

**Clinical trial results:****A PHASE 2 MULTI-CENTER, RANDOMIZED, DOUBLE-MASKED, PLACEBO CONTROLLED, MULTI-DOSE STUDY TO INVESTIGATE THE EFFICACY, SAFETY, PHARMACOKINETICS AND PHARMACODYNAMICS OF RN6G (PF 04382923) IN SUBJECTS WITH GEOGRAPHIC ATROPHY SECONDARY TO AGE-RELATED MACULAR DEGENERATION****Summary**

EudraCT number	2012-000823-42
Trial protocol	DE GB IT
Global end of trial date	10 October 2013

Results information

Result version number	v1 (current)
This version publication date	29 June 2016
First version publication date	12 July 2015

Trial information**Trial identification**

Sponsor protocol code	B1181003
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01577381
WHO universal trial number (UTN)	-
Other trial identifiers	US IND Number : 102691

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, 10017
Public contact	Clinical Trials.gov Call Center, Pfizer Inc, +1 8007181021, ClinicalTrials.govCallCenter@pfizer.com
Scientific contact	Clinical Trials.gov Call Center, Pfizer Inc, +1 8007181021, ClinicalTrials.govCallCenter@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	15 September 2014
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	10 October 2013
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To determine the efficacy of RN6G (PF-04382923) in subjects with geographic atrophy in the study eye.

Protection of trial subjects:

This study used an External Data Monitoring Committee (E-DMC). The E-DMC (consisted of physicians, ophthalmologists, safety specialists and statisticians) was responsible for ongoing safety monitoring of subjects in the study and may review efficacy in the context of risk-benefit assessment.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 June 2012
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	United States: 10
Worldwide total number of subjects	10
EEA total number of subjects	0

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)	2
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study was conducted in the United States of America (USA). Eligible subjects were men and women (of non-childbearing potential) between the ages of 60 and 90 years with a diagnosis of a well-demarcated area of geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD).

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

Arms

Are arms mutually exclusive?	Yes
Arm title	PF-04382923 2.5 mg/kg

Arm description:

PF-04382923 (RN6G) at 2.5 milligrams per kilogram (mg/kg) was administered as an intravenous (IV) infusion over 30 minutes every 28 days for 11 doses.

Arm type	Experimental
Investigational medicinal product name	PF-04382923
Investigational medicinal product code	
Other name	RN6G
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

IV infusion over at least 30 minutes every 28 days for 11 doses.

Arm title	PF-04382923 7.5 mg/kg
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Arm description:

PF-04382923 at 7.5 mg/kg was administered as an IV infusion over 30 minutes every 28 days for 11 doses.

Arm type	Experimental
Investigational medicinal product name	PF-04382923
Investigational medicinal product code	
Other name	RN6G
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

IV infusion over at least 30 minutes every 28 days for 11 doses.

Arm title	PF-04382923 15.0 mg/kg
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Arm description:

PF-04382923 at 15.0 mg/kg was administered as an IV infusion over 30 minutes every 28 days for 11 doses.

Arm type	Experimental
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Investigational medicinal product name	PF-04382923
Investigational medicinal product code	
Other name	RN6G
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

IV infusion over at least 30 minutes every 28 days for 11 doses.

Arm title	Placebo
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Arm description:

Placebo was administered as an IV infusion over at least 30 minutes every 28 days for 11 doses.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

IV infusion over at least 30 minutes every 28 days for 11 doses.

Number of subjects in period 1	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg
Started	2	3	3
Completed	0	0	0
Not completed	2	3	3
Consent withdrawn by subject	2	1	2
Ongoing at Date of Cut-Off	-	2	1

Number of subjects in period 1	Placebo
Started	2
Completed	0
Not completed	2
Consent withdrawn by subject	2
Ongoing at Date of Cut-Off	-

Baseline characteristics

Reporting groups

Reporting group title	PF-04382923 2.5 mg/kg
Reporting group description:	PF-04382923 (RN6G) at 2.5 milligrams per kilogram (mg/kg) was administered as an intravenous (IV) infusion over 30 minutes every 28 days for 11 doses.
Reporting group title	PF-04382923 7.5 mg/kg
Reporting group description:	PF-04382923 at 7.5 mg/kg was administered as an IV infusion over 30 minutes every 28 days for 11 doses.
Reporting group title	PF-04382923 15.0 mg/kg
Reporting group description:	PF-04382923 at 15.0 mg/kg was administered as an IV infusion over 30 minutes every 28 days for 11 doses.
Reporting group title	Placebo
Reporting group description:	Placebo was administered as an IV infusion over at least 30 minutes every 28 days for 11 doses.

Reporting group values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg
Number of subjects	2	3	3
Age categorical Units: Subjects			
Adults (18-64 years)	0	1	1
From 65-84 years	2	2	2
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	82.5	71	74
standard deviation	± 0.7	± 6.2	± 12.2
Gender categorical Units: Subjects			
Female	1	3	3
Male	1	0	0

Reporting group values	Placebo	Total	
Number of subjects	2	10	
Age categorical Units: Subjects			
Adults (18-64 years)	0	2	
From 65-84 years	2	8	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	73	-	
standard deviation	± 11.3	-	
Gender categorical Units: Subjects			
Female	0	7	

Male	2	3	
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End points

End points reporting groups

Reporting group title	PF-04382923 2.5 mg/kg
Reporting group description: PF-04382923 (RN6G) at 2.5 milligrams per kilogram (mg/kg) was administered as an intravenous (IV) infusion over 30 minutes every 28 days for 11 doses.	
Reporting group title	PF-04382923 7.5 mg/kg
Reporting group description: PF-04382923 at 7.5 mg/kg was administered as an IV infusion over 30 minutes every 28 days for 11 doses.	
Reporting group title	PF-04382923 15.0 mg/kg
Reporting group description: PF-04382923 at 15.0 mg/kg was administered as an IV infusion over 30 minutes every 28 days for 11 doses.	
Reporting group title	Placebo
Reporting group description: Placebo was administered as an IV infusion over at least 30 minutes every 28 days for 11 doses.	

Primary: Mean Reduction (in Study Eye) in Rate of Geographic Atrophy (GA) at Day 309

End point title	Mean Reduction (in Study Eye) in Rate of Geographic Atrophy (GA) at Day 309 ^[1]
End point description: GA is the advanced form of dry age-related macular degeneration (AMD). The reduction in GA area of the study eye was based on Fundus Autofluorescence (FAF) at 30 days post last dose administration (Day 309).	
End point type	Primary
End point timeframe: Baseline and Day 309	
Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: Analysis of GA reduction was not performed due to early study termination.	

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[2]	0 ^[3]	0 ^[4]	0 ^[5]
Units: square millimeter per month (mm ² /month)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[2] - Analysis of GA reduction was not performed due to early study termination.

[3] - Analysis of GA reduction was not performed due to early study termination.

[4] - Analysis of GA reduction was not performed due to early study termination.

[5] - Analysis of GA reduction was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Primary: Mean Reduction (in Study Eye) in Rate of Growth of GA at Day 449 (End of Study)

End point title	Mean Reduction (in Study Eye) in Rate of Growth of GA at Day 449 (End of Study) ^[6]
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End point description:

GA is the advanced form of dry AMD. The reduction in GA area in the study eye was based on FAF at end of study (Day 449).

End point type	Primary
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End point timeframe:

Baseline and Day 449

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Analysis of GA reduction was not performed due to early study termination.

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[7]	0 ^[8]	0 ^[9]	0 ^[10]
Units: mm ² / month				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[7] - Analysis of GA reduction was not performed due to early study termination.

[8] - Analysis of GA reduction was not performed due to early study termination.

[9] - Analysis of GA reduction was not performed due to early study termination.

[10] - Analysis of GA reduction was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Best Corrected Visual Acuity (BCVA) at 9, 12, 15 Months and End of Study

End point title	Mean Best Corrected Visual Acuity (BCVA) at 9, 12, 15 Months and End of Study
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End point description:

BCVA is measured using an eye chart and is reported as the number of letters read correctly (ranging from 0 to 100 letters) in the study eye. The lower the number of letters read correctly on the eye chart, the worse the vision (or visual acuity).

End point type	Secondary
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End point timeframe:

Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[11]	0 ^[12]	0 ^[13]	0 ^[14]
Units: correct letters read				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[11] - Analysis of BCVA was not performed due to early study termination.

[12] - Analysis of BCVA was not performed due to early study termination.

[13] - Analysis of BCVA was not performed due to early study termination.

[14] - Analysis of BCVA was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change From Baseline in BCVA Correct Number of Letters at 9, 12, 15 Months and End of Study

End point title	Percentage Change From Baseline in BCVA Correct Number of Letters at 9, 12, 15 Months and End of Study
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End point description:

BCVA is measured using an eye chart and is reported as the number of letters read correctly (ranging from 0 to 100 letters) in the study eye. The lower the number of letters read correctly on the eye chart, the worse the vision (or visual acuity).

End point type	Secondary
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End point timeframe:

Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[15]	0 ^[16]	0 ^[17]	0 ^[18]
Units: percent change				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[15] - Analysis of BCVA was not performed due to early study termination.

[16] - Analysis of BCVA was not performed due to early study termination.

[17] - Analysis of BCVA was not performed due to early study termination.

[18] - Analysis of BCVA was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change From Baseline in BCVA Correct Number of Lines at Months 9, 12, 15 Months and End of Study

End point title	Percentage Change From Baseline in BCVA Correct Number of
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End point description:

BCVA is measured using an eye chart and is reported as the number of lines read correctly in the study eye. The lower the number of lines read correctly on the eye chart, the worse the vision (or visual acuity).

End point type Secondary

End point timeframe:

Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[19]	0 ^[20]	0 ^[21]	0 ^[22]
Units: percent change				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[19] - Analysis of BCVA was not performed due to early study termination.

[20] - Analysis of BCVA was not performed due to early study termination.

[21] - Analysis of BCVA was not performed due to early study termination.

[22] - Analysis of BCVA was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Low Luminance Best Corrected Visual Acuity (LL-BCVA) at 9, 12, 15 Months and End of Study

End point title Mean Low Luminance Best Corrected Visual Acuity (LL-BCVA) at 9, 12, 15 Months and End of Study

End point description:

LL-BCVA is the measure of visual acuity under low light conditions.

End point type Secondary

End point timeframe:

Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[23]	0 ^[24]	0 ^[25]	0 ^[26]
Units: correct letters read				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[23] - Analysis of LL-BCVA was not performed due to early study termination.

[24] - Analysis of LL-BCVA was not performed due to early study termination.

[25] - Analysis of LL-BCVA was not performed due to early study termination.

[26] - Analysis of LL-BCVA was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change From Baseline in LL-BCVA Correct Number of Letters at 9, 12, 15 Months and End of Study

End point title	Percentage Change From Baseline in LL-BCVA Correct Number of Letters at 9, 12, 15 Months and End of Study
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End point description:

LL-BCVA is the measure of visual acuity under low light conditions.

End point type	Secondary
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End point timeframe:

Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[27]	0 ^[28]	0 ^[29]	0 ^[30]
Units: percent change				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[27] - Analysis of LL-BCVA was not performed due to early study termination.

[28] - Analysis of LL-BCVA was not performed due to early study termination.

[29] - Analysis of LL-BCVA was not performed due to early study termination.

[30] - Analysis of LL-BCVA was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change From Baseline in LL-BCVA Correct Number of Lines at 9, 12, 15 Months and End of Study

End point title	Percentage Change From Baseline in LL-BCVA Correct Number of Lines at 9, 12, 15 Months and End of Study
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End point description:

LL-BCVA is the measure of visual acuity under low light conditions.

End point type	Secondary
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End point timeframe:

Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[31]	0 ^[32]	0 ^[33]	0 ^[34]
Units: percent change				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[31] - Analysis of LL-BCVA was not performed due to early study termination.

[32] - Analysis of LL-BCVA was not performed due to early study termination.

[33] - Analysis of LL-BCVA was not performed due to early study termination.

[34] - Analysis of LL-BCVA was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Contrast Sensitivity at 9, 12, 15 Months and End of Study

End point title	Change From Baseline in Contrast Sensitivity at 9, 12, 15 Months and End of Study
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End point description:

Contrast sensitivity was measured using the Pelli-Robson chart at 1 meter. Participants were tested for contrast sensitivity using +0.50 addition over the protocol refraction providing the best-corrected distance VA. Contrast sensitivity was recorded as the log of the faintest triplet for which 2 of the 3 letters were read correctly.

End point type	Secondary
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End point timeframe:

Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[35]	0 ^[36]	0 ^[37]	0 ^[38]
Units: Logmar units				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[35] - Analysis of contrast sensitivity was not performed due to early study termination.

[36] - Analysis of contrast sensitivity was not performed due to early study termination.

[37] - Analysis of contrast sensitivity was not performed due to early study termination.

[38] - Analysis of contrast sensitivity was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change From Baseline in Contrast Sensitivity at 9, 12, 15 Months and End of Study

End point title	Percentage Change From Baseline in Contrast Sensitivity at 9, 12, 15 Months and End of Study
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End point description:

Contrast sensitivity was measured using the Pelli-Robson chart at 1 meter. Subjects were tested for contrast sensitivity using +0.50 addition over the protocol refraction providing the best-corrected distance VA. Contrast sensitivity was recorded as the log of the faintest triplet for which 2 of the 3 letters were read correctly.

End point type	Secondary
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End point timeframe:

Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[39]	0 ^[40]	0 ^[41]	0 ^[42]
Units: percent change				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[39] - Analysis of contrast sensitivity was not performed due to early study termination.

[40] - Analysis of contrast sensitivity was not performed due to early study termination.

[41] - Analysis of contrast sensitivity was not performed due to early study termination.

[42] - Analysis of contrast sensitivity was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Reading Speed at 9, 12, 15 Months and End of Study

End point title	Change From Baseline in Reading Speed at 9, 12, 15 Months and End of Study
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End point description:

Reading speed in the study eye was assessed using modified Bailey-Lovie word charts. Participants read the chart for 2 minutes and the number of words read correctly per minute was totaled. An increase in the number of words read correctly indicated an improvement and a decrease in the number of words read correctly indicated a worsening.

End point type	Secondary
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End point timeframe:

Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[43]	0 ^[44]	0 ^[45]	0 ^[46]
Units: correct words read per minute				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[43] - Analysis of reading speed was not performed due to early study termination.

[44] - Analysis of reading speed was not performed due to early study termination.

[45] - Analysis of reading speed was not performed due to early study termination.

[46] - Analysis of reading speed was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Placebo in Reading Speed at 9, 12, 15 Months and End of Study

End point title	Change From Placebo in Reading Speed at 9, 12, 15 Months and End of Study
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End point description:

Reading speed in the study eye was assessed using modified Bailey-Lovie word charts. Participants read the chart for 2 minutes and the number of words read correctly per minute was totaled. An increase in the number of words read correctly indicated an improvement and a decrease in the number of words read correctly indicated a worsening.

End point type	Secondary
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End point timeframe:

Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[47]	0 ^[48]	0 ^[49]	0 ^[50]
Units: correct words read per minute				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[47] - Analysis of reading speed was not performed due to early study termination.

[48] - Analysis of reading speed was not performed due to early study termination.

[49] - Analysis of reading speed was not performed due to early study termination.

[50] - Analysis of reading speed was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change From Baseline in Reading Speed at 9, 12, 15 Months and End of Study

End point title	Percentage Change From Baseline in Reading Speed at 9, 12, 15 Months and End of Study
End point description:	Reading speed in the study eye was assessed using modified Bailey-Lovie word charts. Participants read the chart for 2 minutes and the number of words read correctly per minute was totaled. An increase in the number of words read correctly indicated an improvement and a decrease in the number of words read correctly indicated a worsening.
End point type	Secondary
End point timeframe:	Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[51]	0 ^[52]	0 ^[53]	0 ^[54]
Units: percent change				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[51] - Analysis of reading speed was not performed due to early study termination.

[52] - Analysis of reading speed was not performed due to early study termination.

[53] - Analysis of reading speed was not performed due to early study termination.

[54] - Analysis of reading speed was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Reading Acuity at 9, 12, 15 Months and End of Study

End point title	Change From Baseline in Reading Acuity at 9, 12, 15 Months and End of Study
End point description:	Reading Acuity was measured using the Radner reading charts and expressed in terms of logRAD (logarithmic Reading Acuity Determination).
End point type	Secondary
End point timeframe:	Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[55]	0 ^[56]	0 ^[57]	0 ^[58]
Units: LogRAD				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[55] - Analysis of reading acuity was not performed due to early study termination.

[56] - Analysis of reading acuity was not performed due to early study termination.

[57] - Analysis of reading acuity was not performed due to early study termination.

[58] - Analysis of reading acuity was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Placebo in Reading Acuity at 9, 12, 15 Months and End of Study

End point title	Change From Placebo in Reading Acuity at 9, 12, 15 Months and End of Study
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End point description:

Reading Acuity was measured using the Radner reading charts and expressed in terms of logRAD.

End point type	Secondary
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End point timeframe:

Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[59]	0 ^[60]	0 ^[61]	0 ^[62]
Units: logRAD				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[59] - Analysis of reading acuity was not performed due to early study termination.

[60] - Analysis of reading acuity was not performed due to early study termination.

[61] - Analysis of reading acuity was not performed due to early study termination.

[62] - Analysis of reading acuity was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change From Baseline in Reading Acuity at 9, 12, 15 Months and End of Study

End point title	Percentage Change From Baseline in Reading Acuity at 9, 12, 15 Months and End of Study
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End point description:

Reading Acuity was measured using the Radner reading charts and expressed in terms of logRAD.

End point type	Secondary
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End point timeframe:

Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[63]	0 ^[64]	0 ^[65]	0 ^[66]
Units: percent change				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[63] - Analysis of reading acuity was not performed due to early study termination.

[64] - Analysis of reading acuity was not performed due to early study termination.

[65] - Analysis of reading acuity was not performed due to early study termination.

[66] - Analysis of reading acuity was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Critical Print Size Reading at 9, 12, 15 Months and End of Study

End point title	Change From Baseline in Critical Print Size Reading at 9, 12, 15 Months and End of Study
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End point description:

The critical print size is the smallest print size at which participants can read with their maximum reading speed.

End point type	Secondary
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End point timeframe:

Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[67]	0 ^[68]	0 ^[69]	0 ^[70]
Units: print size				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[67] - Analysis of critical print size reading was not performed due to early study termination.

[68] - Analysis of critical print size reading was not performed due to early study termination.

[69] - Analysis of critical print size reading was not performed due to early study termination.

[70] - Analysis of critical print size reading was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Placebo in Critical Print Size Reading at 9, 12, 15 Months and End of Study

End point title	Change From Placebo in Critical Print Size Reading at 9, 12, 15 Months and End of Study
End point description:	The critical print size is the smallest print size at which participants can read with their maximum reading speed.
End point type	Secondary
End point timeframe:	Baseline, Month 9, Month 12, Month 15, and End of Study

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[71]	0 ^[72]	0 ^[73]	0 ^[74]
Units: print size				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[71] - Analysis of critical print size reading was not performed due to early study termination.

[72] - Analysis of critical print size reading was not performed due to early study termination.

[73] - Analysis of critical print size reading was not performed due to early study termination.

[74] - Analysis of critical print size reading was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Treatment-Emergent Laboratory Abnormalities

End point title	Number of Participants with Treatment-Emergent Laboratory Abnormalities
End point description:	Laboratory assessments include: hematology (hemoglobin, hematocrit, red blood cell count, platelet count, white blood cell count, total neutrophils, eosinophils, monocytes, basophils, lymphocytes); blood chemistry (blood urea nitrogen, creatinine, glucose, calcium, sodium, potassium, chloride, total bicarbonate, aspartate aminotransferase, alanine aminotransferase, total bilirubin, alkaline phosphatase, uric acid, albumin, total protein); coagulation assessments.
End point type	Secondary
End point timeframe:	Day 85 and Day 169

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[75]	0 ^[76]	0 ^[77]	0 ^[78]
Units: participants				

Notes:

[75] - Analysis of laboratory abnormalities was not performed due to early study termination.

[76] - Analysis of laboratory abnormalities was not performed due to early study termination.

[77] - Analysis of laboratory abnormalities was not performed due to early study termination.

[78] - Analysis of laboratory abnormalities was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Abnormal Change From Baseline in Vital Signs

End point title	Number of Participants with Abnormal Change From Baseline in Vital Signs
End point description:	Vital sign assessments include: supine systolic and diastolic blood pressure, pulse rate and body temperature.
End point type	Secondary
End point timeframe:	Screening, Days 28, 57, 85, 113, 141, and 169

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[79]	0 ^[80]	0 ^[81]	0 ^[82]
Units: participants				

Notes:

[79] - Analysis of vital signs was not performed due to early study termination.

[80] - Analysis of vital signs was not performed due to early study termination.

[81] - Analysis of vital signs was not performed due to early study termination.

[82] - Analysis of vital signs was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Clinically Significant Treatment-Emergent Electrocardiogram (ECG) Findings

End point title	Number of Participants with Clinically Significant Treatment-Emergent Electrocardiogram (ECG) Findings
End point description:	Clinically significant ECG findings include: corrected QT (QTc) > 450 msec, QTc >500 msec, change in

QTc between 30 and 60 msec, change in QTc greater than or equal to 60 msec.

End point type	Secondary
End point timeframe:	
Days 28, 57, 85, 113 and 169	

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[83]	0 ^[84]	0 ^[85]	0 ^[86]
Units: participants				

Notes:

[83] - Analysis of ECG parameters was not performed due to early study termination.

[84] - Analysis of ECG parameters was not performed due to early study termination.

[85] - Analysis of ECG parameters was not performed due to early study termination.

[86] - Analysis of ECG parameters was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Positive Anti-Drug Antibody (ADA)

End point title	Number of Participants with Positive Anti-Drug Antibody (ADA)
End point description:	
The number of participants with positive ADA was to be summarized for each treatment arm.	
End point type	Secondary
End point timeframe:	
Day 57 and Day 169	

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[87]	0 ^[88]	0 ^[89]	0 ^[90]
Units: participants				

Notes:

[87] - Analysis of ADA was not performed due to early study termination.

[88] - Analysis of ADA was not performed due to early study termination.

[89] - Analysis of ADA was not performed due to early study termination.

[90] - Analysis of ADA was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Treatment-Emergent Adverse Events (TEAEs) According to Seriousness

End point title	Number of Participants with Treatment-Emergent Adverse Events (TEAEs) According to Seriousness
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End point description:

An adverse event (AE) was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. Seriousness of an AE was assessed under the criteria of serious adverse event (SAE). An SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly.

End point type	Secondary
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End point timeframe:

Days 28, 57, 85, 113, 141 and 169

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	3	2
Units: participants				
AE	2	0	1	1
SAE	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Treatment-Related TEAEs

End point title	Number of Participants with Treatment-Related TEAEs
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End point description:

An AE was an untoward medical occurrence in a participant who received study drug without regard to causal relationship. An investigator's relationship assessment is the determination of whether there exists a reasonable possibility that the investigational product caused or contributed to an AE.

End point type	Secondary
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End point timeframe:

Days 28, 57, 85, 113, 141 and 169

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	3	2
Units: participants	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax)

End point title Maximum Observed Plasma Concentration (Cmax)^[91]

End point description:

End point type Secondary

End point timeframe:

Days 1, 28, 57, 85, 169, 253, 281, 309, 337, and 449

Notes:

[91] - 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: PK parameters were not planned for the placebo group.

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[92]	0 ^[93]	0 ^[94]	
Units: nanogram per milliter (ng/mL)				
geometric mean (geometric coefficient of variation)	()	()	()	

Notes:

[92] - Analysis of Cmax was not performed due to early study termination.

[93] - Analysis of Cmax was not performed due to early study termination.

[94] - Analysis of Cmax was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Minimum Observed Plasma Trough Concentration (Cmin)

End point title Minimum Observed Plasma Trough Concentration (Cmin)^[95]

End point description:

End point type Secondary

End point timeframe:

Days 1, 28, 57, 85, 169, 253, 281, 309, 337, and 449

Notes:

[95] - 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: PK parameters were not planned for the placebo group.

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[96]	0 ^[97]	0 ^[98]	
Units: ng/mL				
geometric mean (geometric coefficient of variation)	()	()	()	

Notes:

[96] - Analysis of Cmin was not performed due to early study termination.

[97] - Analysis of Cmin was not performed due to early study termination.

[98] - Analysis of Cmin was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Concentration-Time Curve From Time Zero Until Last Sampling Time (AUCt)

End point title	Area Under the Concentration-Time Curve From Time Zero Until Last Sampling Time (AUCt) ^[99]
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End point description:

End point type	Secondary
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End point timeframe:

Days 1, 28, 57, 85, 169, 253, 281, 309, 337, and 449

Notes:

[99] - 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: PK parameters were not planned for the placebo group.

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[100]	0 ^[101]	0 ^[102]	
Units: nanogram*hour per milliliter (ng*hr/mL)				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[100] - Analysis of AUCt was not performed due to early study termination.

[101] - Analysis of AUCt was not performed due to early study termination.

[102] - Analysis of AUCt was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Clearance at Steady State (CLss)

End point title	Clearance at Steady State (CLss) ^[103]
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End point description:

Steady state total body clearance equals infusion rate (zero order) divided by steady state plasma concentration of study drug (R0/Css).

End point type	Secondary
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End point timeframe:

Days 1, 28, 57, 85, 169, 253, 281, 309, 337, and 449

Notes:

[103] - 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: PK parameters were not planned for the placebo group.

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[104]	0 ^[105]	0 ^[106]	
Units: liters per hour (L/hr)				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[104] - Analysis of CLss was not performed due to early study termination.

[105] - Analysis of CLss was not performed due to early study termination.

[106] - Analysis of CLss was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Accumulation Ratio (Rac) for AUcT

End point title	Accumulation Ratio (Rac) for AUcT ^[107]
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End point description:

End point type	Secondary
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End point timeframe:

Days 1, 28, 57, 85, 169, 253, 281, 309, 337, and 449

Notes:

[107] - 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: PK parameters were not planned for the placebo group.

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[108]	0 ^[109]	0 ^[110]	
Units: ratio				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[108] - Analysis of Rac for AUcT was not performed due to early study termination.

[109] - Analysis of Rac for AUcT was not performed due to early study termination.

[110] - Analysis of Rac for AUcT was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Population PK Parameters

End point title	Plasma Population PK Parameters ^[111]
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End point description:

Population PK parameters were to be evaluated for C_{max}, AUC_t, C_{min}, CL_{ss}, and Rac for AUC_t between the first and last (11th) doses.

End point type Secondary

End point timeframe:

Days 1, 28, 57, 85, 169, 253, 281, 309, 337 and 449

Notes:

[111] - 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: PK parameters were not planned for the placebo group.

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[112]	0 ^[113]	0 ^[114]	
Units: population PK analysis				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[112] - Analysis of population PK parameters was not performed due to early study termination.

[113] - Analysis of population PK parameters was not performed due to early study termination.

[114] - Analysis of population PK parameters was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total Amyloid Beta (A-Beta) 1-x Plasma Concentration at End of Study (Day 449)

End point title Change From Baseline in Total Amyloid Beta (A-Beta) 1-x Plasma Concentration at End of Study (Day 449)

End point description:

Concentration of total amino acid peptide, known as A-Beta 1-x, in plasma.

End point type Secondary

End point timeframe:

Baseline, Day 449

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[115]	0 ^[116]	0 ^[117]	0 ^[118]
Units: picogram per milliliter (pg/mL)				
least squares mean (standard error)	()	()	()	()

Notes:

[115] - Analysis of A-Beta 1-x was not performed due to early study termination.

[116] - Analysis of A-Beta 1-x was not performed due to early study termination.

[117] - Analysis of A-Beta 1-x was not performed due to early study termination.

[118] - Analysis of A-Beta 1-x was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Amyloid Beta (A-Beta) 1-40 Plasma Concentration at End of Study (Day 449)

End point title	Change From Baseline in Amyloid Beta (A-Beta) 1-40 Plasma Concentration at End of Study (Day 449)
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End point description:

Concentration of amino acid peptide, known as A-Beta 1-40, in plasma.

End point type	Secondary
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End point timeframe:

Baseline, Day 449

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[119]	0 ^[120]	0 ^[121]	0 ^[122]
Units: pg/mL				
least squares mean (standard error)	()	()	()	()

Notes:

[119] - Analysis of A-Beta 1-40 was not performed due to early study termination.

[120] - Analysis of A-Beta 1-40 was not performed due to early study termination.

[121] - Analysis of A-Beta 1-40 was not performed due to early study termination.

[122] - Analysis of A-Beta 1-40 was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Amyloid Beta (A-Beta) 1-42 Plasma Concentration at End of Study (Day 449)

End point title	Change From Baseline in Amyloid Beta (A-Beta) 1-42 Plasma Concentration at End of Study (Day 449)
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End point description:

Concentration of amino acid peptide, known as A-Beta 1-42, in plasma.

End point type	Secondary
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End point timeframe:

Baseline, Day 449

End point values	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[123]	0 ^[124]	0 ^[125]	0 ^[126]
Units: pg/mL				
least squares mean (standard error)	()	()	()	()

Notes:

[123] - Analysis of A-Beta 1-42 was not performed due to early study termination.

[124] - Analysis of A-Beta 1-42 was not performed due to early study termination.

[125] - Analysis of A-Beta 1-42 was not performed due to early study termination.

[126] - Analysis of A-Beta 1-42 was not performed due to early study termination.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Days 28, 57, 85, 113, 141, and 169 (or early termination)

Adverse event reporting additional description:

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

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	17.1
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Reporting groups

Reporting group title	PF-04382923 2.5 mg/kg
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Reporting group description:

PF-04382923 (RN6G) at 2.5 milligrams per kilogram (mg/kg) was administered as an intravenous (IV) infusion over 30 minutes every 28 days for 11 doses.

Reporting group title	PF-04382923 7.5 mg/kg
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Reporting group description:

PF-04382923 at 7.5 mg/kg was administered as an IV infusion over 30 minutes every 28 days for 11 doses.

Reporting group title	PF-04382923 15.0 mg/kg
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Reporting group description:

PF-04382923 at 15.0 mg/kg was administered as an IV infusion over 30 minutes every 28 days for 11 doses.

Reporting group title	Placebo
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Reporting group description:

Placebo was administered as an IV infusion over at least 30 minutes every 28 days for 11 doses.

Serious adverse events	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Carotid artery stenosis			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)		

number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Nervous system disorders			
Carotid artery stenosis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	PF-04382923 2.5 mg/kg	PF-04382923 7.5 mg/kg	PF-04382923 15.0 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Gastrointestinal disorders			
Irritable bowel syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Nephropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Tendonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Influenza			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1

Non-serious adverse events	Placebo		
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 2 (50.00%)		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Gastrointestinal disorders Irritable bowel syndrome subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Renal and urinary disorders Nephropathy subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Musculoskeletal and connective tissue disorders Tendonitis subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1		
Infections and infestations Influenza subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		

Urinary tract infection subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study was terminated early due to an organizational decision, which was not based on safety or efficacy concerns. As only 10 participants enrolled at the time of termination, there were not enough subjects or data to perform meaningful analyses

Notes: