Clinical trial results:
A Phase 3 Double-blind,Randomized, Placebo-Controlled,Parallel-Group Study to Assess The Efficacy, Safety and Tolerability of PF-04950615 in Subjects With Primary Hyperlipidemia or Mixed Dyslipidemia at Risk of Cardiovascular Events

Summary

EudraCT number	2013-002642-37
Trial protocol	CZ DE IT PL
Global end of trial date	05 April 2016

Results information

Result version number	v1 (current)
This version publication date	22 April 2017
First version publication date	22 April 2017

Trial information

Trial identification

Sponsor protocol code	B1481019

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01968954
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	08 February 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 April 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate a superior low-density lipoprotein-cholesterol (LDL-C) lowering effect of PF-04950615 150 milligram (mg) administered by the subcutaneous (SC) route every 2 weeks compared to placebo, in subjects with primary hyperlipidemia or mixed dyslipidemia at high and very high risk for cardiovascular events receiving a maximally tolerated dose of statin therapy and whose LDL-C was greater than or equal to (>=) 70 milligram per deciliter (mg/dL) (1.81 millimoles per liter [mmol/L]).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 October 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 18
Country: Number of subjects enrolled	Canada: 39
Country: Number of subjects enrolled	Czech Republic: 7
Country: Number of subjects enrolled	Germany: 30
Country: Number of subjects enrolled	Hong Kong: 6
Country: Number of subjects enrolled	Italy: 27
Country: Number of subjects enrolled	Korea, Republic of: 68
Country: Number of subjects enrolled	Poland: 95
Country: Number of subjects enrolled	United States: 421
Worldwide total number of subjects	711
EEA total number of subjects	159

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)	413
From 65 to 84 years	297
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study was conducted from 23 October 2013 to 05 April 2016 in Australia, Canada, Czech Republic, Germany, Hong Kong, Italy, Korea, Republic of, Poland and United States.

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, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received single dose of placebo matched to PF-04950615 subcutaneous injection once in every 2 weeks over a period of 52 weeks. Subjects were followed up to 58 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received single dose of placebo matched to PF-04950615 subcutaneous injection once in every 2 weeks over a period of 52 weeks.

Arm title	PF-04950615 150 mg

Arm description:

Subjects received single dose of PF-04950615 150 mg subcutaneous injection once in every 2 weeks over a period of 52 weeks. Subjects were followed up to 58 weeks.

Arm type	Experimental
Investigational medicinal product name	PF-04950615
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received single dose of PF-04950615 150 mg subcutaneous injection once in every 2 weeks over a period of 52 weeks.

Number of subjects in period 1	Placebo	PF-04950615 150 mg
Started	354	357
Treated	353	356
Completed	314	314
Not completed	40	43
Consent withdrawn by subject	20	23
Did not meet inclusion criteria	-	2
Unspecified	8	10
Adverse Events	6	3
Lost to follow-up	6	4
Protocol deviation	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects received single dose of placebo matched to PF-04950615 subcutaneous injection once in every 2 weeks over a period of 52 weeks. Subjects were followed up to 58 weeks.	
Reporting group title	PF-04950615 150 mg
Reporting group description:	
Subjects received single dose of PF-04950615 150 mg subcutaneous injection once in every 2 weeks over a period of 52 weeks. Subjects were followed up to 58 weeks.	

Reporting group values	Placebo	PF-04950615 150 mg	Total
Number of subjects	354	357	711
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)	201	212	413
From 65-84 years	153	144	297
85 years and over	0	1	1
Age Continuous Units: years			
arithmetic mean	61.5	61.1	
standard deviation	± 9.7	± 10.2	-
Gender, Male/Female Units: Subjects			
Female	130	136	266
Male	224	221	445

Confidence interval	
level	95 %
sides	2-sided
lower limit	-61
upper limit	-53.1
Variability estimate	Standard error of the mean
Dispersion value	2

Secondary: Percent Change From Baseline in Total Cholesterol (TC) at Week 12, 24 and 52

End point title	Percent Change From Baseline in Total Cholesterol (TC) at Week 12, 24 and 52

End point description:

FAS included all subjects who were randomized. Here, 'n' signifies those subjects who were evaluable at specified time points for each arm.

End point type	Secondary

End point timeframe:

Baseline, Week 12, 24, 52

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: percent change				
arithmetic mean (standard deviation)				
Week 12 (n =330, 340)	1 (± 14.85)	-35.1 (± 19.23)		
Week 24 (n =331, 337)	3.2 (± 19.35)	-31.7 (± 20.47)		
Week 52 (n =313, 315)	1.8 (± 18.5)	-27.3 (± 23.57)		

Statistical analyses

Statistical analysis title	Week 12

Statistical analysis description:

LS-mean difference, associated 95% confidence intervals and p values were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.

Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-36.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-38.8
upper limit	-33.6
Variability estimate	Standard error of the mean
Dispersion value	1.33

Statistical analysis title	Week 24
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-34.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37.7
upper limit	-31.7
Variability estimate	Standard error of the mean
Dispersion value	1.52

Statistical analysis title	Week 52
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.3
upper limit	-25.7
Variability estimate	Standard error of the mean
Dispersion value	1.69

Secondary: Percent Change From Baseline in Non-High Density Lipoprotein-Cholesterol (Non HDL-C) at Week 12, 24 and 52	
End point title	Percent Change From Baseline in Non-High Density Lipoprotein-Cholesterol (Non HDL-C) at Week 12, 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, 'n' signifies those subjects who were evaluable at specified time points for each arm.	
End point type	Secondary
End point timeframe:	
Baseline, Week 12, 24, 52	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: percent change				
arithmetic mean (standard deviation)				
Week 12 (n =330, 339)	1.3 (± 19.53)	-50 (± 26.28)		
Week 24 (n =329, 336)	4.7 (± 27.81)	-46.2 (± 28.52)		
Week 52 (n =312, 314)	2.3 (± 25.22)	-38.9 (± 33.32)		

Statistical analyses

Statistical analysis title	Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals and p values were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-51.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-55.2
upper limit	-48.1
Variability estimate	Standard error of the mean
Dispersion value	1.8

Statistical analysis title	Week 52
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-41.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-45.8
upper limit	-36.5
Variability estimate	Standard error of the mean
Dispersion value	2.38

Statistical analysis title	Week 24
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-50.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-54.9
upper limit	-46.4
Variability estimate	Standard error of the mean
Dispersion value	2.15

Secondary: Percent Change From Baseline in Apolipoprotein B (ApoB) at Week 12, 24 and 52

End point title	Percent Change From Baseline in Apolipoprotein B (ApoB) at Week 12, 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, ‘n’ signifies those subjects who were evaluable at specified time points for each arm.	

End point type	Secondary

End point timeframe:

Baseline, Week 12, 24, 52

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: percent change				
arithmetic mean (standard deviation)				
Week 12 (n =330, 339)	0.3 (± 19.1)	-51.1 (± 27.62)		
Week 24 (n =331, 335)	3.5 (± 22.39)	-47.3 (± 30.43)		
Week 52 (n =313, 313)	1.9 (± 22.25)	-39.1 (± 33.39)		

Statistical analyses

Statistical analysis title	Week 12

Statistical analysis description:

LS-mean difference, associated 95% confidence intervals and p values were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.

Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-51.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-55.1
upper limit	-47.9
Variability estimate	Standard error of the mean
Dispersion value	1.84

Statistical analysis title	Week 24

Statistical analysis description:

LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.

Comparison groups	Placebo v PF-04950615 150 mg

Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-50.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-54.6
upper limit	-46.6
Variability estimate	Standard error of the mean
Dispersion value	2.05

Statistical analysis title	Week 52
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-40.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-45.2
upper limit	-36.3
Variability estimate	Standard error of the mean
Dispersion value	2.26

Secondary: Percent Change From Baseline in Lipoprotein(a) at Week 12, 24 and 52	
End point title	Percent Change From Baseline in Lipoprotein(a) at Week 12, 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, ‘n’ signifies those subjects who were evaluable at specified time points for each arm.	
End point type	Secondary
End point timeframe:	
Baseline, Week 12, 24, 52	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: percent change				
arithmetic mean (standard deviation)				
Week 12 (n =330, 339)	4.7 (± 84.86)	1.9 (± 508.44)		
Week 24 (n =331, 336)	1.9 (± 51.82)	4.4 (± 465.24)		
Week 52 (n =311, 311)	1.1 (± 42.47)	17.3 (± 562.63)		

Statistical analyses

Statistical analysis title	Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals and p values were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.86
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-2.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.4
upper limit	29.5
Variability estimate	Standard error of the mean
Dispersion value	16.55

Statistical analysis title	Week 24
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	2.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-47.2
upper limit	51.4
Variability estimate	Standard error of the mean
Dispersion value	25.11

Statistical analysis title	Week 52
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	12.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.5
upper limit	70.4
Variability estimate	Standard error of the mean
Dispersion value	29.25

Secondary: Percent Change From Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 12, 24 and 52

End point title	Percent Change From Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 12, 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, 'n' signifies those subjects who were evaluable at specified time points for each arm.	
End point type	Secondary
End point timeframe:	
Baseline, Week 12, 24, 52	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: percent change				
arithmetic mean (standard deviation)				
Week 12 (n= 330, 339)	1.9 (± 17.24)	6.6 (± 14.24)		

Week 24 (n =329, 336)	1 (± 15.78)	7.8 (± 15.91)		
Week 52 (n =312, 314)	2 (± 15.73)	5.3 (± 16.59)		

Statistical analyses

Statistical analysis title	Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals and p values were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	4.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.4
upper limit	7
Variability estimate	Standard error of the mean
Dispersion value	1.19

Statistical analysis title	Week 24
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	6.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.5
upper limit	9.1
Variability estimate	Standard error of the mean
Dispersion value	1.18

Statistical analysis title	Week 52
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	5.8
Variability estimate	Standard error of the mean
Dispersion value	1.25

Secondary: Percent Change From Baseline in Fasting Low-Density Lipoprotein-Cholesterol (LDL-C) at Week 12 in Subjects With Primary Hyperlipidemia	
End point title	Percent Change From Baseline in Fasting Low-Density Lipoprotein-Cholesterol (LDL-C) at Week 12 in Subjects With Primary Hyperlipidemia
End point description:	
Subjects with primary hyperlipidemia was defined as subjects with triglycerides (TG) level less than (<) 200 mg/dL (2.26 mmol/L) at pre-randomization. FAS included all subjects who were randomized. Here, "number of subjects analyzed" signifies those subjects who were evaluable in this endpoint.	
End point type	Secondary
End point timeframe:	
Baseline, Week 12	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	262	266		
Units: percent change				
arithmetic mean (standard deviation)	1.5 (± 20.89)	-56.8 (± 27.78)		

Statistical analyses

Statistical analysis title	Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals and p values were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	528
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-59.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-63.4
upper limit	-54.8
Variability estimate	Standard error of the mean
Dispersion value	2.19

Secondary: Percent Change From Baseline in Fasting Low-Density Lipoprotein-Cholesterol (LDL-C) at Week 12 in Subjects With Mixed Dyslipidemia

End point title	Percent Change From Baseline in Fasting Low-Density Lipoprotein-Cholesterol (LDL-C) at Week 12 in Subjects With Mixed Dyslipidemia
End point description:	
Subjects with mixed dyslipidemia were defined as TG level >=200 mg/dL (2.26 mmol/L) at pre-randomization. FAS included all subjects who were randomized. Here, "number of subjects analyzed" signifies those subjects who were evaluable in this endpoint.	
End point type	Secondary
End point timeframe:	
Baseline, Week 12	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	70		
Units: percent change				
arithmetic mean (standard deviation)	-1 (± 20.95)	-50.9 (± 33.78)		

Statistical analyses

Statistical analysis title	Week 12

Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals and p values were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-48.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-58
upper limit	-39.3
Variability estimate	Standard error of the mean
Dispersion value	4.72

Secondary: Percent Change From Baseline in Fasting Low Density Lipoprotein-Cholesterol (LDL-C) at Week 24 and 52

End point title	Percent Change From Baseline in Fasting Low Density Lipoprotein-Cholesterol (LDL-C) at Week 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, 'n' signifies those subjects who were evaluable at specified time points for each arm.	
End point type	Secondary
End point timeframe:	
Baseline, Week 24, 52	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: percent change				
arithmetic mean (standard deviation)				
Week 24 (n =331, 336)	6.3 (± 32.52)	-50 (± 31.36)		
Week 52 (n =311, 313)	5.2 (± 29.69)	-40.9 (± 38.02)		

Statistical analyses

Statistical analysis title	Week 24
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed	

effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.

Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-60.8
upper limit	-51.2
Variability estimate	Standard error of the mean
Dispersion value	2.45

Statistical analysis title	Week 52

Statistical analysis description:

LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.

Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-46.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-51.8
upper limit	-41
Variability estimate	Standard error of the mean
Dispersion value	2.77

Secondary: Percent Change From Baseline in Fasting Low Density Lipoprotein Cholesterol (LDL-C) at Week 24 and 52 by Triglyceride Cut-off

End point title	Percent Change From Baseline in Fasting Low Density Lipoprotein Cholesterol (LDL-C) at Week 24 and 52 by Triglyceride Cut-off

End point description:

Percent change from baseline in fasting LDL-C among subjects with TG cut-off of <200 mg/dL and >=200 mg/dL (2.26 mmol/L) were reported in this endpoint. FAS included all subjects who were randomized. Here, ‘n’ signifies those subjects who were evaluable at specified time point for each arm.

End point type	Secondary

End point timeframe:

Baseline, Week 24, 52

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: percent change				
arithmetic mean (standard deviation)				
TG <200 mg/dL: Week 24 (n =261, 265)	7.2 (± 34.38)	-50.8 (± 30.9)		
TG <200 mg/dL: Week 52(n =243, 248)	6.2 (± 29.95)	-41.1 (± 38.35)		
TG >=200 mg/dL: Week 24(n =70, 71)	3 (± 24.3)	-46.9 (± 33.05)		
TG >=200 mg/dL: Week 52(n =68, 65)	2 (± 28.74)	-40.1 (± 37.01)		

Statistical analyses

Statistical analysis title	TG <200 mg/dL: Week 24

Statistical analysis description:

LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region.

Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-57.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-63.1
upper limit	-52
Variability estimate	Standard error of the mean
Dispersion value	2.82

Statistical analysis title	TG <200 mg/dL: Week 52

Statistical analysis description:

LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region.

Comparison groups	Placebo v PF-04950615 150 mg

Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-47.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-53.9
upper limit	-41.5
Variability estimate	Standard error of the mean
Dispersion value	3.16

Statistical analysis title	TG >=200 mg/dL: Week 24
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-49.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-58.9
upper limit	-39.8
Variability estimate	Standard error of the mean
Dispersion value	4.83

Statistical analysis title	TG >=200 mg/dL: Week 52
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-41.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-52.2
upper limit	-30.1

Variability estimate	Standard error of the mean
Dispersion value	5.6

Secondary: Percent Change From Baseline in Fasting Triglyceride (TG) at Week 12, 24 and 52

End point title	Percent Change From Baseline in Fasting Triglyceride (TG) at Week 12, 24 and 52

End point description:

FAS included all subjects who were randomized. Here, 'n' signifies those subjects who were evaluable at specified time points for each arm.

End point type	Secondary

End point timeframe:

Baseline, Week 12, 24, 52

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: percent change				
arithmetic mean (standard deviation)				
Week 12 (n =330, 340)	5.9 (± 34.9)	-9.4 (± 42)		
Week 24 (n =331, 336)	7 (± 37.79)	-13.8 (± 33.24)		
Week 52 (n =313, 315)	0.6 (± 38.33)	-9.3 (± 48.47)		

Statistical analyses

Statistical analysis title	Week 12

Statistical analysis description:

LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.

Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-14.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.9
upper limit	-8.5
Variability estimate	Standard error of the mean
Dispersion value	2.88

Statistical analysis title	Week 24
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-19.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.1
upper limit	-14.7
Variability estimate	Standard error of the mean
Dispersion value	2.65

Statistical analysis title	Week 52
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-9.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.7
upper limit	-2.8
Variability estimate	Standard error of the mean
Dispersion value	3.31

Secondary: Percent Change From Baseline in ApolipoproteinA-I (ApoA-I) at Week 12, 24 and 52

End point title	Percent Change From Baseline in ApolipoproteinA-I (ApoA-I) at Week 12, 24 and 52

End point description:

FAS included all subjects who were randomized. Here, ‘n’ signifies those subjects who were evaluable at specified time points for each arm.

End point type	Secondary

End point timeframe:

Baseline, Week 12, 24, 52

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: percent change				
arithmetic mean (standard deviation)				
Week 12 (n =330, 339)	-0.3 (± 14.05)	3.7 (± 12.56)		
Week 24 (n =331, 336)	-0.8 (± 12.77)	4.3 (± 12.25)		
Week 52 (n =313, 313)	0.4 (± 13.13)	3.3 (± 13)		

Statistical analyses

Statistical analysis title	Week 12

Statistical analysis description:

LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.

Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.8
upper limit	5.7
Variability estimate	Standard error of the mean
Dispersion value	1

Statistical analysis title	Week 24

Statistical analysis description:

LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.

Comparison groups	Placebo v PF-04950615 150 mg

Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.1
upper limit	6.7
Variability estimate	Standard error of the mean
Dispersion value	0.91

Statistical analysis title	Week 54
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	4.6
Variability estimate	Standard error of the mean
Dispersion value	0.98

Secondary: Percent Change From Baseline in ApolipoproteinA-II (ApoA-II) at Week 12, 24 and 52

End point title	Percent Change From Baseline in ApolipoproteinA-II (ApoA-II) at Week 12, 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, ‘n’ signifies those subjects who were evaluable at specified time points for each arm.	
End point type	Secondary
End point timeframe:	
Baseline, Week 12, 24, 52	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: percent change				
arithmetic mean (standard deviation)				
Week 12 (n =327, 339)	-1.8 (± 12.92)	-1.9 (± 12.1)		
Week 24 (n =331, 335)	-3.7 (± 14.4)	-1.9 (± 13.25)		
Week 52 (n =310, 310)	-3 (± 14.76)	-1.6 (± 12.91)		

Statistical analyses

Statistical analysis title	Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	1.7
Variability estimate	Standard error of the mean
Dispersion value	0.93

Statistical analysis title	Week 24
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	3.9

Variability estimate	Standard error of the mean
Dispersion value	1.02

Statistical analysis title	Week 52
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	3.1
Variability estimate	Standard error of the mean
Dispersion value	1.03

Secondary: Percent Change From Baseline in Very Low Density Lipoprotein-Cholesterol (VLDL-C) at Week 12, 24 and 52	
End point title	Percent Change From Baseline in Very Low Density Lipoprotein-Cholesterol (VLDL-C) at Week 12, 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, 'n' signifies those subjects who were evaluable at specified time points for each arm.	
End point type	Secondary
End point timeframe:	
Baseline, Week 12, 24, 52	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: percent change				
arithmetic mean (standard deviation)				
Week 12 (n =330, 340)	5.9 (± 34.9)	-9.4 (± 42)		
Week 24 (n =331, 336)	7 (± 37.79)	-13.8 (± 33.24)		
Week 52 (n =313, 315)	0.6 (± 38.33)	-9.3 (± 48.47)		

Statistical analyses

Statistical analysis title	Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS-Mean Difference
Point estimate	-14.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.9
upper limit	-8.5
Variability estimate	Standard error of the mean
Dispersion value	2.88

Statistical analysis title	Week 24
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-19.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.1
upper limit	-14.7
Variability estimate	Standard error of the mean
Dispersion value	2.65

Statistical analysis title	Week 52

Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-9.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.7
upper limit	-2.8
Variability estimate	Standard error of the mean
Dispersion value	3.31

Secondary: Absolute Change From Baseline in Fasting Low Density Lipoprotein-Cholesterol (LDL-C) at Week 12 by Trigylceride Cut-Off	
End point title	Absolute Change From Baseline in Fasting Low Density Lipoprotein-Cholesterol (LDL-C) at Week 12 by Trigylceride Cut-Off
End point description:	
Change from baseline in fasting LDL-C among subjects with TG cut-off of <200 mg/dL and >=200 mg/dL (2.26 mmol/L) were reported in this endpoint. FAS included all subjects who were randomized. Here, 'number of subjects analyzed' signifies those subjects who were evaluable in this endpoint and 'n' signifies those subjects who were evaluable at specified time points for each arm.	
End point type	Secondary
End point timeframe:	
Baseline, Week 12	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	353	357		
Units: mg/dL				
arithmetic mean (standard deviation)				
TG <200 mg/dL: Baseline (n =282, 282)	111.2 (± 31.28)	112.8 (± 36.42)		
TG <200 mg/dL: Change at Week12 (n =262, 266)	0.4 (± 22.6)	-63.4 (± 37.38)		
TG >=200 mg/dL: Baseline (n =71, 75)	126.5 (± 42.07)	125.7 (± 42.1)		

Statistical analyses

Statistical analysis title	TG <200 mg/dL: Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	710
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-64.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-69.1
upper limit	-59.2
Variability estimate	Standard error of the mean
Dispersion value	2.51

Statistical analysis title	TG >=200 mg/dL: Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	710
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-59.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-71.4
upper limit	-47.7
Variability estimate	Standard error of the mean
Dispersion value	5.99

Secondary: Absolute Change From Baseline in Fasting Low Density Lipoprotein-Cholesterol (LDL-C) at Week 12, 24 and 52

End point title	Absolute Change From Baseline in Fasting Low Density Lipoprotein-Cholesterol (LDL-C) at Week 12, 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, ‘n’ signifies those subjects who were evaluable at specified time points for each arm.	
End point type	Secondary

End point timeframe:
Baseline, Week 12, 24, 52

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: mg/dL				
arithmetic mean (standard deviation)				
Baseline (n =353, 357)	114.3 (± 34.22)	115.5 (± 37.99)		
Change at Week 12 (n =329, 336)	-0.2 (± 23.55)	-63.3 (± 39)		
Change at Week 24 (n =331, 336)	5.5 (± 33.14)	-56 (± 39.34)		
Change at Week 52 (n =311, 313)	3.9 (± 32.17)	-45.9 (± 46.43)		

Statistical analyses

Statistical analysis title	Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-63.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-68
upper limit	-58.8
Variability estimate	Standard error of the mean
Dispersion value	2.35

Secondary: Absolute Change From Baseline in Total Cholesterol (TC) at Week 12, 24 and 52

End point title	Absolute Change From Baseline in Total Cholesterol (TC) at Week 12, 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, ‘n’ signifies those subjects who were evaluable at specified time points for each arm.	
End point type	Secondary

End point timeframe:

Baseline, Week 12, 24, 52

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: mg/dL				
arithmetic mean (standard deviation)				
Baseline (n =354, 357)	186 (± 40.04)	189 (± 44.68)		
Change at Week 12 (n =330, 340)	0.6 (± 27.64)	-66.8 (± 42.38)		
Change at Week 24 (n =331, 337)	5.1 (± 35.83)	-60.1 (± 43.33)		
Change at Week 52 (n =313, 315)	1.8 (± 35.18)	-51.9 (± 49.68)		

Statistical analyses

Statistical analysis title	Week 12

Statistical analysis description:

LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.

Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-67.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-72.2
upper limit	-62.1
Variability estimate	Standard error of the mean
Dispersion value	2.59

Secondary: Absolute Change From Baseline in Non-High Density Lipoprotein Cholesterol (Non-HDL-C) at Week 12, 24 and 52

End point title	Absolute Change From Baseline in Non-High Density Lipoprotein Cholesterol (Non-HDL-C) at Week 12, 24 and 52

End point description:

FAS included all subjects who were randomized. Here, ‘n’ signifies those subjects who were evaluable at specified time points for each arm.

End point type	Secondary

End point timeframe:
Baseline, Week 12, 24, 52

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: mg/dL				
arithmetic mean (standard deviation)				
Baseline (n =354, 357)	137.2 (± 37.38)	140.1 (± 43.48)		
Change at Week 12 (n =330, 339)	0.3 (± 26.53)	-69.8 (± 43.53)		
Change at Week 24 (n =329, 336)	5.2 (± 35.91)	-63.6 (± 44.37)		
Change at Week 52 (n =312, 314)	1.3 (± 33.93)	-53.9 (± 51.1)		

Statistical analyses

Statistical analysis title	Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-69.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-74.7
upper limit	-64.6
Variability estimate	Standard error of the mean
Dispersion value	2.57

Secondary: Absolute Change From Baseline in Apolipoprotein-B (ApoB) at Week 12, 24 and 52

End point title	Absolute Change From Baseline in Apolipoprotein-B (ApoB) at Week 12, 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, 'n' signifies those subjects who were evaluable at specified time point for each arm.	
End point type	Secondary

End point timeframe:
Baseline, Week 12, 24, 52

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: mg/dL				
arithmetic mean (standard deviation)				
Baseline (n =354, 357)	94 (± 21.51)	95.1 (± 25.57)		
Change at Week 12 (n =330, 339)	-0.5 (± 17.32)	-47.9 (± 28.4)		
Change at Week 24 (n =331, 335)	2.5 (± 19.87)	-43.9 (± 29.95)		
Change at Week 52 (n =313, 313)	0.9 (± 20.59)	-36.4 (± 32.23)		

Statistical analyses

Statistical analysis title	Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-47.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-50.7
upper limit	-43.8
Variability estimate	Standard error of the mean
Dispersion value	1.74

Secondary: Absolute Change From Baseline in Lipoprotein(a) at Week 12, 24 and 52	
End point title	Absolute Change From Baseline in Lipoprotein(a) at Week 12, 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, 'n' signifies those subjects who were evaluable at specified time points for each arm.	
End point type	Secondary
End point timeframe:	
Baseline, Week 12, 24, 52	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: mg/dL				
arithmetic mean (standard deviation)				
Baseline (n =353, 356)	44 (± 45.93)	45.1 (± 52.3)		
Change at Week 12 (n =330, 339)	-0.6 (± 10.42)	-11.4 (± 22.19)		
Change at Week 24 (n =331, 336)	-1.2 (± 12.62)	-10.6 (± 20.16)		
Change at Week 52 (n =311, 311)	-1 (± 10.71)	-8.6 (± 23.78)		

Statistical analyses

Statistical analysis title	Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-10.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.9
upper limit	-8.3
Variability estimate	Standard error of the mean
Dispersion value	1.17

Secondary: Absolute Change From Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 12, 24 and 52

End point title	Absolute Change From Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 12, 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, ‘n’ signifies those subjects who were evaluable at specified time points for each arm.	
End point type	Secondary
End point timeframe:	
Baseline, Week 12, 24, 52	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: mg/dL				
arithmetic mean (standard deviation)				
Baseline (n =354, 357)	48.7 (± 12.52)	49 (± 13.23)		
Change at Week 12 (n =330, 339)	0.4 (± 7.5)	2.9 (± 6.92)		
Change at Week 24 (n =329, 336)	0 (± 7.9)	3.3 (± 7.41)		
Change at Week 52 (n =312, 314)	0.6 (± 7.59)	2.1 (± 8.32)		

Statistical analyses

Statistical analysis title	Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	3.5
Variability estimate	Standard error of the mean
Dispersion value	0.55

Secondary: Absolute Change From Baseline in Ratio of Fasting Total Cholesterol to High Density Lipoprotein-Cholesterol (TC/HDL-C ratio) at Week 12, 24 and 52

End point title	Absolute Change From Baseline in Ratio of Fasting Total Cholesterol to High Density Lipoprotein-Cholesterol (TC/HDL-C ratio) at Week 12, 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, ‘n’ signifies those subjects who were evaluable at specified time points for each arm.	
End point type	Secondary
End point timeframe:	
Baseline, Week 12, 24, 52	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: ratio				
arithmetic mean (standard deviation)				
Baseline (n =354, 357)	4 (± 1.1)	4.1 (± 1.26)		
Change at Week 12 (n =330, 339)	0 (± 0.71)	-1.6 (± 1.17)		
Change at Week 24 (n =329, 336)	0.1 (± 0.93)	-1.5 (± 1.21)		
Change at Week 52 (n =312, 314)	0 (± 0.85)	-1.2 (± 1.35)		

Statistical analyses

Statistical analysis title	Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	-1.4
Variability estimate	Standard error of the mean
Dispersion value	0.06

Statistical analysis title	Week 24
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg

Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	-1.4
Variability estimate	Standard error of the mean
Dispersion value	0.08

Statistical analysis title	Week 52
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	-1
Variability estimate	Standard error of the mean
Dispersion value	0.08

Secondary: Absolute Change From Baseline in Ratio of Apolipoprotein-B to ApolipoproteinA-I (ApoB/ApoA-I ratio) at Week 12, 24 and 52

End point title	Absolute Change From Baseline in Ratio of Apolipoprotein-B to ApolipoproteinA-I (ApoB/ApoA-I ratio) at Week 12, 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, ‘n’ signifies those subjects who were evaluable at specified time points for each arm.	
End point type	Secondary
End point timeframe:	
Baseline, Week 12, 24, 52	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: ratio				
arithmetic mean (standard deviation)				
Baseline (n =354, 357)	0.7 (± 0.18)	0.7 (± 0.21)		
Change at Week 12 (n =330, 339)	0 (± 0.12)	-0.3 (± 0.21)		
Change at Week 24 (n =331, 335)	0 (± 0.16)	-0.3 (± 0.24)		
Change at Week 52 (n =313, 313)	0 (± 0.14)	-0.3 (± 0.25)		

Statistical analyses

Statistical analysis title	Week 12
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	-0.3
Variability estimate	Standard error of the mean
Dispersion value	0.01

Statistical analysis title	Week 24
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	-0.3

Variability estimate	Standard error of the mean
Dispersion value	0.01

Statistical analysis title	Week 52
Statistical analysis description:	
LS-mean difference, associated 95% confidence intervals were derived from MMRM model with fixed effects for treatment group, visit, treatment group*visit interaction, baseline value, baseline value*visit interaction, geographical region, triglyceride subgroup.	
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS mean difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	-0.2
Variability estimate	Standard error of the mean
Dispersion value	0.02

Secondary: Percentage of Subjects Achieving Fasting Low Density Lipoprotein-Cholesterol (LDL-C) Less Than or Equal to (<=) 100 Milligram per Deciliter (2.59 Millimoles per Litre) at Week 12, 24 and 52

End point title	Percentage of Subjects Achieving Fasting Low Density Lipoprotein-Cholesterol (LDL-C) Less Than or Equal to (<=) 100 Milligram per Deciliter (2.59 Millimoles per Litre) at Week 12, 24 and 52
End point description:	
FAS included all subjects who were randomized. Here, 'n' signifies those subjects who were evaluable at specified time points for each arm.	
End point type	Secondary
End point timeframe:	
Week 12, 24 and 52	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: percentage of subjects				
number (not applicable)				
Week 12 (n =330, 336)	41.5	87.5		
Week 24 (n =332, 336)	37.3	82.1		
Week 52 (n =312, 313)	36.9	77.3		

Secondary: Percentage of Subjects Achieving Fasting Low Density Lipoprotein-Cholesterol (LDL-C) Less Than or Equal to (<=) 70 Milligram per Deciliter (1.81 Millimoles per Litre) at Week 12, 24 and 52	
End point title	Percentage of Subjects Achieving Fasting Low Density Lipoprotein-Cholesterol (LDL-C) Less Than or Equal to (<=) 70 Milligram per Deciliter (1.81 Millimoles per Litre) at Week 12, 24 and 52
End point description: FAS included all subjects who were randomized. Here, 'n' signifies those subjects who were evaluable at specified time point for each arm.	
End point type	Secondary
End point timeframe: Week 12, 24 and 52	

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: percentage of subjects				
number (not applicable)				
Week 12 (n =330, 336)	5.5	76.8		
Week 24 (n =332, 336)	3.3	69.6		
Week 52 (n =312, 313)	6.4	61.7		

Statistical analyses

Statistical analysis title	Week 12
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	95.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	52.09
upper limit	173.91

Statistical analysis title	Week 24
Comparison groups	Placebo v PF-04950615 150 mg

Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	112.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	55.81
upper limit	225.52

Statistical analysis title	Week 52
Comparison groups	Placebo v PF-04950615 150 mg
Number of subjects included in analysis	711
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	29.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.13
upper limit	49.49

Secondary: Plasma PF-04950615 Concentrations at Week 12, 24 and 52	
End point title	Plasma PF-04950615 Concentrations at Week 12, 24 and 52[1]
End point description:	
Analysis set included subjects who received at least 1 dose of PF-04950615. Here, 'n' signifies those subjects who were evaluable at specified time points.	
End point type	Secondary
End point timeframe:	
Week 12, 24, 52	
Notes:	
[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: No statistical analysis was performed for this endpoint.	

End point values	PF-04950615 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	356			
Units: microgram per milliliter				
arithmetic mean (standard deviation)				
Week 12 (n =332)	5.53 (± 5.666)			
Week 24 (n =327)	5.36 (± 6.029)			
Week 52 (n =306)	4.07 (± 4.947)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Adverse Events (AEs) Related to Type 1 or 3 Hypersensitivity Reactions and Injection Site Reactions

End point title	Number of Subjects With Adverse Events (AEs) Related to Type 1 or 3 Hypersensitivity Reactions and Injection Site Reactions

End point description:

Type 1 hypersensitivity or allergic reactions were possible in response to any injected protein and included shortness of breath, urticaria, anaphylaxis and angioedema. Type 3 hypersensitivity reactions were similar to Type 1 hypersensitivity reactions but were likely to be delayed from the time of injection and included symptoms such as rash, urticaria, polyarthritis, myalgia's, polysynovitis, fever and if severe then included glomerulonephritis as well. Injection site reactions included injection site bruising, discolouration, erythema, haematoma, haemorrhage, nodule, induration, pain, pruritus and rash. Subjects with type 1 or type 3 hypersensitivity reactions and participants with injection site reactions were reported in this endpoint. Safety analysis set included all subjects who received at least 1 dose of study treatment.

End point type	Secondary

End point timeframe:

Baseline up to the end of study (up to 58 weeks)

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	353	356		
Units: subjects				
Type 1 or 3 hypersensitivity reactions	2	1		
Injection site reactions	5	42		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PF-04950615 Anti-Drug Antibodies (ADA) and Neutralizing Antibodies (nAb)

End point title	Percentage of Subjects With PF-04950615 Anti-Drug Antibodies (ADA) and Neutralizing Antibodies (nAb)[2]

End point description:

Percentage of subjects with at least 1 positive ADA titer and 1 positive nAb titer were reported. Subjects with their ADA titer >=6.23 were considered to be ADA positive and participants with their nAb titer >=1.58 were considered to be nAb positive. Safety analysis set includes all subjects who received at least 1 dose of study treatment. Here, "number of subjects analyzed" signifies those subjects who were evaluable in this endpoint.

End point type	Secondary

End point timeframe:

Baseline up to the end of study (up to 58 weeks)

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: No statistical analysis was performed for this endpoint.

End point values	PF-04950615 150 mg			
Subject group type	Reporting group			
Number of subjects analysed	352			
Units: percentage of subjects				
ADA	44			
nAb	27			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Absolute Change From Baseline in Triglyceride (TG) at Week 12, 24 and 52

End point title	Absolute Change From Baseline in Triglyceride (TG) at Week 12, 24 and 52

End point description:

FAS included all subjects who were randomized. Here, 'n' signifies those subjects who were evaluable at specified time points for each arm.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 12, 24, 52

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: mg/dL				
arithmetic mean (standard deviation)				
Baseline (n =354, 357)	149.5 (± 66.83)	156.2 (± 78.75)		
Change at Week 12 (n =330, 340)	3.8 (± 57.04)	-23 (± 71.52)		
Change at Week 24 (n =331, 336)	5 (± 64.34)	-28.9 (± 68.41)		
Change at Week 52 (n =313, 315)	-7.7 (± 64.14)	-24.3 (± 82.21)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Absolute Change From Baseline in ApolipoproteinA-I (ApoA-I) at Week 12, 24 and 52

End point title	Absolute Change From Baseline in ApolipoproteinA-I (ApoA-I) at Week 12, 24 and 52

End point description:

FAS included all subjects who were randomized. Here, 'n' signifies those subjects who were evaluable at specified time points for each arm.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 12, 24, 52

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: mg/dL				
arithmetic mean (standard deviation)				
Baseline (n =354, 357)	147.5 (± 24.25)	147.2 (± 24.96)		
Change at Week 12 (n =330, 339)	-1.2 (± 19.46)	4.6 (± 18.32)		
Change at Week 24 (n =331, 336)	-2.3 (± 19.33)	5.6 (± 17.53)		
Change at Week 52 (n =313, 313)	-0.2 (± 19.56)	3.8 (± 18.86)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Absolute Change From Baseline in ApolipoproteinA-II (ApoA-II) at Week 12, 24 and 52

End point title	Absolute Change From Baseline in ApolipoproteinA-II (ApoA-II) at Week 12, 24 and 52

End point description:

FAS included all subjects who were randomized. Here, 'n' signifies those subjects who were evaluable at specified time points for each arm.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 12, 24, 52

End point values	Placebo	PF-04950615 150 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	357		
Units: mg/dL				
arithmetic mean (standard deviation)				
Baseline (n =353, 356)	38.1 (± 6.46)	38.2 (± 6.58)		
Change at Week 12 (n =327, 339)	-0.9 (± 4.95)	-0.9 (± 4.63)		
Change at Week 24 (n =331, 335)	-1.7 (± 5.65)	-1 (± 5.07)		
Change at Week 52 (n =310, 310)	-1.5 (± 5.54)	-0.9 (± 5.15)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to the end of study (up to 58 weeks)

Adverse event reporting additional description:

The same events may occur as both an adverse event (AE) and a serious adverse event (SAE). However, what is presented are distinct events. An event may be categorized as serious in one subject and as nonserious in another subject, or one subject may have experienced both a serious and nonserious event during the study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects received single dose of placebo matched to PF-04950615 subcutaneous injection once in every 2 weeks over a period of 52 weeks. Subjects were followed up to 58 weeks.

Reporting group title	PF-04950615 150 mg

Reporting group description:

Subjects received single dose of PF-04950615 150 mg subcutaneous injection once in every 2 weeks over a period of 52 weeks. Subjects were followed up to 58 weeks.

Serious adverse events	Placebo	PF-04950615 150 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	40 / 353 (11.33%)	45 / 356 (12.64%)	
number of deaths (all causes)	3	2	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder cancer			
subjects affected / exposed	0 / 353 (0.00%)	2 / 356 (0.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			

subjects affected / exposed	2 / 353 (0.57%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Malignant melanoma of sites other than skin			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to central nervous system			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Prostate cancer	Additional description: This is gender specific event. The number of subjects evaluable for this event were 224 and 221.		
subjects affected / exposed[1]	1 / 224 (0.45%)	0 / 221 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic aneurysm rupture			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Peripheral vascular disorder			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	2 / 353 (0.57%)	4 / 356 (1.12%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	3 / 353 (0.85%)	2 / 356 (0.56%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Completed suicide			

subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Suicidal behaviour			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Craniocerebral injury			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 353 (0.00%)	2 / 356 (0.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	1 / 353 (0.28%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	1 / 353 (0.28%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			

subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	1 / 353 (0.28%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft complication			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	2 / 353 (0.57%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	1 / 353 (0.28%)	3 / 356 (0.84%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			

subjects affected / exposed	1 / 353 (0.28%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	2 / 353 (0.57%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	2 / 353 (0.57%)	2 / 356 (0.56%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	3 / 353 (0.85%)	5 / 356 (1.40%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Myocardial ischaemia			
subjects affected / exposed	1 / 353 (0.28%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Silent myocardial infarction			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			

Anaemia			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Retinal aneurysm			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal haemorrhage			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Faecaloma			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Large intestine polyp			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery stenosis			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 353 (0.57%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Bursitis			

subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	1 / 353 (0.28%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			

subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis infective			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	1 / 353 (0.28%)	2 / 356 (0.56%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis staphylococcal			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis B			

subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 353 (0.28%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	1 / 353 (0.28%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 353 (0.57%)	0 / 356 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			

subjects affected / exposed	0 / 353 (0.00%)	1 / 356 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	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: This is gender specific event. The number of subjects evaluable for this event were 224 and 221.

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Placebo	PF-04950615 150 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	185 / 353 (52.41%)	205 / 356 (57.58%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	4 / 353 (1.13%)	1 / 356 (0.28%)	
occurrences (all)	4	1	
Vascular disorders			
Hypertension			
subjects affected / exposed	11 / 353 (3.12%)	12 / 356 (3.37%)	
occurrences (all)	12	12	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	4 / 353 (1.13%)	2 / 356 (0.56%)	
occurrences (all)	4	2	
Fatigue			
subjects affected / exposed	5 / 353 (1.42%)	7 / 356 (1.97%)	
occurrences (all)	6	8	
Injection site bruising			
subjects affected / exposed	2 / 353 (0.57%)	5 / 356 (1.40%)	
occurrences (all)	3	9	
Injection site erythema			
subjects affected / exposed	3 / 353 (0.85%)	9 / 356 (2.53%)	
occurrences (all)	3	17	
Injection site haemorrhage			
subjects affected / exposed	2 / 353 (0.57%)	4 / 356 (1.12%)	
occurrences (all)	5	5	
Injection site pain			

subjects affected / exposed	4 / 353 (1.13%)	6 / 356 (1.69%)	
occurrences (all)	32	8	
Injection site pruritus			
subjects affected / exposed	0 / 353 (0.00%)	4 / 356 (1.12%)	
occurrences (all)	0	4	
Injection site reaction			
subjects affected / exposed	5 / 353 (1.42%)	42 / 356 (11.80%)	
occurrences (all)	7	175	
Non-cardiac chest pain			
subjects affected / exposed	5 / 353 (1.42%)	1 / 356 (0.28%)	
occurrences (all)	7	1	
Pain			
subjects affected / exposed	5 / 353 (1.42%)	0 / 356 (0.00%)	
occurrences (all)	5	0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia	Additional description: This is gender specific event. The number of subjects evaluable for this event were 224 and 221.		
subjects affected / exposed[2]	3 / 224 (1.34%)	1 / 221 (0.45%)	
occurrences (all)	3	1	
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	3 / 353 (0.85%)	6 / 356 (1.69%)	
occurrences (all)	3	7	
Cough			
subjects affected / exposed	9 / 353 (2.55%)	8 / 356 (2.25%)	
occurrences (all)	10	8	
Dyspnoea			
subjects affected / exposed	6 / 353 (1.70%)	3 / 356 (0.84%)	
occurrences (all)	6	3	
Sleep apnoea syndrome			
subjects affected / exposed	2 / 353 (0.57%)	4 / 356 (1.12%)	
occurrences (all)	2	4	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	5 / 353 (1.42%)	1 / 356 (0.28%)	
occurrences (all)	5	1	

Depression			
subjects affected / exposed	3 / 353 (0.85%)	6 / 356 (1.69%)	
occurrences (all)	3	6	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	4 / 353 (1.13%)	0 / 356 (0.00%)	
occurrences (all)	4	0	
Blood cortisol decreased			
subjects affected / exposed	5 / 353 (1.42%)	6 / 356 (1.69%)	
occurrences (all)	5	7	
Blood creatine phosphokinase increased			
subjects affected / exposed	4 / 353 (1.13%)	3 / 356 (0.84%)	
occurrences (all)	4	3	
Gamma-glutamyltransferase increased			
subjects affected / exposed	6 / 353 (1.70%)	1 / 356 (0.28%)	
occurrences (all)	6	1	
Vitamin D decreased			
subjects affected / exposed	3 / 353 (0.85%)	5 / 356 (1.40%)	
occurrences (all)	3	5	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	2 / 353 (0.57%)	4 / 356 (1.12%)	
occurrences (all)	2	4	
Fall			
subjects affected / exposed	13 / 353 (3.68%)	10 / 356 (2.81%)	
occurrences (all)	13	11	
Muscle strain			
subjects affected / exposed	1 / 353 (0.28%)	5 / 356 (1.40%)	
occurrences (all)	1	6	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	4 / 353 (1.13%)	5 / 356 (1.40%)	
occurrences (all)	4	5	
Palpitations			

subjects affected / exposed	2 / 353 (0.57%)	4 / 356 (1.12%)	
occurrences (all)	2	5	
Nervous system disorders			
Dizziness			
subjects affected / exposed	12 / 353 (3.40%)	1 / 356 (0.28%)	
occurrences (all)	12	1	
Headache			
subjects affected / exposed	14 / 353 (3.97%)	8 / 356 (2.25%)	
occurrences (all)	14	8	
Hypoaesthesia			
subjects affected / exposed	4 / 353 (1.13%)	1 / 356 (0.28%)	
occurrences (all)	4	1	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	4 / 353 (1.13%)	4 / 356 (1.12%)	
occurrences (all)	4	4	
Constipation			
subjects affected / exposed	4 / 353 (1.13%)	8 / 356 (2.25%)	
occurrences (all)	5	8	
Diarrhoea			
subjects affected / exposed	6 / 353 (1.70%)	12 / 356 (3.37%)	
occurrences (all)	7	13	
Dyspepsia			
subjects affected / exposed	4 / 353 (1.13%)	1 / 356 (0.28%)	
occurrences (all)	4	1	
Gastrooesophageal reflux disease			
subjects affected / exposed	5 / 353 (1.42%)	3 / 356 (0.84%)	
occurrences (all)	5	3	
Nausea			
subjects affected / exposed	7 / 353 (1.98%)	7 / 356 (1.97%)	
occurrences (all)	8	9	
Vomiting			
subjects affected / exposed	5 / 353 (1.42%)	4 / 356 (1.12%)	
occurrences (all)	5	7	
Skin and subcutaneous tissue disorders			

Rash			
subjects affected / exposed	4 / 353 (1.13%)	3 / 356 (0.84%)	
occurrences (all)	4	3	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	7 / 353 (1.98%)	13 / 356 (3.65%)	
occurrences (all)	8	15	
Back pain			
subjects affected / exposed	8 / 353 (2.27%)	15 / 356 (4.21%)	
occurrences (all)	9	17	
Muscle spasms			
subjects affected / exposed	8 / 353 (2.27%)	4 / 356 (1.12%)	
occurrences (all)	9	5	
Musculoskeletal pain			
subjects affected / exposed	5 / 353 (1.42%)	7 / 356 (1.97%)	
occurrences (all)	5	7	
Myalgia			
subjects affected / exposed	9 / 353 (2.55%)	8 / 356 (2.25%)	
occurrences (all)	9	9	
Osteoarthritis			
subjects affected / exposed	3 / 353 (0.85%)	5 / 356 (1.40%)	
occurrences (all)	3	5	
Pain in extremity			
subjects affected / exposed	11 / 353 (3.12%)	5 / 356 (1.40%)	
occurrences (all)	12	5	
Tendonitis			
subjects affected / exposed	2 / 353 (0.57%)	4 / 356 (1.12%)	
occurrences (all)	2	4	
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	3 / 353 (0.85%)	5 / 356 (1.40%)	
occurrences (all)	4	5	
Bronchitis			
subjects affected / exposed	14 / 353 (3.97%)	13 / 356 (3.65%)	
occurrences (all)	16	13	
Cellulitis			

subjects affected / exposed	4 / 353 (1.13%)	2 / 356 (0.56%)	
occurrences (all)	4	2	
Gastroenteritis			
subjects affected / exposed	8 / 353 (2.27%)	2 / 356 (0.56%)	
occurrences (all)	8	2	
Herpes zoster			
subjects affected / exposed	3 / 353 (0.85%)	4 / 356 (1.12%)	
occurrences (all)	3	4	
Influenza			
subjects affected / exposed	7 / 353 (1.98%)	10 / 356 (2.81%)	
occurrences (all)	7	13	
Nasopharyngitis			
subjects affected / exposed	27 / 353 (7.65%)	26 / 356 (7.30%)	
occurrences (all)	32	31	
Pharyngitis			
subjects affected / exposed	3 / 353 (0.85%)	6 / 356 (1.69%)	
occurrences (all)	5	6	
Pneumonia			
subjects affected / exposed	1 / 353 (0.28%)	8 / 356 (2.25%)	
occurrences (all)	1	8	
Rhinitis			
subjects affected / exposed	1 / 353 (0.28%)	4 / 356 (1.12%)	
occurrences (all)	1	4	
Sinusitis			
subjects affected / exposed	5 / 353 (1.42%)	10 / 356 (2.81%)	
occurrences (all)	5	10	
Upper respiratory tract infection			
subjects affected / exposed	19 / 353 (5.38%)	14 / 356 (3.93%)	
occurrences (all)	23	17	
Urinary tract infection			
subjects affected / exposed	6 / 353 (1.70%)	11 / 356 (3.09%)	
occurrences (all)	6	14	
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	3 / 353 (0.85%)	4 / 356 (1.12%)	
occurrences (all)	3	4	

Hypoglycaemia			
subjects affected / exposed	4 / 353 (1.13%)	5 / 356 (1.40%)	
occurrences (all)	4	6	
Type 2 diabetes mellitus			
subjects affected / exposed	5 / 353 (1.42%)	4 / 356 (1.12%)	
occurrences (all)	5	4	
Vitamin D deficiency			
subjects affected / exposed	36 / 353 (10.20%)	19 / 356 (5.34%)	
occurrences (all)	36	19	

Notes:

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This is gender specific event. The number of subjects evaluable for this event were 224 and 221.