 (± 99999999.9)	99999999.9 (± 99999999.9)

End point values	PF-05280586/PF-			

	05280586/PF-05280586 (US)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: nanograms per milliliter				
arithmetic mean (standard deviation)				
Course 1/Week 1 (n=51, 27, 31, 29, 28)	980 (± 2091.41)			
Course 1/Week 3 (n=57, 31, 33, 30, 30)	107790 (± 26168.99)			
Course 1/Week 13 (n=56, 30, 33, 30, 29)	31006.6 (± 23055.79)			
Course 1/Week 25 (n=32, 10, 20, 12, 19)	3005.6 (± 5227.33)			
Course 2/Week 1 (n=54, 30, 31, 29, 29)	3596.1 (± 5514.43)			
Course 2/Week 3 (n=53, 30, 30, 29, 27)	114992.6 (± 31832.89)			
Course 2/Week 13 (n=52, 30, 30, 29, 29)	36007.9 (± 23651.2)			
Course 2/Week 25 (n=29, 10, 18, 14, 15)	5228.6 (± 7171.47)			
Course 3/Week 1 (n=48, 30, 30, 27, 29)	4372 (± 5836.09)			
Course 3/Week 3 (n=48, 30, 30, 27, 29)	116134.5 (± 29028.01)			
Course 3/Week 13 (n=46, 29, 29, 25, 29)	33489.7 (± 21522.53)			
Course 3/Week 25 (EOT) (n=53, 30, 31, 28, 26)	4887.2 (± 5543.05)			
Follow up-Month 3 (n=35, 22, 21, 15, 22)	4199.1 (± 15777.12)			
Follow up-Month 6 (n=29, 19, 15, 9, 19)	4631.8 (± 19826.17)			
Follow up-Month 9 (n=4, N/A, N/A, N/A, 2)	0 (± 0)			
Follow up-Month 12 (n=N/A, N/A, N/A, N/A, 1)	0 (± 0)			

Statistical analyses

No statistical analyses for this end point

Primary: Cluster of Differentiation 19 (CD19+) B Cell Count

End point title	Cluster of Differentiation 19 (CD19+) B Cell Count[20]

End point description:

Blood samples were assayed for CD19+ B-cell counts using laser scanning cytometry. 99999.9=Not Applicable

End point type	Primary

End point timeframe:

Weeks 1, 6, 13, and 25 (Course 1 and Course 2), Weeks 1, 13, 25 (Course 3), and Follow up Months 3, 6, and 9.

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586/PF-05280586/PF-05280586	Rituximab-EU/PF-05280586/PF-05280586	PF-05280586/PF-05280586/PF-05280586 (EU)	Rituximab-US/PF-05280586/PF-05280586
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	32	33	30
Units: cells per microliter				
median (full range (min-max))				
Course 1/Week 1 (n=49, 28, 22, 23, 25)	0 (0 to 109.2)	1.1 (0 to 105.6)	0.6 (0 to 55.9)	0 (0 to 115.9)
Course 1/Week 6 (n=57, 28, 33, 29, 28)	0 (0 to 0)	0 (0 to 16.7)	0 (0 to 0.6)	0 (0 to 1.8)
Course 1/Week 13 (n=54, 31, 33, 29, 27)	0 (0 to 0.2)	0 (0 to 34.9)	0 (0 to 4.2)	0 (0 to 0.4)
Course 1/Week 25 (n=34, 10, 22, 13, 18)	0 (0 to 27.9)	0 (0 to 62.7)	0 (0 to 67.9)	0 (0 to 123.4)
Course 2/Week 1 (n=51, 29, 29, 28, 28)	0 (0 to 146.1)	0 (0 to 164)	0 (0 to 77.3)	0 (0 to 89.1)
Course 2/Week 6 (n=49, 30, 28, 29, 27)	0 (0 to 410.3)	0 (0 to 1.5)	0 (0 to 13.3)	0 (0 to 0.8)
Course 2/Week 13 (n=50, 28, 29, 27, 29)	0 (0 to 8.6)	0 (0 to 1.7)	0 (0 to 13.8)	0 (0 to 0.6)
Course 2/Week 25 (n=27, 9, 20, 15, 15)	0 (0 to 7.7)	0 (0 to 68.4)	0 (0 to 11.3)	0 (0 to 1.7)
Course 3/Week 1 (n=44, 29, 29, 25, 27)	0 (0 to 15.8)	0 (0 to 140.1)	0 (0 to 25.2)	0 (0 to 56)
Course 3/Week 13 (n=43, 28, 28, 23, 24)	0 (0 to 9)	0 (0 to 2.4)	0 (0 to 1.3)	0 (0 to 32.7)
Course 3/Week 25 (EOT) (n=49, 28, 30, 27, 29)	0 (0 to 23.8)	0 (0 to 27.3)	0 (0 to 10.1)	0 (0 to 321.9)
Follow up-month 3 (n=30, 19, 17, 13, 19)	0.2 (0 to 66.5)	0 (0 to 60.9)	1.7 (0 to 94.8)	0.5 (0 to 50.2)
Follow up-Month 6 (n=25, 18, 14, 7, 15)	7.5 (0 to 131.6)	0.4 (0 to 124.7)	6.8 (0 to 109.5)	10.5 (0 to 77.3)
Follow up-Month 9 (n=2, 0, 0, 0, 1)	39.4 (5 to 73.9)	99999999.9 (99999999.9 to 99999999.9)	99999999.9 (99999999.9 to 99999999.9)	99999999.9 (99999999.9 to 99999999.9)

End point values	PF-05280586/PF-05280586/PF-05280586 (US)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: cells per microliter				
median (full range (min-max))				
Course 1/Week 1 (n=49, 28, 22, 23, 25)	0.6 (0 to 677.5)			
Course 1/Week 6 (n=57, 28, 33, 29, 28)	0 (0 to 9.2)			
Course 1/Week 13 (n=54, 31, 33, 29, 27)	0 (0 to 10.3)			
Course 1/Week 25 (n=34, 10, 22, 13, 18)	0 (0 to 0)			
Course 2/Week 1 (n=51, 29, 29, 28, 28)	0 (0 to 79.8)			

Course 2/Week 6 (n=49, 30, 28, 29, 27)	0 (0 to 0.5)			
Course 2/Week 13 (n=50, 28, 29, 27, 29)	0 (0 to 16.7)			
Course 2/Week 25 (n=27, 9, 20, 15, 15)	0 (0 to 9.6)			
Course 3/Week 1 (n=44, 29, 29, 25, 27)	0 (0 to 14.3)			
Course 3/Week 13 (n=43, 28, 28, 23, 24)	0 (0 to 2.7)			
Course 3/Week 25 (EOT) (n=49, 28, 30, 27, 29)	0 (0 to 50.5)			
Follow up-month 3 (n=30, 19, 17, 13, 19)	0 (0 to 211.6)			
Follow up-Month 6 (n=25, 18, 14, 7, 15)	1.1 (0 to 177.8)			
Follow up-Month 9 (n=2, 0, 0, 0, 1)	66.3 (66.3 to 66.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Circulating Immunoglobulin G (IgG) Concentrations

End point title	Circulating Immunoglobulin G (IgG) Concentrations[21]

End point description:

Blood samples for immunoglobulin assessments were obtained to determine IgG levels in serum.

End point type	Primary

End point timeframe:

Screening, Week 25 (Course 1), and Weeks 1 and 25 (Course 2 and Course 3).

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586/PF-05280586/PF-05280586	Rituximab-EU/PF-05280586/PF-05280586	PF-05280586/PF-05280586/PF-05280586 (EU)	Rituximab-US/PF-05280586/PF-05280586
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	32	33	30
Units: grams per liter (g/L)				
arithmetic mean (standard deviation)				
Screening (n=53, 30, 32, 29, 30)	11.7 (± 3.06)	10.9 (± 2.54)	11.6 (± 2.85)	11.3 (± 3.12)
Course 1/Week 25 (n=35, 9, 22, 13, 19)	10.4 (± 3.2)	10.7 (± 3.71)	11.2 (± 2.5)	10.3 (± 3.5)
Course 2/Week 1 (n=54, 30, 31, 29, 29)	10.5 (± 2.73)	10.2 (± 2.78)	10.8 (± 2.55)	10.2 (± 2.29)
Course 2/Week 25 (n=29, 9, 20, 15, 16)	10.6 (± 2.85)	8.9 (± 2.4)	10.4 (± 2.11)	9.2 (± 2)
Course 3/Week 1 (n=48, 30, 30, 27, 29)	10.6 (± 2.92)	10.2 (± 2.61)	10.6 (± 2.81)	9.7 (± 2.44)
Course 3/Week 25 (EOT) (n=54, 31, 30, 29, 30)	10.4 (± 2.86)	9.8 (± 3.04)	10.3 (± 2.34)	9.7 (± 2.3)

End point values	PF-05280586/PF-05280586/PF-05280586 (US)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: grams per liter (g/L)				
arithmetic mean (standard deviation)				
Screening (n=53, 30, 32, 29, 30)	11.8 (± 3.52)			
Course 1/Week 25 (n=35, 9, 22, 13, 19)	11.4 (± 3.92)			
Course 2/Week 1 (n=54, 30, 31, 29, 29)	10.9 (± 3.59)			
Course 2/Week 25 (n=29, 9, 20, 15, 16)	11.4 (± 4.08)			
Course 3/Week 1 (n=48, 30, 30, 27, 29)	10.3 (± 3.88)			
Course 3/Week 25 (EOT) (n=54, 31, 30, 29, 30)	10.2 (± 3.25)			

Statistical analyses

No statistical analyses for this end point

Primary: Circulating Immunoglobulin M (IgM) Concentrations

End point title	Circulating Immunoglobulin M (IgM) Concentrations[22]

End point description:

Blood samples for immunoglobulin assessments were obtained to determine IgM levels in serum.

End point type	Primary

End point timeframe:

Screening, Week 25 (Course 1), and Weeks 1 and 25 (Course 2 and Course 3).

Notes:

[22] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586/PF-05280586/PF-05280586	Rituximab-EU/PF-05280586/PF-05280586	PF-05280586/PF-05280586/PF-05280586 (EU)	Rituximab-US/PF-05280586/PF-05280586
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	32	33	30
Units: g/L				
arithmetic mean (standard deviation)				
Screening (n=45, 22, 19, 22, 23)	1 (± 0.5)	1.1 (± 0.73)	1.1 (± 0.7)	1.1 (± 0.79)
Course 1/Week 25 (n=35, 10, 22, 13, 19)	0.8 (± 0.47)	1.1 (± 0.62)	0.9 (± 0.6)	1 (± 0.72)
Course 2/Week 1 (n=54, 30, 31, 29, 29)	0.8 (± 0.48)	0.9 (± 0.56)	0.9 (± 0.64)	0.9 (± 0.61)

Course 2/Week 25 (n=29, 9, 20, 15, 16)	0.8 (± 0.55)	0.8 (± 0.46)	0.9 (± 0.64)	0.9 (± 0.63)
Course 3/Week 1 (n=48, 30, 30, 27, 29)	0.8 (± 0.43)	0.8 (± 0.46)	0.8 (± 0.57)	0.8 (± 0.52)
Course 3/Week 25 (EOT) (n=54, 31, 30, 29, 30)	0.7 (± 0.39)	0.7 (± 0.44)	0.8 (± 0.54)	0.8 (± 0.52)

End point values	PF-05280586/PF-05280586/PF-05280586 (US)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: g/L				
arithmetic mean (standard deviation)				
Screening (n=45, 22, 19, 22, 23)	1 (± 0.57)			
Course 1/Week 25 (n=35, 10, 22, 13, 19)	0.9 (± 0.45)			
Course 2/Week 1 (n=54, 30, 31, 29, 29)	0.8 (± 0.47)			
Course 2/Week 25 (n=29, 9, 20, 15, 16)	0.8 (± 0.5)			
Course 3/Week 1 (n=48, 30, 30, 27, 29)	0.7 (± 0.4)			
Course 3/Week 25 (EOT) (n=54, 31, 30, 29, 30)	0.7 (± 0.38)			

Statistical analyses

No statistical analyses for this end point

Primary: Circulating Rheumatoid Factor (RF) Concentrations

End point title	Circulating Rheumatoid Factor (RF) Concentrations[23]

End point description:

RF is the auto-antibody directed against IgG. Blood samples were obtained to determine RF levels in serum.

End point type	Primary

End point timeframe:

Week 1 and 25 (Course 1, Course 2, and Course 3).

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586/PF-05280586/PF-05280586	Rituximab-EU/PF-05280586/PF-05280586	PF-05280586/PF-05280586/PF-05280586 (EU)	Rituximab-US/PF-05280586/PF-05280586
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	32	33	30
Units: international units per milliliter				
arithmetic mean (standard deviation)				

Course 1/Week 1 (n=53, 28, 31, 25, 29)	105.6 (± 203.88)	431.3 (± 1074.13)	128.7 (± 201.11)	75.2 (± 102.41)
Course 1/Week 25 (n=35, 10, 22, 13, 19)	56.1 (± 104.12)	714.8 (± 1471.95)	101.5 (± 165.85)	53.2 (± 59.22)
Course 2/Week 1 (n=54, 30, 31, 29, 29)	92.6 (± 181.91)	279.3 (± 737)	132.9 (± 234.84)	59.5 (± 76.56)
Course 2/Week 25 (n=29, 9, 20, 15, 16)	59.5 (± 117.79)	448 (± 945.12)	62.4 (± 89.14)	52 (± 54.97)
Course 3/Week 1 (n=48, 30, 30, 27, 29)	51.7 (± 89.51)	217.3 (± 697.3)	74.9 (± 128.83)	51.8 (± 92.06)
Course 3/Week 25 (EOT) (n=55, 31, 30, 29, 30)	46.2 (± 76.85)	181.2 (± 551.49)	57.1 (± 107.47)	45 (± 66.43)

End point values	PF-05280586/PF-05280586/PF-05280586 (US)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: international units per milliliter				
arithmetic mean (standard deviation)				
Course 1/Week 1 (n=53, 28, 31, 25, 29)	109.1 (± 139.79)			
Course 1/Week 25 (n=35, 10, 22, 13, 19)	66.5 (± 69.7)			
Course 2/Week 1 (n=54, 30, 31, 29, 29)	58.6 (± 73.13)			
Course 2/Week 25 (n=29, 9, 20, 15, 16)	44.2 (± 44.34)			
Course 3/Week 1 (n=48, 30, 30, 27, 29)	40.4 (± 45.9)			
Course 3/Week 25 (EOT) (n=55, 31, 30, 29, 30)	38.2 (± 41.46)			

Statistical analyses

No statistical analyses for this end point

Primary: Anti-Cyclic Citrullinated Peptide (anti-CCP) and Complement

End point title	Anti-Cyclic Citrullinated Peptide (anti-CCP) and Complement[24]

End point description:

Blood samples were obtained to determine anti-CCP and compliment levels in serum.

End point type	Primary

End point timeframe:

Week 1 and 25 (Course 1, Course 2, and Course 3).

Notes:

[24] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586/PF-05280586/PF-05280586	Rituximab-EU/PF-05280586/PF-05280586	PF-05280586/PF-05280586/PF-05280586 (EU)	Rituximab-US/PF-05280586/PF-05280586
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	32	33	30
Units: U/mL				
arithmetic mean (standard deviation)				
Course 1/Week 1 (n=54, 28, 31, 26, 28)	293.7 (± 206.64)	346.1 (± 206.78)	311.5 (± 198.13)	223.9 (± 224.86)
Course 1/Week 25 (n=34, 9, 22, 11, 19)	266.9 (± 222.12)	230.8 (± 207.06)	300.9 (± 199.02)	258 (± 227.91)
Course 2/Week 1 (n=54, 30, 31, 29, 29)	285.7 (± 211.65)	305.2 (± 208.41)	324.6 (± 196.92)	241.5 (± 229)
Course 2/Week 25 (n=29, 9, 20, 15, 16)	259 (± 224.11)	332 (± 184.78)	273.3 (± 188.63)	230.1 (± 232.38)
Course 3/Week 1 (n=48, 30, 30, 27, 29)	270 (± 213.62)	290.2 (± 200.75)	308.3 (± 189.51)	214.3 (± 228.46)
Course 3/Week 25 (EOT) (n=55, 30, 30, 29, 30)	249.6 (± 212.37)	250.4 (± 190.55)	265.7 (± 207.79)	214.4 (± 222.43)

End point values	PF-05280586/PF-05280586/PF-05280586 (US)			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: U/mL				
arithmetic mean (standard deviation)				
Course 1/Week 1 (n=54, 28, 31, 26, 28)	306.1 (± 210.82)			
Course 1/Week 25 (n=34, 9, 22, 11, 19)	263.6 (± 190.26)			
Course 2/Week 1 (n=54, 30, 31, 29, 29)	262.2 (± 210.17)			
Course 2/Week 25 (n=29, 9, 20, 15, 16)	237.9 (± 204.7)			
Course 3/Week 1 (n=48, 30, 30, 27, 29)	234.6 (± 212.97)			
Course 3/Week 25 (EOT) (n=55, 30, 30, 29, 30)	245.1 (± 207.29)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean Change from Initial Study Baseline in Disease Activity Score (DAS28)-C-Reactive Protein (CRP) - by the end of Course 1

End point title	Mean Change from Initial Study Baseline in Disease Activity Score (DAS28)-C-Reactive Protein (CRP) - by the end of Course 1[25]

End point description:

The disease activity score (DAS) assessment is a continuous composite measure derived using

differential weighting given to the following 4 components: tender/painful joint count (28 joints), swollen joint count (28 joints), CRP and patient's global assessment of arthritis Visual Analog Scale (VAS). The formula for calculation of DAS28-CRP from these 4 components is DAS28-CRP equals (=) 0.56 square root (sqrt) (DAS 28 tender joint count) + 0.28 sqrt (DAS 28 swollen joint count) + 0.36 natural log [ln] (CRP [milligrams per liter, mg/L] +1) + 0.014 (global assessment of health [GH]) + 0.96. Total score range: 0 to 9.4, higher score indicated more disease activity.

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1).

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 1	Rituximab-EU: by the end of Course 1	PF-05280586 (EU): by the end of Course 1	Rituximab-US: by the end of Course 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	32	33	30
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=58, 32, 33, 30, 30)	5.59 (± 0.862)	5.81 (± 0.926)	5.8 (± 0.988)	6.16 (± 0.87)
Change at Course 1/Week 1 (n=51, 28, 31, 25, 28)	-2.14 (± 1.073)	-2.64 (± 1.087)	-2.56 (± 1.15)	-3.01 (± 1.11)
Change at Course 1/Week 6 (n=56, 31, 32, 30, 28)	-2.64 (± 1.05)	-3.24 (± 1.105)	-3.03 (± 1.178)	-3.2 (± 0.97)
Change at Course 1/Week 13 (n=56, 30, 33, 29, 29)	-2.87 (± 0.969)	-3.33 (± 1.13)	-3.16 (± 1.144)	-3.49 (± 1.016)
Change at Course 1/Week 25 (n=35, 10, 22, 13, 19)	-2.79 (± 1.027)	-2.97 (± 0.977)	-2.6 (± 1.02)	-2.73 (± 0.896)

End point values	PF-05280586 (US): by the end of Course 1			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=58, 32, 33, 30, 30)	6.12 (± 0.784)			
Change at Course 1/Week 1 (n=51, 28, 31, 25, 28)	-2.78 (± 1.263)			
Change at Course 1/Week 6 (n=56, 31, 32, 30, 28)	-3.26 (± 1.062)			
Change at Course 1/Week 13 (n=56, 30, 33, 29, 29)	-3.34 (± 1.043)			
Change at Course 1/Week 25 (n=35, 10, 22, 13, 19)	-3.03 (± 1.016)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean Change from Initial Study Baseline in Disease Activity Score (DAS28)-C-Reactive Protein (CRP) - by the end of Course 2

End point title	Mean Change from Initial Study Baseline in Disease Activity Score (DAS28)-C-Reactive Protein (CRP) - by the end of Course 2[26]

End point description:

The disease activity score (DAS) assessment is a continuous composite measure derived using differential weighting given to the following 4 components: tender/painful joint count (28 joints), swollen joint count (28 joints), CRP and patient's global assessment of arthritis Visual Analog Scale (VAS). The formula for calculation of DAS28-CRP from these 4 components is DAS28-CRP equals (=) 0.56 square root (sqrt) (DAS 28 tender joint count) + 0.28 sqrt (DAS 28 swollen joint count) + 0.36 natural log [ln] (CRP [milligrams per liter, mg/L] +1) + 0.014 (global assessment of health [GH]) + 0.96. Total score range: 0 to 9.4, higher score indicated more disease activity.

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1 and Course 2).

Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 2	Rituximab-EU/PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	30	31	29
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=54, 30, 31, 29, 29)	5.59 (± 0.893)	5.81 (± 0.956)	5.77 (± 1.009)	6.13 (± 0.865)
Change at Course 1/Week 1 (n=49, 26, 29, 24, 27)	-2.14 (± 1.08)	-2.66 (± 1.124)	-2.54 (± 1.038)	-2.96 (± 1.102)
Change at Course 1/Week 6 (n=53, 30, 30, 29, 27)	-2.69 (± 1.053)	-3.23 (± 1.122)	-3 (± 1.127)	-3.16 (± 0.967)
Change at Course 1/Week 13 (n=54, 30, 31, 28, 29)	-2.88 (± 0.985)	-3.33 (± 1.13)	-3.17 (± 1.07)	-3.43 (± 0.982)
Change at Course 1/Week 25 (n=35, 10, 20, 12, 19)	-2.79 (± 1.027)	-2.97 (± 0.977)	-2.57 (± 0.872)	-2.64 (± 0.874)
Change at Course 2/Week 1 (n=54, 30, 31, 29, 29)	-2.69 (± 1.233)	-2.88 (± 1.296)	-2.63 (± 1.121)	-2.97 (± 1.181)
Change at Course 2/Week 6 (n=52, 29, 29, 29, 29)	-3.03 (± 0.965)	-3.45 (± 1.119)	-3.11 (± 1.108)	-3.55 (± 1.018)
Change at Course 2/Week 13 (n=52, 29, 30, 27, 29)	-2.87 (± 1.067)	-3.19 (± 1.389)	-3 (± 1.065)	-3.36 (± 1.122)
Change at Course 2/Week 25 (n=29, 9, 20, 15, 16)	-2.72 (± 0.954)	-3.52 (± 1.083)	-2.87 (± 1.186)	-2.69 (± 0.926)

End point values	PF-05280586 (US): by the end of Course 2			

Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=54, 30, 31, 29, 29)	6.1 (± 0.792)			
Change at Course 1/Week 1 (n=49, 26, 29, 24, 27)	-2.8 (± 1.285)			
Change at Course 1/Week 6 (n=53, 30, 30, 29, 27)	-3.29 (± 1.073)			
Change at Course 1/Week 13 (n=54, 30, 31, 28, 29)	-3.34 (± 1.043)			
Change at Course 1/Week 25 (n=35, 10, 20, 12, 19)	-3.03 (± 1.016)			
Change at Course 2/Week 1 (n=54, 30, 31, 29, 29)	-3.09 (± 1.09)			
Change at Course 2/Week 6 (n=52, 29, 29, 29, 29)	-3.61 (± 0.962)			
Change at Course 2/Week 13 (n=52, 29, 30, 27, 29)	-3.64 (± 1.034)			
Change at Course 2/Week 25 (n=29, 9, 20, 15, 16)	-3.38 (± 0.983)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean Change from Initial Study Baseline in Disease Activity Score (DAS28)-C-Reactive Protein (CRP) - by the end of Course 3

End point title	Mean Change from Initial Study Baseline in Disease Activity Score (DAS28)-C-Reactive Protein (CRP) - by the end of Course 3[27]

End point description:

The disease activity score (DAS) assessment is a continuous composite measure derived using differential weighting given to the following 4 components: tender/painful joint count (28 joints), swollen joint count (28 joints), CRP and patient's global assessment of arthritis Visual Analog Scale (VAS). The formula for calculation of DAS28-CRP from these 4 components is DAS28-CRP equals (=) 0.56 square root (sqrt) (DAS 28 tender joint count) + 0.28 sqrt (DAS 28 swollen joint count) + 0.36 natural log [ln] (CRP [milligrams per liter, mg/L] +1) + 0.014 (global assessment of health [GH]) + 0.96. Total score range: 0 to 9.4, higher score indicated more disease activity.

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1 and Course 2), and Week 1, 13, and 25 (Course 3).

Notes:

[27] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	30	30	27

Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=48, 30, 30, 27, 29)	5.54 (± 0.896)	5.81 (± 0.956)	5.79 (± 1.019)	6.14 (± 0.886)
Change at Course 1/Week 1 (n=44, 26, 28, 23, 27)	-2.11 (± 1.101)	-2.66 (± 1.124)	-2.5 (± 1.036)	-3.03 (± 1.073)
Change at Course 1/Week 6 (n=47, 30, 29, 27, 27)	-2.71 (± 1.069)	-3.23 (± 1.122)	-3 (± 1.146)	-3.23 (± 0.954)
Change at Course 1/Week 13 (n=48, 30, 30, 26, 29)	-2.92 (± 0.969)	-3.33 (± 1.13)	-3.15 (± 1.082)	-3.49 (± 0.962)
Change at Course 1/Week 25 (n=32, 10, 19, 11, 19)	-2.72 (± 0.998)	-2.97 (± 0.977)	-2.53 (± 0.875)	-2.77 (± 0.776)
Change at Course 2/Week 1 (n=48, 30, 30, 27, 29)	-2.62 (± 1.203)	-2.88 (± 1.296)	-2.6 (± 1.132)	-3.04 (± 1.195)
Change at Course 2/Week 6 (n=47, 29, 29, 27, 29)	-2.99 (± 0.971)	-3.45 (± 1.119)	-3.11 (± 1.108)	-3.63 (± 0.983)
Change at Course 2/Week 13 (n=47, 29, 30, 25, 29)	-2.85 (± 1.084)	-3.19 (± 1.389)	-3 (± 1.065)	-3.42 (± 1.145)
Change at Course 2/Week 25 (n=26, 9, 20, 14, 16)	-2.78 (± 0.989)	-3.52 (± 1.083)	-2.87 (± 1.186)	-2.73 (± 0.947)
Change at Course 3/Week 1 (n=48, 30, 30, 27, 29)	-2.52 (± 1.274)	-3.11 (± 1.481)	-2.85 (± 1.117)	-3.15 (± 1.272)
Change at Course 3/Week 13 (n=46, 30, 29, 25, 29)	-2.92 (± 1.114)	-3.33 (± 1.338)	-3.1 (± 1.025)	-3.58 (± 1.129)
Change at Course 3/Week 25 (n=47, 29, 29, 27, 29)	-2.79 (± 0.959)	-3.1 (± 1.436)	-3.03 (± 1.058)	-3.46 (± 0.816)

End point values	PF-05280586 (US): by the end of Course 3			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=48, 30, 30, 27, 29)	6.1 (± 0.792)			
Change at Course 1/Week 1 (n=44, 26, 28, 23, 27)	-2.8 (± 1.285)			
Change at Course 1/Week 6 (n=47, 30, 29, 27, 27)	-3.29 (± 1.073)			
Change at Course 1/Week 13 (n=48, 30, 30, 26, 29)	-3.34 (± 1.043)			
Change at Course 1/Week 25 (n=32, 10, 19, 11, 19)	-3.03 (± 1.016)			
Change at Course 2/Week 1 (n=48, 30, 30, 27, 29)	-3.09 (± 1.09)			
Change at Course 2/Week 6 (n=47, 29, 29, 27, 29)	-3.61 (± 0.962)			
Change at Course 2/Week 13 (n=47, 29, 30, 25, 29)	-3.64 (± 1.034)			
Change at Course 2/Week 25 (n=26, 9, 20, 14, 16)	-3.38 (± 0.983)			
Change at Course 3/Week 1 (n=48, 30, 30, 27, 29)	-3.18 (± 1.239)			
Change at Course 3/Week 13 (n=46, 30, 29, 25, 29)	-3.51 (± 1.118)			

Change at Course 3/Week 25 (n=47, 29, 29, 27, 29)	-3.46 (± 1.111)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Good European League Against Rheumatism (EULAR) Response Based on DAS28 - by the end of Course 1

End point title	Percentage of Participants with Good European League Against Rheumatism (EULAR) Response Based on DAS28 - by the end of Course 1[28]

End point description:

The DAS28-based EULAR response criteria were used to measure individual response as none, good, and moderate, depending on the extent of change from baseline and the level of disease activity reached. Good responders had a change from baseline greater than (>) 1.2 with present DAS28 less than or equal to (≤) 3.2; moderate responders had a change from baseline >0.6 and ≤1.2 with present DAS28 ≤3.2 or change from baseline >0.6 with present DAS28 >3.2 and ≤5.1 or change from baseline >1.2 with present DAS28 >5.1; non-responders had a change from baseline ≤0.6 with present DAS28 ≤5.1 or change from baseline ≤1.2 with present DAS28 >5.1.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1).

Notes:

[28] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 1	Rituximab-EU: by the end of Course 1	PF-05280586 (EU): by the end of Course 1	Rituximab-US: by the end of Course 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	32	33	30
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=51, 28, 31, 25, 28)	33.3	42.9	45.2	52
Course 1/Week 6 (n=56, 31, 32, 30, 28)	58.9	77.4	65.6	60
Course 1/Week 13 (n=56, 30, 33, 29, 29)	69.6	76.7	69.7	79.3
Course 1/Week 25 (n=35, 10, 22, 13, 19)	68.6	50	59.1	53.8

End point values	PF-05280586 (US): by the end of Course 1			
Subject group type	Subject analysis set			
Number of subjects analysed	30			

Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=51, 28, 31, 25, 28)	35.7			
Course 1/Week 6 (n=56, 31, 32, 30, 28)	64.3			
Course 1/Week 13 (n=56, 30, 33, 29, 29)	65.5			
Course 1/Week 25 (n=35, 10, 22, 13, 19)	63.2			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Good European League Against Rheumatism (EULAR) Response Based on DAS28 - by the end of Course 2

End point title	Percentage of Participants with Good European League Against Rheumatism (EULAR) Response Based on DAS28 - by the end of Course 2[29]

End point description:

The DAS28-based EULAR response criteria were used to measure individual response as none, good, and moderate, depending on the extent of change from baseline and the level of disease activity reached. Good responders had a change from baseline greater than (>) 1.2 with present DAS28 less than or equal to (≤) 3.2; moderate responders had a change from baseline >0.6 and ≤1.2 with present DAS28 ≤3.2 or change from baseline >0.6 with present DAS28 >3.2 and ≤5.1 or change from baseline >1.2 with present DAS28 >5.1; non-responders had a change from baseline ≤0.6 with present DAS28 ≤5.1 or change from baseline ≤1.2 with present DAS28 >5.1.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1 and Course 2).

Notes:

[29] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 2	Rituximab-EU/PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	30	31	29
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=49, 26, 29, 24, 27)	32.7	46.2	44.8	50
Course 1/Week 6 (n=53, 30, 30, 29, 27)	62.3	76.7	66.7	58.6
Course 1/Week 13 (n=54, 30, 31, 28, 29)	68.5	76.7	71	78.6
Course 1/Week 25 (n=35, 10, 20, 12, 19)	68.6	50	60	58.3
Course 2/Week 1 (n=54, 30, 31, 29, 29)	63	63.3	54.8	48.3

Course 2/Week 6 (n=52, 29, 29, 29, 29)	76.9	79.3	75.9	79.3
Course 2/Week 13 (n=52, 29, 30, 27, 29)	67.3	65.5	63.3	74.1
Course 2/Week 25 (n=29, 9, 20, 15, 16)	65.5	77.8	55	53.3

End point values	PF-05280586 (US): by the end of Course 2			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=49, 26, 29, 24, 27)	37			
Course 1/Week 6 (n=53, 30, 30, 29, 27)	66.7			
Course 1/Week 13 (n=54, 30, 31, 28, 29)	65.5			
Course 1/Week 25 (n=35, 10, 20, 12, 19)	63.2			
Course 2/Week 1 (n=54, 30, 31, 29, 29)	48.3			
Course 2/Week 6 (n=52, 29, 29, 29, 29)	79.3			
Course 2/Week 13 (n=52, 29, 30, 27, 29)	82.8			
Course 2/Week 25 (n=29, 9, 20, 15, 16)	62.5			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Good European League Against Rheumatism (EULAR) Response Based on DAS28 - by the end of Course 3

End point title	Percentage of Participants with Good European League Against Rheumatism (EULAR) Response Based on DAS28 - by the end of Course 3[30]

End point description:

The DAS28-based EULAR response criteria were used to measure individual response as none, good, and moderate, depending on the extent of change from baseline and the level of disease activity reached. Good responders had a change from baseline greater than (>) 1.2 with present DAS28 less than or equal to (≤) 3.2; moderate responders had a change from baseline >0.6 and ≤1.2 with present DAS28 ≤3.2 or change from baseline >0.6 with present DAS28 >3.2 and ≤5.1 or change from baseline >1.2 with present DAS28 >5.1; non-responders had a change from baseline ≤0.6 with present DAS28 ≤5.1 or change from baseline ≤1.2 with present DAS28 >5.1.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1 and Course 2) and Week 1, 13, and 25 (Course 3).

Notes:

[30] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	30	30	27
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=44, 26, 28, 23, 27)	34.1	46.2	42.9	52.2
Course 1/Week 6 (n=47, 30, 29, 27, 27)	66	76.7	65.5	63
Course 1/Week 13 (n=48, 30, 30, 26, 29)	70.8	76.7	70	80.8
Course 1/Week 25 (n=32, 10, 19, 11, 19)	65.6	50	57.9	63.6
Course 2/Week 1 (n=48, 30, 30, 27, 29)	62.5	63.3	53.3	51.9
Course 2/Week 6 (n=47, 29, 29, 27, 29)	74.5	79.3	75.9	81.5
Course 2/Week 13 (n=47, 29, 30, 25, 29)	66	65.5	63.3	76
Course 2/Week 25 (n=26, 9, 20, 14, 16)	65.4	77.8	55	57.1
Course 3/Week 1 (n=48, 30, 30, 27, 29)	62.5	66.7	56.7	51.9
Course 3/Week 13 (n=46, 30, 29, 25, 29)	76.1	76.7	75.9	64
Course 3/Week 25 (EOT) (n=47, 29, 29, 27, 29)	70.2	62.1	69	70.4

End point values	PF-05280586 (US): by the end of Course 3			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=44, 26, 28, 23, 27)	37			
Course 1/Week 6 (n=47, 30, 29, 27, 27)	66.7			
Course 1/Week 13 (n=48, 30, 30, 26, 29)	65.5			
Course 1/Week 25 (n=32, 10, 19, 11, 19)	63.2			
Course 2/Week 1 (n=48, 30, 30, 27, 29)	48.3			

Course 2/Week 6 (n=47, 29, 29, 27, 29)	79.3			
Course 2/Week 13 (n=47, 29, 30, 25, 29)	82.8			
Course 2/Week 25 (n=26, 9, 20, 14, 16)	62.5			
Course 3/Week 1 (n=48, 30, 30, 27, 29)	58.6			
Course 3/Week 13 (n=46, 30, 29, 25, 29)	65.5			
Course 3/Week 25 (EOT) (n=47, 29, 29, 27, 29)	72.4			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Low Disease Activity State (LDAS) (≤3.2) - by the end of Course 1

End point title	Percentage of Participants with Low Disease Activity State (LDAS) (≤3.2) - by the end of Course 1[31]

End point description:

The DAS assessment is a continuous composite measure derived using differential weighting given to the following 4 components: tender/painful joint count (28 joints), swollen joint count (28 joints), CRP and patient's global assessment of arthritis VAS. The formula for calculation of DAS28-CRP from these 4 components is DAS28-CRP = 0.56 sqrt (DAS 28 tender joint count) + 0.28 sqrt (DAS 28 swollen joint count) + 0.36 (ln CRP [mg/L] +1) + 0.014 (GH) + 0.96. Total score range: 0 to 9.4, higher score indicated more disease activity. DAS28-CRP ≤3.2 implied low disease activity.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1).

Notes:

[31] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 1	Rituximab-EU: by the end of Course 1	PF-05280586 (EU): by the end of Course 1	Rituximab-US: by the end of Course 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	32	33	30
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=51, 28, 31, 25, 28)	33.3	42.9	48.4	52
Course 1/Week 6 (n=56, 31, 32, 30, 28)	58.9	77.4	65.6	60
Course 1/Week 13 (n=56, 30, 33, 29, 29)	71.4	76.7	69.7	79.3
Course 1/Week 25 (n=35, 10, 22, 13, 19)	68.6	50	59.1	53.8

End point values	PF-05280586 (US): by the end of Course 1			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=51, 28, 31, 25, 28)	35.7			
Course 1/Week 6 (n=56, 31, 32, 30, 28)	64.3			
Course 1/Week 13 (n=56, 30, 33, 29, 29)	65.5			
Course 1/Week 25 (n=35, 10, 22, 13, 19)	63.2			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Low Disease Activity State (LDAS) (≤3.2) - by the end of Course 2

End point title	Percentage of Participants with Low Disease Activity State (LDAS) (≤3.2) - by the end of Course 2[32]

End point description:

The DAS assessment is a continuous composite measure derived using differential weighting given to the following 4 components: tender/painful joint count (28 joints), swollen joint count (28 joints), CRP and patient's global assessment of arthritis VAS. The formula for calculation of DAS28-CRP from these 4 components is DAS28-CRP = 0.56 sqrt (DAS 28 tender joint count) + 0.28 sqrt (DAS 28 swollen joint count) + 0.36 (ln CRP [mg/L] +1) + 0.014 (GH) + 0.96. Total score range: 0 to 9.4, higher score indicated more disease activity. DAS28-CRP ≤3.2 implied low disease activity.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1 and Course 2).

Notes:

[32] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 2	Rituximab-EU/PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	30	31	29
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=49, 26, 29, 24, 27)	32.7	46.2	48.3	50
Course 1/Week 6 (n=53, 30, 30, 29, 27)	62.3	76.7	66.7	58.6
Course 1/Week 13 (n=54, 30, 31, 28, 29)	70.4	76.7	71	78.6

Course 1/Week 25 (n=35, 10, 20, 12, 19)	68.6	50	60	58.3
Course 2/Week 1 (n=54, 30, 31, 29, 29)	63	63.3	58.1	48.3
Course 2/Week 6 (n=52, 29, 29, 29, 29)	76.9	79.3	79.3	79.3
Course 2/Week 13 (n=52, 29, 30, 27, 29)	69.2	69	63.3	74.1
Course 2/Week 25 (n=29, 9, 20, 15, 16)	65.5	77.8	55	53.3

End point values	PF-05280586 (US): by the end of Course 2			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=49, 26, 29, 24, 27)	37			
Course 1/Week 6 (n=53, 30, 30, 29, 27)	66.7			
Course 1/Week 13 (n=54, 30, 31, 28, 29)	65.5			
Course 1/Week 25 (n=35, 10, 20, 12, 19)	63.2			
Course 2/Week 1 (n=54, 30, 31, 29, 29)	48.3			
Course 2/Week 6 (n=52, 29, 29, 29, 29)	79.3			
Course 2/Week 13 (n=52, 29, 30, 27, 29)	82.8			
Course 2/Week 25 (n=29, 9, 20, 15, 16)	62.5			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Low Disease Activity State (LDAS) (≤3.2) - by the end of Course 3

End point title	Percentage of Participants with Low Disease Activity State (LDAS) (≤3.2) - by the end of Course 3[33]

End point description:

The DAS assessment is a continuous composite measure derived using differential weighting given to the following 4 components: tender/painful joint count (28 joints), swollen joint count (28 joints), CRP and patient's global assessment of arthritis VAS. The formula for calculation of DAS28-CRP from these 4 components is DAS28-CRP = 0.56 sqrt (DAS 28 tender joint count) + 0.28 sqrt (DAS 28 swollen joint count) + 0.36 (ln CRP [mg/L] +1) + 0.014 (GH) + 0.96. Total score range: 0 to 9.4, higher score indicated more disease activity. DAS28-CRP ≤3.2 implied low disease activity.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1 and Course 2), and Week 1, 13, and 25 (Course 3).

Notes:

[33] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	30	30	27
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=44, 26, 28, 23, 27)	34.1	46.2	46.4	52.2
Course 1/Week 6 (n=47, 30, 29, 27, 27)	66	76.7	65.5	63
Course 1/Week 13 (n=48, 30, 30, 26, 29)	72.9	76.7	70	80.8
Course 1/Week 25 (n=32, 10, 19, 11, 19)	65.6	50	57.9	63.6
Course 2/Week 1 (n=48, 30, 30, 27, 29)	62.5	63.3	56.7	51.9
Course 2/Week 6 (n=47, 29, 29, 27, 29)	74.5	79.3	79.3	81.5
Course 2/Week 13 (n=47, 29, 30, 25, 29)	68.1	69	63.3	76
Course 2/Week 25 (n=26, 9, 20, 14, 16)	65.4	77.8	55	57.1
Course 3/Week 1 (n=48, 30, 30, 27, 29)	62.5	66.7	56.7	51.9
Course 3/Week 13 (n=46, 30, 29, 25, 29)	78.3	76.7	75.9	64
Course 3/Week 25 (EOT) (n=47, 29, 29, 27, 29)	70.2	62.1	69	70.4

End point values	PF-05280586 (US): by the end of Course 3			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=44, 26, 28, 23, 27)	37			
Course 1/Week 6 (n=47, 30, 29, 27, 27)	66.7			
Course 1/Week 13 (n=48, 30, 30, 26, 29)	65.5			
Course 1/Week 25 (n=32, 10, 19, 11, 19)	63.2			
Course 2/Week 1 (n=48, 30, 30, 27, 29)	48.3			

Course 2/Week 6 (n=47, 29, 29, 27, 29)	79.3			
Course 2/Week 13 (n=47, 29, 30, 25, 29)	82.8			
Course 2/Week 25 (n=26, 9, 20, 14, 16)	62.5			
Course 3/Week 1 (n=48, 30, 30, 27, 29)	58.6			
Course 3/Week 13 (n=46, 30, 29, 25, 29)	65.5			
Course 3/Week 25 (EOT) (n=47, 29, 29, 27, 29)	72.4			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with DAS Remission (DAS28-CRP less than [<] 2.6) - by the end of Course 1

End point title	Percentage of Participants with DAS Remission (DAS28-CRP less than [<] 2.6) - by the end of Course 1[34]

End point description:

The DAS assessment is a continuous composite measure derived using differential weighting given to the following 4 components: tender/painful joint count (28 joints), swollen joint count (28 joints), CRP and patient's global assessment of arthritis VAS. The formula for calculation of DAS28-CRP from these 4 components is DAS28-CRP = 0.56 sqrt (DAS 28 tender joint count) + 0.28 sqrt (DAS 28 swollen joint count) + 0.36 (ln CRP [mg/L] +1) + 0.014 (GH) + 0.96. Total score range: 0 to 9.4, higher score indicated more disease activity. DAS28-CRP <2.6 implied remission.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1).

Notes:

[34] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 1	Rituximab-EU: by the end of Course 1	PF-05280586 (EU): by the end of Course 1	Rituximab-US: by the end of Course 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	32	33	30
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=51, 28, 31, 25, 28)	19.6	28.6	29	32
Course 1/Week 6 (n=56, 31, 32, 30, 28)	39.3	54.8	50	40
Course 1/Week 13 (n=56, 30, 33, 29, 29)	48.2	60	60.6	41.4
Course 1/Week 25 (n=35, 10, 22, 13, 19)	51.4	30	45.5	23.1

End point values	PF-05280586 (US): by the end of Course 1			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=51, 28, 31, 25, 28)	21.4			
Course 1/Week 6 (n=56, 31, 32, 30, 28)	53.6			
Course 1/Week 13 (n=56, 30, 33, 29, 29)	51.7			
Course 1/Week 25 (n=35, 10, 22, 13, 19)	31.6			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with DAS Remission (DAS28-CRP less than [<] 2.6) - by the end of Course 2

End point title	Percentage of Participants with DAS Remission (DAS28-CRP less than [<] 2.6) - by the end of Course 2[35]

End point description:

The DAS assessment is a continuous composite measure derived using differential weighting given to the following 4 components: tender/painful joint count (28 joints), swollen joint count (28 joints), CRP and patient's global assessment of arthritis VAS. The formula for calculation of DAS28-CRP from these 4 components is DAS28-CRP = 0.56 sqrt (DAS 28 tender joint count) + 0.28 sqrt (DAS 28 swollen joint count) + 0.36 (ln CRP [mg/L] +1) + 0.014 (GH) + 0.96. Total score range: 0 to 9.4, higher score indicated more disease activity. DAS28-CRP <2.6 implied remission.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1 and Course 2).

Notes:

[35] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 2	Rituximab-EU/PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	30	31	29
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=49, 26, 29, 24, 27)	20.4	30.8	27.6	33.3
Course 1/Week 6 (n=53, 30, 30, 29, 27)	41.5	53.3	50	41.4
Course 1/Week 13 (n=54, 30, 31, 28, 29)	50	60	61.3	39.3

Course 1/Week 25 (n=35, 10, 20, 12, 19)	51.4	30	45	25
Course 2/Week 1 (n=54, 30, 31, 29, 29)	42.6	43.3	32.3	31
Course 2/Week 6 (n=52, 29, 29, 29, 29)	51.9	65.5	41.4	51.7
Course 2/Week 13 (n=52, 29, 30, 27, 29)	42.3	55.2	43.3	33.3
Course 2/Week 25 (n=29, 9, 20, 15, 16)	34.5	55.6	50	33.3

End point values	PF-05280586 (US): by the end of Course 2			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=49, 26, 29, 24, 27)	22.2			
Course 1/Week 6 (n=53, 30, 30, 29, 27)	55.6			
Course 1/Week 13 (n=54, 30, 31, 28, 29)	51.7			
Course 1/Week 25 (n=35, 10, 20, 12, 19)	31.6			
Course 2/Week 1 (n=54, 30, 31, 29, 29)	34.5			
Course 2/Week 6 (n=52, 29, 29, 29, 29)	51.7			
Course 2/Week 13 (n=52, 29, 30, 27, 29)	58.6			
Course 2/Week 25 (n=29, 9, 20, 15, 16)	50			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with DAS Remission (DAS28-CRP less than [<] 2.6) - by the end of Course 3

End point title	Percentage of Participants with DAS Remission (DAS28-CRP less than [<] 2.6) - by the end of Course 3[36]

End point description:

The DAS assessment is a continuous composite measure derived using differential weighting given to the following 4 components: tender/painful joint count (28 joints), swollen joint count (28 joints), CRP and patient's global assessment of arthritis VAS. The formula for calculation of DAS28-CRP from these 4 components is DAS28-CRP = 0.56 sqrt (DAS 28 tender joint count) + 0.28 sqrt (DAS 28 swollen joint count) + 0.36 (ln CRP [mg/L] +1) + 0.014 (GH) + 0.96. Total score range: 0 to 9.4, higher score indicated more disease activity. DAS28-CRP <2.6 implied remission.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1 and Course 2), and Week 1, 13, and 25 (Course 3).

Notes:

[36] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	30	30	27
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=44, 26, 28, 23, 27)	20.5	30.8	25	34.8
Course 1/Week 6 (n=47, 30, 29, 27, 27)	44.7	53.3	48.3	44.4
Course 1/Week 13 (n=48, 30, 30, 26, 29)	56.3	60	60	42.3
Course 1/Week 25 (n=32, 10, 19, 11, 19)	50	30	42.1	27.3
Course 2/Week 1 (n=48, 30, 30, 27, 29)	41.7	43.3	30	33.3
Course 2/Week 6 (n=47, 29, 29, 27, 29)	53.2	65.5	41.4	55.6
Course 2/Week 13 (n=47, 29, 30, 25, 29)	42.6	55.2	43.3	36
Course 2/Week 25 (n=26, 9, 20, 14, 16)	38.5	55.6	50	35.7
Course 3/Week 1 (n=48, 30, 30, 27, 29)	33.3	43.3	40	37
Course 3/Week 13 (n=46, 30, 29, 25, 29)	54.3	60	58.6	52
Course 3/Week 25 (EOT) (n=47, 29, 29, 27, 29)	42.6	51.7	44.8	48.1

End point values	PF-05280586 (US): by the end of Course 3			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=44, 26, 28, 23, 27)	22.2			
Course 1/Week 6 (n=47, 30, 29, 27, 27)	55.6			
Course 1/Week 13 (n=48, 30, 30, 26, 29)	51.7			
Course 1/Week 25 (n=32, 10, 19, 11, 19)	31.6			
Course 2/Week 1 (n=48, 30, 30, 27, 29)	34.5			

Course 2/Week 6 (n=47, 29, 29, 27, 29)	51.7			
Course 2/Week 13 (n=47, 29, 30, 25, 29)	58.6			
Course 2/Week 25 (n=26, 9, 20, 14, 16)	50			
Course 3/Week 1 (n=48, 30, 30, 27, 29)	44.8			
Course 3/Week 13 (n=46, 30, 29, 25, 29)	55.2			
Course 3/Week 25 (EOT) (n=47, 29, 29, 27, 29)	55.2			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with American College of Rheumatology (ACR) 20% Improvement (ACR20) Response - by the end of Course 1

End point title	Percentage of Participants with American College of Rheumatology (ACR) 20% Improvement (ACR20) Response - by the end of Course 1[37]

End point description:

ACR20 response: ≥ 20 percent (%) improvement in tender/painful joint count; ≥ 20% improvement in swollen joint count; and ≥ 20% improvement in at least 3 of 5 remaining ACR core measures: participant assessment of arthritis pain; participant global assessment of arthritis; physician global assessment of arthritis; self-assessed disability (disability index of the Health Assessment Questionnaire [HAQ]); and CRP.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1).

Notes:

[37] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 1	Rituximab-EU: by the end of Course 1	PF-05280586 (EU): by the end of Course 1	Rituximab-US: by the end of Course 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	32	33	30
Units: Percentage of participants				
number (not applicable)				
Course 1/Week 1 (n=58, 32, 33, 30, 30)	50	59.4	63.6	66.7
Course 1/Week 6 (n=57, 31, 33, 30, 30)	66.7	71	84.8	73.3
Course 1/Week 13 (n=56, 31, 33, 30, 29)	69.6	77.4	84.8	83.3
Course 1/Week 25 (n=35, 10, 22, 13, 19)	77.1	90	81.8	76.9

End point values	PF-05280586 (US): by the end of Course 1			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Percentage of participants				
number (not applicable)				
Course 1/Week 1 (n=58, 32, 33, 30, 30)	60			
Course 1/Week 6 (n=57, 31, 33, 30, 30)	76.7			
Course 1/Week 13 (n=56, 31, 33, 30, 29)	82.8			
Course 1/Week 25 (n=35, 10, 22, 13, 19)	73.7			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with American College of Rheumatology (ACR) 20% Improvement (ACR20) Response - by the end of Course 2

End point title	Percentage of Participants with American College of Rheumatology (ACR) 20% Improvement (ACR20) Response - by the end of Course 2[38]

End point description:

ACR20 response: ≥ 20 percent (%) improvement in tender/painful joint count; ≥ 20% improvement in swollen joint count; and ≥ 20% improvement in at least 3 of 5 remaining ACR core measures: participant assessment of arthritis pain; participant global assessment of arthritis; physician global assessment of arthritis; self-assessed disability (disability index of the Health Assessment Questionnaire [HAQ]); and CRP.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1 and Course 2).

Notes:

[38] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 2	Rituximab-EU/PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	30	31	29
Units: Percentage of participants				
number (not applicable)				
Course 1/Week 1 (n=54, 30, 31, 29, 29)	51.9	60	64.5	65.5
Course 1/Week 6 (n=54, 30, 31, 29, 29)	70.4	70	87.1	72.4
Course 1/Week 13 (n=54, 30, 31, 29, 29)	70.4	76.7	87.1	82.8

Course 1/Week 25 (n=35, 10, 20, 12, 19)	77.1	90	80	75
Course 2/Week 1 (n=54, 30, 31, 29, 29)	66.7	63.3	71	72.4
Course 2/Week 6 (n=53, 30, 29, 29, 29)	79.2	70	93.1	79.3
Course 2/Week 13 (n=53, 30, 30, 28, 29)	66	60	86.7	78.6
Course 2/Week 25 (n=29, 9, 20, 15, 16)	79.3	88.9	85	80

End point values	PF-05280586 (US): by the end of Course 2			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percentage of participants				
number (not applicable)				
Course 1/Week 1 (n=54, 30, 31, 29, 29)	62.1			
Course 1/Week 6 (n=54, 30, 31, 29, 29)	75.9			
Course 1/Week 13 (n=54, 30, 31, 29, 29)	82.8			
Course 1/Week 25 (n=35, 10, 20, 12, 19)	73.7			
Course 2/Week 1 (n=54, 30, 31, 29, 29)	69			
Course 2/Week 6 (n=53, 30, 29, 29, 29)	86.2			
Course 2/Week 13 (n=53, 30, 30, 28, 29)	89.7			
Course 2/Week 25 (n=29, 9, 20, 15, 16)	93.8			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with American College of Rheumatology (ACR) 20% Improvement (ACR20) Response - by the end of Course 3

End point title	Percentage of Participants with American College of Rheumatology (ACR) 20% Improvement (ACR20) Response - by the end of Course 3[39]

End point description:

ACR20 response: ≥ 20 percent (%) improvement in tender/painful joint count; ≥ 20% improvement in swollen joint count; and ≥ 20% improvement in at least 3 of 5 remaining ACR core measures: participant assessment of arthritis pain; participant global assessment of arthritis; physician global assessment of arthritis; self-assessed disability (disability index of the Health Assessment Questionnaire [HAQ]); and CRP.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1 and Course 2), and Week 1, 13, and 25 (Course 3).

Notes:

[39] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	30	30	27
Units: Percentage of participants				
number (not applicable)				
Course 1/Week 1 (n=48, 30, 30, 27, 29)	50	60	63.3	70.4
Course 1/Week 6 (n=48, 30, 30, 27, 29)	70.8	70	86.7	74.1
Course 1/Week 13 (n=48, 30, 30, 27, 29)	70.8	76.7	86.7	85.2
Course 1/Week 25 (n=32, 10, 19, 11, 19)	75	90	78.9	81.8
Course 2/Week 1 (n=48, 30, 30, 27, 29)	68.8	63.3	70	74.1
Course 2/Week 6 (n=48, 30, 29, 27, 29)	77.1	70	93.1	81.5
Course 2/Week 13 (n=48, 30, 30, 26, 29)	64.6	60	86.7	76.9
Course 2/Week 25 (n=26, 9, 20, 14, 16)	80.8	88.9	85	85.7
Course 3/Week 1 (n=48, 30, 30, 27, 29)	60.4	56.7	70	59.3
Course 3/Week 13 (n=46, 30, 29, 26, 29)	67.4	73.3	82.8	69.2
Course 3/Week 25 (EOT) (n=47, 30, 29, 27, 29)	59.6	66.7	89.7	74.1

End point values	PF-05280586 (US): by the end of Course 3			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percentage of participants				
number (not applicable)				
Course 1/Week 1 (n=48, 30, 30, 27, 29)	62.1			
Course 1/Week 6 (n=48, 30, 30, 27, 29)	75.9			
Course 1/Week 13 (n=48, 30, 30, 27, 29)	82.8			
Course 1/Week 25 (n=32, 10, 19, 11, 19)	73.7			
Course 2/Week 1 (n=48, 30, 30, 27, 29)	69			

Course 2/Week 6 (n=48, 30, 29, 27, 29)	86.2			
Course 2/Week 13 (n=48, 30, 30, 26, 29)	89.7			
Course 2/Week 25 (n=26, 9, 20, 14, 16)	93.8			
Course 3/Week 1 (n=48, 30, 30, 27, 29)	69			
Course 3/Week 13 (n=46, 30, 29, 26, 29)	82.8			
Course 3/Week 25 (EOT) (n=47, 30, 29, 27, 29)	86.2			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with American College of Rheumatology (ACR) 50% Improvement (ACR50) Response - by the end of Course 1

End point title	Percentage of Participants with American College of Rheumatology (ACR) 50% Improvement (ACR50) Response - by the end of Course 1[40]

End point description:

ACR50 response: ≥50% improvement in tender/painful joint count; ≥50% improvement in swollen joint count; and ≥50% improvement in at least 3 of 5 remaining ACR core measures: participant assessment of arthritis pain; participant global assessment of arthritis; physician global assessment of arthritis; self-assessed disability (disability index of the HAQ); and CRP.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1).

Notes:

[40] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 1	Rituximab-EU: by the end of Course 1	PF-05280586 (EU): by the end of Course 1	Rituximab-US: by the end of Course 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	32	33	30
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=58, 32, 33, 30, 30)	17.2	28.1	48.5	30
Course 1/Week 6 (n=57, 31, 33, 30, 30)	33.3	51.6	51.5	50
Course 1/Week 13 (n=56, 31, 33, 30, 29)	37.5	41.9	66.7	66.7
Course 1/Week 25 (n=35, 10, 22, 13, 19)	51.4	30	63.6	46.2

End point values	PF-05280586 (US): by the end of Course 1			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=58, 32, 33, 30, 30)	30			
Course 1/Week 6 (n=57, 31, 33, 30, 30)	53.3			
Course 1/Week 13 (n=56, 31, 33, 30, 29)	58.6			
Course 1/Week 25 (n=35, 10, 22, 13, 19)	36.8			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with American College of Rheumatology (ACR) 50% Improvement (ACR50) Response - by the end of Course 2

End point title	Percentage of Participants with American College of Rheumatology (ACR) 50% Improvement (ACR50) Response - by the end of Course 2[41]

End point description:

ACR50 response: ≥50% improvement in tender/painful joint count; ≥50% improvement in swollen joint count; and ≥50% improvement in at least 3 of 5 remaining ACR core measures: participant assessment of arthritis pain; participant global assessment of arthritis; physician global assessment of arthritis; self-assessed disability (disability index of the HAQ); and CRP.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1 and Course 2).

Notes:

[41] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 2	Rituximab-EU/PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	30	31	29
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=54, 30, 31, 29, 29)	18.5	26.7	48.4	27.6
Course 1/Week 6 (n=54, 30, 31, 29, 29)	35.2	50	51.6	48.3
Course 1/Week 13 (n=54, 30, 31, 29, 29)	38.9	40	67.7	65.5
Course 1/Week 25 (n=35, 10, 20, 12, 19)	51.4	30	65	41.7

Course 2/Week 1 (n=54, 30, 31, 29, 29)	40.7	33.3	41.9	34.5
Course 2/Week 6 (n=53, 30, 29, 29, 29)	50.9	53.3	58.6	55.2
Course 2/Week 13 (n=53, 30, 30, 28, 29)	47.2	46.7	56.7	53.6
Course 2/Week 25 (n=29, 9, 20, 15, 16)	58.6	55.6	50	40

End point values	PF-05280586 (US): by the end of Course 2			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=54, 30, 31, 29, 29)	31			
Course 1/Week 6 (n=54, 30, 31, 29, 29)	55.2			
Course 1/Week 13 (n=54, 30, 31, 29, 29)	58.6			
Course 1/Week 25 (n=35, 10, 20, 12, 19)	36.8			
Course 2/Week 1 (n=54, 30, 31, 29, 29)	24.1			
Course 2/Week 6 (n=53, 30, 29, 29, 29)	55.2			
Course 2/Week 13 (n=53, 30, 30, 28, 29)	55.2			
Course 2/Week 25 (n=29, 9, 20, 15, 16)	50			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with American College of Rheumatology (ACR) 50% Improvement (ACR50) Response - by the end of Course 3

End point title	Percentage of Participants with American College of Rheumatology (ACR) 50% Improvement (ACR50) Response - by the end of Course 3[42]

End point description:

ACR50 response: ≥50% improvement in tender/painful joint count; ≥50% improvement in swollen joint count; and ≥50% improvement in at least 3 of 5 remaining ACR core measures: participant assessment of arthritis pain; participant global assessment of arthritis; physician global assessment of arthritis; self-assessed disability (disability index of the HAQ); and CRP.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1 and Course 2), and Week 1, 13, and 25 (Course 3).

Notes:

[42] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	30	30	27
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=48, 30, 30, 27, 29)	18.8	26.7	46.7	29.6
Course 1/Week 6 (n=48, 30, 30, 27, 29)	33.3	50	50	51.9
Course 1/Week 13 (n=48, 30, 30, 27, 29)	43.8	40	66.7	66.7
Course 1/Week 25 (n=32, 10, 19, 11, 19)	46.9	30	63.2	45.5
Course 2/Week 1 (n=48, 30, 30, 27, 29)	41.7	33.3	40	37
Course 2/Week 6 (n=48, 30, 29, 27, 29)	50	53.3	58.6	55.6
Course 2/Week 13 (n=48, 30, 30, 26, 29)	45.8	46.7	56.7	57.7
Course 2/Week 25 (n=26, 9, 20, 14, 16)	65.4	55.6	50	42.9
Course 3/Week 1 (n=48, 30, 30, 27, 29)	31.3	43.3	33.3	44.4
Course 3/Week 13 (n=46, 30, 29, 26, 29)	58.7	56.7	58.6	53.8
Course 3/Week 25 (EOT) (n=47, 30, 29, 27, 29)	42.6	43.3	62.1	59.3

End point values	PF-05280586 (US): by the end of Course 3			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=48, 30, 30, 27, 29)	31			
Course 1/Week 6 (n=48, 30, 30, 27, 29)	55.2			
Course 1/Week 13 (n=48, 30, 30, 27, 29)	58.6			
Course 1/Week 25 (n=32, 10, 19, 11, 19)	36.8			
Course 2/Week 1 (n=48, 30, 30, 27, 29)	24.1			

Course 2/Week 6 (n=48, 30, 29, 27, 29)	55.2			
Course 2/Week 13 (n=48, 30, 30, 26, 29)	55.2			
Course 2/Week 25 (n=26, 9, 20, 14, 16)	50			
Course 3/Week 1 (n=48, 30, 30, 27, 29)	37.9			
Course 3/Week 13 (n=46, 30, 29, 26, 29)	62.1			
Course 3/Week 25 (EOT) (n=47, 30, 29, 27, 29)	62.1			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with American College of Rheumatology (ACR) 70% Improvement (ACR70) Response - by the end of Course 1

End point title	Percentage of Participants with American College of Rheumatology (ACR) 70% Improvement (ACR70) Response - by the end of Course 1[43]

End point description:

ACR70 response: ≥70% improvement in tender/painful joint count; ≥70% improvement in swollen joint count; and ≥70% improvement in at least 3 of 5 remaining ACR core measures: participant assessment of arthritis pain; participant global assessment of arthritis; physician global assessment of arthritis; self-assessed disability (disability index of the HAQ); and CRP.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1).

Notes:

[43] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 1	Rituximab-EU: by the end of Course 1	PF-05280586 (EU): by the end of Course 1	Rituximab-US: by the end of Course 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	32	33	30
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=58, 32, 33, 30, 30)	5.2	12.5	21.2	16.7
Course 1/Week 6 (n=57, 31, 33, 30, 30)	21.1	22.6	33.3	26.7
Course 1/Week 13 (n=56, 31, 33, 30, 29)	23.2	32.3	36.4	33.3
Course 1/Week 25 (n=35, 10, 22, 13, 19)	22.9	10	36.4	0

End point values	PF-05280586 (US): by the end of Course 1			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=58, 32, 33, 30, 30)	10			
Course 1/Week 6 (n=57, 31, 33, 30, 30)	30			
Course 1/Week 13 (n=56, 31, 33, 30, 29)	34.5			
Course 1/Week 25 (n=35, 10, 22, 13, 19)	15.8			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with American College of Rheumatology (ACR) 70% Improvement (ACR70) Response - by the end of Course 2

End point title	Percentage of Participants with American College of Rheumatology (ACR) 70% Improvement (ACR70) Response - by the end of Course 2[44]

End point description:

ACR70 response: ≥70% improvement in tender/painful joint count; ≥70% improvement in swollen joint count; and ≥70% improvement in at least 3 of 5 remaining ACR core measures: participant assessment of arthritis pain; participant global assessment of arthritis; physician global assessment of arthritis; self-assessed disability (disability index of the HAQ); and CRP.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1 and Course 2).

Notes:

[44] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 2	Rituximab-EU/PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	30	31	29
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=54, 30, 31, 29, 29)	5.6	10	19.4	13.8
Course 1/Week 6 (n=54, 30, 31, 29, 29)	22.2	20	32.3	24.1
Course 1/Week 13 (n=54, 30, 31, 29, 29)	24.1	30	35.5	31
Course 1/Week 25 (n=35, 10, 20, 12, 19)	22.9	10	35	0

Course 2/Week 1 (n=54, 30, 31, 29, 29)	13	16.7	19.4	17.2
Course 2/Week 6 (n=53, 30, 29, 29, 29)	26.4	30	37.9	24.1
Course 2/Week 13 (n=53, 30, 30, 28, 29)	30.2	30	33.3	32.1
Course 2/Week 25 (n=29, 9, 20, 15, 16)	24.1	22.2	30	20

End point values	PF-05280586 (US): by the end of Course 2			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=54, 30, 31, 29, 29)	10.3			
Course 1/Week 6 (n=54, 30, 31, 29, 29)	31			
Course 1/Week 13 (n=54, 30, 31, 29, 29)	34.5			
Course 1/Week 25 (n=35, 10, 20, 12, 19)	15.8			
Course 2/Week 1 (n=54, 30, 31, 29, 29)	10.3			
Course 2/Week 6 (n=53, 30, 29, 29, 29)	24.1			
Course 2/Week 13 (n=53, 30, 30, 28, 29)	24.1			
Course 2/Week 25 (n=29, 9, 20, 15, 16)	31.3			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with American College of Rheumatology (ACR) 70% Improvement (ACR70) Response - by the end of Course 3

End point title	Percentage of Participants with American College of Rheumatology (ACR) 70% Improvement (ACR70) Response - by the end of Course 3[45]

End point description:

ACR70 response: ≥70% improvement in tender/painful joint count; ≥70% improvement in swollen joint count; and ≥70% improvement in at least 3 of 5 remaining ACR core measures: participant assessment of arthritis pain; participant global assessment of arthritis; physician global assessment of arthritis; self-assessed disability (disability index of the HAQ); and CRP.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1 and Course 2), and Week 1, 13, and 25 (Course 3).

Notes:

[45] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	30	30	27
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=48, 30, 30, 27, 29)	6.3	10	16.7	14.8
Course 1/Week 6 (n=48, 30, 30, 27, 29)	22.9	20	30	25.9
Course 1/Week 13 (n=48, 30, 30, 27, 29)	27.1	30	33.3	33.3
Course 1/Week 25 (n=32, 10, 19, 11, 19)	21.9	10	31.6	0
Course 2/Week 1 (n=48, 30, 30, 27, 29)	12.5	16.7	16.7	18.5
Course 2/Week 6 (n=48, 30, 29, 27, 29)	27.1	30	37.9	25.9
Course 2/Week 13 (n=48, 30, 30, 26, 29)	29.2	30	33.3	34.6
Course 2/Week 25 (n=26, 9, 20, 14, 16)	26.9	22.2	30	21.4
Course 3/Week 1 (n=48, 30, 30, 27, 29)	12.5	23.3	20	33.3
Course 3/Week 13 (n=46, 30, 29, 26, 29)	30.4	33.3	37.9	42.3
Course 3/Week 25 (EOT) (n=47, 30, 29, 27, 29)	25.5	20	34.5	37

End point values	PF-05280586 (US): by the end of Course 3			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percentage of Participants				
number (not applicable)				
Course 1/Week 1 (n=48, 30, 30, 27, 29)	10.3			
Course 1/Week 6 (n=48, 30, 30, 27, 29)	31			
Course 1/Week 13 (n=48, 30, 30, 27, 29)	34.5			
Course 1/Week 25 (n=32, 10, 19, 11, 19)	15.8			
Course 2/Week 1 (n=48, 30, 30, 27, 29)	10.3			

Course 2/Week 6 (n=48, 30, 29, 27, 29)	24.1			
Course 2/Week 13 (n=48, 30, 30, 26, 29)	24.1			
Course 2/Week 25 (n=26, 9, 20, 14, 16)	31.3			
Course 3/Week 1 (n=48, 30, 30, 27, 29)	20.7			
Course 3/Week 13 (n=46, 30, 29, 26, 29)	34.5			
Course 3/Week 25 (EOT) (n=47, 30, 29, 27, 29)	24.1			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR response: Tender/Painful Joint Count - by the end of Course 1

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR response: Tender/Painful Joint Count - by the end of Course 1[46]

End point description:

Sixty-eight joints were assessed by a blinded joint assessor to determine the number of joints that were considered tender or painful. For consistency, a single assessor was preferred to perform all evaluations across the study for an individual participant. The response to pressure/motion on each joint was assessed using the following scale: Present/Absent/Not Done/Not Applicable (to be used for artificial or missing joints). Artificial joints were not be assessed.

End point type	Primary

End point timeframe:

Baseline B3281001, Screening, Week 1, 6, 13, and 25 (Course 1).

Notes:

[46] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 1	Rituximab-EU: by the end of Course 1	PF-05280586 (EU): by the end of Course 1	Rituximab-US: by the end of Course 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	32	33	30
Units: Percent change in joint count				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=58, 32, 33, 30, 30)	21.9 (± 12.8)	24.3 (± 12.27)	22.9 (± 13.9)	30.1 (± 15.02)
Change at Screening (n=58, 32, 32, 30, 30)	-52.2 (± 31.46)	-57.1 (± 37.14)	-64.2 (± 29.79)	-57 (± 39.55)
Change at Course 1/Week 1 (n=58, 32, 33, 30, 30)	-41.4 (± 46.1)	-51.1 (± 44.62)	-57.8 (± 40.25)	-50.5 (± 44.08)
Change at Course 1/Week 6 (n=57, 31, 33, 30, 30)	-52.2 (± 117.76)	-72.1 (± 29.69)	-72.5 (± 31.75)	-68.7 (± 36.39)
Change at Course 1/Week 13 (n=56, 31, 33, 30, 29)	-70.2 (± 41.21)	-76.6 (± 32.37)	-72.9 (± 28.99)	-70.6 (± 37.69)
Change at Course 1/Week 25 (n=35, 10, 22, 13, 19)	-52.2 (± 31.46)	-57.1 (± 37.14)	-64.2 (± 29.79)	-57 (± 39.55)

End point values	PF-05280586 (US): by the end of Course 1			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Percent change in joint count				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=58, 32, 33, 30, 30)	27.9 (± 13.46)			
Change at Screening (n=58, 32, 32, 30, 30)	-55.2 (± 31.97)			
Change at Course 1/Week 1 (n=58, 32, 33, 30, 30)	-51.6 (± 33)			
Change at Course 1/Week 6 (n=57, 31, 33, 30, 30)	-69.5 (± 37.71)			
Change at Course 1/Week 13 (n=56, 31, 33, 30, 29)	-68.7 (± 33.16)			
Change at Course 1/Week 25 (n=35, 10, 22, 13, 19)	-55.2 (± 31.97)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR response: Tender/Painful Joint Count - by the end of Course 2

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR response: Tender/Painful Joint Count - by the end of Course 2[47]

End point description:

Sixty-eight joints were assessed by a blinded joint assessor to determine the number of joints that were considered tender or painful. For consistency, a single assessor was preferred to perform all evaluations across the study for an individual participant. The response to pressure/motion on each joint was assessed using the following scale: Present/Absent/Not Done/Not Applicable (to be used for artificial or missing joints). Artificial joints were not be assessed.

End point type	Primary

End point timeframe:

Baseline B3281001, Screening, Week 1, 6, 13, and 25 (Course 1 and Course 2).

Notes:

[47] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 2	Rituximab-EU/PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	30	31	29
Units: Percent change in joint count				

arithmetic mean (standard deviation)				
Baseline B3281001 (n=54, 30, 31, 29, 29)	21.4 (± 12.28)	24.1 (± 12.63)	22.8 (± 14.29)	30.3 (± 15.24)
Change at Screening (n=54, 30, 30, 29, 29)	-54.1 (± 31)	-56 (± 38.11)	-64.7 (± 28.61)	-55.5 (± 39.39)
Change at Course 1/Week 1 (n=54, 30, 31, 29, 29)	-42.7 (± 46.01)	-48.9 (± 45.19)	-57.8 (± 40.07)	-49.1 (± 44.15)
Change at Course 1/Week 6 (n=54, 30, 31, 29, 29)	-53.4 (± 120.45)	-71.5 (± 29.97)	-74.1 (± 29.12)	-67.8 (± 36.66)
Change at Course 1/Week 13 (n=54, 30, 31, 29, 29)	-70.9 (± 40.98)	-75.8 (± 32.62)	-74.5 (± 25.85)	-69.6 (± 37.93)
Change at Course 1/Week 25 (n=35, 10, 20, 12, 19)	-70.7 (± 34.48)	-74 (± 19.08)	-70.3 (± 26.87)	-49.8 (± 44.9)
Change at Course 2/Week 1 (n=54, 30, 31, 29, 29)	-54.6 (± 68.22)	-61.5 (± 30.9)	-60 (± 39.43)	-55.4 (± 38.38)
Change at Course 2/Week 6 (n=53, 30, 29, 29, 29)	-81.5 (± 24.73)	-73.7 (± 31.95)	-79.5 (± 25.12)	-70.1 (± 32.79)
Change at Course 2/Week 13 (n=53, 30, 30, 28, 29)	-70.7 (± 35.12)	-69.3 (± 39.85)	-77.5 (± 22.83)	-74.4 (± 34.04)
Change at Course 2/Week 25 (n=29, 9, 20, 15, 16)	-76.5 (± 19.3)	-84.9 (± 19.6)	-72.4 (± 25.01)	-69.7 (± 27.1)

End point values	PF-05280586 (US): by the end of Course 2			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percent change in joint count				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=54, 30, 31, 29, 29)	27.7 (± 13.63)			
Change at Screening (n=54, 30, 30, 29, 29)	-55.9 (± 32.29)			
Change at Course 1/Week 1 (n=54, 30, 31, 29, 29)	-51.9 (± 33.54)			
Change at Course 1/Week 6 (n=54, 30, 31, 29, 29)	-70.5 (± 37.95)			
Change at Course 1/Week 13 (n=54, 30, 31, 29, 29)	-68.7 (± 33.16)			
Change at Course 1/Week 25 (n=35, 10, 20, 12, 19)	-69.9 (± 20.36)			
Change at Course 2/Week 1 (n=54, 30, 31, 29, 29)	-60 (± 30.18)			
Change at Course 2/Week 6 (n=53, 30, 29, 29, 29)	-77.3 (± 27.37)			
Change at Course 2/Week 13 (n=53, 30, 30, 28, 29)	-82.5 (± 21.63)			
Change at Course 2/Week 25 (n=29, 9, 20, 15, 16)	-75.5 (± 14.06)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR response: Tender/Painful Joint Count - by the end of Course 3

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR response: Tender/Painful Joint Count - by the end of Course 3[48]

End point description:

Sixty-eight joints were assessed by a blinded joint assessor to determine the number of joints that were considered tender or painful. For consistency, a single assessor was preferred to perform all evaluations across the study for an individual participant. The response to pressure/motion on each joint was assessed using the following scale: Present/Absent/Not Done/Not Applicable (to be used for artificial or missing joints). Artificial joints were not be assessed.

End point type	Primary

End point timeframe:

Baseline B3281001, Screening, Week 1, 6, 13, and 25 (Course 1 and Course 2), and Screening, Week 1, 13, and 25 (Course 3).

Notes:

[48] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	30	30	27
Units: Percent change in joint count				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=48, 30, 30, 27, 29)	21.1 (± 11.87)	24.1 (± 12.63)	23.2 (± 14.33)	30.9 (± 15.66)
Change at Screening (n=48, 30, 29, 27, 29)	-53.4 (± 31.93)	-56 (± 38.11)	-63.5 (± 28.31)	-59.6 (± 37.63)
Change at Course 1/Week 1 (n=48, 30, 30, 27, 29)	-41.5 (± 47.81)	-48.9 (± 45.19)	-56.4 (± 39.97)	-53.7 (± 41.95)
Change at Course 1/Week 6 (n=48, 30, 30, 27, 29)	-53.6 (± 127.05)	-71.5 (± 29.97)	-73.3 (± 29.22)	-72.4 (± 33.42)
Change at Course 1/Week 13 (n=48, 30, 30, 27, 29)	-75.1 (± 30.47)	-75.8 (± 32.62)	-73.7 (± 25.85)	-74.4 (± 28.15)
Change at Course 1/Week 25 (n=32, 10, 19, 11, 19)	-69 (± 35.57)	-74 (± 19.08)	-68.8 (± 26.66)	-58.9 (± 33.62)
Change at Course 2/Week 1 (n=48, 30, 30, 27, 29)	-54.9 (± 69.76)	-61.5 (± 30.9)	-58.7 (± 39.38)	-59.2 (± 36.67)
Change at Course 2/Week 6 (n=48, 30, 29, 27, 29)	-81.5 (± 25.65)	-73.7 (± 31.95)	-79.5 (± 25.12)	-73.2 (± 30.5)
Change at Course 2/Week 13 (n=48, 30, 30, 26, 29)	-69.4 (± 36.44)	-69.3 (± 39.85)	-77.5 (± 22.83)	-76 (± 34.73)
Change at Course 2/Week 25 (n=26, 9, 20, 14, 16)	-75.7 (± 19.82)	-84.9 (± 19.6)	-72.4 (± 25.01)	-72.8 (± 25.18)
Change at Course 3/Week 1 (n=48, 30, 30, 27, 29)	-57.3 (± 63.73)	-65.6 (± 32.53)	-66.5 (± 30.69)	-59.5 (± 41.25)
Change at Course 3/Week 13 (n=46, 30, 29, 26, 29)	-69.1 (± 54.91)	-69.2 (± 52.97)	-79.6 (± 22.21)	-80.8 (± 21.63)
Change at Course 3/Week 25 (n=47, 30, 29, 27, 29)	-71.8 (± 31.2)	-59.2 (± 80.64)	-75.6 (± 29.79)	-79 (± 17.65)

End point values	PF-05280586 (US): by the end of Course 3			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percent change in joint count				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=48, 30, 30, 27, 29)	27.7 (± 13.63)			
Change at Screening (n=48, 30, 29, 27, 29)	-55.9 (± 32.29)			
Change at Course 1/Week 1 (n=48, 30, 30, 27, 29)	-51.9 (± 33.54)			
Change at Course 1/Week 6 (n=48, 30, 30, 27, 29)	-70.5 (± 37.95)			
Change at Course 1/Week 13 (n=48, 30, 30, 27, 29)	-68.7 (± 33.16)			
Change at Course 1/Week 25 (n=32, 10, 19, 11, 19)	-69.9 (± 20.36)			
Change at Course 2/Week 1 (n=48, 30, 30, 27, 29)	-60 (± 30.18)			
Change at Course 2/Week 6 (n=48, 30, 29, 27, 29)	-77.3 (± 27.37)			
Change at Course 2/Week 13 (n=48, 30, 30, 26, 29)	-82.5 (± 21.63)			
Change at Course 2/Week 25 (n=26, 9, 20, 14, 16)	-75.5 (± 14.06)			
Change at Course 3/Week 1 (n=48, 30, 30, 27, 29)	-67.8 (± 26.58)			
Change at Course 3/Week 13 (n=46, 30, 29, 26, 29)	-79.6 (± 22.11)			
Change at Course 3/Week 25 (n=47, 30, 29, 27, 29)	-78.6 (± 24.11)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR response: Swollen Joint Count - by the end of Course 1

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR response: Swollen Joint Count - by the end of Course 1[49]

End point description:

Sixty-six joints were assessed by a blinded joint assessor for swelling. For consistency, a single assessor was preferred to perform all evaluations across the study for an individual participant. The response was assessed using the following scale: Present/Absent/Not Done/Not Applicable (to be used for artificial or missing joints). Artificial joints were not be assessed.

End point type	Primary

End point timeframe:

Baseline B3281001, Screening, Week 1, 6, 13, and 25 (Course 1).

Notes:

[49] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 1	Rituximab-EU: by the end of Course 1	PF-05280586 (EU): by the end of Course 1	Rituximab-US: by the end of Course 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	32	33	30
Units: Percent change in joint count				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=58, 32, 33, 30, 30)	14.7 (± 8.53)	17.8 (± 10.33)	17.8 (± 11.41)	18.1 (± 8.35)
Change at Screening (n=58, 32, 32, 30, 30)	-58.1 (± 33.22)	-54.2 (± 39.43)	-62.9 (± 32.45)	-54.9 (± 41.05)
Change at Course 1/Week 1 (n=58, 32, 33, 30, 30)	-51.7 (± 40.21)	-49.9 (± 46.14)	-53.4 (± 48.36)	-47.9 (± 55.08)
Change at Course 1/Week 6 (n=57, 31, 33, 30, 30)	-60.2 (± 116.58)	-55.1 (± 94.22)	-70.6 (± 35.2)	-68.2 (± 45.65)
Change at Course 1/Week 13 (n=56, 31, 33, 30, 29)	-78 (± 29.2)	-47.2 (± 133.31)	-75.6 (± 34.36)	-79.5 (± 22.58)
Change at Course 1/Week 25 (n=35, 10, 22, 13, 19)	-75 (± 27.92)	-74.1 (± 16.33)	-74.7 (± 27.15)	-58.6 (± 50.63)

End point values	PF-05280586 (US): by the end of Course 1			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Percent change in joint count				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=58, 32, 33, 30, 30)	19.3 (± 7.94)			
Change at Screening (n=58, 32, 32, 30, 30)	-59.1 (± 29.43)			
Change at Course 1/Week 1 (n=58, 32, 33, 30, 30)	-58.4 (± 32.65)			
Change at Course 1/Week 6 (n=57, 31, 33, 30, 30)	-76.9 (± 26.79)			
Change at Course 1/Week 13 (n=56, 31, 33, 30, 29)	-70 (± 44.41)			
Change at Course 1/Week 25 (n=35, 10, 22, 13, 19)	-67.2 (± 28.49)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR response: Swollen Joint Count - by the end of Course 2

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR response: Swollen Joint Count - by the end of Course 2[50]

End point description:

Sixty-six joints were assessed by a blinded joint assessor for swelling. For consistency, a single assessor was preferred to perform all evaluations across the study for an individual participant. The response was assessed using the following scale: Present/Absent/Not Done/Not Applicable (to be used for artificial or missing joints). Artificial joints were not be assessed.

End point type	Primary

End point timeframe:

Baseline B3281001, Screening, Week 1, 6, 13, and 25 (Course 1 and Course 2).

Notes:

[50] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 2	Rituximab-EU/PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	30	31	29
Units: Percent change in joint count				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=54, 30, 31, 29, 29)	14.9 (± 8.79)	17.1 (± 10.26)	17.5 (± 11.57)	17.9 (± 8.42)
Change at Screening (n=54, 30, 30, 29, 29)	-60.4 (± 29.31)	-52.5 (± 40.15)	-64 (± 30.26)	-53.3 (± 40.86)
Change at Course 1/Week 1 (n=54, 30, 31, 29, 29)	-55.1 (± 35.01)	-47.7 (± 46.81)	-53.8 (± 48.02)	-46.4 (± 55.43)
Change at Course 1/Week 6 (n=54, 30, 31, 29, 29)	-62.7 (± 117.28)	-53.8 (± 95.58)	-72.5 (± 32.18)	-67.2 (± 46.15)
Change at Course 1/Week 13 (n=54, 30, 31, 29, 29)	-78.3 (± 29.13)	-45.4 (± 135.23)	-77.8 (± 30.83)	-78.7 (± 22.64)
Change at Course 1/Week 25 (n=35, 10, 20, 12, 19)	-75 (± 27.92)	-74.1 (± 16.33)	-76 (± 25.18)	-55.9 (± 51.86)
Change at Course 2/Week 1 (n=54, 30, 31, 29, 29)	-58 (± 76.91)	-51 (± 54.16)	-53.1 (± 46.17)	-59.2 (± 39.14)
Change at Course 2/Week 6 (n=53, 30, 29, 29, 29)	-81.3 (± 25.98)	-64.6 (± 51.49)	-82.3 (± 21.43)	-74.3 (± 32.1)
Change at Course 2/Week 13 (n=53, 30, 30, 28, 29)	-77.3 (± 30.1)	-54.7 (± 91.62)	-75 (± 34.02)	-76.7 (± 29.58)
Change at Course 2/Week 25 (n=29, 9, 20, 15, 16)	-75 (± 26.74)	-84.4 (± 16.09)	-77.9 (± 21.66)	-77.1 (± 28.22)

End point values	PF-05280586 (US): by the end of Course 2			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percent change in joint count				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=54, 30, 31, 29, 29)	19.1 (± 7.98)			

Change at Screening (n=54, 30, 30, 29, 29)	-60.2 (± 29.3)			
Change at Course 1/Week 1 (n=54, 30, 31, 29, 29)	-59.2 (± 32.91)			
Change at Course 1/Week 6 (n=54, 30, 31, 29, 29)	-78.2 (± 26.25)			
Change at Course 1/Week 13 (n=54, 30, 31, 29, 29)	-70 (± 44.41)			
Change at Course 1/Week 25 (n=35, 10, 20, 12, 19)	-67.2 (± 28.49)			
Change at Course 2/Week 1 (n=54, 30, 31, 29, 29)	-56.2 (± 45.29)			
Change at Course 2/Week 6 (n=53, 30, 29, 29, 29)	-82 (± 20.56)			
Change at Course 2/Week 13 (n=53, 30, 30, 28, 29)	-81.3 (± 26.43)			
Change at Course 2/Week 25 (n=29, 9, 20, 15, 16)	-80 (± 21.86)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR response: Swollen Joint Count - by the end of Course 3

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR response: Swollen Joint Count - by the end of Course 3[51]

End point description:

Sixty-six joints were assessed by a blinded joint assessor for swelling. For consistency, a single assessor was preferred to perform all evaluations across the study for an individual participant. The response was assessed using the following scale: Present/Absent/Not Done/Not Applicable (to be used for artificial or missing joints). Artificial joints were not be assessed.

End point type	Primary

End point timeframe:

Baseline B3281001, Screening, Week 1, 6, 13, and 25 (Course 1 and Course 2), and Screening, Week 1, 13, and 25 (Course 3).

Notes:

[51] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	30	30	27
Units: Percent change in joint count				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=48, 30, 30, 27, 29)	14.5 (± 7.74)	17.1 (± 10.26)	17.7 (± 11.68)	18.5 (± 8.44)
Change at Screening (n=48, 30, 29, 27, 29)	-60.5 (± 30.41)	-52.5 (± 40.15)	-62.7 (± 30.01)	-53.9 (± 42.34)

Change at Course 1/Week 1 (n=48, 30, 30, 27, 29)	-55.6 (± 36.38)	-47.7 (± 46.81)	-52.2 (± 48.06)	-49 (± 55.86)
Change at Course 1/Week 6 (n=48, 30, 30, 27, 29)	-62.1 (± 124.1)	-53.8 (± 95.58)	-71.5 (± 32.31)	-68.2 (± 47.4)
Change at Course 1/Week 13 (n=48, 30, 30, 27, 29)	-79.3 (± 27.17)	-45.4 (± 135.23)	-77 (± 31.08)	-79.2 (± 22.12)
Change at Course 1/Week 25 (n=32, 10, 19, 11, 19)	-73.5 (± 28.74)	-74.1 (± 16.33)	-74.8 (± 25.21)	-59.9 (± 52.34)
Change at Course 2/Week 1 (n=48, 30, 30, 27, 29)	-57.8 (± 80.94)	-51 (± 54.16)	-51.5 (± 46.11)	-60.8 (± 38.8)
Change at Course 2/Week 6 (n=48, 30, 29, 27, 29)	-81.5 (± 26.08)	-64.6 (± 51.49)	-82.3 (± 21.43)	-73.2 (± 32.9)
Change at Course 2/Week 13 (n=48, 30, 30, 26, 29)	-76.4 (± 31.23)	-54.7 (± 91.62)	-75 (± 34.02)	-76.8 (± 30.73)
Change at Course 2/Week 25 (n=26, 9, 20, 14, 16)	-78.1 (± 24.72)	-84.4 (± 16.09)	-77.9 (± 21.66)	-76.1 (± 29.01)
Change at Course 3/Week 1 (n=48, 30, 30, 27, 29)	-66.3 (± 55.96)	-59.9 (± 45.11)	-63.9 (± 39.07)	-74.3 (± 29.11)
Change at Course 3/Week 13 (n=46, 30, 29, 26, 29)	-78.6 (± 36.94)	-70.4 (± 37.09)	-76.7 (± 29.14)	-84 (± 24.36)
Change at Course 3/Week 25 (n=47, 30, 29, 27, 29)	-72.2 (± 46.88)	-51.5 (± 94.79)	-75.7 (± 29.79)	-79.1 (± 27.77)

End point values	PF-05280586 (US): by the end of Course 3			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percent change in joint count				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=48, 30, 30, 27, 29)	19.1 (± 7.98)			
Change at Screening (n=48, 30, 29, 27, 29)	-60.2 (± 29.3)			
Change at Course 1/Week 1 (n=48, 30, 30, 27, 29)	-59.2 (± 32.91)			
Change at Course 1/Week 6 (n=48, 30, 30, 27, 29)	-78.2 (± 26.25)			
Change at Course 1/Week 13 (n=48, 30, 30, 27, 29)	-70 (± 44.41)			
Change at Course 1/Week 25 (n=32, 10, 19, 11, 19)	-67.2 (± 28.49)			
Change at Course 2/Week 1 (n=48, 30, 30, 27, 29)	-56.2 (± 45.29)			
Change at Course 2/Week 6 (n=48, 30, 29, 27, 29)	-82 (± 20.56)			
Change at Course 2/Week 13 (n=48, 30, 30, 26, 29)	-81.3 (± 26.43)			
Change at Course 2/Week 25 (n=26, 9, 20, 14, 16)	-80 (± 21.86)			
Change at Course 3/Week 1 (n=48, 30, 30, 27, 29)	-66.2 (± 31.33)			
Change at Course 3/Week 13 (n=46, 30, 29, 26, 29)	-83.2 (± 26.99)			
Change at Course 3/Week 25 (n=47, 30, 29, 27, 29)	-76.6 (± 37.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Patient's Assessment of Arthritis Pain - by the end of Course 1

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Patient's Assessment of Arthritis Pain - by the end of Course 1[52]

End point description:

Participants assessed the severity of their arthritis pain using a 100 millimeter (mm) VAS by placing a mark on the scale between 0 (no pain) and 100 (most severe pain), which corresponded to the magnitude of their pain.

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1).

Notes:

[52] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 1	Rituximab-EU: by the end of Course 1	PF-05280586 (EU): by the end of Course 1	Rituximab-US: by the end of Course 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	32	33	30
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=58, 32, 33, 30, 30)	64.3 (± 18.56)	62.9 (± 20.62)	67.8 (± 21.6)	73.4 (± 20.47)
Change at Course 1/Week 1 (n=58, 32, 33, 30, 30)	-18.2 (± 67.42)	-36.3 (± 44.85)	-44 (± 58.9)	-38.8 (± 39.7)
Change at Course 1/Week 6 (n=57, 31, 33, 30, 30)	-31.9 (± 79.38)	-51.5 (± 44.45)	-59.7 (± 33.09)	-42.5 (± 46.78)
Change at Course 1/Week 13 (n=56, 31, 33, 30, 29)	-34.6 (± 52.28)	-42.4 (± 57.97)	-65.3 (± 28.79)	-54.8 (± 41.14)
Change at Course 1/Week 25 (n=35, 10, 22, 13, 19)	-49.7 (± 35.41)	-19.6 (± 75.23)	-52.5 (± 42.73)	-32.7 (± 67.3)

End point values	PF-05280586 (US): by the end of Course 1			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Percent change in score				
arithmetic mean (standard deviation)				

Baseline B3281001 (n=58, 32, 33, 30, 30)	70.4 (± 16.26)			
Change at Course 1/Week 1 (n=58, 32, 33, 30, 30)	-39.8 (± 27.6)			
Change at Course 1/Week 6 (n=57, 31, 33, 30, 30)	-55.2 (± 28.28)			
Change at Course 1/Week 13 (n=56, 31, 33, 30, 29)	-50.1 (± 30.48)			
Change at Course 1/Week 25 (n=35, 10, 22, 13, 19)	-45.4 (± 32.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Patient's Assessment of Arthritis Pain - by the end of Course 2

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Patient's Assessment of Arthritis Pain - by the end of Course 2[53]

End point description:

Participants assessed the severity of their arthritis pain using a 100 millimeter (mm) VAS by placing a mark on the scale between 0 (no pain) and 100 (most severe pain), which corresponded to the magnitude of their pain.

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1 and Course 2).

Notes:

[53] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 2	Rituximab-EU/PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	30	31	29
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=54, 30, 31, 29, 29)	64.6 (± 18.93)	63.3 (± 21)	67.7 (± 21.67)	73.2 (± 20.81)
Change at Course 1/Week 1 (n=54, 30, 31, 29, 29)	-19.4 (± 68.24)	-34.9 (± 44.82)	-43.2 (± 59.94)	-37.1 (± 39.36)
Change at Course 1/Week 6 (n=54, 30, 31, 29, 29)	-33.2 (± 80.43)	-50.1 (± 44.48)	-59.1 (± 33.46)	-40.9 (± 46.73)
Change at Course 1/Week 13 (n=54, 30, 31, 29, 29)	-36.1 (± 51.66)	-40.5 (± 58.05)	-64.8 (± 29.18)	-53.4 (± 41.2)
Change at Course 1/Week 25 (n=35, 10, 20, 12, 19)	-49.7 (± 35.41)	-19.6 (± 75.23)	-50.5 (± 43.76)	-31 (± 70.03)
Change at Course 2/Week 1 (n=54, 30, 31, 29, 29)	-26.1 (± 77.23)	-36.4 (± 57.62)	-43.9 (± 46.93)	-40.6 (± 47.26)
Change at Course 2/Week 6 (n=53, 30, 29, 29, 29)	-42.8 (± 69.12)	-50.5 (± 48.6)	-55.3 (± 30.66)	-60.1 (± 33.26)

Change at Course 2/Week 13 (n=53, 30, 30, 29, 29)	-33.1 (± 61.98)	-40.6 (± 65.18)	-53 (± 42.09)	-36 (± 94.22)
Change at Course 2/Week 25 (n=29, 9, 20, 15, 16)	-50.7 (± 41.77)	-59.4 (± 29.28)	-55.8 (± 31.08)	-44.8 (± 25.66)

End point values	PF-05280586 (US): by the end of Course 2			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=54, 30, 31, 29, 29)	69.9 (± 16.34)			
Change at Course 1/Week 1 (n=54, 30, 31, 29, 29)	-40.1 (± 28.05)			
Change at Course 1/Week 6 (n=54, 30, 31, 29, 29)	-56.1 (± 28.28)			
Change at Course 1/Week 13 (n=54, 30, 31, 29, 29)	-50.1 (± 30.48)			
Change at Course 1/Week 25 (n=35, 10, 20, 12, 19)	-45.4 (± 32.5)			
Change at Course 2/Week 1 (n=54, 30, 31, 29, 29)	-41.6 (± 30.62)			
Change at Course 2/Week 6 (n=53, 30, 29, 29, 29)	-58.1 (± 26.39)			
Change at Course 2/Week 13 (n=53, 30, 30, 29, 29)	-55.9 (± 28.76)			
Change at Course 2/Week 25 (n=29, 9, 20, 15, 16)	-61.3 (± 24.95)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Patient's Assessment of Arthritis Pain - by the end of Course 3

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Patient's Assessment of Arthritis Pain - by the end of Course 3[54]

End point description:

Participants assessed the severity of their arthritis pain using a 100 millimeter (mm) VAS by placing a mark on the scale between 0 (no pain) and 100 (most severe pain), which corresponded to the magnitude of their pain.

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1 and Course 2), and Week 1, 13, and 25 (Course 3).

Notes:

[54] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	30	30	27
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=48, 30, 30, 27, 29)	64.6 (± 19.67)	63.3 (± 21)	67.6 (± 22.03)	72.6 (± 21.45)
Change at Course 1/Week 1 (n=48, 30, 30, 27, 29)	-19.1 (± 70.91)	-34.9 (± 44.82)	-41.6 (± 60.23)	-38.2 (± 40.64)
Change at Course 1/Week 6 (n=48, 30, 30, 27, 29)	-31.8 (± 84.65)	-50.1 (± 44.48)	-58 (± 33.47)	-40.7 (± 48.45)
Change at Course 1/Week 13 (n=48, 30, 30, 27, 29)	-39.2 (± 51.83)	-40.5 (± 58.05)	-63.8 (± 29.15)	-52.5 (± 42.6)
Change at Course 1/Week 25 (n=32, 10, 19, 11, 19)	-49 (± 36.46)	-19.6 (± 75.23)	-48.4 (± 43.85)	-31.7 (± 73.41)
Change at Course 2/Week 1 (n=48, 30, 30, 27, 29)	-26.4 (± 80.49)	-36.4 (± 57.62)	-42.5 (± 47.03)	-40 (± 48.91)
Change at Course 2/Week 6 (n=48, 30, 29, 27, 29)	-41.1 (± 71.99)	-50.5 (± 48.6)	-55.3 (± 30.66)	-60.3 (± 34.45)
Change at Course 2/Week 13 (n=48, 30, 30, 27, 29)	-33.9 (± 62.57)	-40.6 (± 65.18)	-53 (± 42.09)	-35.8 (± 97.72)
Change at Course 2/Week 25 (n=26, 9, 20, 14, 16)	-56.7 (± 33.85)	-59.4 (± 29.28)	-55.8 (± 31.08)	-47.8 (± 23.72)
Change at Course 3/Week 1 (n=48, 30, 30, 27, 29)	-24 (± 74.65)	-39.4 (± 50.56)	-37.2 (± 62.77)	-39.3 (± 44.07)
Change at Course 3/Week 13 (n=46, 30, 29, 26, 29)	-37.9 (± 63.45)	-45.7 (± 52.35)	-57.9 (± 33.8)	-43.3 (± 50.22)
Change at Course 3/Week 25 (n=47, 30, 30, 27, 29)	-28.5 (± 69.63)	-44.1 (± 45.48)	-53.9 (± 36.8)	-43.4 (± 62.71)

End point values	PF-05280586 (US): by the end of Course 3			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=48, 30, 30, 27, 29)	69.9 (± 16.34)			
Change at Course 1/Week 1 (n=48, 30, 30, 27, 29)	-40.1 (± 28.05)			
Change at Course 1/Week 6 (n=48, 30, 30, 27, 29)	-56.1 (± 28.28)			
Change at Course 1/Week 13 (n=48, 30, 30, 27, 29)	-50.1 (± 30.48)			
Change at Course 1/Week 25 (n=32, 10, 19, 11, 19)	-45.4 (± 32.5)			
Change at Course 2/Week 1 (n=48, 30, 30, 27, 29)	-41.6 (± 30.62)			
Change at Course 2/Week 6 (n=48, 30, 29, 27, 29)	-58.1 (± 26.39)			

Change at Course 2/Week 13 (n=48, 30, 30, 27, 29)	-55.9 (± 28.76)			
Change at Course 2/Week 25 (n=26, 9, 20, 14, 16)	-61.3 (± 24.95)			
Change at Course 3/Week 1 (n=48, 30, 30, 27, 29)	-45.3 (± 34.84)			
Change at Course 3/Week 13 (n=46, 30, 29, 26, 29)	-55.7 (± 31.01)			
Change at Course 3/Week 25 (n=47, 30, 30, 27, 29)	-53.9 (± 35.77)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR response: Patient's Global Assessment of Arthritis - by the end of Course 1

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR response: Patient's Global Assessment of Arthritis - by the end of Course 1[55]

End point description:

Participants were asked the following question, "Considering all the ways your arthritis affects you, how are you feeling today?" Their response was recorded using a 100 mm VAS between 0 (very well) and 100 (very poor).

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1).

Notes:

[55] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 1	Rituximab-EU: by the end of Course 1	PF-05280586 (EU): by the end of Course 1	Rituximab-US: by the end of Course 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	32	33	30
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=58, 32, 33, 30, 30)	67.2 (± 17.81)	66.9 (± 18.29)	66.8 (± 23.23)	74.7 (± 16.29)
Change at Course 1/Week 1 (n=57, 32, 33, 30, 29)	-18.9 (± 62.81)	-43.8 (± 41.27)	-40.3 (± 55.42)	-45.1 (± 32.92)
Change at Course 1/Week 6 (n=57, 31, 33, 30, 30)	-34.6 (± 65.37)	-56.2 (± 34.62)	-56.8 (± 34.01)	-51 (± 33.61)
Change at Course 1/Week 13 (n=55, 31, 33, 30, 29)	-39.1 (± 48.65)	-55.9 (± 46.04)	-62 (± 29.52)	-61.3 (± 29.78)
Change at Course 1/Week 25 (n=35, 10, 22, 13, 19)	-52.6 (± 33.84)	-42.3 (± 52.55)	-48.4 (± 42.71)	-47.7 (± 22.7)

End point values	PF-05280586 (US): by the			

	end of Course 1			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=58, 32, 33, 30, 30)	73.7 (± 16.22)			
Change at Course 1/Week 1 (n=57, 32, 33, 30, 29)	-39.2 (± 23.89)			
Change at Course 1/Week 6 (n=57, 31, 33, 30, 30)	-58.3 (± 24.77)			
Change at Course 1/Week 13 (n=55, 31, 33, 30, 29)	-56.2 (± 27.35)			
Change at Course 1/Week 25 (n=35, 10, 22, 13, 19)	-46.5 (± 31.47)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR response: Patient's Global Assessment of Arthritis - by the end of Course 2

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR response: Patient's Global Assessment of Arthritis - by the end of Course 2[56]

End point description:

Participants were asked the following question, "Considering all the ways your arthritis affects you, how are you feeling today?" Their response was recorded using a 100 mm VAS between 0 (very well) and 100 (very poor).

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1 and Course 2).

Notes:

[56] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 2	Rituximab-EU/PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	30	31	29
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=54, 30, 31, 29, 29)	67.6 (± 17.95)	67.5 (± 18.42)	66.8 (± 23.97)	74.5 (± 16.54)
Change at Course 1/Week 1 (n=54, 30, 31, 29, 28)	-21.5 (± 62.57)	-41.7 (± 41.5)	-40.5 (± 55.52)	-43.8 (± 32.81)
Change at Course 1/Week 6 (n=54, 30, 31, 29, 29)	-37.4 (± 64.66)	-55 (± 34.56)	-56.4 (± 34.31)	-49.7 (± 33.52)
Change at Course 1/Week 13 (n=54, 30, 31, 29, 29)	-41.2 (± 47.09)	-54.6 (± 46.26)	-62.2 (± 29.35)	-60.3 (± 29.79)

Change at Course 1/Week 25 (n=35, 10, 20, 12, 19)	-52.6 (± 33.84)	-42.3 (± 52.55)	-47.1 (± 43.42)	-46.3 (± 23.14)
Change at Course 2/Week 1 (n=54, 30, 31, 29, 29)	-32.1 (± 62.08)	-41.9 (± 54.71)	-39.1 (± 45.93)	-50.6 (± 31.39)
Change at Course 2/Week 6 (n=53, 30, 29, 29, 29)	-46.8 (± 46.61)	-51.5 (± 49.96)	-46.2 (± 49.97)	-62 (± 29.11)
Change at Course 2/Week 13 (n=53, 30, 30, 29, 29)	-43.7 (± 40.69)	-45.1 (± 55.55)	-29.8 (± 142.51)	-53.3 (± 41.09)
Change at Course 2/Week 25 (n=29, 9, 20, 15, 16)	-55.6 (± 33.12)	-59.1 (± 29.99)	-51 (± 33.35)	-47.3 (± 28.57)

End point values	PF-05280586 (US): by the end of Course 2			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=54, 30, 31, 29, 29)	73.4 (± 16.43)			
Change at Course 1/Week 1 (n=54, 30, 31, 29, 28)	-39.9 (± 24.05)			
Change at Course 1/Week 6 (n=54, 30, 31, 29, 29)	-59.5 (± 24.29)			
Change at Course 1/Week 13 (n=54, 30, 31, 29, 29)	-56.2 (± 27.35)			
Change at Course 1/Week 25 (n=35, 10, 20, 12, 19)	-46.5 (± 31.47)			
Change at Course 2/Week 1 (n=54, 30, 31, 29, 29)	-43.3 (± 27.34)			
Change at Course 2/Week 6 (n=53, 30, 29, 29, 29)	-59 (± 25.26)			
Change at Course 2/Week 13 (n=53, 30, 30, 29, 29)	-57.2 (± 23.56)			
Change at Course 2/Week 25 (n=29, 9, 20, 15, 16)	-60.9 (± 21.76)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR response: Patient's Global Assessment of Arthritis - by the end of Course 3

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR response: Patient's Global Assessment of Arthritis - by the end of Course 3[57]

End point description:

Participants were asked the following question, "Considering all the ways your arthritis affects you, how are you feeling today?" Their response was recorded using a 100 mm VAS between 0 (very well) and 100 (very poor).

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1 and Course 2), and Week 1, 13, and 25 (Course 3).

Notes:

[57] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	30	30	27
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=48, 30, 30, 27, 29)	66.9 (± 18.61)	67.5 (± 18.42)	66.6 (± 24.34)	73.9 (± 16.98)
Change at Course 1/Week 1 (n=48, 30, 30, 27, 28)	-21.7 (± 65.6)	-41.7 (± 41.5)	-38.8 (± 55.71)	-44.4 (± 33.89)
Change at Course 1/Week 6 (n=48, 30, 30, 27, 29)	-36.9 (± 67.42)	-55 (± 34.56)	-55.5 (± 34.55)	-50.2 (± 34.42)
Change at Course 1/Week 13 (n=48, 30, 30, 27, 29)	-44.1 (± 48.95)	-54.6 (± 46.26)	-61.3 (± 29.42)	-60.1 (± 30.8)
Change at Course 1/Week 25 (n=32, 10, 19, 11, 19)	-51.5 (± 35.06)	-42.3 (± 52.55)	-44.8 (± 43.28)	-47.4 (± 23.93)
Change at Course 2/Week 1 (n=48, 30, 30, 27, 29)	-31 (± 65.11)	-41.9 (± 54.71)	-37.5 (± 45.85)	-50.2 (± 32.39)
Change at Course 2/Week 6 (n=48, 30, 29, 27, 29)	-45.1 (± 48.34)	-51.5 (± 49.96)	-46.2 (± 49.97)	-63.5 (± 29.54)
Change at Course 2/Week 13 (n=48, 30, 30, 27, 29)	-43.3 (± 41.5)	-45.1 (± 55.55)	-29.8 (± 142.51)	-54.7 (± 42.05)
Change at Course 2/Week 25 (n=26, 9, 20, 14, 16)	-59.1 (± 31.65)	-59.1 (± 29.99)	-51 (± 33.35)	-49.9 (± 27.77)
Change at Course 3/Week 1 (n=48, 30, 30, 27, 29)	-26.9 (± 63.81)	-45.4 (± 41.98)	-39.1 (± 46.9)	-42.9 (± 43.85)
Change at Course 3/Week 13 (n=46, 30, 29, 26, 29)	-40.5 (± 48.27)	-52.6 (± 45.33)	-53.2 (± 34.27)	-52.3 (± 35.92)
Change at Course 3/Week 25 (n=47, 30, 30, 27, 29)	-34.7 (± 50.49)	-43.3 (± 44.82)	-50.6 (± 39.52)	-53.9 (± 42.61)

End point values	PF-05280586 (US): by the end of Course 3			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=48, 30, 30, 27, 29)	73.4 (± 16.43)			
Change at Course 1/Week 1 (n=48, 30, 30, 27, 28)	-39.9 (± 24.05)			
Change at Course 1/Week 6 (n=48, 30, 30, 27, 29)	-59.5 (± 24.29)			

Change at Course 1/Week 13 (n=48, 30, 30, 27, 29)	-56.2 (± 27.35)			
Change at Course 1/Week 25 (n=32, 10, 19, 11, 19)	-46.5 (± 31.47)			
Change at Course 2/Week 1 (n=48, 30, 30, 27, 29)	-43.3 (± 27.34)			
Change at Course 2/Week 6 (n=48, 30, 29, 27, 29)	-59 (± 25.26)			
Change at Course 2/Week 13 (n=48, 30, 30, 27, 29)	-57.2 (± 23.56)			
Change at Course 2/Week 25 (n=26, 9, 20, 14, 16)	-60.9 (± 21.76)			
Change at Course 3/Week 1 (n=48, 30, 30, 27, 29)	-48.6 (± 34.18)			
Change at Course 3/Week 13 (n=46, 30, 29, 26, 29)	-55.2 (± 28.16)			
Change at Course 3/Week 25 (n=47, 30, 30, 27, 29)	-50.3 (± 44.57)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Physician's Global Assessment of Arthritis - by the end of Course 1

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Physician's Global Assessment of Arthritis - by the end of Course 1[58]

End point description:

The investigator assessed how the participant's overall arthritis appeared at the time of the visit. This evaluation was based on the participant's disease signs, functional capacity and physical examination, and was independent of the Patient's Global Assessment of Arthritis. The investigator's response was recorded using a 100 mm VAS by placing a mark on the scale between 0 (very good) and 100 (very poor).

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1).

Notes:

[58] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 1	Rituximab-EU: by the end of Course 1	PF-05280586 (EU): by the end of Course 1	Rituximab-US: by the end of Course 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	32	33	30
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=58, 32, 33, 30, 30)	65.2 (± 15.52)	63.8 (± 15.33)	66.9 (± 15.59)	68.3 (± 14.66)
Change at Course 1/Week 1 (n=58, 32, 33, 30, 30)	-40.3 (± 42.01)	-46.1 (± 42.81)	-54.2 (± 34.06)	-55 (± 26.03)

Change at Course 1/Week 6 (n=57, 31, 33, 30, 30)	-60.4 (± 45.47)	-66.1 (± 40.4)	-71.3 (± 24.62)	-59.5 (± 39.66)
Change at Course 1/Week 13 (n=56, 31, 33, 30, 29)	-69.3 (± 30.36)	-68.1 (± 37.74)	-76.1 (± 14.01)	-71 (± 27.86)
Change at Course 1/Week 25 (n=35, 10, 22, 13, 19)	-67 (± 29.61)	-73.2 (± 25)	-71.4 (± 23.32)	-55.1 (± 28.56)

End point values	PF-05280586 (US): by the end of Course 1			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=58, 32, 33, 30, 30)	71.4 (± 15.45)			
Change at Course 1/Week 1 (n=58, 32, 33, 30, 30)	-52.4 (± 26.51)			
Change at Course 1/Week 6 (n=57, 31, 33, 30, 30)	-73 (± 22.41)			
Change at Course 1/Week 13 (n=56, 31, 33, 30, 29)	-69.9 (± 21.09)			
Change at Course 1/Week 25 (n=35, 10, 22, 13, 19)	-59.9 (± 25.95)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Physician's Global Assessment of Arthritis - by the end of Course 2

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Physician's Global Assessment of Arthritis - by the end of Course 2[59]

End point description:

The investigator assessed how the participant's overall arthritis appeared at the time of the visit. This evaluation was based on the participant's disease signs, functional capacity and physical examination, and was independent of the Patient's Global Assessment of Arthritis. The investigator's response was recorded using a 100 mm VAS by placing a mark on the scale between 0 (very good) and 100 (very poor).

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1 and Course 2).

Notes:

[59] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 2	Rituximab-EU/PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	30	31	29
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=54, 30, 31, 29, 29)	65.2 (± 15.82)	63.7 (± 15.27)	67 (± 15.72)	68.5 (± 14.87)
Change at Course 1/Week 1 (n=54, 30, 31, 29, 29)	-41.3 (± 42.2)	-45.4 (± 43.77)	-54.4 (± 33.27)	-54 (± 25.84)
Change at Course 1/Week 6 (n=54, 30, 31, 29, 29)	-62.1 (± 44.83)	-65.1 (± 40.66)	-72.3 (± 23.31)	-58.5 (± 40.01)
Change at Course 1/Week 13 (n=54, 30, 31, 29, 29)	-70.3 (± 28.43)	-67.2 (± 38.04)	-76.5 (± 13.39)	-70.3 (± 28.11)
Change at Course 1/Week 25 (n=35, 10, 20, 12, 19)	-67 (± 29.61)	-73.2 (± 25)	-71.5 (± 22.98)	-54.7 (± 29.79)
Change at Course 2/Week 1 (n=54, 30, 31, 28, 29)	-56.9 (± 50.62)	-49.5 (± 43.91)	-59.3 (± 28.59)	-56.6 (± 31.54)
Change at Course 2/Week 6 (n=53, 30, 29, 29, 29)	-76.4 (± 26.53)	-66.9 (± 36.14)	-74 (± 24.77)	-69.4 (± 25.81)
Change at Course 2/Week 13 (n=53, 30, 30, 29, 29)	-74 (± 24.66)	-64.6 (± 44.61)	-72.1 (± 22.92)	-69 (± 35.02)
Change at Course 2/Week 25 (n=29, 9, 20, 15, 16)	-68.5 (± 26.4)	-73.7 (± 21.26)	-71.9 (± 27.15)	-58.9 (± 34.65)

End point values	PF-05280586 (US): by the end of Course 2			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=54, 30, 31, 29, 29)	70.8 (± 15.36)			
Change at Course 1/Week 1 (n=54, 30, 31, 29, 29)	-53.9 (± 25.58)			
Change at Course 1/Week 6 (n=54, 30, 31, 29, 29)	-74.4 (± 21.44)			
Change at Course 1/Week 13 (n=54, 30, 31, 29, 29)	-69.9 (± 21.09)			
Change at Course 1/Week 25 (n=35, 10, 20, 12, 19)	-59.9 (± 25.95)			
Change at Course 2/Week 1 (n=54, 30, 31, 28, 29)	-60.7 (± 23.54)			
Change at Course 2/Week 6 (n=53, 30, 29, 29, 29)	-74.6 (± 21.81)			
Change at Course 2/Week 13 (n=53, 30, 30, 29, 29)	-72.9 (± 30.55)			
Change at Course 2/Week 25 (n=29, 9, 20, 15, 16)	-68.7 (± 32.49)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Physician's Global Assessment of Arthritis - by the end of Course 3

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Physician's Global Assessment of Arthritis - by the end of Course 3[60]

End point description:

The investigator assessed how the participant's overall arthritis appeared at the time of the visit. This evaluation was based on the participant's disease signs, functional capacity and physical examination, and was independent of the Patient's Global Assessment of Arthritis. The investigator's response was recorded using a 100 mm VAS by placing a mark on the scale between 0 (very good) and 100 (very poor).

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1 and Course 2), and Week 1, 13, and 25 (Course 3).

Notes:

[60] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	30	30	27
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=48, 30, 30, 27, 29)	64.9 (± 15.85)	63.7 (± 15.27)	67 (± 15.99)	68.3 (± 15.21)
Change at Course 1/Week 1 (n=48, 30, 30, 27, 29)	-39.7 (± 43.82)	-45.4 (± 43.77)	-53.1 (± 32.94)	-55.6 (± 25.07)
Change at Course 1/Week 6 (n=48, 30, 30, 27, 29)	-62.8 (± 45.89)	-65.1 (± 40.66)	-71.6 (± 23.44)	-61 (± 40.38)
Change at Course 1/Week 13 (n=48, 30, 30, 27, 29)	-72.5 (± 29.26)	-67.2 (± 38.04)	-76 (± 13.34)	-70.5 (± 29.13)
Change at Course 1/Week 25 (n=32, 10, 19, 11, 19)	-65.9 (± 30.76)	-73.2 (± 25)	-70.4 (± 22.98)	-60.1 (± 24.56)
Change at Course 2/Week 1 (n=48, 30, 30, 26, 29)	-57.2 (± 53.03)	-49.5 (± 43.91)	-58.2 (± 28.45)	-56.2 (± 31.66)
Change at Course 2/Week 6 (n=48, 30, 29, 27, 29)	-75.3 (± 27.47)	-66.9 (± 36.14)	-74 (± 24.77)	-70.2 (± 26.55)
Change at Course 2/Week 13 (n=48, 30, 30, 27, 29)	-73.4 (± 25.64)	-64.6 (± 44.61)	-72.1 (± 22.92)	-69.7 (± 36.19)

Change at Course 2/Week 25 (n=26, 9, 20, 14, 16)	-70.6 (± 24.17)	-73.7 (± 21.26)	-71.9 (± 27.15)	-63.8 (± 30.1)
Change at Course 3/Week 1 (n=48, 30, 30, 27, 29)	-52.6 (± 55.21)	-54.6 (± 43.47)	-59.6 (± 29.85)	-52.8 (± 44.2)
Change at Course 3/Week 13 (n=46, 30, 29, 26, 28)	-74.6 (± 33.44)	-62.3 (± 54.14)	-73.3 (± 19.12)	-71.5 (± 22.57)
Change at Course 3/Week 25 (n=47, 30, 28, 27, 29)	-74 (± 25.59)	-59.9 (± 42.55)	-74.3 (± 20.48)	-72.7 (± 23.3)

End point values	PF-05280586 (US): by the end of Course 3			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=48, 30, 30, 27, 29)	70.8 (± 15.36)			
Change at Course 1/Week 1 (n=48, 30, 30, 27, 29)	-53.9 (± 25.58)			
Change at Course 1/Week 6 (n=48, 30, 30, 27, 29)	-74.4 (± 21.44)			
Change at Course 1/Week 13 (n=48, 30, 30, 27, 29)	-69.9 (± 21.09)			
Change at Course 1/Week 25 (n=32, 10, 19, 11, 19)	-59.9 (± 25.95)			
Change at Course 2/Week 1 (n=48, 30, 30, 26, 29)	-60.7 (± 23.54)			
Change at Course 2/Week 6 (n=48, 30, 29, 27, 29)	-74.6 (± 21.81)			
Change at Course 2/Week 13 (n=48, 30, 30, 27, 29)	-72.9 (± 30.55)			
Change at Course 2/Week 25 (n=26, 9, 20, 14, 16)	-68.7 (± 32.49)			
Change at Course 3/Week 1 (n=48, 30, 30, 27, 29)	-62.9 (± 28.65)			
Change at Course 3/Week 13 (n=46, 30, 29, 26, 28)	-73 (± 23.11)			
Change at Course 3/Week 25 (n=47, 30, 28, 27, 29)	-70.9 (± 26.63)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Health Assessment Questionnaire – Disability Index (HAQ-DI) - by the end of Course 1

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Health Assessment Questionnaire – Disability Index (HAQ-DI) - by the end of Course 1[61]

End point description:

The HAQ-DI assessed the degree of difficulty a participant had experienced during the past week in 8 domains of daily living activities: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities. Each activity category consisted of 2 to 3 items. For each question in the questionnaire, the level of difficulty was scored from 0 to 3 with 0 representing "no difficulty," 1 as "some difficulty," 2 as "much difficulty," and 3 as "unable to do." Any activity that required assistance from another individual or required the use of an assistive device adjusted to a minimum score of 2 to represent a more limited functional status. This questionnaire was to be completed by the participant prior to any procedures being performed at the visit, if possible.

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1).

Notes:

[61] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 1	Rituximab-EU: by the end of Course 1	PF-05280586 (EU): by the end of Course 1	Rituximab-US: by the end of Course 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	32	33	30
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=58, 32, 33, 30, 30)	1.6 (± 0.56)	1.6 (± 0.53)	1.6 (± 0.51)	1.8 (± 0.61)
Change at Course 1/Week 1 (n=58, 32, 33, 30, 30)	-12.2 (± 54.91)	-31 (± 38.52)	-39.1 (± 45.85)	-28.8 (± 33.42)
Change at Course 1/Week 6 (n=57, 31, 33, 30, 30)	-20 (± 48.09)	-39.1 (± 38.66)	-45.8 (± 35.63)	-35.9 (± 30.65)
Change at Course 1/Week 13 (n=56, 31, 33, 30, 29)	-17.7 (± 41.95)	-40 (± 43.21)	-47.5 (± 34.34)	-30 (± 37.25)
Change at Course 1/Week 25 (n=35, 10, 22, 13, 19)	-26.3 (± 42.52)	-24.1 (± 32.5)	-43.6 (± 38.36)	-33.9 (± 39.17)

End point values	PF-05280586 (US): by the end of Course 1			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=58, 32, 33, 30, 30)	1.6 (± 0.68)			
Change at Course 1/Week 1 (n=58, 32, 33, 30, 30)	-27.7 (± 36.15)			
Change at Course 1/Week 6 (n=57, 31, 33, 30, 30)	-31.7 (± 36.38)			
Change at Course 1/Week 13 (n=56, 31, 33, 30, 29)	-35.8 (± 33.09)			
Change at Course 1/Week 25 (n=35, 10, 22, 13, 19)	-27.2 (± 41.12)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Health Assessment Questionnaire – Disability Index (HAQ-DI) - by the end of Course 2

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Health Assessment Questionnaire – Disability Index (HAQ-DI) - by the end of Course 2[62]

End point description:

The HAQ-DI assessed the degree of difficulty a participant had experienced during the past week in 8 domains of daily living activities: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities. Each activity category consisted of 2 to 3 items. For each question in the questionnaire, the level of difficulty was scored from 0 to 3 with 0 representing "no difficulty," 1 as "some difficulty," 2 as "much difficulty," and 3 as "unable to do." Any activity that required assistance from another individual or required the use of an assistive device adjusted to a minimum score of 2 to represent a more limited functional status. This questionnaire was to be completed by the participant prior to any procedures being performed at the visit, if possible.

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1 and Course 2).

Notes:

[62] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 2	Rituximab-EU/PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	30	31	29
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=54, 30, 31, 29, 29)	1.7 (± 0.55)	1.6 (± 0.54)	1.6 (± 0.52)	1.8 (± 0.62)
Change at Course 1/Week 1 (n=54, 30, 31, 29, 29)	-15.6 (± 45.37)	-29.3 (± 37.54)	-40 (± 43.05)	-26.7 (± 32.08)
Change at Course 1/Week 6 (n=54, 30, 31, 29, 29)	-23.4 (± 41.6)	-37.1 (± 37.61)	-46.8 (± 31.78)	-34.1 (± 29.58)
Change at Course 1/Week 13 (n=54, 30, 31, 29, 29)	-21.6 (± 34.03)	-38 (± 42.46)	-48.4 (± 31.07)	-28 (± 36.26)
Change at Course 1/Week 25 (n=35, 10, 20, 12, 19)	-26.3 (± 42.52)	-24.1 (± 32.5)	-44 (± 35.3)	-31.5 (± 39.92)
Change at Course 2/Week 1 (n=54, 30, 31, 29, 29)	-19.4 (± 44.16)	-36.6 (± 41.08)	-44.9 (± 34.41)	-24.2 (± 35.47)
Change at Course 2/Week 6 (n=53, 30, 29, 29, 29)	-27.3 (± 42.86)	-38.2 (± 41.14)	-44.1 (± 38.55)	-27.2 (± 40.71)

Change at Course 2/Week 13 (n=53, 30, 30, 29, 29)	-24.9 (± 44.4)	-38.5 (± 40.36)	-45.3 (± 41.12)	-28.4 (± 38.05)
Change at Course 2/Week 25 (n=29, 9, 20, 15, 16)	-23.4 (± 79.52)	-30.7 (± 37)	-43.2 (± 38.79)	-22.3 (± 29.32)

End point values	PF-05280586 (US): by the end of Course 2			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=54, 30, 31, 29, 29)	1.6 (± 0.67)			
Change at Course 1/Week 1 (n=54, 30, 31, 29, 29)	-28.4 (± 36.53)			
Change at Course 1/Week 6 (n=54, 30, 31, 29, 29)	-32.6 (± 36.66)			
Change at Course 1/Week 13 (n=54, 30, 31, 29, 29)	-35.8 (± 33.09)			
Change at Course 1/Week 25 (n=35, 10, 20, 12, 19)	-27.2 (± 41.12)			
Change at Course 2/Week 1 (n=54, 30, 31, 29, 29)	-27.6 (± 32.91)			
Change at Course 2/Week 6 (n=53, 30, 29, 29, 29)	-35.4 (± 44.1)			
Change at Course 2/Week 13 (n=53, 30, 30, 29, 29)	-32.3 (± 64.88)			
Change at Course 2/Week 25 (n=29, 9, 20, 15, 16)	-48.7 (± 27.77)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Health Assessment Questionnaire – Disability Index (HAQ-DI) - by the end of Course 3

End point title	Percent Change from Initial Study Baseline in Individual Components of the ACR Response: Health Assessment Questionnaire – Disability Index (HAQ-DI) - by the end of Course 3[63]

End point description:

The HAQ-DI assessed the degree of difficulty a participant had experienced during the past week in 8 domains of daily living activities: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities. Each activity category consisted of 2 to 3 items. For each question in the questionnaire, the level of difficulty was scored from 0 to 3 with 0 representing "no difficulty," 1 as "some difficulty," 2 as "much difficulty," and 3 as "unable to do." Any activity that required assistance from another individual or required the use of an assistive device adjusted to a minimum score of 2 to represent a more limited functional status. This questionnaire was to be completed by the participant prior to any procedures being performed at the visit, if possible.

End point type	Primary

End point timeframe:

Baseline B3281001, Week 1, 6, 13, and 25 (Course 1 and Course 2), and Week 1, 13, and 25 (Course 3).

Notes:

[63] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	30	30	27
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=48, 30, 30, 27, 29)	1.7 (± 0.51)	1.6 (± 0.54)	1.6 (± 0.51)	1.8 (± 0.64)
Change at Course 1/Week 1 (n=48, 30, 30, 27, 29)	-13.9 (± 46.19)	-29.3 (± 37.54)	-38.6 (± 42.99)	-26.7 (± 31.76)
Change at Course 1/Week 6 (n=48, 30, 30, 27, 29)	-23.1 (± 42.48)	-37.1 (± 37.61)	-45.2 (± 31.03)	-33.4 (± 30.08)
Change at Course 1/Week 13 (n=48, 30, 30, 27, 29)	-23.2 (± 35.62)	-38 (± 42.46)	-46.8 (± 30.36)	-27.7 (± 37.07)
Change at Course 1/Week 25 (n=32, 10, 19, 11, 19)	-26.7 (± 44.36)	-24.1 (± 32.5)	-41.3 (± 34.12)	-30.2 (± 41.61)
Change at Course 2/Week 1 (n=48, 30, 30, 27, 29)	-18.8 (± 45.07)	-36.6 (± 41.08)	-43.2 (± 33.71)	-24.3 (± 36.6)
Change at Course 2/Week 6 (n=48, 30, 29, 27, 29)	-26.6 (± 43.6)	-38.2 (± 41.14)	-44.1 (± 38.55)	-26.6 (± 42.19)
Change at Course 2/Week 13 (n=48, 30, 30, 27, 29)	-22.9 (± 44.48)	-38.5 (± 40.36)	-45.3 (± 41.12)	-27.2 (± 39.12)
Change at Course 2/Week 25 (n=26, 9, 20, 14, 16)	-21 (± 82.68)	-30.7 (± 37)	-43.2 (± 38.79)	-25 (± 28.3)
Change at Course 3/Week 1 (n=48, 30, 30, 27, 29)	-18.7 (± 54.57)	-37.2 (± 41.42)	-41.5 (± 47.06)	-20.4 (± 43.26)
Change at Course 3/Week 13 (n=46, 30, 29, 26, 29)	-25.3 (± 43.76)	-32.6 (± 42.25)	-40.8 (± 50.01)	-24.8 (± 36.5)
Change at Course 3/Week 25 (n=47, 30, 30, 27, 29)	-23.7 (± 42.05)	-37.7 (± 42.58)	-48.7 (± 29.85)	-31.1 (± 32.38)

End point values	PF-05280586 (US): by the end of Course 3			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Percent change in score				
arithmetic mean (standard deviation)				
Baseline B3281001 (n=48, 30, 30, 27, 29)	1.6 (± 0.67)			
Change at Course 1/Week 1 (n=48, 30, 30, 27, 29)	-28.4 (± 36.53)			
Change at Course 1/Week 6 (n=48, 30, 30, 27, 29)	-32.6 (± 36.66)			

Change at Course 1/Week 13 (n=48, 30, 30, 27, 29)	-35.8 (± 33.09)			
Change at Course 1/Week 25 (n=32, 10, 19, 11, 19)	-27.2 (± 41.12)			
Change at Course 2/Week 1 (n=48, 30, 30, 27, 29)	-27.6 (± 32.91)			
Change at Course 2/Week 6 (n=48, 30, 29, 27, 29)	-35.4 (± 44.1)			
Change at Course 2/Week 13 (n=48, 30, 30, 27, 29)	-32.3 (± 64.88)			
Change at Course 2/Week 25 (n=26, 9, 20, 14, 16)	-48.7 (± 27.77)			
Change at Course 3/Week 1 (n=48, 30, 30, 27, 29)	-22.5 (± 60.13)			
Change at Course 3/Week 13 (n=46, 30, 29, 26, 29)	-40.7 (± 44.12)			
Change at Course 3/Week 25 (n=47, 30, 30, 27, 29)	-34.5 (± 46.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Outcome Measure Using HAQ-DI - by the end of Course 1

End point title	Outcome Measure Using HAQ-DI - by the end of Course 1[64]

End point description:

The HAQ-DI assessed the degree of difficulty a participant had experienced during the past week in 8 domains of daily living activities: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities. Each activity category consisted of 2 to 3 items. For each question in the questionnaire, the level of difficulty was scored from 0 to 3 with 0 representing "no difficulty," 1 as "some difficulty," 2 as "much difficulty," and 3 as "unable to do." Any activity that required assistance from another individual or required the use of an assistive device adjusted to a minimum score of 2 to represent a more limited functional status. This questionnaire was to be completed by the participant prior to any procedures being performed at the visit, if possible.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1).

Notes:

[64] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 1	Rituximab-EU: by the end of Course 1	PF-05280586 (EU): by the end of Course 1	Rituximab-US: by the end of Course 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	58	32	33	30
Units: Score on a scale				
number (not applicable)				
Course 1/Week 1 (n=58, 32, 33, 30, 30)	1.4	1.1	1	1.2
Course 1/Week 6 (n=57, 31, 33, 30, 30)	1.3	1	0.9	1.1
Course 1/Week 13 (n=56, 31, 33, 30, 29)	1.3	1	0.8	1.2

Course 1/Week 25 (n=35, 10, 22, 13, 19)	1.2	1.3	0.9	1.1

End point values	PF-05280586 (US): by the end of Course 1			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: Score on a scale				
number (not applicable)				
Course 1/Week 1 (n=58, 32, 33, 30, 30)	1.3			
Course 1/Week 6 (n=57, 31, 33, 30, 30)	1.2			
Course 1/Week 13 (n=56, 31, 33, 30, 29)	1.1			
Course 1/Week 25 (n=35, 10, 22, 13, 19)	1.1			

Statistical analyses

No statistical analyses for this end point

Primary: Outcome Measure Using HAQ-DI - by the end of Course 2

End point title	Outcome Measure Using HAQ-DI - by the end of Course 2[65]

End point description:

The HAQ-DI assessed the degree of difficulty a participant had experienced during the past week in 8 domains of daily living activities: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities. Each activity category consisted of 2 to 3 items. For each question in the questionnaire, the level of difficulty was scored from 0 to 3 with 0 representing "no difficulty," 1 as "some difficulty," 2 as "much difficulty," and 3 as "unable to do." Any activity that required assistance from another individual or required the use of an assistive device adjusted to a minimum score of 2 to represent a more limited functional status. This questionnaire was to be completed by the participant prior to any procedures being performed at the visit, if possible.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1 and Course 2).

Notes:

[65] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 2	Rituximab-EU/PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	54	30	31	29
Units: Score on a scale				
number (not applicable)				

Course 1/Week 1 (n=54, 30, 31, 29, 29)	1.4	1.2	1	1.3
Course 1/Week 6 (n=54, 30, 31, 29, 29)	1.3	1	0.9	1.1
Course 1/Week 13 (n=54, 30, 31, 29, 29)	1.3	1	0.8	1.2
Course 1/Week 25 (N=35, 10, 20, 12, 19)	1.2	1.3	0.9	1.1
Course 2/Week 1 (n=54, 30, 31, 29, 29)	1.3	1	0.9	1.3
Course 2/Week 6 (n=53, 30, 29, 29, 29)	1.2	1	0.9	1.2
Course 2/Week 13 (n=53, 30, 30, 29, 29)	1.2	1	0.9	1.2
Course 2/Week 25 (n=29, 9, 20, 15, 16)	1.1	1.2	0.9	1.4

End point values	PF-05280586 (US): by the end of Course 2			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Score on a scale				
number (not applicable)				
Course 1/Week 1 (n=54, 30, 31, 29, 29)	1.2			
Course 1/Week 6 (n=54, 30, 31, 29, 29)	1.1			
Course 1/Week 13 (n=54, 30, 31, 29, 29)	1.1			
Course 1/Week 25 (N=35, 10, 20, 12, 19)	1.1			
Course 2/Week 1 (n=54, 30, 31, 29, 29)	1.2			
Course 2/Week 6 (n=53, 30, 29, 29, 29)	1			
Course 2/Week 13 (n=53, 30, 30, 29, 29)	1			
Course 2/Week 25 (n=29, 9, 20, 15, 16)	0.8			

Statistical analyses

No statistical analyses for this end point

Primary: Outcome Measure Using HAQ-DI - by the end of Course 3

End point title	Outcome Measure Using HAQ-DI - by the end of Course 3[66]

End point description:

The HAQ-DI assessed the degree of difficulty a participant had experienced during the past week in 8 domains of daily living activities: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities. Each activity category consisted of 2 to 3 items. For each question in the questionnaire, the level of difficulty was scored from 0 to 3 with 0 representing "no difficulty," 1 as "some difficulty," 2 as "much difficulty," and 3 as "unable to do." Any activity that required assistance

from another individual or required the use of an assistive device adjusted to a minimum score of 2 to represent a more limited functional status. This questionnaire was to be completed by the participant prior to any procedures being performed at the visit, if possible.

End point type	Primary

End point timeframe:

Week 1, 6, 13, and 25 (Course 1 and Course 2), and Week 1, 13, and 25 (Course 3).

Notes:

[66] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per the protocol, the planned analysis was descriptive only.

End point values	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	30	30	27
Units: Score on a scale				
number (not applicable)				
Course 1/Week 1 (n=48, 30, 30, 27, 29)	1.4	1.2	1	1.3
Course 1/Week 6 (n=48, 30, 30, 27, 29)	1.2	1	0.9	1.2
Course 1/Week 13 (n=48, 30, 30, 27, 29)	1.2	1	0.9	1.2
Course 1/Week 25 (n=32, 10, 19, 11, 19)	1.1	1.3	1	1.1
Course 2/Week 1 (n=48, 30, 30, 27, 29)	1.3	1	0.9	1.3
Course 2/Week 6 (n=48, 30, 29, 27, 29)	1.2	1	0.9	1.2
Course 2/Week 13 (n=48, 30, 30, 27, 29)	1.2	1	0.9	1.2
Course 2/Week 25 (n=26, 9, 20, 14, 16)	1.1	1.2	0.9	1.3
Course 3/Week 1 (n=48, 30, 30, 27, 29)	1.3	1	0.9	1.3
Course 3/Week 13 (n=46, 30, 29, 26, 29)	1.2	1.1	0.9	1.2
Course 3/Week 25 (EOT) (n=47, 30, 30, 27, 29)	1.2	1	0.9	1.2

End point values	PF-05280586 (US): by the end of Course 3			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: Score on a scale				
number (not applicable)				
Course 1/Week 1 (n=48, 30, 30, 27, 29)	1.2			
Course 1/Week 6 (n=48, 30, 30, 27, 29)	1.1			

Course 1/Week 13 (n=48, 30, 30, 27, 29)	1.1			
Course 1/Week 25 (n=32, 10, 19, 11, 19)	1.1			
Course 2/Week 1 (n=48, 30, 30, 27, 29)	1.2			
Course 2/Week 6 (n=48, 30, 29, 27, 29)	1			
Course 2/Week 13 (n=48, 30, 30, 27, 29)	1			
Course 2/Week 25 (n=26, 9, 20, 14, 16)	0.8			
Course 3/Week 1 (n=48, 30, 30, 27, 29)	1.1			
Course 3/Week 13 (n=46, 30, 29, 26, 29)	0.9			
Course 3/Week 25 (EOT) (n=47, 30, 30, 27, 29)	1			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

SAEs were collected from informed consent through & including 28 calendar days after last administration of study drug or Long Term Follow-Up, whichever was longer. AEs were recorded from first dose of study treatment through last visit.

Adverse event reporting additional description:

SAEs & AEs were summarized by course for events with first onset on or after the first dose of study drug in that course & before the first dose of in the subsequent course, or any pre-existing event that worsened in severity during that course. An event may appear twice as data is cumulative for participants who received treatment in Course 2 & 3.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Rituximab-EU: by the end of Course 1

Reporting group description:

This treatment group, which received Rituximab-EU in the B3281001 study, received IV rituximab (MabThera) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Reporting group title	PF-05280586: by the end of Course 1

Reporting group description:

This treatment group, which received PF-05280586 during the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Reporting group title	PF-05280586 (EU): by the end of Course 1

Reporting group description:

This treatment group, which received Rituximab-EU in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Reporting group title	Rituximab-US: by the end of Course 1

Reporting group description:

This treatment group, which received Rituximab-US in the B3281001 study, received IV rituximab (Rituxan) infusion 1000 mg/500 mL (preceded by 100 mg methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) for up to 25 weeks. Folate supplementation was encouraged according to local standard of care.

Reporting group title	PF-05280586 (US): by the end of Course 1

Reporting group description:

This treatment group, which received Rituximab-US in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Reporting group title	Rituximab-EU/PF-05280586: by the end of Course 2

Reporting group description:

This treatment group, which received Rituximab-EU in the B3281001 study, received IV rituximab (MabThera) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study, followed by IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the second 24-week (±8 week) course. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Reporting group title	PF-05280586: by the end of Course 2

Reporting group description:

This treatment group, which received PF-05280586 in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first two 24-week (±8 week) courses in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Reporting group title	PF-05280586 (EU): by the end of Course 2

Reporting group description:

This treatment group, which received Rituximab-EU in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first two 24-week (±8 week) courses in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Reporting group title	Rituximab-US/PF-05280586: by the end of Course 2

Reporting group description:

This treatment group, which received Rituximab-US in the B3281001 study, received IV rituximab (Rituxan) infusion 1000 mg/500 mL (preceded by 100 mg methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study, followed by IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the second 24-week (±8 week) course. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) for up to 25 weeks. Folate supplementation was encouraged according to local standard of care.

Reporting group title	PF-05280586 (US): by the end of Course 2

Reporting group description:

This treatment group, which received Rituximab-US in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first two 24-week (±8 week) courses in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Reporting group title	PF-05280586: by the end of Course 3

Reporting group description:

This treatment group, which received PF-05280586 in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of all three 24-week (±8 week) courses in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Reporting group title	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3

Reporting group description:

This treatment group, which received Rituximab-EU in the B3281001 study, received IV rituximab (MabThera) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study, followed by IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the second and third 24-week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Reporting group title	PF-05280586 (EU): by the end of Course 3

Reporting group description:

This treatment group, which received Rituximab-EU in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of all three 24-week (±8 week) courses in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Reporting group title	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3

Reporting group description:

This treatment group, which received Rituximab-US in the B3281001 study, received IV rituximab (Rituxan) infusion 1000 mg/500 mL (preceded by 100 mg methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the first 24-week (±8 week) course in this three course study, followed by IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of the second and third 24-week (±8 week) courses. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance) for up to 25 weeks. Folate supplementation was encouraged according to local standard of care.

Reporting group title	PF-05280586 (US): by the end of Course 3

Reporting group description:

This treatment group, which received Rituximab-US in the B3281001 study, received IV rituximab (PF-05280586) infusion 1000 mg/500 mL (preceded by 100 mg IV methylprednisolone or its equivalent, an antipyretic, and an antihistamine) on Study Days 1 and 15 of all three 24-week (±8 week) courses in this three course study. Participants continued to receive a stable background regimen of methotrexate 10 to 25 mg/week (7.5 mg/week in the event of prior poor tolerance). Folate supplementation was encouraged according to local standard of care.

Serious adverse events	Rituximab-EU: by the end of Course 1	PF-05280586: by the end of Course 1	PF-05280586 (EU): by the end of Course 1
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 32 (6.25%)	4 / 58 (6.90%)	2 / 33 (6.06%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Cardiac disorders			
Pericarditis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 32 (0.00%)	1 / 58 (1.72%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischemic Attack			

subjects affected / exposed	1 / 32 (3.13%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Blighted Ovum			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	1 / 33 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Neutropenia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diaphragmatic Hernia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 32 (0.00%)	1 / 58 (1.72%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	1 / 32 (3.13%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	1 / 32 (3.13%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Arthritis Infective			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 32 (0.00%)	1 / 58 (1.72%)	1 / 33 (3.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			

subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection Staphylococcal			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis Bacterial			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 32 (0.00%)	1 / 58 (1.72%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Rituximab-US: by the end of Course 1	PF-05280586 (US): by the end of Course 1	Rituximab-EU/PF-05280586: by the end of Course 2
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)	1 / 30 (3.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Cardiac disorders			
Pericarditis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Syncope			

subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischemic Attack			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Blighted Ovum			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Neutropenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diaphragmatic Hernia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Umbilical Hernia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Arthritis Infective			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection Staphylococcal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis Bacterial			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 54 (11.11%)	4 / 31 (12.90%)	2 / 29 (6.90%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Cardiac disorders			
Pericarditis			
subjects affected / exposed	0 / 54 (0.00%)	1 / 31 (3.23%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 54 (1.85%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischemic Attack			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Blighted Ovum			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 54 (0.00%)	1 / 31 (3.23%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Neutropenia			
subjects affected / exposed	1 / 54 (1.85%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diaphragmatic Hernia			
subjects affected / exposed	1 / 54 (1.85%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			

subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	1 / 54 (1.85%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Arthritis Infective			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 54 (0.00%)	1 / 31 (3.23%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			

subjects affected / exposed	1 / 54 (1.85%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 54 (1.85%)	2 / 31 (6.45%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	1 / 54 (1.85%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection Staphylococcal			
subjects affected / exposed	0 / 54 (0.00%)	1 / 31 (3.23%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis Bacterial			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PF-05280586 (US): by the end of Course 2	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 29 (3.45%)	4 / 48 (8.33%)	1 / 30 (3.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Cardiac disorders			
Pericarditis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischemic Attack			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Blighted Ovum			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Neutropenia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 48 (2.08%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diaphragmatic Hernia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 48 (2.08%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			

subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 29 (0.00%)	1 / 48 (2.08%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Arthritis Infective			
subjects affected / exposed	0 / 29 (0.00%)	1 / 48 (2.08%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 48 (2.08%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection Staphylococcal			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis Bacterial			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the	PF-05280586 (US): by the end of Course 3

		end of Course 3	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 30 (13.33%)	1 / 27 (3.70%)	1 / 29 (3.45%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Cardiac disorders			
Pericarditis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischemic Attack			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Blighted Ovum			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Neutropenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diaphragmatic Hernia			

subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 27 (3.70%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 27 (3.70%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Arthritis Infective			

subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 30 (6.67%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection Staphylococcal			
subjects affected / exposed	1 / 30 (3.33%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis Bacterial			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			

subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Rituximab-EU: by the end of Course 1	PF-05280586: by the end of Course 1	PF-05280586 (EU): by the end of Course 1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 32 (34.38%)	32 / 58 (55.17%)	17 / 33 (51.52%)
Investigations			
Neutrophil Count Decreased			
subjects affected / exposed	1 / 32 (3.13%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 32 (3.13%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Wrist Fracture			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	1 / 33 (3.03%)
occurrences (all)	0	0	1
Nervous system disorders			

Dizziness			
subjects affected / exposed	0 / 32 (0.00%)	1 / 58 (1.72%)	1 / 33 (3.03%)
occurrences (all)	0	1	1
Headache			
subjects affected / exposed	0 / 32 (0.00%)	1 / 58 (1.72%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 32 (0.00%)	3 / 58 (5.17%)	0 / 33 (0.00%)
occurrences (all)	0	3	0
Oedema Peripheral			
subjects affected / exposed	1 / 32 (3.13%)	1 / 58 (1.72%)	0 / 33 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 32 (0.00%)	1 / 58 (1.72%)	1 / 33 (3.03%)
occurrences (all)	0	1	1
Nausea			
subjects affected / exposed	0 / 32 (0.00%)	2 / 58 (3.45%)	1 / 33 (3.03%)
occurrences (all)	0	2	1
Vomiting			
subjects affected / exposed	0 / 32 (0.00%)	1 / 58 (1.72%)	2 / 33 (6.06%)
occurrences (all)	0	1	2
Dyspepsia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 32 (0.00%)	2 / 58 (3.45%)	0 / 33 (0.00%)
occurrences (all)	0	2	0

Oropharyngeal Pain			
subjects affected / exposed	0 / 32 (0.00%)	1 / 58 (1.72%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Skin Lesion			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 32 (0.00%)	1 / 58 (1.72%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 32 (0.00%)	1 / 58 (1.72%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
Back Pain			
subjects affected / exposed	0 / 32 (0.00%)	1 / 58 (1.72%)	1 / 33 (3.03%)
occurrences (all)	0	1	1
Rheumatoid Arthritis			
subjects affected / exposed	1 / 32 (3.13%)	4 / 58 (6.90%)	3 / 33 (9.09%)
occurrences (all)	1	4	4
Pain In Extremity			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 32 (9.38%)	1 / 58 (1.72%)	1 / 33 (3.03%)
occurrences (all)	4	1	2
Urinary Tract Infection			
subjects affected / exposed	0 / 32 (0.00%)	4 / 58 (6.90%)	1 / 33 (3.03%)
occurrences (all)	0	4	1
Bronchitis			
subjects affected / exposed	1 / 32 (3.13%)	2 / 58 (3.45%)	0 / 33 (0.00%)
occurrences (all)	1	2	0
Nasopharyngitis			

subjects affected / exposed	0 / 32 (0.00%)	1 / 58 (1.72%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
Oral Candidiasis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 32 (3.13%)	1 / 58 (1.72%)	1 / 33 (3.03%)
occurrences (all)	1	2	1
Gastroenteritis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Viral Infection			
subjects affected / exposed	0 / 32 (0.00%)	2 / 58 (3.45%)	0 / 33 (0.00%)
occurrences (all)	0	2	0
Oral Herpes			
subjects affected / exposed	0 / 32 (0.00%)	0 / 58 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Vitamin D Deficiency			
subjects affected / exposed	1 / 32 (3.13%)	0 / 58 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1

Non-serious adverse events	Rituximab-US: by the end of Course 1	PF-05280586 (US): by the end of Course 1	Rituximab-EU/PF-05280586: by the end of Course 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 30 (53.33%)	12 / 30 (40.00%)	20 / 30 (66.67%)
Investigations			
Neutrophil Count Decreased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	1	0	2
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
White Blood Cell Count Decreased			

subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Fall			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	2	0	2
Wrist Fracture			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Headache			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	3	0	0
Paraesthesia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Fatigue			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	0	2
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)	1 / 30 (3.33%)
occurrences (all)	3	2	1

Nausea			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	3	0	0
Vomiting			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	2	0	1
Dyspepsia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
Skin and subcutaneous tissue disorders			
Skin Lesion			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	2	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 30 (10.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	4	0	0
Back Pain			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Rheumatoid Arthritis			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	2 / 30 (6.67%)
occurrences (all)	1	2	2
Pain In Extremity			

subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Infections and infestations			
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	4 / 30 (13.33%)
occurrences (all)	1	1	5
Urinary Tract Infection			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	0	1	1
Bronchitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	1	0	2
Nasopharyngitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Oral Candidiasis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	2 / 30 (6.67%)
occurrences (all)	1	1	2
Gastroenteritis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal Viral Infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Oral Herpes			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	1	0	1
Metabolism and nutrition disorders			
Vitamin D Deficiency			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1

Non-serious adverse events	PF-05280586: by the end of Course 2	PF-05280586 (EU): by the end of Course 2	Rituximab-US/PF-05280586: by the end of Course 2

Total subjects affected by non-serious adverse events subjects affected / exposed	35 / 54 (64.81%)	20 / 31 (64.52%)	20 / 29 (68.97%)
Investigations			
Neutrophil Count Decreased subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Alanine Aminotransferase Increased subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Aspartate Aminotransferase Increased subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
White Blood Cell Count Decreased subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Foot Fracture subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	3
Fall subjects affected / exposed	0 / 54 (0.00%)	1 / 31 (3.23%)	1 / 29 (3.45%)
occurrences (all)	0	1	2
Wrist Fracture subjects affected / exposed	0 / 54 (0.00%)	1 / 31 (3.23%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Dizziness subjects affected / exposed	2 / 54 (3.70%)	1 / 31 (3.23%)	2 / 29 (6.90%)
occurrences (all)	2	1	2
Headache subjects affected / exposed	2 / 54 (3.70%)	1 / 31 (3.23%)	2 / 29 (6.90%)
occurrences (all)	2	1	3
Paraesthesia subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	2
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	2
Fatigue			
subjects affected / exposed	3 / 54 (5.56%)	0 / 31 (0.00%)	1 / 29 (3.45%)
occurrences (all)	3	0	1
Oedema Peripheral			
subjects affected / exposed	1 / 54 (1.85%)	1 / 31 (3.23%)	1 / 29 (3.45%)
occurrences (all)	1	1	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 54 (3.70%)	1 / 31 (3.23%)	3 / 29 (10.34%)
occurrences (all)	2	1	5
Nausea			
subjects affected / exposed	4 / 54 (7.41%)	1 / 31 (3.23%)	2 / 29 (6.90%)
occurrences (all)	5	1	3
Vomiting			
subjects affected / exposed	2 / 54 (3.70%)	2 / 31 (6.45%)	2 / 29 (6.90%)
occurrences (all)	3	2	3
Dyspepsia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 54 (5.56%)	1 / 31 (3.23%)	2 / 29 (6.90%)
occurrences (all)	3	1	2
Oropharyngeal Pain			
subjects affected / exposed	1 / 54 (1.85%)	1 / 31 (3.23%)	0 / 29 (0.00%)
occurrences (all)	1	1	0
Skin and subcutaneous tissue disorders			
Skin Lesion			
subjects affected / exposed	1 / 54 (1.85%)	0 / 31 (0.00%)	2 / 29 (6.90%)
occurrences (all)	1	0	2
Psychiatric disorders			
Depression			

subjects affected / exposed	2 / 54 (3.70%)	0 / 31 (0.00%)	2 / 29 (6.90%)
occurrences (all)	2	0	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 54 (0.00%)	1 / 31 (3.23%)	2 / 29 (6.90%)
occurrences (all)	0	1	4
Back Pain			
subjects affected / exposed	2 / 54 (3.70%)	2 / 31 (6.45%)	2 / 29 (6.90%)
occurrences (all)	2	4	2
Rheumatoid Arthritis			
subjects affected / exposed	5 / 54 (9.26%)	3 / 31 (9.68%)	2 / 29 (6.90%)
occurrences (all)	6	6	3
Pain In Extremity			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Infections and infestations			
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 54 (1.85%)	1 / 31 (3.23%)	3 / 29 (10.34%)
occurrences (all)	1	2	3
Urinary Tract Infection			
subjects affected / exposed	5 / 54 (9.26%)	1 / 31 (3.23%)	0 / 29 (0.00%)
occurrences (all)	6	1	0
Bronchitis			
subjects affected / exposed	4 / 54 (7.41%)	1 / 31 (3.23%)	2 / 29 (6.90%)
occurrences (all)	5	1	2
Nasopharyngitis			
subjects affected / exposed	2 / 54 (3.70%)	0 / 31 (0.00%)	3 / 29 (10.34%)
occurrences (all)	2	0	3
Oral Candidiasis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	2
Sinusitis			
subjects affected / exposed	4 / 54 (7.41%)	2 / 31 (6.45%)	2 / 29 (6.90%)
occurrences (all)	5	2	2
Gastroenteritis			

subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Viral Infection			
subjects affected / exposed	2 / 54 (3.70%)	0 / 31 (0.00%)	0 / 29 (0.00%)
occurrences (all)	2	0	0
Oral Herpes			
subjects affected / exposed	0 / 54 (0.00%)	0 / 31 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Vitamin D Deficiency			
subjects affected / exposed	0 / 54 (0.00%)	2 / 31 (6.45%)	1 / 29 (3.45%)
occurrences (all)	0	2	1

Non-serious adverse events	PF-05280586 (US): by the end of Course 2	PF-05280586: by the end of Course 3	Rituximab-EU/PF-05280586/PF-05280586: by the end of Course 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 29 (62.07%)	34 / 48 (70.83%)	21 / 30 (70.00%)
Investigations			
Neutrophil Count Decreased			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	0	3
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 29 (3.45%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 29 (3.45%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
White Blood Cell Count Decreased			
subjects affected / exposed	1 / 29 (3.45%)	0 / 48 (0.00%)	2 / 30 (6.67%)
occurrences (all)	1	0	2
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Fall			

subjects affected / exposed	0 / 29 (0.00%)	1 / 48 (2.08%)	3 / 30 (10.00%)
occurrences (all)	0	2	3
Wrist Fracture			
subjects affected / exposed	1 / 29 (3.45%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 29 (3.45%)	2 / 48 (4.17%)	1 / 30 (3.33%)
occurrences (all)	1	2	1
Headache			
subjects affected / exposed	1 / 29 (3.45%)	1 / 48 (2.08%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Paraesthesia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 29 (0.00%)	2 / 48 (4.17%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
Oedema Peripheral			
subjects affected / exposed	0 / 29 (0.00%)	1 / 48 (2.08%)	2 / 30 (6.67%)
occurrences (all)	0	1	2
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 29 (6.90%)	1 / 48 (2.08%)	1 / 30 (3.33%)
occurrences (all)	2	1	1
Nausea			
subjects affected / exposed	2 / 29 (6.90%)	3 / 48 (6.25%)	0 / 30 (0.00%)
occurrences (all)	2	4	0
Vomiting			
subjects affected / exposed	1 / 29 (3.45%)	2 / 48 (4.17%)	1 / 30 (3.33%)
occurrences (all)	1	3	1
Dyspepsia			

subjects affected / exposed	1 / 29 (3.45%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 29 (0.00%)	2 / 48 (4.17%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
Oropharyngeal Pain			
subjects affected / exposed	2 / 29 (6.90%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Skin Lesion			
subjects affected / exposed	0 / 29 (0.00%)	1 / 48 (2.08%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 29 (0.00%)	3 / 48 (6.25%)	1 / 30 (3.33%)
occurrences (all)	0	3	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 48 (2.08%)	1 / 30 (3.33%)
occurrences (all)	0	1	1
Back Pain			
subjects affected / exposed	0 / 29 (0.00%)	2 / 48 (4.17%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
Rheumatoid Arthritis			
subjects affected / exposed	2 / 29 (6.90%)	5 / 48 (10.42%)	3 / 30 (10.00%)
occurrences (all)	3	8	4
Pain In Extremity			
subjects affected / exposed	2 / 29 (6.90%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 29 (6.90%)	2 / 48 (4.17%)	4 / 30 (13.33%)
occurrences (all)	2	2	6
Urinary Tract Infection			

subjects affected / exposed	2 / 29 (6.90%)	5 / 48 (10.42%)	1 / 30 (3.33%)
occurrences (all)	2	8	1
Bronchitis			
subjects affected / exposed	1 / 29 (3.45%)	5 / 48 (10.42%)	2 / 30 (6.67%)
occurrences (all)	2	6	2
Nasopharyngitis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 48 (2.08%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Oral Candidiasis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	2 / 29 (6.90%)	4 / 48 (8.33%)	2 / 30 (6.67%)
occurrences (all)	3	4	2
Gastroenteritis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 48 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal Viral Infection			
subjects affected / exposed	1 / 29 (3.45%)	3 / 48 (6.25%)	0 / 30 (0.00%)
occurrences (all)	1	3	0
Oral Herpes			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Vitamin D Deficiency			
subjects affected / exposed	0 / 29 (0.00%)	0 / 48 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1

Non-serious adverse events	PF-05280586 (EU): by the end of Course 3	Rituximab-US/PF-05280586/PF-05280586: by the end of Course 3	PF-05280586 (US): by the end of Course 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 30 (76.67%)	20 / 27 (74.07%)	21 / 29 (72.41%)
Investigations			
Neutrophil Count Decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Alanine Aminotransferase Increased			

subjects affected / exposed	0 / 30 (0.00%)	1 / 27 (3.70%)	2 / 29 (6.90%)
occurrences (all)	0	1	2
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	2
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 30 (0.00%)	2 / 27 (7.41%)	0 / 29 (0.00%)
occurrences (all)	0	3	0
Fall			
subjects affected / exposed	2 / 30 (6.67%)	1 / 27 (3.70%)	0 / 29 (0.00%)
occurrences (all)	2	2	0
Wrist Fracture			
subjects affected / exposed	1 / 30 (3.33%)	0 / 27 (0.00%)	2 / 29 (6.90%)
occurrences (all)	1	0	2
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 30 (3.33%)	1 / 27 (3.70%)	1 / 29 (3.45%)
occurrences (all)	1	1	1
Headache			
subjects affected / exposed	2 / 30 (6.67%)	1 / 27 (3.70%)	1 / 29 (3.45%)
occurrences (all)	2	1	1
Paraesthesia			
subjects affected / exposed	0 / 30 (0.00%)	2 / 27 (7.41%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 27 (3.70%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	0 / 30 (0.00%)	1 / 27 (3.70%)	1 / 29 (3.45%)
occurrences (all)	0	1	1

Oedema Peripheral			
subjects affected / exposed	1 / 30 (3.33%)	3 / 27 (11.11%)	0 / 29 (0.00%)
occurrences (all)	1	3	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 30 (3.33%)	3 / 27 (11.11%)	2 / 29 (6.90%)
occurrences (all)	1	5	2
Nausea			
subjects affected / exposed	1 / 30 (3.33%)	1 / 27 (3.70%)	2 / 29 (6.90%)
occurrences (all)	1	1	2
Vomiting			
subjects affected / exposed	2 / 30 (6.67%)	1 / 27 (3.70%)	1 / 29 (3.45%)
occurrences (all)	2	1	1
Dyspepsia			
subjects affected / exposed	0 / 30 (0.00%)	2 / 27 (7.41%)	1 / 29 (3.45%)
occurrences (all)	0	2	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 30 (3.33%)	2 / 27 (7.41%)	0 / 29 (0.00%)
occurrences (all)	1	2	0
Oropharyngeal Pain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 27 (0.00%)	2 / 29 (6.90%)
occurrences (all)	2	0	2
Skin and subcutaneous tissue disorders			
Skin Lesion			
subjects affected / exposed	0 / 30 (0.00%)	2 / 27 (7.41%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 30 (0.00%)	2 / 27 (7.41%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 30 (6.67%)	2 / 27 (7.41%)	0 / 29 (0.00%)
occurrences (all)	2	4	0
Back Pain			

subjects affected / exposed	2 / 30 (6.67%)	2 / 27 (7.41%)	0 / 29 (0.00%)
occurrences (all)	4	2	0
Rheumatoid Arthritis			
subjects affected / exposed	3 / 30 (10.00%)	2 / 27 (7.41%)	2 / 29 (6.90%)
occurrences (all)	7	3	3
Pain In Extremity			
subjects affected / exposed	0 / 30 (0.00%)	1 / 27 (3.70%)	2 / 29 (6.90%)
occurrences (all)	0	1	3
Infections and infestations			
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 30 (3.33%)	4 / 27 (14.81%)	3 / 29 (10.34%)
occurrences (all)	2	4	3
Urinary Tract Infection			
subjects affected / exposed	3 / 30 (10.00%)	1 / 27 (3.70%)	2 / 29 (6.90%)
occurrences (all)	3	1	2
Bronchitis			
subjects affected / exposed	2 / 30 (6.67%)	3 / 27 (11.11%)	2 / 29 (6.90%)
occurrences (all)	3	3	4
Nasopharyngitis			
subjects affected / exposed	1 / 30 (3.33%)	1 / 27 (3.70%)	2 / 29 (6.90%)
occurrences (all)	1	1	2
Oral Candidiasis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 27 (3.70%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	2 / 30 (6.67%)	2 / 27 (7.41%)	2 / 29 (6.90%)
occurrences (all)	3	3	3
Gastroenteritis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	3
Gastrointestinal Viral Infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 27 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Oral Herpes			
subjects affected / exposed	0 / 30 (0.00%)	2 / 27 (7.41%)	1 / 29 (3.45%)
occurrences (all)	0	2	1

Metabolism and nutrition disorders Vitamin D Deficiency subjects affected / exposed occurrences (all)	2 / 30 (6.67%) 2	1 / 27 (3.70%) 1	0 / 29 (0.00%) 0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported