Clinical trial results:
A Multicenter, Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of Lampalizumab (FCFD4514S) in Patients With Geographic Atrophy Who Have Completed Genentech-Sponsored Lampalizumab Studies

Summary

EudraCT number	2012-000578-41
Trial protocol	DE
Global end of trial date	09 February 2018

Results information

Result version number	v1 (current)
This version publication date	07 February 2019
First version publication date	07 February 2019

Trial information

Trial identification

Sponsor protocol code	GX28198

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01602120
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.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	09 February 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 February 2018
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate the long-term ocular and systemic safety and tolerability of lampalizumab administered intravitreally (ITV), monthly.

Protection of trial subjects:

All study subjects were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 May 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 147
Country: Number of subjects enrolled	Germany: 12
Worldwide total number of subjects	159
EEA total number of subjects	12

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	120
85 years and over	37

Subject disposition

Recruitment

Recruitment details:

This study enrolled eligible patients who had completed the 18-month treatment period of Study NCT01229215 (CFD4870g) or the 24-week treatment period of Study NCT02288559 (GX29455). This study was terminated early by the Sponsor due to lack of efficacy.

Pre-assignment

Screening details:

This study enrolled subjects with geographic atrophy at 43 study sites in two countries.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	CFD4870g Sham

Arm description:

Subjects who were administered sham comparator in Study NCT01229215 (CFD4870g), received lampalizumab 10 milligrams (mg), intravitreally (ITV), either once in every 4 weeks (Q4W) or once in every 8 weeks (Q8W) in accordance with their previously assigned treatment frequency assignment in Study CFD4870g followed by Q4W administration for the remainder of the extension study.

Arm type	Experimental
Investigational medicinal product name	Lampalizumab
Investigational medicinal product code	RO5490249
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intravitreal use

Dosage and administration details:

Lampalizumab was administered at a dose of 10 mg as an ITV injection, starting at the Day 1 visit, Q4W or Q6W, for approximately 96 weeks.

Arm title	CFD4870g Lampalizumab

Arm description:

Subjects received lampalizumab 10 mg, ITV, Q4W or Q8W in accordance with their previously assigned treatment frequency assignment in Study NCT01229215 (CFD4870g) followed by Q4W administration for the remainder of the extension study.

Arm type	Experimental
Investigational medicinal product name	Lampalizumab
Investigational medicinal product code	RO5490249
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intravitreal use

Dosage and administration details:

Lampalizumab was administered at a dose of 10 mg as an ITV injection, starting at the Day 1 visit, Q4W or Q6W, for approximately 96 weeks.

Arm title	GX29455 Sham

Arm description:

Subjects who were administered sham comparator in Study NCT02288559 (GX29455), received lampalizumab 10 mg, ITV, Q4W throughout the extension study.

Arm type	Experimental

Investigational medicinal product name	Lampalizumab
Investigational medicinal product code	RO5490249
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intravitreal use

Dosage and administration details:

Lampalizumab was administered at a dose of 10 mg as an ITV injection, starting at the Day 1 visit, Q4W, for approximately 54 months.

Arm title	GX29455 Lampalizumab

Arm description:

Subject who were administered lampalizumab in Study NCT02288559 (GX29455), received lampalizumab 10 mg, ITV, Q4W throughout the extension study.

Arm type	Experimental
Investigational medicinal product name	Lampalizumab
Investigational medicinal product code	RO5490249
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intravitreal use

Dosage and administration details:

Lampalizumab was administered at a dose of 10 mg as an ITV injection, starting at the Day 1 visit, Q4W, for approximately 54 months.

Number of subjects in period 1	CFD4870g Sham	CFD4870g Lampalizumab	GX29455 Sham
Started	29	60	17
Completed	0	0	0
Not completed	29	60	17
Unspecified Reason	3	1	-
Consent withdrawn by subject	8	17	-
Physician decision	2	3	-
Adverse Event	3	6	-
Death	-	4	-
Non-compliance	-	3	-
Study Terminated by Sponsor	12	24	17
Lost to follow-up	-	1	-
Protocol deviation	1	1	-

Number of subjects in period 1	GX29455 Lampalizumab
Started	53
Completed	0
Not completed	53
Unspecified Reason	2
Consent withdrawn by subject	3
Physician decision	-
Adverse Event	2

Death	-
Non-compliance	1
Study Terminated by Sponsor	44
Lost to follow-up	1
Protocol deviation	-

Baseline characteristics

Reporting groups	
Reporting group title	CFD4870g Sham
Reporting group description:	
Subjects who were administered sham comparator in Study NCT01229215 (CFD4870g), received lampalizumab 10 milligrams (mg), intravitreally (ITV), either once in every 4 weeks (Q4W) or once in every 8 weeks (Q8W) in accordance with their previously assigned treatment frequency assignment in Study CFD4870g followed by Q4W administration for the remainder of the extension study.	
Reporting group title	CFD4870g Lampalizumab
Reporting group description:	
Subjects received lampalizumab 10 mg, ITV, Q4W or Q8W in accordance with their previously assigned treatment frequency assignment in Study NCT01229215 (CFD4870g) followed by Q4W administration for the remainder of the extension study.	
Reporting group title	GX29455 Sham
Reporting group description:	
Subjects who were administered sham comparator in Study NCT02288559 (GX29455), received lampalizumab 10 mg, ITV, Q4W throughout the extension study.	
Reporting group title	GX29455 Lampalizumab
Reporting group description:	
Subject who were administered lampalizumab in Study NCT02288559 (GX29455), received lampalizumab 10 mg, ITV, Q4W throughout the extension study.	

Reporting group values	CFD4870g Sham	CFD4870g Lampalizumab	GX29455 Sham
Number of subjects	29	60	17
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	79.4	79.4	76.7
standard deviation	± 6.6	± 6.8	± 6.6
Sex: Female, Male Units: Subjects			
Female	17	33	12
Male	12	27	5

Reporting group values	GX29455 Lampalizumab	Total	
Number of subjects	53	159	
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	79.5		
standard deviation	± 7.6	-	
Sex: Female, Male Units: Subjects			
Female	27	89	
Male	26	70	

End points

End points reporting groups

Reporting group title	CFD4870g Sham

Reporting group description:

Subjects who were administered sham comparator in Study NCT01229215 (CFD4870g), received lampalizumab 10 milligrams (mg), intravitreally (ITV), either once in every 4 weeks (Q4W) or once in every 8 weeks (Q8W) in accordance with their previously assigned treatment frequency assignment in Study CFD4870g followed by Q4W administration for the remainder of the extension study.

Reporting group title	CFD4870g Lampalizumab

Reporting group description:

Subjects received lampalizumab 10 mg, ITV, Q4W or Q8W in accordance with their previously assigned treatment frequency assignment in Study NCT01229215 (CFD4870g) followed by Q4W administration for the remainder of the extension study.

Reporting group title	GX29455 Sham

Reporting group description:

Subjects who were administered sham comparator in Study NCT02288559 (GX29455), received lampalizumab 10 mg, ITV, Q4W throughout the extension study.

Reporting group title	GX29455 Lampalizumab

Reporting group description:

Subject who were administered lampalizumab in Study NCT02288559 (GX29455), received lampalizumab 10 mg, ITV, Q4W throughout the extension study.

Subject analysis set title	All Subjects
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All subjects in the study received lampalizumab 10 mg, ITV, Q4W.

Primary: Percentage of Subjects With Ocular and Non-ocular Adverse Events (AEs)

End point title	Percentage of Subjects With Ocular and Non-ocular Adverse Events (AEs)[1]

End point description:

An AE was defined as any unfavourable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product, whether considered related to the medicinal product, any new disease or exacerbation of an existing disease, recurrence of an intermittent medical condition, or any deterioration in a laboratory value or other clinical test. Ocular AEs are events localized to the eye. Non-ocular events include all other events. Safety population included all subjects who were enrolled and received at least one lampalizumab injection in the extension study.

End point type	Primary

End point timeframe:

From Day 1 through the last study visit (up to approximately 62 months)

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: Descriptive statistics only

End point values	CFD4870g Sham	CFD4870g Lampalizumab	GX29455 Sham	GX29455 Lampalizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	60	17	53
Units: percentage of subjects				
number (not applicable)				
Ocular AEs in Study Eye	62.1	78.3	52.9	50.9
Ocular AEs in Fellow Eye	62.1	68.3	29.4	60.4
Non-Ocular AEs	79.3	90.0	82.4	67.9

End point values	All Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	159			
Units: percentage of subjects				
number (not applicable)				
Ocular AEs in Study Eye	63.5			
Ocular AEs in Fellow Eye	60.4			
Non-Ocular AEs	79.9			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Day 1 through the last study visit (up to approximately 62 months)

Adverse event reporting additional description:

If the subject had any ongoing adverse events from Study CFD4870g or GX29455 at time of enrolment the events were counted in this Study. Safety population: all subjects who were enrolled and received at least one lampalizumab injection in this study. The arm All Subjects represents the total number of adverse events in the four arms of the study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	CFD4870g Sham

Reporting group description:

Subjects who were administered sham comparator in Study NCT01229215 (CFD4870g), received lampalizumab 10 milligrams (mg), intravitreally (ITV), either once in every 4 weeks (Q4W) or once in every 8 weeks (Q8W) in accordance with their previously assigned treatment frequency assignment in Study CFD4870g followed by Q4W administration for the remainder of the extension study.

Reporting group title	CFD4870g Lampalizumab

Reporting group description:

Subjects received lampalizumab 10 mg, ITV, Q4W or Q8W in accordance with their previously assigned treatment frequency assignment in Study NCT01229215 (CFD4870g) followed by Q4W administration for the remainder of the extension study.

Reporting group title	GX29455 Sham

Reporting group description:

Subjects who were administered sham comparator in Study NCT02288559 (GX29455), received lampalizumab 10 mg, ITV, Q4W throughout the extension study.

Reporting group title	GX29455 Lampalizumab

Reporting group description:

Subjects who were administered lampalizumab in Study NCT02288559 (GX29455), received lampalizumab 10 mg, ITV, Q4W throughout the extension study.

Reporting group title	All Subjects

Reporting group description:

All subjects in the study received lampalizumab 10 mg, ITV, Q4W.

Serious adverse events	CFD4870g Sham	CFD4870g Lampalizumab	GX29455 Sham
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 29 (55.17%)	40 / 60 (66.67%)	5 / 17 (29.41%)
number of deaths (all causes)	1	6	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma pancreas			

subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bladder cancer			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Hepatic cancer			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lung carcinoma cell type unspecified stage III			

subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Meningioma			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	1 / 29 (3.45%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Transitional cell carcinoma			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	1 / 29 (3.45%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site haemorrhage			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Fatigue			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			

subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 29 (0.00%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 29 (0.00%)	2 / 60 (3.33%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Pneumothorax spontaneous			

subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Intraocular pressure increased			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corneal abrasion			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fall			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body aspiration			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital injury			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 29 (0.00%)	2 / 60 (3.33%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pubis fracture			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	2 / 29 (6.90%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			

subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 29 (0.00%)	5 / 60 (8.33%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Cardiac failure congestive			

subjects affected / exposed	0 / 29 (0.00%)	4 / 60 (6.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Cardiac perforation			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 29 (0.00%)	2 / 60 (3.33%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Sinus node dysfunction			
subjects affected / exposed	0 / 29 (0.00%)	2 / 60 (3.33%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricle rupture			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			

subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Carotid artery stenosis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Cerebrovascular accident			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Epilepsy			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Ischaemic stroke			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Syncope			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			

subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 29 (0.00%)	2 / 60 (3.33%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness transient			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye haemorrhage			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Retinal detachment			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual acuity reduced			
subjects affected / exposed	2 / 29 (6.90%)	2 / 60 (3.33%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	1 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			
subjects affected / exposed	0 / 29 (0.00%)	2 / 60 (3.33%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitritis			

subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Dysphagia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Thyroid mass			

subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	2 / 29 (6.90%)	2 / 60 (3.33%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diverticulitis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Endophthalmitis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected lymphocele			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 29 (3.45%)	4 / 60 (6.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Urosepsis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	0 / 17 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	GX29455 Lampalizumab	All Subjects	
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 53 (16.98%)	70 / 159 (44.03%)	
number of deaths (all causes)	1	8	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma pancreas			

subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bladder cancer			
subjects affected / exposed	1 / 53 (1.89%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 53 (1.89%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Breast cancer			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukaemia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung carcinoma cell type unspecified stage III			

subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoma			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Meningioma			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site haemorrhage			
subjects affected / exposed	1 / 53 (1.89%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Fatigue			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral swelling			

subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 53 (0.00%)	3 / 159 (1.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax spontaneous			

subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep apnoea syndrome			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Intraocular pressure increased			
subjects affected / exposed	1 / 53 (1.89%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 1	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal abrasion			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	1 / 53 (1.89%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Fall			
subjects affected / exposed	1 / 53 (1.89%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body aspiration			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital injury			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	1 / 53 (1.89%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pubis fracture			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			

subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	1 / 53 (1.89%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
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	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 53 (0.00%)	5 / 159 (3.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			

subjects affected / exposed	0 / 53 (0.00%)	4 / 159 (2.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Cardiac perforation			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
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	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricle rupture			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			

subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Carotid artery stenosis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			

subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Blindness transient			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye haemorrhage			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual acuity reduced			
subjects affected / exposed	0 / 53 (0.00%)	5 / 159 (3.14%)	
occurrences causally related to treatment / all	0 / 0	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitritis			

subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Dysphagia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 53 (1.89%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Thyroid mass			

subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 53 (0.00%)	4 / 159 (2.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

Diverticulitis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endophthalmitis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected lymphocele			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
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 / 53 (1.89%)	6 / 159 (3.77%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
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	1 / 53 (1.89%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
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	1 / 53 (1.89%)	2 / 159 (1.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypernatraemia			
subjects affected / exposed	1 / 53 (1.89%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	CFD4870g Sham	CFD4870g Lampalizumab	GX29455 Sham
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 29 (82.76%)	56 / 60 (93.33%)	16 / 17 (94.12%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	3 / 29 (10.34%)	2 / 60 (3.33%)	1 / 17 (5.88%)
occurrences (all)	5	7	1

Benign neoplasm of skin			
subjects affected / exposed	2 / 29 (6.90%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences (all)	6	1	0
Blepharal papilloma			
subjects affected / exposed	0 / 29 (0.00%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	4	0
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 29 (6.90%)	7 / 60 (11.67%)	1 / 17 (5.88%)
occurrences (all)	2	7	1
Hypotension			
subjects affected / exposed	0 / 29 (0.00%)	4 / 60 (6.67%)	1 / 17 (5.88%)
occurrences (all)	0	4	1
Peripheral vascular disorder			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Surgical and medical procedures			
Cataract operation			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	2 / 29 (6.90%)	3 / 60 (5.00%)	1 / 17 (5.88%)
occurrences (all)	2	3	1
Pain			
subjects affected / exposed	1 / 29 (3.45%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	1	3	0
Asthenia			
subjects affected / exposed	0 / 29 (0.00%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Injection site pain			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Immune system disorders			
Seasonal allergy			

subjects affected / exposed	1 / 29 (3.45%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	2	3	0
Drug hypersensitivity			
subjects affected / exposed	0 / 29 (0.00%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	4	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 29 (6.90%)	5 / 60 (8.33%)	0 / 17 (0.00%)
occurrences (all)	3	6	0
Dyspnoea			
subjects affected / exposed	0 / 29 (0.00%)	3 / 60 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 29 (3.45%)	2 / 60 (3.33%)	1 / 17 (5.88%)
occurrences (all)	2	2	1
Oropharyngeal pain			
subjects affected / exposed	2 / 29 (6.90%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Sinus congestion			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 29 (3.45%)	4 / 60 (6.67%)	0 / 17 (0.00%)
occurrences (all)	1	4	0
Anxiety			
subjects affected / exposed	0 / 29 (0.00%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Hallucination, visual			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Investigations			
Intraocular pressure increased			
subjects affected / exposed	3 / 29 (10.34%)	6 / 60 (10.00%)	0 / 17 (0.00%)
occurrences (all)	4	13	0
Blood glucose increased			

subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	7 / 29 (24.14%)	13 / 60 (21.67%)	3 / 17 (17.65%)
occurrences (all)	12	18	3
Contusion			
subjects affected / exposed	0 / 29 (0.00%)	5 / 60 (8.33%)	0 / 17 (0.00%)
occurrences (all)	0	6	0
Procedural pain			
subjects affected / exposed	1 / 29 (3.45%)	5 / 60 (8.33%)	0 / 17 (0.00%)
occurrences (all)	1	5	0
Corneal abrasion			
subjects affected / exposed	1 / 29 (3.45%)	4 / 60 (6.67%)	0 / 17 (0.00%)
occurrences (all)	1	5	0
Laceration			
subjects affected / exposed	0 / 29 (0.00%)	3 / 60 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	6	1
Ligament sprain			
subjects affected / exposed	0 / 29 (0.00%)	3 / 60 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	3	2
Rib fracture			
subjects affected / exposed	1 / 29 (3.45%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	1	3	0
Muscle strain			
subjects affected / exposed	0 / 29 (0.00%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Skin abrasion			
subjects affected / exposed	2 / 29 (6.90%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Foot fracture			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Forearm fracture			

subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	2 / 29 (6.90%)	10 / 60 (16.67%)	1 / 17 (5.88%)
occurrences (all)	2	10	3
Coronary artery disease			
subjects affected / exposed	1 / 29 (3.45%)	4 / 60 (6.67%)	0 / 17 (0.00%)
occurrences (all)	1	4	0
Cardiac failure congestive			
subjects affected / exposed	0 / 29 (0.00%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 29 (3.45%)	8 / 60 (13.33%)	0 / 17 (0.00%)
occurrences (all)	1	12	0
Dementia			
subjects affected / exposed	1 / 29 (3.45%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	1	3	0
Dizziness			
subjects affected / exposed	0 / 29 (0.00%)	2 / 60 (3.33%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Neuropathy peripheral			
subjects affected / exposed	1 / 29 (3.45%)	2 / 60 (3.33%)	1 / 17 (5.88%)
occurrences (all)	2	2	1
Paraesthesia			
subjects affected / exposed	2 / 29 (6.90%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Migraine			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 29 (6.90%)	1 / 60 (1.67%)	1 / 17 (5.88%)
occurrences (all)	3	1	1
Leukocytosis			

subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	4 / 29 (13.79%)	18 / 60 (30.00%)	3 / 17 (17.65%)
occurrences (all)	5	47	3
Retinal haemorrhage			
subjects affected / exposed	4 / 29 (13.79%)	13 / 60 (21.67%)	2 / 17 (11.76%)
occurrences (all)	9	21	2
Eye pain			
subjects affected / exposed	3 / 29 (10.34%)	14 / 60 (23.33%)	0 / 17 (0.00%)
occurrences (all)	5	22	0
Cataract			
subjects affected / exposed	1 / 29 (3.45%)	9 / 60 (15.00%)	0 / 17 (0.00%)
occurrences (all)	1	17	0
Posterior capsule opacification			
subjects affected / exposed	3 / 29 (10.34%)	3 / 60 (5.00%)	2 / 17 (11.76%)
occurrences (all)	5	4	2
Vitreous detachment			
subjects affected / exposed	4 / 29 (13.79%)	2 / 60 (3.33%)	0 / 17 (0.00%)
occurrences (all)	8	2	0
Vitreous floaters			
subjects affected / exposed	2 / 29 (6.90%)	6 / 60 (10.00%)	1 / 17 (5.88%)
occurrences (all)	3	10	2
Dry eye			
subjects affected / exposed	1 / 29 (3.45%)	6 / 60 (10.00%)	0 / 17 (0.00%)
occurrences (all)	2	10	0
Punctate keratitis			
subjects affected / exposed	1 / 29 (3.45%)	7 / 60 (11.67%)	2 / 17 (11.76%)
occurrences (all)	3	13	3
Visual impairment			

subjects affected / exposed	0 / 29 (0.00%)	5 / 60 (8.33%)	1 / 17 (5.88%)
occurrences (all)	0	8	1
Cataract nuclear			
subjects affected / exposed	1 / 29 (3.45%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	2	4	0
Blepharitis			
subjects affected / exposed	1 / 29 (3.45%)	4 / 60 (6.67%)	0 / 17 (0.00%)
occurrences (all)	2	14	0
Neovascular age−related macular degeneration			
subjects affected / exposed	2 / 29 (6.90%)	3 / 60 (5.00%)	1 / 17 (5.88%)
occurrences (all)	2	3	1
Vision blurred			
subjects affected / exposed	3 / 29 (10.34%)	4 / 60 (6.67%)	0 / 17 (0.00%)
occurrences (all)	7	5	0
Iritis			
subjects affected / exposed	1 / 29 (3.45%)	4 / 60 (6.67%)	1 / 17 (5.88%)
occurrences (all)	1	5	2
Blindness transient			
subjects affected / exposed	1 / 29 (3.45%)	4 / 60 (6.67%)	0 / 17 (0.00%)
occurrences (all)	3	4	0
Cataract subcapsular			
subjects affected / exposed	0 / 29 (0.00%)	4 / 60 (6.67%)	1 / 17 (5.88%)
occurrences (all)	0	5	1
Dry age−related macular degeneration			
subjects affected / exposed	2 / 29 (6.90%)	2 / 60 (3.33%)	0 / 17 (0.00%)
occurrences (all)	2	2	0
Eye pruritus			
subjects affected / exposed	1 / 29 (3.45%)	3 / 60 (5.00%)	1 / 17 (5.88%)
occurrences (all)	1	4	2
Lacrimation increased			
subjects affected / exposed	2 / 29 (6.90%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences (all)	3	2	0
Ocular hyperaemia			

subjects affected / exposed	1 / 29 (3.45%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	1	5	0
Foreign body sensation in eyes			
subjects affected / exposed	1 / 29 (3.45%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	1	3	0
Visual acuity reduced			
subjects affected / exposed	2 / 29 (6.90%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences (all)	3	1	0
Blepharochalasis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Conjunctival hyperaemia			
subjects affected / exposed	2 / 29 (6.90%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences (all)	2	1	0
Ocular hypertension			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Open angle glaucoma			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	2	0	2
Trichiasis			
subjects affected / exposed	2 / 29 (6.90%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences (all)	9	1	0
Corneal erosion			
subjects affected / exposed	2 / 29 (6.90%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences (all)	4	0	0
Corneal opacity			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	1 / 17 (5.88%)
occurrences (all)	0	1	2
Vitreous haemorrhage			
subjects affected / exposed	2 / 29 (6.90%)	0 / 60 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Corneal oedema			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Eyelid ptosis			

subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Macular oedema			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	2 / 29 (6.90%)	9 / 60 (15.00%)	1 / 17 (5.88%)
occurrences (all)	2	9	1
Diarrhoea			
subjects affected / exposed	1 / 29 (3.45%)	7 / 60 (11.67%)	0 / 17 (0.00%)
occurrences (all)	1	9	0
Nausea			
subjects affected / exposed	1 / 29 (3.45%)	5 / 60 (8.33%)	0 / 17 (0.00%)
occurrences (all)	1	6	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 29 (6.90%)	5 / 60 (8.33%)	0 / 17 (0.00%)
occurrences (all)	2	5	0
Gastritis			
subjects affected / exposed	0 / 29 (0.00%)	5 / 60 (8.33%)	0 / 17 (0.00%)
occurrences (all)	0	6	0
Skin and subcutaneous tissue disorders			
Ingrowing nail			
subjects affected / exposed	2 / 29 (6.90%)	1 / 60 (1.67%)	0 / 17 (0.00%)
occurrences (all)	2	1	0
Hyperkeratosis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Skin ulcer			
subjects affected / exposed	1 / 29 (3.45%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	2	0	1
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 29 (3.45%)	4 / 60 (6.67%)	0 / 17 (0.00%)
occurrences (all)	1	5	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	1 / 29 (3.45%)	5 / 60 (8.33%)	1 / 17 (5.88%)
occurrences (all)	1	7	1
Back pain			
subjects affected / exposed	2 / 29 (6.90%)	4 / 60 (6.67%)	0 / 17 (0.00%)
occurrences (all)	2	4	0
Arthritis			
subjects affected / exposed	3 / 29 (10.34%)	3 / 60 (5.00%)	1 / 17 (5.88%)
occurrences (all)	4	3	1
Pain in extremity			
subjects affected / exposed	2 / 29 (6.90%)	4 / 60 (6.67%)	1 / 17 (5.88%)
occurrences (all)	2	4	1
Musculoskeletal pain			
subjects affected / exposed	3 / 29 (10.34%)	2 / 60 (3.33%)	0 / 17 (0.00%)
occurrences (all)	3	2	0
Osteoporosis			
subjects affected / exposed	0 / 29 (0.00%)	3 / 60 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Sjogren’s syndrome			
subjects affected / exposed	0 / 29 (0.00%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	5	0
Foot deformity			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Bone swelling			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Metatarsalgia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 60 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	8 / 29 (27.59%)	11 / 60 (18.33%)	1 / 17 (5.88%)
occurrences (all)	17	27	2
Urinary tract infection			

subjects affected / exposed	3 / 29 (10.34%)	13 / 60 (21.67%)	1 / 17 (5.88%)
occurrences (all)	6	17	1
Upper respiratory tract infection			
subjects affected / exposed	4 / 29 (13.79%)	9 / 60 (15.00%)	3 / 17 (17.65%)
occurrences (all)	5	14	3
Bronchitis			
subjects affected / exposed	5 / 29 (17.24%)	7 / 60 (11.67%)	0 / 17 (0.00%)
occurrences (all)	6	8	0
Sinusitis			
subjects affected / exposed	4 / 29 (13.79%)	5 / 60 (8.33%)	1 / 17 (5.88%)
occurrences (all)	6	8	1
Pneumonia			
subjects affected / exposed	0 / 29 (0.00%)	6 / 60 (10.00%)	1 / 17 (5.88%)
occurrences (all)	0	8	1
Herpes zoster			
subjects affected / exposed	1 / 29 (3.45%)	4 / 60 (6.67%)	0 / 17 (0.00%)
occurrences (all)	1	4	0
Influenza			
subjects affected / exposed	0 / 29 (0.00%)	6 / 60 (10.00%)	1 / 17 (5.88%)
occurrences (all)	0	6	1
Cystitis			
subjects affected / exposed	1 / 29 (3.45%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	1	5	0
Ear infection			
subjects affected / exposed	0 / 29 (0.00%)	4 / 60 (6.67%)	1 / 17 (5.88%)
occurrences (all)	0	4	1
Conjunctivitis			
subjects affected / exposed	1 / 29 (3.45%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	2	4	0
Tooth infection			
subjects affected / exposed	1 / 29 (3.45%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	1	3	0
Cellulitis			
subjects affected / exposed	1 / 29 (3.45%)	1 / 60 (1.67%)	1 / 17 (5.88%)
occurrences (all)	2	1	1
Diverticulitis			

subjects affected / exposed	0 / 29 (0.00%)	3 / 60 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	5	0
Oral herpes			
subjects affected / exposed	0 / 29 (0.00%)	1 / 60 (1.67%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 29 (0.00%)	5 / 60 (8.33%)	0 / 17 (0.00%)
occurrences (all)	0	5	0
Hypercholesterolaemia			
subjects affected / exposed	2 / 29 (6.90%)	2 / 60 (3.33%)	0 / 17 (0.00%)
occurrences (all)	2	2	0
Hyperlipidaemia			
subjects affected / exposed	0 / 29 (0.00%)	4 / 60 (6.67%)	0 / 17 (0.00%)
occurrences (all)	0	4	0
Diabetes mellitus			
subjects affected / exposed	1 / 29 (3.45%)	1 / 60 (1.67%)	1 / 17 (5.88%)
occurrences (all)	1	1	1

Non-serious adverse events	GX29455 Lampalizumab	All Subjects	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	41 / 53 (77.36%)	137 / 159 (86.16%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 53 (0.00%)	6 / 159 (3.77%)	
occurrences (all)	0	13	
Benign neoplasm of skin			
subjects affected / exposed	0 / 53 (0.00%)	3 / 159 (1.89%)	
occurrences (all)	0	7	
Blepharal papilloma			
subjects affected / exposed	0 / 53 (0.00%)	3 / 159 (1.89%)	
occurrences (all)	0	4	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 53 (1.89%)	11 / 159 (6.92%)	
occurrences (all)	1	11	

Hypotension			
subjects affected / exposed	0 / 53 (0.00%)	5 / 159 (3.14%)	
occurrences (all)	0	5	
Peripheral vascular disorder			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	1	
Surgical and medical procedures			
Cataract operation			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	2	
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	2 / 53 (3.77%)	8 / 159 (5.03%)	
occurrences (all)	2	8	
Pain			
subjects affected / exposed	0 / 53 (0.00%)	4 / 159 (2.52%)	
occurrences (all)	0	4	
Asthenia			
subjects affected / exposed	0 / 53 (0.00%)	3 / 159 (1.89%)	
occurrences (all)	0	3	
Injection site pain			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	1	
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 53 (0.00%)	4 / 159 (2.52%)	
occurrences (all)	0	5	
Drug hypersensitivity			
subjects affected / exposed	0 / 53 (0.00%)	3 / 159 (1.89%)	
occurrences (all)	0	4	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 53 (1.89%)	8 / 159 (5.03%)	
occurrences (all)	1	10	
Dyspnoea			

subjects affected / exposed	1 / 53 (1.89%)	5 / 159 (3.14%)	
occurrences (all)	1	5	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 53 (0.00%)	4 / 159 (2.52%)	
occurrences (all)	0	5	
Oropharyngeal pain			
subjects affected / exposed	1 / 53 (1.89%)	3 / 159 (1.89%)	
occurrences (all)	1	3	
Sinus congestion			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	1	
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 53 (1.89%)	6 / 159 (3.77%)	
occurrences (all)	1	6	
Anxiety			
subjects affected / exposed	2 / 53 (3.77%)	5 / 159 (3.14%)	
occurrences (all)	2	5	
Hallucination, visual			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences (all)	0	3	
Investigations			
Intraocular pressure increased			
subjects affected / exposed	3 / 53 (5.66%)	12 / 159 (7.55%)	
occurrences (all)	3	20	
Blood glucose increased			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	2 / 53 (3.77%)	25 / 159 (15.72%)	
occurrences (all)	3	36	
Contusion			
subjects affected / exposed	1 / 53 (1.89%)	6 / 159 (3.77%)	
occurrences (all)	1	7	
Procedural pain			

subjects affected / exposed	0 / 53 (0.00%)	6 / 159 (3.77%)	
occurrences (all)	0	6	
Corneal abrasion			
subjects affected / exposed	0 / 53 (0.00%)	5 / 159 (3.14%)	
occurrences (all)	0	6	
Laceration			
subjects affected / exposed	0 / 53 (0.00%)	4 / 159 (2.52%)	
occurrences (all)	0	7	
Ligament sprain			
subjects affected / exposed	0 / 53 (0.00%)	4 / 159 (2.52%)	
occurrences (all)	0	5	
Rib fracture			
subjects affected / exposed	0 / 53 (0.00%)	4 / 159 (2.52%)	
occurrences (all)	0	4	
Muscle strain			
subjects affected / exposed	0 / 53 (0.00%)	3 / 159 (1.89%)	
occurrences (all)	0	3	
Skin abrasion			
subjects affected / exposed	1 / 53 (1.89%)	3 / 159 (1.89%)	
occurrences (all)	1	3	
Foot fracture			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	1	
Forearm fracture			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	1	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	2 / 53 (3.77%)	15 / 159 (9.43%)	
occurrences (all)	2	17	
Coronary artery disease			
subjects affected / exposed	0 / 53 (0.00%)	5 / 159 (3.14%)	
occurrences (all)	0	5	
Cardiac failure congestive			
subjects affected / exposed	1 / 53 (1.89%)	4 / 159 (2.52%)	
occurrences (all)	1	4	

Nervous system disorders			
Headache			
subjects affected / exposed	0 / 53 (0.00%)	9 / 159 (5.66%)	
occurrences (all)	0	13	
Dementia			
subjects affected / exposed	1 / 53 (1.89%)	5 / 159 (3.14%)	
occurrences (all)	1	5	
Dizziness			
subjects affected / exposed	1 / 53 (1.89%)	4 / 159 (2.52%)	
occurrences (all)	1	4	
Neuropathy peripheral			
subjects affected / exposed	0 / 53 (0.00%)	4 / 159 (2.52%)	
occurrences (all)	0	5	
Paraesthesia			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences (all)	0	2	
Migraine			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 53 (3.77%)	6 / 159 (3.77%)	
occurrences (all)	2	7	
Leukocytosis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	1	
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	3 / 53 (5.66%)	28 / 159 (17.61%)	
occurrences (all)	4	59	
Retinal haemorrhage			
subjects affected / exposed	3 / 53 (5.66%)	22 / 159 (13.84%)	
occurrences (all)	3	35	

Eye pain			
subjects affected / exposed	4 / 53 (7.55%)	21 / 159 (13.21%)	
occurrences (all)	6	33	
Cataract			
subjects affected / exposed	5 / 53 (9.43%)	15 / 159 (9.43%)	
occurrences (all)	6	24	
Posterior capsule opacification			
subjects affected / exposed	5 / 53 (9.43%)	13 / 159 (8.18%)	
occurrences (all)	5	16	
Vitreous detachment			
subjects affected / exposed	6 / 53 (11.32%)	12 / 159 (7.55%)	
occurrences (all)	8	18	
Vitreous floaters			
subjects affected / exposed	3 / 53 (5.66%)	12 / 159 (7.55%)	
occurrences (all)	4	19	
Dry eye			
subjects affected / exposed	4 / 53 (7.55%)	11 / 159 (6.92%)	
occurrences (all)	8	20	
Punctate keratitis			
subjects affected / exposed	1 / 53 (1.89%)	11 / 159 (6.92%)	
occurrences (all)	2	21	
Visual impairment			
subjects affected / exposed	3 / 53 (5.66%)	9 / 159 (5.66%)	
occurrences (all)	5	14	
Cataract nuclear			
subjects affected / exposed	4 / 53 (7.55%)	8 / 159 (5.03%)	
occurrences (all)	6	12	
Blepharitis			
subjects affected / exposed	2 / 53 (3.77%)	7 / 159 (4.40%)	
occurrences (all)	4	20	
Neovascular age−related macular degeneration			
subjects affected / exposed	1 / 53 (1.89%)	7 / 159 (4.40%)	
occurrences (all)	1	7	
Vision blurred			

subjects affected / exposed	0 / 53 (0.00%)	7 / 159 (4.40%)	
occurrences (all)	0	12	
Iritis			
subjects affected / exposed	0 / 53 (0.00%)	6 / 159 (3.77%)	
occurrences (all)	0	8	
Blindness transient			
subjects affected / exposed	0 / 53 (0.00%)	5 / 159 (3.14%)	
occurrences (all)	0	7	
Cataract subcapsular			
subjects affected / exposed	0 / 53 (0.00%)	5 / 159 (3.14%)	
occurrences (all)	0	6	
Dry age−related macular degeneration			
subjects affected / exposed	1 / 53 (1.89%)	5 / 159 (3.14%)	
occurrences (all)	1	5	
Eye pruritus			
subjects affected / exposed	0 / 53 (0.00%)	5 / 159 (3.14%)	
occurrences (all)	0	7	
Lacrimation increased			
subjects affected / exposed	2 / 53 (3.77%)	5 / 159 (3.14%)	
occurrences (all)	4	9	
Ocular hyperaemia			
subjects affected / exposed	1 / 53 (1.89%)	5 / 159 (3.14%)	
occurrences (all)	1	7	
Foreign body sensation in eyes			
subjects affected / exposed	0 / 53 (0.00%)	4 / 159 (2.52%)	
occurrences (all)	0	4	
Visual acuity reduced			
subjects affected / exposed	1 / 53 (1.89%)	4 / 159 (2.52%)	
occurrences (all)	1	5	
Blepharochalasis			
subjects affected / exposed	3 / 53 (5.66%)	3 / 159 (1.89%)	
occurrences (all)	8	8	
Conjunctival hyperaemia			
subjects affected / exposed	0 / 53 (0.00%)	3 / 159 (1.89%)	
occurrences (all)	0	3	

Ocular hypertension			
subjects affected / exposed	3 / 53 (5.66%)	3 / 159 (1.89%)	
occurrences (all)	3	3	
Open angle glaucoma			
subjects affected / exposed	1 / 53 (1.89%)	3 / 159 (1.89%)	
occurrences (all)	1	5	
Trichiasis			
subjects affected / exposed	0 / 53 (0.00%)	3 / 159 (1.89%)	
occurrences (all)	0	10	
Corneal erosion			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences (all)	0	4	
Corneal opacity			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences (all)	0	3	
Vitreous haemorrhage			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences (all)	0	2	
Corneal oedema			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	1	
Eyelid ptosis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	1	
Macular oedema			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 53 (1.89%)	13 / 159 (8.18%)	
occurrences (all)	1	13	
Diarrhoea			
subjects affected / exposed	2 / 53 (3.77%)	10 / 159 (6.29%)	
occurrences (all)	2	12	
Nausea			

subjects affected / exposed	2 / 53 (3.77%)	8 / 159 (5.03%)	
occurrences (all)	2	9	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 53 (0.00%)	7 / 159 (4.40%)	
occurrences (all)	0	7	
Gastritis			
subjects affected / exposed	0 / 53 (0.00%)	5 / 159 (3.14%)	
occurrences (all)	0	6	
Skin and subcutaneous tissue disorders			
Ingrowing nail			
subjects affected / exposed	0 / 53 (0.00%)	3 / 159 (1.89%)	
occurrences (all)	0	3	
Hyperkeratosis			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences (all)	0	2	
Skin ulcer			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences (all)	0	3	
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 53 (0.00%)	5 / 159 (3.14%)	
occurrences (all)	0	6	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 53 (3.77%)	9 / 159 (5.66%)	
occurrences (all)	2	11	
Back pain			
subjects affected / exposed	2 / 53 (3.77%)	8 / 159 (5.03%)	
occurrences (all)	2	8	
Arthritis			
subjects affected / exposed	0 / 53 (0.00%)	7 / 159 (4.40%)	
occurrences (all)	0	8	
Pain in extremity			
subjects affected / exposed	0 / 53 (0.00%)	7 / 159 (4.40%)	
occurrences (all)	0	7	
Musculoskeletal pain			

subjects affected / exposed	1 / 53 (1.89%)	6 / 159 (3.77%)	
occurrences (all)	1	6	
Osteoporosis			
subjects affected / exposed	1 / 53 (1.89%)	5 / 159 (3.14%)	
occurrences (all)	1	5	
Sjogren’s syndrome			
subjects affected / exposed	0 / 53 (0.00%)	3 / 159 (1.89%)	
occurrences (all)	0	5	
Foot deformity			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences (all)	0	2	
Bone swelling			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	1	
Metatarsalgia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 159 (0.63%)	
occurrences (all)	0	1	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	4 / 53 (7.55%)	24 / 159 (15.09%)	
occurrences (all)	5	51	
Urinary tract infection			
subjects affected / exposed	4 / 53 (7.55%)	21 / 159 (13.21%)	
occurrences (all)	6	30	
Upper respiratory tract infection			
subjects affected / exposed	4 / 53 (7.55%)	20 / 159 (12.58%)	
occurrences (all)	4	26	
Bronchitis			
subjects affected / exposed	2 / 53 (3.77%)	14 / 159 (8.81%)	
occurrences (all)	2	16	
Sinusitis			
subjects affected / exposed	1 / 53 (1.89%)	11 / 159 (6.92%)	
occurrences (all)	1	16	
Pneumonia			
subjects affected / exposed	2 / 53 (3.77%)	9 / 159 (5.66%)	
occurrences (all)	2	11	

Herpes zoster			
subjects affected / exposed	2 / 53 (3.77%)	7 / 159 (4.40%)	
occurrences (all)	2	7	
Influenza			
subjects affected / exposed	0 / 53 (0.00%)	7 / 159 (4.40%)	
occurrences (all)	0	7	
Cystitis			
subjects affected / exposed	1 / 53 (1.89%)	5 / 159 (3.14%)	
occurrences (all)	1	7	
Ear infection			
subjects affected / exposed	0 / 53 (0.00%)	5 / 159 (3.14%)	
occurrences (all)	0	5	
Conjunctivitis			
subjects affected / exposed	0 / 53 (0.00%)	4 / 159 (2.52%)	
occurrences (all)	0	6	
Tooth infection			
subjects affected / exposed	0 / 53 (0.00%)	4 / 159 (2.52%)	
occurrences (all)	0	4	
Cellulitis			
subjects affected / exposed	0 / 53 (0.00%)	3 / 159 (1.89%)	
occurrences (all)	0	4	
Diverticulitis			
subjects affected / exposed	0 / 53 (0.00%)	3 / 159 (1.89%)	
occurrences (all)	0	5	
Oral herpes			
subjects affected / exposed	0 / 53 (0.00%)	2 / 159 (1.26%)	
occurrences (all)	0	2	
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	1 / 53 (1.89%)	6 / 159 (3.77%)	
occurrences (all)	1	6	
Hypercholesterolaemia			
subjects affected / exposed	1 / 53 (1.89%)	5 / 159 (3.14%)	
occurrences (all)	1	5	
Hyperlipidaemia			

subjects affected / exposed	0 / 53 (0.00%)	4 / 159 (2.52%)	
occurrences (all)	0	4	
Diabetes mellitus			
subjects affected / exposed	0 / 53 (0.00%)	3 / 159 (1.89%)	
occurrences (all)	0	3	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 September 2013	Study was amended to ensure that subjects received the most efficacious treatment. Consequently, subjects in the lampalizumab every–other-month treatment group were crossed over to the lampalizumab monthly treatment group. Subjects who declined to provide informed consent for crossover to the monthly group were discontinued from the study. In addition, the treatment period was extended by 24 months to create a revised treatment period of 42 months, total. As of 11 April 2013, FCFD4514S received an International Nonproprietary Name of "lampalizumab" and referred to in the text as such. In some figure legends, study titles, and appendices, the name "FCFD4514S" might still be referenced and should be read as synonymous with lampalizumab. An optional, single, whole-blood sample was collected at German sites, at any timepoint, for genotyping analysis. A one-time, subject-reported height and weight was obtained at any point during the study.
25 June 2015	Study was amended to include a cohort of subjects with geographic atrophy secondary to age related macular degeneration who had completed the Genentech−sponsored Study NCT02288559 (GX29455). This cohort of subjects undertook the same assessments at the same timepoint as the rest of the subjects enrolled to Study GX28198, according to schedule of assessments and received monthly study treatment with 10 milligrams (mg) of lampalizumab. The study duration was expanded by 24 months for a total duration of 66 months. At the discretion of the investigator, enrolled subjects who were receiving study treatment and are diagnosed with choroidal neovascularization in either eye treated with ranibizumab. The Section "Safety" was updated to reflect the current protocol standard and safety program for lampalizumab. The investigator requirements section was updated to reflect the current protocol standard. The inclusion criterion around contraception was updated to be consistent with 2014 Clinical Trial Facilitation Group recommendations.
18 May 2017	The study duration was extended an additional 30 months to provide study subjects with access to treatment until potential commercialisation of lampalizumab; total study duration was now 96 months. Table 1 (Dosing Schema) was updated to clarify that no study treatment was administered at the early termination visit. Clarifying language was added to Section "All Extension Study Patients" regarding unscheduled safety assessment visits in the event of new ocular symptoms after injection. Language was added to clarify the rationale for the crossover to monthly treatment in Study NCT01229215 (CFD4870g). The safety plan was updated to reflect the current safety information for lampalizumab. Section "Patient Selection" was updated to include a notation regarding administration of the first intravitreal (ITV) injection of lampalizumab. The language was modified to reflect updates to the protocol template in Section "Safety". Changes included, Sections "Events that Occur after Study Drug Initiation" and "Post-study Adverse Events" were revised regarding reporting in the event that the Electronic Data Capture (EDC) system was unavailable. Section "Deaths" was modified to prohibit use of the term "sudden death" on the Adverse Event electronic Case Report Form (eCRF), unless it was combined with the presumed cause of death (e.g., "sudden cardiac death"), as use of the term "sudden death" would require the Sponsor to query the site for clarification on the cause of death.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
09 February 2018	The study was terminated early by the Sponsor due to lack of efficacy of the compound.	-

Notes:

Limitations and caveats

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

This study was terminated early by the Sponsor because the compound had demonstrated lack of efficacy. Thus, no subject in this study completed the full duration of treatment.

Notes: