



Clinical trial results: A Multicenter Open-Label Extension Study for Subjects Who Participated in Study B0151003 (Andante II)

Summary

EudraCT number	2011-000722-30
Trial protocol	GB IE GR BE DK HU IT CZ AT SE
Global end of trial date	01 March 2016

Results information

Result version number	v1 (current)
This version publication date	15 February 2017
First version publication date	15 February 2017

Trial information

Trial identification

Sponsor protocol code	B0151005
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 1 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	24 August 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 March 2016
Global end of trial reached?	Yes
Global end of trial date	01 March 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the long term safety, tolerability, and immunogenicity of PF-04236921.

Protection of trial subjects:

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 Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. In addition, all local regulatory requirements were followed, in particular, those affording greater protection to the safety of trial subjects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 June 2011
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	7 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 7
Country: Number of subjects enrolled	Belgium: 15
Country: Number of subjects enrolled	Brazil: 5
Country: Number of subjects enrolled	Canada: 15
Country: Number of subjects enrolled	Czech Republic: 8
Country: Number of subjects enrolled	Denmark: 13
Country: Number of subjects enrolled	France: 5
Country: Number of subjects enrolled	Germany: 9
Country: Number of subjects enrolled	Hungary: 6
Country: Number of subjects enrolled	Ireland: 5
Country: Number of subjects enrolled	Israel: 11
Country: Number of subjects enrolled	Italy: 15
Country: Number of subjects enrolled	New Zealand: 4
Country: Number of subjects enrolled	Switzerland: 6
Country: Number of subjects enrolled	United Kingdom: 4
Country: Number of subjects enrolled	United States: 63

Worldwide total number of subjects	191
EEA total number of subjects	80

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)	186
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 191 subjects were assigned to study treatment.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	PF-04236921
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Arm description:

All subjects entering this study were given a 50 mg subcutaneous (SC) dose of PF-04236921 at baseline and then every 8 weeks through Week 40. The subjects were on active treatment through Week 48. A one-time dose escalation to 100 mg was allowed, if subjects experienced a clinical deterioration or unacceptably low level of response to study drug. Dose escalation was not allowed before Week 8.

Arm type	Experimental
Investigational medicinal product name	PF-04236921
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Doses of PF-04236921 (50 mg [and 100 mg, if dose was escalated]) were administered SC at baseline and then every 8 weeks through Week 40.

Number of subjects in period 1	PF-04236921
Started	191
Completed	111
Not completed	80
Consent withdrawn by subject	41
Adverse event, non-fatal	16
Unspecified	3
Lost to follow-up	2
Protocol deviation	1
Lack of efficacy	17

Baseline characteristics

Reporting groups

Reporting group title	PF-04236921
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Reporting group description:

All subjects entering this study were given a 50 mg subcutaneous (SC) dose of PF-04236921 at baseline and then every 8 weeks through Week 40. The subjects were on active treatment through Week 48. A one-time dose escalation to 100 mg was allowed, if subjects experienced a clinical deterioration or unacceptably low level of response to study drug. Dose escalation was not allowed before Week 8.

Reporting group values	PF-04236921	Total	
Number of subjects	191	191	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	186	186	
From 65-84 years	5	5	
85 years and over	0	0	
Age Continuous			
Units: years			
arithmetic mean	40.1		
standard deviation	± 12.9	-	
Gender, Male/Female			
Units: Subjects			
FEMALE	108	108	
MALE	83	83	

End points

End points reporting groups

Reporting group title	PF-04236921
Reporting group description:	
All subjects entering this study were given a 50 mg subcutaneous (SC) dose of PF-04236921 at baseline and then every 8 weeks through Week 40. The subjects were on active treatment through Week 48. A one-time dose escalation to 100 mg was allowed, if subjects experienced a clinical deterioration or unacceptably low level of response to study drug. Dose escalation was not allowed before Week 8.	

Primary: Number of Subjects with On-Treatment Treatment-Emergent Adverse Events (AEs), Serious Adverse Events (SAEs), and Discontinuations Due to AEs

End point title	Number of Subjects with On-Treatment Treatment-Emergent Adverse Events (AEs), Serious Adverse Events (SAEs), and Discontinuations Due to AEs ^[1]
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End point description:

An AE was any untoward medical occurrence without regard to causality in a subject who received study drug. An SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of death); persistent or significant disability/incapacity; congenital anomaly. Lack of efficacy was reported as an AE when it was associated with a SAE. An AE was considered treatment emergent if it started for the first time in a subject on or after the first day of active treatment, or the event started before the first day of active treatment but increased in severity during active treatment. AEs included both SAEs and non-serious AEs.

End point type	Primary
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End point timeframe:

Baseline up to Week 48

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: No statistical analysis was planned for this primary end point.

End point values	PF-04236921			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: subjects				
Subjects with AEs	171			
Subjects with SAEs	58			
Subjects discontinued due to AEs	54			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Developing Anti-Drug Antibodies (ADAs) and Neutralizing Antibodies (NABs)

End point title	Percentage of Subjects Developing Anti-Drug Antibodies (ADAs) and Neutralizing Antibodies (NABs) ^[2]
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End point description:

Samples were analyzed using the semi-quantitative electrochemiluminescent (ECL) immunoassay method, a validated analytical method in compliance with sponsor's standard operating procedures. ADA positive is defined as ADA titer greater than or equal to (\geq) 4.32. Any positive ADA sample was further tested for NAb.

End point type	Primary
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End point timeframe:

At Baseline and Weeks 8, 16, 24, 32, 40, 48, 56, 64, 72 and 76.

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: No statistical analysis was planned for this primary end point.

End point values	PF-04236921			
Subject group type	Reporting group			
Number of subjects analysed	191			
Units: percentage of subjects				
number (not applicable)				
ADA positive	0.52			
NAb positive	0.52			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to Week 76

Adverse event reporting additional description:

The same event might have appeared as both an AE and a SAE. However, what is presented are distinct events. An event may be categorized as serious in one subject and as non-serious in another subject, or one subject might have experienced both a serious and non-serious event during the study.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.1
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Reporting groups

Reporting group title	PF-04236921
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Reporting group description:

All subjects entering this study were given a 50 mg SC dose of PF-04236921 at baseline and then every 8 weeks through Week 40. The subjects were on active treatment through Week 48. A one-time dose escalation to 100 mg was allowed, if subjects experienced a clinical deterioration or unacceptably low level of response to study drug. Dose escalation was not allowed before Week 8.

Serious adverse events	PF-04236921		
Total subjects affected by serious adverse events			
subjects affected / exposed	79 / 191 (41.36%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oncocytoma			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion missed			

subjects affected / exposed ^[1]	1 / 108 (0.93%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Weight decreased			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Anastomotic fistula			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Concussion			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal anastomotic leak			

subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal anastomosis complication			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower limb fracture			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural haemorrhage			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Procedural complication			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Multiple sclerosis relapse			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			

Ulcerative keratitis			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain lower			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Anal fistula			
subjects affected / exposed	4 / 191 (2.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Anorectal disorder			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Crohn's disease			
subjects affected / exposed	41 / 191 (21.47%)		
occurrences causally related to treatment / all	5 / 44		
deaths causally related to treatment / all	0 / 0		
Dyspepsia			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fistula of small intestine			

subjects affected / exposed	2 / 191 (1.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Enterovesical fistula			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastritis erosive			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Large intestine perforation			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	2 / 191 (1.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			

subjects affected / exposed	2 / 191 (1.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal perforation			
subjects affected / exposed	3 / 191 (1.57%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	2 / 191 (1.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cholangitis sclerosing			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis chronic			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic function abnormal			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Calculus ureteric			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			

subjects affected / exposed	2 / 191 (1.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal colic			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	4 / 191 (2.09%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Anal abscess			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Abscess			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Bartholin's abscess			
subjects affected / exposed ^[2]	1 / 108 (0.93%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Cytomegalovirus infection				
subjects affected / exposed	2 / 191 (1.05%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	1 / 191 (0.52%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Groin abscess				
subjects affected / exposed	1 / 191 (0.52%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Infectious colitis				
subjects affected / exposed	1 / 191 (0.52%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Latent tuberculosis				
subjects affected / exposed	1 / 191 (0.52%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Mesenteric abscess				
subjects affected / exposed	1 / 191 (0.52%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Perirectal abscess				
subjects affected / exposed	1 / 191 (0.52%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	1 / 191 (0.52%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peritonsillar abscess				

subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal abscess			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	2 / 191 (1.05%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Retroperitoneal abscess			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	2 / 191 (1.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Tooth abscess			

subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Tuberculosis			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 191 (0.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 191 (1.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: Percentage of gender specific events were calculated using the corresponding gender count as denominator.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: Percentage of gender specific events were calculated using the corresponding gender count as denominator.

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

Non-serious adverse events	PF-04236921		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	150 / 191 (78.53%)		
Nervous system disorders			
Headache			
subjects affected / exposed	23 / 191 (12.04%)		
occurrences (all)	32		
Blood and lymphatic system disorders			

Anaemia subjects affected / exposed occurrences (all)	15 / 191 (7.85%) 16		
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all)	14 / 191 (7.33%) 17		
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) Crohn's disease subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	39 / 191 (20.42%) 49 45 / 191 (23.56%) 57 20 / 191 (10.47%) 25 21 / 191 (10.99%) 29 22 / 191 (11.52%) 26		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	13 / 191 (6.81%) 14		
Skin and subcutaneous tissue disorders Erythema subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all)	14 / 191 (7.33%) 16 18 / 191 (9.42%) 20		
Psychiatric disorders			

Anxiety subjects affected / exposed occurrences (all)	10 / 191 (5.24%) 10		
Insomnia subjects affected / exposed occurrences (all)	11 / 191 (5.76%) 11		
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	23 / 191 (12.04%) 33		
Back pain subjects affected / exposed occurrences (all)	12 / 191 (6.28%) 12		
Infections and infestations			
Bronchitis subjects affected / exposed occurrences (all)	12 / 191 (6.28%) 13		
Gastroenteritis subjects affected / exposed occurrences (all)	11 / 191 (5.76%) 12		
Nasopharyngitis subjects affected / exposed occurrences (all)	31 / 191 (16.23%) 40		
Urinary tract infection subjects affected / exposed occurrences (all)	16 / 191 (8.38%) 18		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	11 / 191 (5.76%) 13		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 May 2011	Harvey-Bradshaw Index category was changed from Health Outcomes Endpoint to Clinical Efficacy Assessment. The last injection site reaction assessment during the treatment period was moved from Week 44 to Week 48. An injection site reaction assessment was also added at the Early Withdrawal Visit.
14 June 2011	Specified that blood chemistry, hematology, urinalysis, autoantibodies, homocysteine, lipid profile, urine pregnancy test, and serum anti-PF-04236921 antibodies were only collected at Post Withdrawal Visits 2, 4, 6, and 8.
03 July 2012	In Pharmacokinetics/Pharmacodynamics (PK/PD) Section, updated to add flexibility in analyzing the Interleukin-6 (IL-6) samples and specified that the analysis might have been performed separately from the clinical study report, but the data listings would be included. Added exacerbation of Crohn's Disease as an expected SAE and added additional information for medically important events into Protocol-Specified Serious and Non-Serious Adverse Events Section.
27 February 2013	Primarily addressed the changes in tuberculosis (TB) testing as a result of a special safety concern that occurred in the B0151006 study investigating PF-04236921 for the indication of systemic lupus erythematosus (SLE).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported